Forms MOP

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ID: _____

Date: ____ / ____ / _____

Prescreen Eligibility Form

Thank you for your interest in the PREMIER study! Your answers to the following questions will help us to determine if you can become part of this important study. All of the information you provide will be kept strictly confidential.

1. Name: _____
   (first) (middle) (last)

2. Address: _____
   (number) (street) (apt. number)

   _____
   (city) (state) (zip code)

3. Daytime phone number: (_____) _____ - _____

4. Evening phone number: (_____) _____ - _____

ID: _____

Date: ____ / ____ / _____

Prescreen Eligibility Form

		Yes	No
1.	Are you 25 years old or older?	❑	❑
2.	Do you take insulin or pills for diabetes?	❑	❑
3.	***For women only:*** Are you pregnant, planning to become pregnant within the next two years, or breastfeeding?	❑	❑
4.	Are you currently taking any medications to control your blood pressure?	❑	❑
5.	Are you currently taking diet pills or any medications to control your weight?	❑	❑
6.	Have you ever had a stroke, heart attack, or heart bypass surgery?	❑	❑
7.	Do you have any other heart problems? *If yes, what?* _____	❑	❑
8.	Are you currently being treated for a serious illness such as cancer, HIV, or liver or kidney disease? *If yes, what disease?* _____	❑	❑
9.	Are you planning to leave the area within the next 2 years?	❑	❑
10.	On the average, how many drinks of alcohol do you have in a week? *If you don't drink alcohol, enter 0.* *(one drink = 1 can of beer or 1 glass of wine or 1 shot of liquor)*	_____ drinks/wk	
11.	How tall are you?	_____ ft.	_____ in
12.	How much do you weigh?	_____ pounds	

		Yes	No
13.	Do you have any physical limitations that would make moderate intensity physical activity (like a brisk walk) difficult? *If yes, specify limitations:* _____	❑	❑
14.	Has a physician or health care professional ever told you to limit the amount of physical activity that you do? *If yes, why?* _____ *is this an ongoing limitation?* _____	❑	❑

15. What is your **primary** race? *(check one answer only)*

- American Indian or Alaskan Native ❑1
- Asian/Pacific Islander ❑2
- Black/African American ❑3
- White ❑4
- Other (specify): _____ ❑5

16. Do you consider yourself to be Hispanic?

- Yes ❑1
- No ❑2

17. What is your sex?

- Male ❑1
- Female ❑2

18. How did you hear about PREMIER? (check one answer only)

- Mailed letter/brochure/flier ❑01
- Coupon pack ❑02
- Other mass distribution ❑03
- Article/story/print advertisement ❑04
- Radio story/advertisement ❑05
- TV story/advertisement ❑06
- E-mail/web site ❑07
- Screening event/presentation ❑08
- Word of mouth ❑09
- Other _____ ❑_ _

19. What is your date of birth? ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy)

20. What are the last 4 digits of your social security number? _____ _____ _____ _____

For Office Use Only

		Yes	No
21.	BMI checked: ❑ eligible ❑ ineligible		
22.	Optional SBP ____ ____ ____ Optional DBP ____ ____ ____		
23.	Interested? (use script)	❑1	❑2
24.	Eligible for SV1	❑1	❑2
25.	What cohort is participant being screened for?	_____	

Reviewed by (staff ID): _____

Entered by (staff ID): _____

PSV Script

This script can be administered over the phone or in person.

- "The purpose of the PREMIER Study is to find out how changes in exercise, diet, alcohol use, and weight affect blood pressure."
- "This is not a drug study."
- "If you join the study, you will be randomly assigned, as in the flip of a coin, to one of three intervention programs to help you lower your blood pressure and improve your overall health."
- "The study will last 18 months."
- "To be eligible to participate, you'll first have to come to _____ for approximately 3 screening visits to make sure that you have higher than optimal blood pressure or mild high blood pressure and are free from any health conditions that would make participation unsafe."
- "Once enrolled in the study, you will be asked to come to _____ on numerous occasions over the next 18 months, both to learn about lifestyle change, and to collect study measurements. "
- "The number of visits depends on the group to which your are assigned."
- "Study measurements include blood pressure, weight, blood and urine specimens, a fitness test, and questions about your diet and physical activity levels."
- "In addition to participation at no charge in the lifestyle programs and regular blood pressure monitoring, you will receive $_____ at the end of the study as our way of saying thanks for your involvement."

Prescreen Eligibility Form Training Manual and Coding Instructions

Overview

The Prescreen Eligibility Form may be completed in one of three contexts:

- over the phone,
- during a community screening activity, or
- in the clinic.

It is recommended that this form be administered in an **interview format.** If this form is given to the participants to complete on their own, question 18 (on how the participant heard about PREMIER) needs to have the definitions of recruitment sources explained to the participant (see attached definitions).

Some of the questions on this form result in immediate exclusion from the study, others are intended to gather demographic information, to aid in recruitment monitoring, and some are used as a flag to be reviewed by a clinician or dietitian.

As soon as a participant is determined to be ineligible, the staff person should check the "No" box under Question 24 and terminate the interview.

ID labels will be affixed to pages 1-3 of this form after it has been entered. At that time, the first page should be detached and filed separately.

Administration Instructions

Using a blue or black pen, fill out the visit date on pages 1 and 2.

The remaining items can be completed by the participant or by the interviewer.

Page	Question	Special Administration Instructions (if any)
1	1	self-explanatory
	2	self-explanatory
	3	self-explanatory
	4	self-explanatory
2	1	If NO, then enter NO for Q24 and terminate interview. If participant will soon have a birthday, you may bring them back after they turn 25 and repeat the prescreen.
	2	If YES, then enter NO for Q24 and terminate interview.
	3	Skip this question for males. If participant is female and answers YES, then enter NO for Q24 and terminate interview. Inform the woman that, because of the effects of pregnancy and/or breastfeeding on blood pressure, she is not eligible for the study at this time. The participant can be rescreened later after they deliver and/or stop breastfeeding. This question may not be checked NO based on the expectation that the participant will deliver and/ or stop breastfeeding in the near future.

Page	Question	Special Administration Instructions (if any)
2	4	If YES, then enter NO for Q24 and terminate interview.
	5	If YES, then enter NO for Q24 and terminate interview.
	6	If YES, then enter NO for Q24 and terminate interview.
	7	If YES, gather as much detail as possible, complete the remainder of the form, and refer the form to the clinician for review (assuming the participant is otherwise eligible). If the clinician decides that the person is eligible, recode the answer to Q7 to NO. Otherwise, enter NO for Q24.
	8	If YES, gather as much detail as possible, complete the remainder of the form, and refer the form to the clinician for review (assuming the participant is otherwise eligible). If the clinician decides that the person is eligible, recode the answer to Q8 to NO. Otherwise, enter NO for Q24.
	9	If YES, then find out exactly when the participant plans to leave the area. If it is after the last followup date for the current cohort, then recode the answer to NO. Otherwise, enter NO for Q24 and terminate interview.
	10	Probe to get a specific number of drinks. If >21, then enter NO for Q24 and terminate interview.
	11	Record height in feet and inches
	12	Record weight in pounds. To determine eligibility, first locate the participant's height (from Q11) on the attached BMI Reference Chart and note the accompanying weight limits. If the participant's weight is below the lower limit, or above the upper limit, check ineligible for Q21, enter NO for Q24 and terminate the interview. Otherwise, check eligible for Q21.
	13-14	If YES, gather as much detail as possible and then exclude the participant (enter NO for Q24) if any of the following limitations/reasons is specified: use of cane, walker, or other walking aid; severe arthritis, musculoskeletal injury, broken limb, or structural foot problems, which would make walking difficult; respiratory disease that causes difficulty in breathing with light exertion. Exclude by entering NO for Q24. If unable to decide, refer to PI or Intervention Director for decision.
3	15	If OTHER, gather as much detail as possible about the participant's self-described primary race and be sure to follow the coding instructions on page 6. If "Hispanic" is recorded, or Q16 is YES, probe for primary race code.
	16	Although often used as a racial category, "Hispanic" actually relates more closely to ethnicity and is thus complementary to Q15.
	17	self-explanatory

Page	Question	Special Administration Instructions (if any)
3	18	Check only one answer. The item that prompted the participant to call or come in should be used. The participant can write in other responses if they want, but it will need to be coded later. See attached table for definitions.
	19	Use a 4-digit year (e.g. 12/10/1999 or 1/15/2000)
	20	If asked, explain to participants that this is used to identify them in case some other participant has the same name.
	21	Fill out based on instructions for Q12
	22	This optional BP measured with a standard mercury sphygmomanometer, is optional. Guidelines for eligibility are SBP 118-179 and DBP 78-109. Clinical discretion may be used to further evaluate potential subjects if they indicate that the pre-screen BP determination was atypical. However, the pre-screening escape guidelines must be followed, and the participant referred to a physician within one week whenever the SBP exceeds 180 or the DBP exceeds 110. If the BP is outside the limits and the clinician does not decide to make an exception, then enter NO for Q24 and terminate the interview.
	23	Read the script describing the study and the nature of the interventions, and ask participant if he/she is still interested in participating. If NO, then enter NO for Q24 and terminate the interview.
	24	If you have gotten to this point and the participant is still eligible, and any necessary clinician review of Q7-8 and interventionist/clinician review of Q13-14 has been completed, then enter YES.
	25	self-explanatory

Coding Instructions

Follow up on any YES answers to Q7, Q8, Q13, or Q14. Recode the answers as appropriate following clinician/interventionist review. Add an explanation of the decision, and initial and date the correction.

Make sure any OTHER answers to Q15 are recoded appropriately. The following table lists some common responses listed under OTHER and how to categorize them. Contact the CC for a decision if you have an answer which is not covered in the table.

Description from participant	Recode to:
Ethiopian, Mulatto, West Indian	3=Black/African American
Spanish, Cape Verdian, Lebanese, Persian, Jewish, Brazilian, Persian, Arab, Portuguese, Milano, Russian	4=White

Make sure any OTHER answers to Q18 are recoded appropriately. Contact the CC for a decision if needed.

Review Instructions

If participant is INELIGIBLE (Q24=NO), confirm that there is at least one item on page 2 that makes them ineligible. This form does not need to be entered, so enter your Staff ID in the "reviewed by" section at the bottom of page 3, and put a large "X" in the "entered by" section.

If the participant is ELIGIBLE (Q24=YES), check the following items:

- Pages 1-2 should be dated.
- Participant's name on page 1 should be complete, legible, and in the right order (first then last, not last then first).
- Page 2:
  - -item 1 should be coded YES;
  - -items 2,5,6,7,8,9,13 and 14 should be coded (or recoded) NO;
  - -item 3 should be coded NO or skipped (males);
  - -item 10 should be less than or equal to 21;
  - -item 12 should be within the range allowed for the height shown in item 11.
- Page 3:
  - -all items should be completed (except the optional Q22).
  - -All items initially coded to OTHER on Q15 and Q18 should now be assigned to an appropriate code. If no code applies, contact the CC for a decision.
- All pages: all corrections should be explained, initialed, and dated. Corrections should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.
- If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 3.
- If the participant remains ELIGIBLE at the end of the review process, then forward the form to the data entry person to be entered. Do not separate page 1 from pages 2-3 until after labels have been generated.

Additional Instructions

Do not enter forms where outcome is ineligible. Forms with outcome="eligible" can be entered at any time (since it is the first form in the sequence).

The Data Entry application will assign a participant ID. **Write the ID number at the top of each page of the form.**

After the form has been entered, use the Data Management application to print labels and attach the labels over the top of the hand-written ID on each page of the form.

Once the form has been labeled, detach page 1 from the rest of the form. If you are ever asked to send the form to the CC for validation or to solve some data problem, send only pages 2 and 3 to avoid transmitting confidential information (name, address, phone).

PSV BMI Reference Chart

Participants weight must be greater than or equal to the minimum weight for their height in the table below, and less than or equal to the maximum weight.

Height in feet and inches	Weight in Pounds	
	Minimum Weight	Maximum Weight
4’ 6”	74	188
4’ 7”	77	196
4’ 8”	80	203
4’ 9”	83	210
4’ 10”	86	217
4’ 11”	89	225
5’ 0”	92	233
5’ 1”	95	240
5’ 2”	98	248
5’ 3”	101	257
5’ 4”	105	265
5’ 5”	108	273
5’ 6”	111	282
5’ 7”	115	290
5’ 8”	118	299
5’ 9”	122	308

Height in feet and inches	Weight in Pounds	
	Minimum Weight	Maximum Weight
5’ 10”	125	317
5’ 11”	129	326
6’ 0”	132	335
6’ 1”	136	344
6’ 2”	140	354
6’ 3”	144	364
6’ 4”	147	373
6’ 5”	151	383
6’ 6”	155	393
6’ 7”	159	403
6’ 8”	163	414
6’ 9”	168	424
6’ 10”	172	435
6’ 11”	176	445
7’ 0”	180	456

Definitions for items in Question 18 :

01: Mailed Letter/Brochure/Flier: any mass mailing of PREMIER information that requests a mail or phone response. This does not include calls or cards returned as a result of distributing brochures by other means (I.e. hand distribution at malls). Those should be coded as "Other Mass Distribution."

02: Coupon Pack: any mass mailing through companies which include PREMIER brochures or special coupons with other coupons.

03: Other Mass Distribution: this includes brochures distributed by hand or left on display at sites, libraries, grocery stores, and pharmacies.

04: Article/story/print advertisement: this includes any participant who heard about the study via a newspaper, newsletter or magazine, regardless of whether it was a story or a paid advertisement.

05: Radio story/advertisement: this includes any participant who heard about the study via the radio, regardless of whether it was a story or a paid advertisement.

06: TV story/advertisement: this includes any participant who heard about the study via a TV, regardless of whether it was a story or a paid advertisement.

07: E-mail/web site: this includes any participant who heard about the study via an e-mail message, electronic bulletin board, or the internet.

08: Screening event/presentation: this includes any participant who attended a gathering, event, or presentation that occurs outside a PREMIER clinic. It may last one or more days. This could include screenings at churches, shopping malls, etc.

09: Word of mouth: this includes any participant who was referred to PREMIER by a friend, family member, physician, health care provider, or public clinic. If the participant also heard of the study through one of the target mailings, code as appropriate for the mailing.

Items listed under Other: if the response can not be coded as 1-9 above, it should be coded as 10 or proceed with instructions under 11.

10: Person was in prior study: anyone who was in a prior research study at the clinical center, including DASH and DASH2.

11: If the item does not fit any of the above categories, contact the CC for a decision.

SV1
ID: _____
Date: ____ / ____ / _____

SV1 Blood Pressure Form

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Arm circumference (cm, round all fractions up)..... _____ _____

Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____

\+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number..... ____ ____

PIL ID: _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value..... __ __ __ / __ __ __

b. Zero value..... __ __

c. Corrected value (a-b)..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value..... __ __ __ / __ __ __

b. Zero value..... __ __

c. Corrected value (a-b)..... __ __ __ / __ __ __

4. COMPUTE SUM

Sum of 2 SBPs and 2 DBPs (2c + 3c)..... __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Ineligible: escape-level BP.....Sum of SBPs ≥ 359 ❑ 1

Sum of DBPs ≥ 219 ❑ 2

If box 1 or 2 is checked: complete form #32 (escape level 1), participant is ineligible

Ineligible: BP too high.....Sum of SBPs 341–358 ❑ 5

Sum of DBPs 201–218 ❑ 6

If box 5 or 6 is checked: complete form #32 (escape level 2), participant is ineligible

Ineligible: BP too low.....Sum of SBPs ≤ 234 ❑ 3

Sum of DBPs ≤ 154 ❑ 4

If box 3 or 4 is checked: participant is ineligible

Eligible..... Sum of SBPs 235-340, Sum of DBPs 155-200 ❑ 7

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

SV1 Blood Pressure Form and Coding Instructions

Overview

The SV1 Blood Pressure Form is filled out by clinic staff and is used for blood pressure screening to determine eligibility of potential participants.

The SV1 Blood Pressure Form must be filled out during each SV1 visit. ID # labels should be printed and placed on the SV1 forms.

If data collected on this form indicates immediate exclusion, "ineligible" should be checked on the SV1 Visit Form (#03) for the SV1 Blood Pressure Form outcome. If blood pressure values are too high for eligibility, the BP escape tracking form (#32) should be completed**.**

If item 1c=No, all subsequent questions are left blank and the participant is ineligible. If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Use correct version of form. The correct version will always be on the site workstation computer.

Place ID labels on pages 1 and 2. Check for accuracy. If an ID # number has not yet been assigned, keep this form stapled to the Prescreen Eligibility Form until that form is entered and an ID is assigned. Then print ID labels, attach to pages 1 & 2 and detach this form from the Prescreen Eligibility Form.

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Page	Question	Special Administration Instructions
1	1	Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
	a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
	b.	Measure the participant's arm circumference. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). Record the rounded arm circumference. Based on the arm circumference obtained, mark an "X" on the corresponding line indicating proper cuff size for the measurement. Use the cuff size obtained at SV1 for all of the participant's blood pressure measurements during screening.
	c.	Indicate here whether or not the cuff fits properly. If the brachial artery is occluded by the cuff, the participant is excluded from participating in PREMIER (see MOP Chapter 17). If this is so, check No, and check "ineligible" on the SV1 Visit Form (Form #3) for the SV1 Blood Pressure Form outcome. If the cuff fits properly, check Yes.

Page	Question		Special Administration Instructions
1			**WAIT 5 MINUTES SEATED**
	1	d.	Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.
		e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
		f.	Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
		g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.
2	2	a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
		b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
		c.	Do Items 3a and 3b first. Then follow instructions for Item #3c.
			Wait 30 seconds
	3	a.	Repeat item #2a.
		b.	Repeat item #2b.
		c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4		Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100.
	5		Using the sum value from item #4, check the **first** applicable box . If ineligible, check "ineligible" on the SV1 visit form (#3) for the SV1 Blood Pressure Form outcome (at the top). If eligible, check "eligible" on the SV1 visit form for the SV1 Blood Pressure Form outcome. If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#32) should be filled out. Refer to MOP Chapter 23 for details and complete form #32.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

If the participant is INELIGIBLE (Q1c=No or Q5=ANY box marked EXCEPT 7), mark as ineligible on the SV1 Visit form (#03) for the SV1 Blood Pressure Form outcome.

Check for correct addition in items 1f, 2c, 3c, and 4.

If the participant is ELIGIBLE (Q5= box #7 marked), check the following items:

- Page 1 should be dated.
- Pages 1-2 should have correct ID# labels.
- Page 1:
  - -items 1a-b and 1d-g should be completed;
  - -item 1c should be coded as Yes;
- Page 2:
  - -items 2 and 3 should be completed;
  - -item 4 should be within the range allowed for blood pressure shown in the last option for item 5, the eligible line;
  - -item 5 should have box 7 marked.
- All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.
- If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2, and enter "eligible" on the SV1 Visit form (#03) for the SV1 Blood Pressure Form outcome (at the top).

Additional Instructions

Use the cuff size obtained at SV1 to record all of a participant's blood pressure measurements during screening.

SV1
ID: _____

SV1 Visit Form

	DONE?
Check visit window (≤4 months since PSV).....	❑
Informed consent (if applicable)	❑
Participant contact information sheet.....	❑

Complete SV1 Blood Pressure Form ..... **eligible** ❑1
ineligible ❑2

Complete Eligibility Questionnaire..... **eligible** ❑1
(including clinician review if necessary) **ineligible** ❑2

	DONE?
Review SV1/SV2 Activity Fact Sheet.....	❑

Complete Diet and Physical Activity Change Checklist ..... **eligible** ❑1
ineligible ❑2

Measure height and weight

Height _____ _____ _____ . _____ cm

Weight _____ _____ _____ . _____ _____ lbs ..... **eligible** ❑ 1
ineligible ❑ 2

Complete Rose Questionnaire – PVD ..... **positive*** ❑1
negative ❑2

Complete Rose Questionnaire – Angina ..... **positive*** ❑1
negative ❑2

SV1 Visit Outcome ..... **eligible** ❑1
ineligible ❑2
refused ❑3

SV2 Visit Date: _____
(remind participant to bring in medications for SV2)

Reviewed by (staff ID): _____
Entered by (staff ID): _____

*Requires physician followup prior to randomization.

SV1 Visit Form Training Manual and Coding Instructions

Overview

The SV1 Visit form is filled out by clinic staff and is used to track the progress of the participant through the components that make up the SV1 visit.

As soon as a participant is determined to be ineligible, check the "Ineligible" box under the Visit Outcome and terminate the visit. If a participant refuses to complete the visit, check the "Refused" box under the Visit Outcome and terminate the visit. For eligible participants, all items must be completed.

Do not enter this form until the visit is complete and a final outcome is determined. If visit is incomplete and will not be completed, either enter "Refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

Administration Instructions

Using a blue or black pen, fill out each of the items on page 1. If a participant becomes ineligible at any point, you do not need to complete the remaining items.

Question	**Special Administration Instructions (if any)**
Check visit window	Make sure that no more than 4 calendar months have elapsed since the PSV visit date. If more than 4 months have elapsed, repeat the PSV visit.
Informed consent	The need for a consent to be done at a specific visit will vary by site. If consent is being done at this visit, check the "Done?" box.
Participant information	After completing form #100, the Participant Information Sheet, check the "Done?" box.
SV1 BP Form	After completing form #2, enter the eligibility outcome. If ineligible, skip to the SV1 Outcome field, check the "ineligible" box, and terminate the visit.
Eligibility Questionnaire	After completing form #4, enter the eligibility outcome. If ineligible, skip to the SV1 Outcome field, check the "ineligible" box, and terminate the visit.
Review fact sheet	After reviewing form #106 with the participant, check the "Done?" box. If the participant decides after reviewing the fact sheet that they do not wish to continue with the study, skip to the SV1 Outcome field, check the "refusal" box, and terminate the visit.
Checklist	After participant completes form #8, enter the eligibility outcome.
Height	Measure the participant's height in centimeters following the procedures in Chapter 20 (Other Clinical Measures). Record the result, rounding to the nearest 0.1 cm.

Question	Special Administration Instructions (if any)
Weight	Measure the participant's weight in pounds following the procedures in Chapter 20 (Other Clinical Measures). Record the result, rounding to the nearest 0.25 lb.
Rose PVD	After completing form #5, enter the positive or negative outcome. For this form, either a positive or a negative outcome makes the participant eligible to continue. If positive and your investigator chooses to exclude the participant without further followup, this must be done with a closeout form, do not check the "ineligible" box on this form.
Rose Angina	After completing form #6, enter the positive or negative outcome. For this form, either a positive or a negative outcome makes the participant eligible to continue. If positive and your investigator chooses to exclude the participant without further followup, this must be done with a closeout form, do not check the "ineligible" box on this form.
BMI Outcome	Use height and weight to compute BMI outcome. See Coding Instructions below
SV1 Visit Outcome	see Coding Instructions below

Coding Instructions

BMI outcome: Using the attached SV1 BMI Reference chart, look up the participant's height. Round off decimals for height (i.e. 150.4 rounds to 150, 150.5 rounds to 151) when looking up heights in the table. If the participant's weight is between the minimum and maximum in the table, check the "eligible" box, otherwise, check the "ineligible" box.

SV1 Visit Outcome: After all other items are complete, enter the visit outcome. If the outcomes for blood pressure, Eligibility Questionnaire, Diet and Physical Activity Change Checklist, and BMI are all "eligible" and the participant wishes to continue, check the "eligible" box. If any item is marked "ineligible," check the "ineligible" box. If the participant refused at any point, check the "refusal" box. If visit is incomplete and will not be completed, either enter "Refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

Review Instructions

Do not review this form until the visit is complete and a final outcome is determined.

If visit is incomplete and will not be completed, either enter "Refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form. For all participants:

- Make sure that the ID label has been attached.

For eligible participants:

- Check that all items have been completed.
- Make sure that all of the eligible/ineligible responses have been checked "eligible."

For ineligible participants:

- All items do not have to be completed, but make sure that at least one eligible/ineligible response has been checked "ineligible."

For refusals:

- No other items are required.

After reviewing the form, enter your staff ID on the "Reviewed by" line.

Additional Instructions

Do not enter this form until:

- the visit is complete
- a final outcome is determined
- all other forms related to the visit (#2, 4, 5, 6) have been entered. (Form #106 is not entered)

If either Rose Questionnaire had a positive outcome, and the SV1 Outcome is "eligible," be sure to begin the process of contacting the participant's physician to get permission for the subject to participate in the trial. This process must be completed before the participant can be randomized.

SV1 BMI Reference Chart (minimum BMI=18.5, maximum BMI=45)

(round off decimals for height: 150.4 rounds to 150, 150.5 rounds to 151)

Height in	Weight in lbs	
cm	Min weight	Max Weight
139	78.00	194.25
140	79.00	197.00
141	80.25	199.75
142	81.25	202.75
143	82.50	205.50
144	83.75	208.50
145	84.75	211.25
146	86.00	214.25
147	87.25	217.25
148	88.50	220.25
149	89.50	223.25
150	90.75	226.00
151	92.00	229.25
152	93.25	232.25
153	94.50	235.25
154	95.75	238.25
155	97.00	241.50
156	98.25	244.50
157	99.50	247.75
158	100.75	250.75
159	102.00	254.00
160	103.25	257.25
161	104.75	260.50
162	106.00	263.75
163	107.25	267.00
164	108.50	270.25
165	110.00	273.50
166	111.25	276.75
167	112.50	280.25
168	114.00	283.50
169	115.25	286.75
170	116.75	290.25
171	118.00	293.75
172	119.50	297.00
173	120.75	300.50
174	122.25	304.00
175	123.75	307.50
176	125.00	311.00

Height in	Weight in lbs	
cm	Min weight	Max Weight
177	126.50	314.50
178	128.00	318.25
179	129.50	321.75
180	130.75	325.25
181	132.25	329.00
182	133.75	332.50
183	135.25	336.25
184	136.75	340.00
185	138.25	343.50
186	139.75	347.25
187	141.25	351.00
188	142.75	354.75
189	144.25	358.50
190	145.75	362.50
191	147.50	366.25
192	149.00	370.00
193	150.50	374.00
194	152.00	377.75
195	153.75	381.75
196	155.25	385.50
197	156.75	389.50
198	158.50	393.50
199	160.00	397.50
200	161.75	401.50
201	163.25	405.50
202	165.00	409.50
203	166.50	413.50
204	168.25	417.75
205	169.75	421.75
206	171.50	425.75
207	173.25	430.00
208	174.75	434.25
209	176.50	438.25
210	178.25	442.50
211	180.00	446.75
212	181.75	451.00
213	183.25	455.25
214	185.00	459.50

SV1
ID: _____
Date: ____ / ____ / _____

Eligibility Questionnaire

NAME_____
(First) (Last)

Please review and answer all of the questions on this form. Indicate your answers by placing an "x" in the appropriate box. Depending upon your answers, some of the questions may be skipped.

Thank you very much for your cooperation.

	Yes	No	Comments
1. Have you ever had any of the following?			
a. Stroke	❑ 1	❑ 2	_____
b. Heart attack	❑ 1	❑ 2	_____
c. Congestive heart failure	❑ 1	❑ 2	_____
d. Coronary bypass surgery or angioplasty	❑ 1	❑ 2	_____
e. Blood vessel surgery to open arteries in your neck or legs	❑ 1	❑ 2	_____
2. Have you ever had cancer? (other than skin cancer)	❑ 1	❑ 2	_____
. 2a. ***If yes,*** was it: Active within the past 2 years or treated with radiation or chemotherapy in the past 2 years?	❑ 1	❑ 2	_____
3. Have you taken any medications to control your blood pressure within the past 3 months?	❑ 1	❑ 2	_____
4. Have you taken any medications to control your weight within the past 3 months? (see attached list)	❑ 1	❑ 2	_____
5. Do you regularly (more than 5 days per month) take any of the following medications?			
a. Steroid or corticosteroid pills? (e.g., prednisone)	❑ 1	❑ 2	_____
b. Oral breathing medications other than inhalers?	❑ 1	❑ 2	_____
c. Insulin or pills for diabetes?	❑ 1	❑ 2	_____
d. Lithium?	❑ 1	❑ 2	_____

ID: _____

	Yes	No	Comments
6. In the last 2 years, have you been hospitalized for psychological or emotional problems?	❑ 1	❑ 2	_____

7 On average, how many drinks of alcohol do you have in a week? (1 drink=1 can of beer or 1 glass of wine or 1 shot of liquor. If you don't drink alcohol, enter 0.) ____ ____ . ____ drinks per week

7a. **If you drink alcohol,** how often do you have six or more drinks on one occasion?

- Never ❑ 1
- Less than monthly ❑ 2
- Monthly ❑ 3
- Weekly ❑ 4
- 2-3 days/week ❑ 5
- 4-7 days/week ❑ 6

	Yes	No	Comments
8. Has your weight changed by more than 15 pounds within the last 3 months?	❑ 1	❑ 2	_____
9. Are you currently participating in any other research studies or clinical trials?	❑ 1	❑ 2	_____
10. Are you planning to move out of the area in the next two years?	❑ 1	❑ 2	_____
11. Do you live in the same household with a PREMIER staff member or a PREMIER participant?	❑ 1	❑ 2	_____
12. Do you live in the same household with someone who is trying out for PREMIER?	❑ 1	❑ 2	_____

Office Use: *If Yes*: Enter the ID number of the household member……. _____

For women only

13. Are you pregnant, planning to become pregnant in the next 24 months, or breast feeding? ..... ❑ 1 ❑ 2 _____

Office Use:

Outcome:	Eligible	❑ 1	Reviewed by (staff ID): _____
	Ineligible	❑ 2	Entered by (staff ID): _____

Weight-loss Drugs (Question 4)

This list includes some but not all the prescription and over the counter weight loss products. Please respond "Yes" if you have used any of these products for weight loss within the past 3 months.

Generic name	Brand name
Benzphetamine	Didrex
dexfenfluramine	Redux
diethylpropion	Tenuate, Tepanil
fenfluramine	Pondimin
phentermine	Adipex, Fastin, Ionamin, Obenix, Oby-Cap, Oby-Trim, Pro-Fast, Zantril
fenfluramine/phentermine	Fen/Phen
mazindol	Sanorex, Mazanor
phendimetrazine	Plegine, X-trozine, Bontril, Prelu-2
phenmetrazine	Preludin
phenylpropanolamine	Dexatrim, Accutrim
d-amphetamine	Dexadrine, Dextrostat
methamphetamine	Desoxyn
orlistat	Xenical
sibutramine	Meridia

Eligibility Questionnaire

Overview

This Eligibility Questionnaire will typically be completed by the participant at the SV1 visit, but can also be completed at the participants home prior to the SV1 visit.

This questionnaire will begin the process of screening applicants for a variety of medical conditions and personal habits that would make participants ineligible. Some of these conditions/habits could interfere with the study by obscuring the effects of the study diet. Others might make it harmful or unwise for an individual to participate.

Administration Instructions

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Place ID labels on pages 1 and 2. If an ID# has not yet been assigned, leave blank and fill in later.

The remaining items can be completed by the participant or by the interviewer.

The following information is intended to help you assist participants in providing accurate answers to these questions. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire so that further review may be undertaken by a study clinician. **Ultimately, all responses must be resolved and coded either "Yes" or "No".**

Page	Question	Special Administration Instructions (if any)
1	name	This field is used for sites that do a combined PSV/SV1 and will not be able to print labels prior to the time the participant fills out this form. It is not a required field. Once labels have been added, this field should be blacked out to avoid any breach of confidentiality when forms are faxed. For sites that do not do combined PSV/SV1 visits, this field can be masked off on the master when you make copies for participants, and then there will be no need to black out participant names later.
	1a-e	These questions are intended to screen for cardiovascular disease <u>other than</u> hypertension. An individual with <u>only</u> hypertension should answer NO to each question. If any question is answered YES, participant is ineligible for the study. Note: question 1a does not include heat stroke.
	2	Enter YES if the participant has ever had a diagnosis of cancer. If there is no history of cancer or participant has only had skin cancer, enter NO.
	2a	For <u>Inactive</u> cancers, those which have (1) been in remission for over two years <u>or</u> were removed over two years ago AND (2) have not resulted in any further treatment within the past two years, **ENTER NO**. For <u>Active</u> cancers, those present within the past two years OR which required treatment within the past two years, **ENTER YES.** If Yes, then participant is ineligible.
	3	If YES, participant is ineligible.

Page	Question	Special Administration Instructions (if any)
	4	If YES, the participant is ineligible for this cohort, but may be screened for a subsequent cohort if they go off the medication. Participants must be off diet pills/weight loss medications 3 months prior to SV1. If No, double check if participant reviewed the list of Weight Loss Drugs on page 3.
1	5	If YES to any of the items (a, b, c, or d), the participant is ineligible. Note: the 5+ days per month do not have to be consecutive.
2	6	If YES, participant is ineligible.
	7	If answer is >21 drinks per week, the participant is ineligible. Participants who do not drink alcohol should enter zero. If the participant asks, a drink is defined as 12 oz. of beer, 5 oz. of wine, or a 1 oz. shot of liquor. If participant gives a range use the mid-range or higher number. For example, code "5-6" as "5.5", code "0.5 to 1" as 1, and code "4 to 6" as "5".
	7a	If 2-3 days/week or 4-7 days/week are checked, the participant is ineligible. Participants who do not drink alcohol should skip this question.
	8	If YES, the participant is ineligible.
	9	Q9 is not necessarily exclusionary. If YES, the clinician can decide if the two trials are in conflict and recode this answer to NO if there is no conflict.
	10	Q10 is not necessarily exclusionary. If YES, then find out exactly when the participant plans to leave the area. If it is after the last follow up date for the current cohort, then recode the answer to NO.
	11	If YES, participant is ineligible.
	12	Two household members may be screened for PREMIER, but only one can eventually be randomized. The other can be invited to participate in the assigned intervention. Screening may continue on both members until one is randomized.
	13	This question should be completed only by women. If YES, Participant is ineligible.
	Office Use:	If you have gotten to this point and the participant is still eligible, and all comments have been resolved, then enter "eligible".

Coding Instructions

Follow up on any blank items, or any items where participant wrote in the comments field. Code or recode the answers as appropriate following clinician/interventionist review. Add an explanation of the decision, and initial and date the correction.

When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID number should not be filled in until the form is entered.

Review Instructions

If the participant is INELIGIBLE (at least ONE question = Yes on page 1 or 2, except Q2-1st part, or Q7 >21 drinks per week), mark as ineligible on the SV1 Visit Form (#03) for the SV1 Eligibility Questionnaire outcome.

If the participant is ELIGIBLE (Office use box is marked eligible), check the following items:

? Page 1 should be dated, pages 1-2 should have correct ID# labels. (See Additional Instructions below)

? Page 1: items 1a-e, 2a,3, 4, 5a-c should be coded (or recoded) NO;

? Pages 2-3: items 6, 8-11, 13 should be coded (or recoded) NO, item 7 should be less than or equal to 21; item 7a should be coded no higher than "weekly". If item 12 is "Yes", be sure to enter the PREMIER ID of the other household member being screened.

If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 3, and enter "eligible" on the SV1 Visit Form (#03) for the SV1 Eligibility Questionnaire outcome.

Additional Instructions

If form was filled out prior to labels being printed, make sure to attach labels prior to data entry. Once the labels are attached, black out the participant's name on page 1.

SV1

ID: _____

Date: __ __ / __ __ / __ __ __ __

Rose Questionnaire – PVD

		Yes	No
1.	In the **past month**, have you had a pain in either leg on walking?	❑ 1	❑ 2 → Stop
2.	Does this pain ever begin when you are standing still or sitting?	❑ 1 → Stop	❑ 2
3.	Do you get this pain in your calf (or calves)?	❑ 1	❑ 2 → Stop
4.	Do you get it when you walk uphill or hurry?	❑ 1	❑ 2 → Stop
5.	Do you get it when you walk at an ordinary pace on the level?	❑ 1	❑ 2
6.	Does the pain ever disappear while you are still walking?	❑ 1 → Stop	❑ 2

7. What do you do if you get it when you are walking?
   - Stop or Slow Down ❑ 1
   - Continue at same pace ❑ 2 → Stop

8. What happens to it if you stand still?
   - Usually disappears in 10 minutes or less ❑ 1
   - Usually continues more than 10 minutes ❑ 2

Office use

9. Outcome:
   - *Positive ❑ 1
   - Negative ❑ 2

* ❑ If positive, refer to clinician and complete follow up worksheet.

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Rose Questionnaire-PVD

Overview

The purpose of this interviewer-administered form is to identify individuals with peripheral vascular disease. This form may be self administered if it is thoroughly explained to the participant. If it is self-administered, it is suggested that the first question be interviewer-administered, and the questionnaire only handed out to participants who answer "Yes" to the first question.

The form will be used at SV1 to identify participants with suspected peripheral vascular disease who need physician approval to continue in the study. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire and send to the study clinician for review.

Administration Instructions

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Place ID label on page 1.

This form should be completed by the interviewer due to its complexity, but can be self administered if thoroughly explained to the participant.

Page	Question	Special Administration Instructions (if any)
1	1	If Yes, Q2 should be completed. If No, Stop.
	2	If Q1 = "Yes", this question may not be left blank. If Yes, Stop. If No, Q3 should be completed.
	3	If Q1 = "Yes" and Q2 = "No", this question may not be left blank. If Yes, Q4 should be completed. (A "Yes" response may include other leg pain, but must include pain in at least one calf.) If No, Stop.
	4	This question refers to pain without exceptional exertion. If both Q1 and Q3 = "Yes" and Q2 = "No", this question may not be left blank. If Yes, Q5 should be completed. If No, Stop. (Clarify all "No" responses. If "No" is marked because they don't walk uphill or hurry, restate the question: "If you did walk up hill or hurry, do you think it would cause pain in either leg?")
	5	If Q1, Q3, and Q4 all = "Yes" and Q2 = "No", this question may not be left blank. Q6 should be completed regardless of the response selected in Q5. This question is to be used by the study clinician to help determine severity. It is not used in determining outcome.
	6	If Q1, Q3 and Q4 all = "Yes", and Q2 = "No", this question may not be left blank. If "Yes", Stop. If "No", Q7 should be completed.
	7	If Q1, Q3, and Q4 all = "Yes," and both Q2 and Q6 = "No", this question may not be left blank. If answer is "Stop or Slow down", Q8 should be completed. If answer is "Continue at same pace", Stop.

Page	Question	Special Administration Instructions (if any)
1	8	If Q1, Q3, and Q4 all = "Yes," both Q2 and Q6 = "No" and Q7 = "Stop or Slow Down", this question may not be left blank.
	9	Should be filled out for all participants. If participant reached a "Stop" outcome above or Q8 = "Usually continues more than 10 minutes" enter "Negative". If you have gotten to this point without reaching a "Stop" and Q8 = "Usually disappears in 10 minutes or less", enter "Positive" and complete the Positive PVD worksheet.

Coding Instructions

Make sure all corrections are initialed and dated with an explanation.

When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID number should not be filled in until the form is entered.

Review Instructions

If the participant is Negative for PVD (Q9 = Negative), confirm that a "Stop" outcome occurred on the form or Q8 = "Usually continues more than 10 minutes", enter "Negative" on the SV1 Visit Form (#03) for the Rose Questionnaire-PVD outcome.

If the participant is Positive for PVD (Q9 = Positive), all of the following conditions must be met:

- Q1 = Yes
- Q2 = No
- Q3, and Q4, = Yes
- Q6 = No
- Q7 = "Stop or Slow Down"
- Q8 = "Usually disappears in 10 minutes or less",

When all the above conditions are met (Q9 = Positive), staff must complete the Positive PVD screening worksheet.

If all of the above items look acceptable, enter your Staff ID number in the "reviewed by" section at the bottom of page 1, and enter "Positive" on the SV1 Visit Form (#03) for the Rose Questionnaire-PVD outcome.

Additional Instructions

Need to write up instructions about how clinician should review form.

Positive PVD Worksheet

This worksheet is to be completed for every participant who is coded as POSITIVE on Q9 of the Rose Questionnaire – PVD.

Steps for all participants

- ❑ Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.

  Referral Date: _____

  Physician Name (if known): _____

  Physician Phone (if known): _____

- ❑ Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM
- ❑ Does participant wish to continue in the trial? (circle one) YES / NO
  *(If YES, then go on to the following section. If NO, close the participant out as a "Refusal" on the visit form or on a closeout form if between visit*s).

Steps for participants who wish to continue in the trial:

- ❑ Contact participant's physician to get approval for participation in the study. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician.

  Physician Name: _____

  Physician Phone: _____

  Date of contact: _____

  Outcome of contact (circle one): EXCLUDE / OK TO CONTINUE*

  Notes: _____

  _____

- ❑ Study clinician reviews study chart

  Study Clinician Name: _____

  Date of Review: _____

  Outcome of review (circle one): EXCLUDE / OK TO CONTINUE*

  Study Clinician Signature: _____

  Notes: _____

  _____

**Participant can only continue if form is determined to be a false positive.*

(If both the participant's physician and the study clinician say the participant is "OK to continue," enter an outcome of "Eligible" on the Pre-Randomization Checklist. Otherwise, enter "Ineligible." To close the participant out prior to completing the Pre-Randomization Checklist, you can enter a closeout form with the reason coded as "Investigator discretion for safety")

ID: _____

Date: ____ / ____ / _____

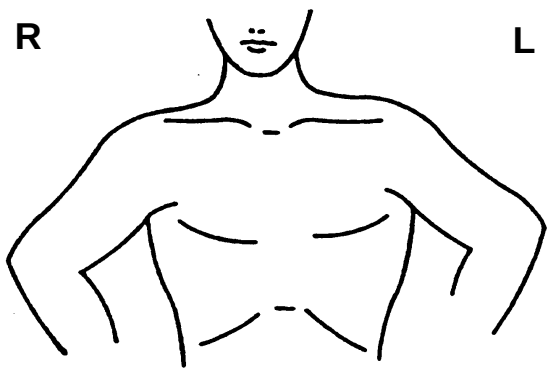
Baseline Rose Questionnaire – Angina

Visit: SV1 ❑ 02

		Yes	No
1.	In the **past month**, have you had any pain or discomfort in your chest?	❑ 1	❑ 2 → Stop
2.	Do you get this pain or discomfort when you walk uphill or hurry?	❑ 1	❑ 2 → Stop
3.	Do you get this pain when you walk at an ordinary pace on the level?	❑ 1	❑ 2
4.	When you get any pain or discomfort in your chest, what do you do?	stop ❑ 1	
		slow down ❑ 2	
		continue ❑ 3 → Stop	

		Yes	No
5.	Does it go away when you stand still?	❑ 1	❑ 2 → Stop
6.	How soon?	10 minutes or less ❑ 1	
		>10 minutes ❑ 2 → Stop	

7. Where do you get this pain or discomfort?
(mark the place(s) with X in the diagram)



Office use

8. Outcome: ..... *Positive ❑ 1

Negative ❑ 2

* ❑ If positive, refer to clinician and complete follow up worksheet.

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Rose Questionnaire-Angina

Overview

The purpose of this interviewer-administered form is to identify individuals with angina of effort. This form may be self administered if it is thoroughly explained to the participant. If it is self-administered, it is suggested that the first question be interviewer-administered, and the questionnaire only handed out to participants who answer "Yes" to the first question.

The form will be used at SV1 to identify participants with suspected peripheral vascular disease who need physician approval to continue in the study. This form is also used during intervention as part of safety monitoring. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire and send to the study clinician for review.

Administration Instructions

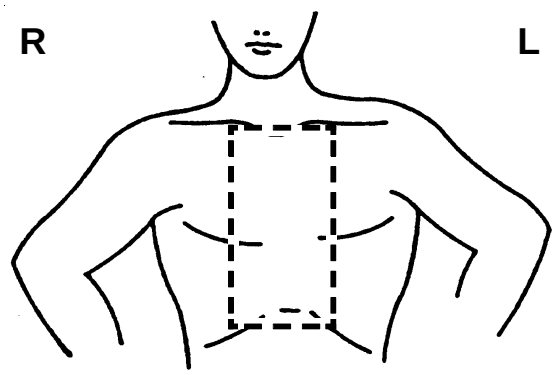
Using a blue or black pen, check the appropriate box to designate which visit this form (#06) was administered: SV1, 3, 6, 12, or 18 month.

Place ID label on page 1.

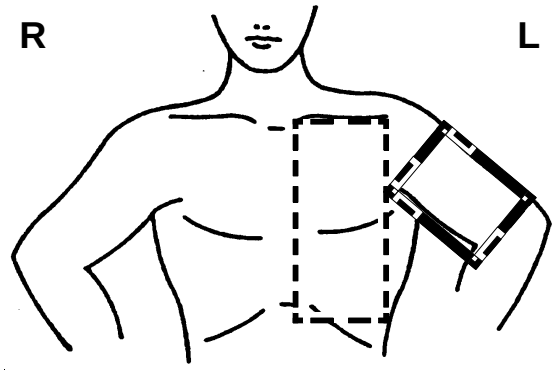
This form can be self administered but due to its complexity you may wish to administer it in an interview format.

Page	Question	Special Administration Instructions (if any)
1	1	If Yes, Q2 should be completed. If No, Stop. Severe indigestion should be coded as Yes.
	2	If Q1 = "Yes", this question may not be left blank. If Yes, Q3 should be completed. If No, Stop. Climbing stairs counts as walking uphill.
	3	If both Q1 and Q2 = "Yes", this question may not be left blank. Q4 should be completed regardless of the response selected in Q3. This question is to be used by the study clinician to help determine severity. It is not used in determining outcome.
	4	If both Q1 and Q2 = "Yes", this question may not be left blank. If answer is "Stop" or "Slow Down", Q5 should be completed. If answer is "Continue", Stop.
	5	If both Q1 and Q2 = "Yes" and Q4 = "Stop" or "Slow Down", this question may not be left blank. If Yes, Q6 should be completed. If No, Stop.
	6	If Q1, Q2 and Q5 all = "Yes", and Q4 = "Stop" or "Slow Down", this question may not be left blank. If "10 minutes or less", Q7 should be completed. If ">10 minutes", Stop.

Page	Question	Special Administration Instructions (if any)
1	7	If Q1, Q2, and Q5 all = "Yes," Q4 = "Stop" or "Slow Down", and Q6 = "10 minutes or less", this question may not be left blank. Participant should mark, using an "X", all places where the pain or discomfort occurs. Valid response = at least one "X" in any area. Staff person should complete Q8.
	8	Should be filled out for all participants. If participant reached a "stop" outcome above, enter "Negative". If at least one "X" appears on the diagram in either of the following areas: the center third of the chest (from clavicle to xiphoid) –OR- if both on the left side of the chest and the left arm, enter "Positive" and complete the worksheet. See diagrams below for the allowable marking locations for a positive result. "X's" must be in the dashed box(es) indicated on the diagrams. For any other pattern of "X's" enter "Negative", regardless of participants' responses to the other questions.



Positive (version 1):
X must be inside the area marked by the dashed box.



Positive (version 2):
An X must be inside the area marked by **each** dashed box (a total of 2 X's).

Coding Instructions

Make sure all corrections are initialed and dated with an explanation.

When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID number should not be filled in until the form is entered.

Review Instructions

If the participant is Negative for Angina (Q8 = Negative), confirm that a "stop" outcome occurred on the form or Q7 has "X's" on the diagram, anywhere, except in the center third of the chest (from clavicle to xiphoid) – OR – on "both on the left side of the chest and the left arm. Enter "Negative" on the SV1 Visit Form (#03) for the Rose Questionnaire-Angina outcome.

If the participant is Positive for angina (Q8 = Positive), all of the following conditions must be met:

? Q1, Q2, = Yes

? Q4 = "Stop" or "Slow Down"

? Q5 = Yes

? Q6 = "10 minutes or less"

? Q7 = At least one "X" appears on the diagram in the center third of the chest (from clavicle to xiphoid) – OR – "X's" appear on the diagram both on the left side of the chest and the left arm.

Note: Right chest pain alone does not make the outcome of this questionnaire positive, even if all other previous conditions are met. Left chest pain does not make the outcome of this questionnaire positive unless left arm pain is also marked. Jaw pain alone does not make the outcome of this questionnaire positive.

When all the above conditions are met (Q8 = Positive), staff must complete the Positive Angina screening worksheet.

If all of the above items look acceptable, enter your Staff ID number in the "reviewed by" section at the bottom of page 1, and enter "Positive" on the SV1 Visit Form (#03) for the Rose Questionnaire-Angina outcome.

Additional Instructions

For follow up visits, all positives trigger an AE form (#30). Study clinician must review all forms to determine if it is a false positive. If not, a serious AE form(#xx) must be completed.

Positive Angina Worksheet – Screening

This worksheet is to be completed for every participant who is coded as POSITIVE on Q8 of the Rose Questionnaire – Angina **during screening**.

Steps for all participants

- ❑ Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.

  Referral Date: _____

  Physician Name (if known): _____

  Physician Phone (if known): _____

- ❑ Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM

- ❑ Does participant wish to continue in the trial? (circle one) YES / NO
  *(If YES, then go on to the following section. If NO, close the participant out as a "Refusal" on the visit form or on a closeout form if between visit*s).

Steps for participants who wish to continue in the trial:

- ❑ Contact participant's physician to get approval for participation in the study. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. Approval requires a letter indicating that patient has had a negative stress test within the last 6 months, and that the physician approves of their participation in the study.

  Physician Name: _____

  Physician Phone: _____

  Date of contact: _____

  Date of physician contact: _____

  Outcome of contact (circle one): EXCLUDE / OK TO CONTINUE

  Notes: _____

  _____

- ❑ Study clinician reviews study chart

  Study Clinician Name: _____

  Date of Review: _____

  Outcome of review (circle one): EXCLUDE / OK TO CONTINUE

  Study Clinician Signature: _____

  Notes: _____

  _____

(If both the participant's physician and the study clinician say the participant is "OK to continue," enter an outcome of "Eligible" on the Pre-Randomization Checklist. Otherwise, enter an outcome of "Ineligible." To close the participant out prior to completing the Pre-Randomization Checklist, you can enter a closeout form with the reason coded as "Investigator discretion for safety")

Positive Angina Worksheet – Follow Up Visits – Repeat Positives

This worksheet is to be completed for every participant who is coded as POSITIVE on Q8 of the Rose Questionnaire – Angina during a follow up visit, and has previously been POSITIVE.

Steps for repeat positives

- ❑ Study clinician reviews study chart for any signs that participant's condition has changed.
  Study Clinician Name: _____
  Date of Review: _____
  Outcome of review (circle one): NEEDS REFERRAL* / OK TO CONTINUE
  Study Clinician Signature: _____
  Notes: _____
  _____

*If study clinician decides that participant needs referral:

- ❑ Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.
  Referral Date: _____
  Physician Name (if known): _____
  Physician Phone (if known): _____
- ❑ Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM

Positive Angina Worksheet – Follow Up Visits – New Positives

This worksheet is to be completed for every participant who is coded as POSITIVE on Q8 of the Rose Questionnaire – Angina during a follow up visit, and has not previously been POSITIVE.

Steps for new positives

- ❑ Ask participant to refrain from participating in the exercise portion of the intervention until the follow-up has been completed.
- ❑ Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.

  Referral Date: _____

  Physician Name (if known): _____

  Physician Phone (if known): _____
- ❑ Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM
- ❑ Contact participant's physician to get approval for their continued participation in the exercise component of the intervention. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. Approval requires a letter indicating that patient has had a negative stress test within the last 6 months, and that the physician approves of their participation in exercise component of the intervention.

  Physician Name: _____

  Physician Phone: _____

  Date of contact: _____

  Date of physician contact: _____

  Outcome of contact (circle one): STOP EXERCISE / OK TO CONTINUE

  Notes: _____

  _____

- ❑ Study clinician reviews study chart

  Study Clinician Name: _____ Date of Review: _____

  Outcome of review (circle one): STOP EXERCISE / OK TO CONTINUE

  Study Clinician Signature: _____

  Notes: _____

  _____

(If both the participant's physician and the study clinician say the participant is "OK to continue," inform participant that they can resume the exercise component of the intervention. Otherwise, notify participant that it has been decided that they should continue to refrain from the exercise component of the intervention.)

ID: _____

Visit: 3 month ❑ 07
6 month ❑ 08
12 month ❑ 09
18 month ❑ 10

Follow-Up Rose Questionnaire – Angina

Date: ____ / ____ / _____

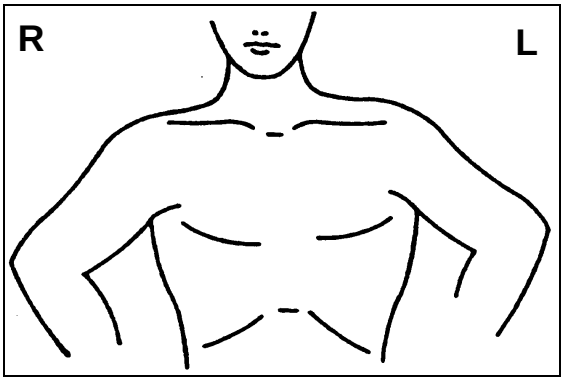
		Yes	No
1.	In the **past month**, have you had any pain or discomfort in your chest?.....	❑ 1	❑ 2 → Stop
2.	Do you get this pain or discomfort when you walk uphill or hurry?.....	❑ 1	❑ 2 → Stop
3.	Do you get this pain when you walk at an ordinary pace on the level?.....	❑ 1	❑ 2

4. When you get any pain or discomfort in your chest, what do you do? ..... stop ❑ 1
slow down ❑ 2
continue ❑ 3 → Stop

		Yes	No
5.	Does it go away when you stand still?.....	❑ 1	❑ 2 → Stop

6. How soon?..... 10 minutes or less ❑ 1
>10 minutes ❑ 2 → Stop

7. Where do you get this pain or discomfort?
(mark the place(s) with X in the diagram)



Office use

8. Outcome:..... *Positive ❑ 1
Negative ❑ 2

9. **If positive,** was angina confirmed by the participant's physician?…… Yes ❑ 1
No ❑ 2

* ❑ If positive, refer to clinician and complete follow up worksheet.

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Rose Questionnaire-Angina

Overview

The purpose of this interviewer-administered form is to identify individuals with angina of effort. This form may be self administered if it is thoroughly explained to the participant. If it is self-administered, it is suggested that the first question be interviewer-administered, and the questionnaire only handed out to participants who answer "Yes" to the first question.

The form will be used at 3, 6, 12, or 18 month visits to identify participants with suspected angina who need physician approval as part of safety monitoring. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire and send to the study clinician for review.

Administration Instructions

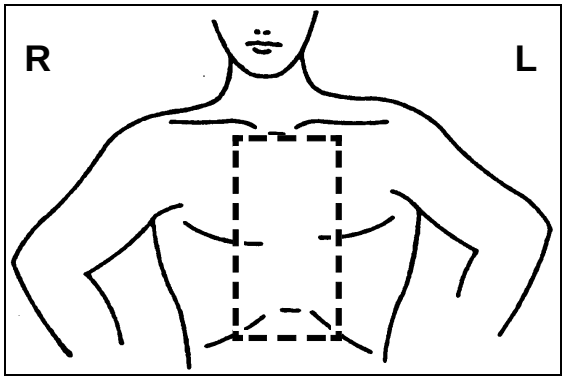
Using a blue or black pen, check the appropriate box to designate which visit this form (#07) was administered: 3, 6, 12, or 18 month.

Place ID label on page 1.

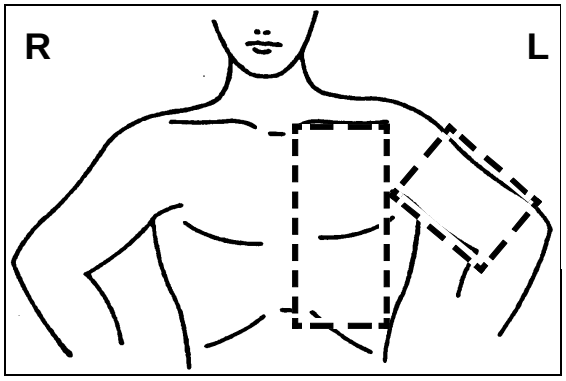
This form can be self administered but due to its complexity you may wish to administer it in an interview format.

Page	Question	Special Administration Instructions (if any)
1	1	If Yes, Q2 should be completed. If No, Stop. Severe indigestion should be coded as Yes.
	2	If Q1 = "Yes", this question may not be left blank. If Yes, Q3 should be completed. If No, Stop. Climbing stairs counts as walking uphill.
	3	If both Q1 and Q2 = "Yes", this question may not be left blank. Q4 should be completed regardless of the response selected in Q3. This question is to be used by the study clinician to help determine severity. It is not used in determining outcome.
	4	If both Q1 and Q2 = "Yes", this question may not be left blank. If answer is "Stop" or "Slow Down", Q5 should be completed. If answer is "Continue", Stop.
	5	If both Q1 and Q2 = "Yes" and Q4 = "Stop" or "Slow Down", this question may not be left blank. If Yes, Q6 should be completed. If No, Stop.
	6	If Q1, Q2 and Q5 all = "Yes", and Q4 = "Stop" or "Slow Down", this question may not be left blank. If "10 minutes or less", Q7 should be completed. If ">10 minutes", Stop.

Page	Question	Special Administration Instructions (if any)
1	7	If Q1, Q2, and Q5 all = "Yes," Q4 = "Stop" or "Slow Down", and Q6 = "10 minutes or less", this question may not be left blank. Participant should mark, using an "X", all places where the pain or discomfort occurs. Valid response = at least one "X" in any area. Staff person should complete Q8.
	8	Should be filled out for all participants. If participant reached a "stop" outcome above, enter "Negative". If at least one "X" appears on the diagram in either of the following areas: the center third of the chest (from clavicle to xiphoid) –OR- if both on the left side of the chest and the left arm, enter "Positive" and complete the worksheet. See diagrams below for the allowable marking locations for a positive result. "X's" must be in the dashed box(es) indicated on the diagrams. For any other pattern of "X's" enter "Negative", regardless of participants' responses to the other questions.
	9	If the participant had a positive outcome, they should be referred to their personal physician for assessment. If the physician confirms the angina, check "Yes" and complete an Adverse Event Form (Form #30). If the angina is not confirmed by the physician, check "No". No Adverse Event Form is needed in this case.



Positive (version 1):
X must be inside the area marked by the dashed box.



Positive (version 2):
An X must be inside the area marked by **each** dashed box (a total of 2 X's).

Coding Instructions

Make sure all corrections are initialed and dated with an explanation.

When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID number should not be filled in until the form is entered.

Review Instructions

If the participant is Negative for Angina (Q8 = Negative), confirm that a "stop" outcome occurred on the form or Q7 has "X's" on the diagram, anywhere, except in the center third of the chest (from clavicle to xiphoid) – OR – on "both on the left side of the chest and the left arm.

If the participant is Positive for angina (Q8 = Positive), all of the following conditions must be met:

- Q1, Q2, = Yes
- Q4 = "Stop" or "Slow Down"
- Q5 = Yes
- Q6 = "10 minutes or less"
- Q7 = At least one "X" appears on the diagram in the center third of the chest (from clavicle to xiphoid) – OR – "X's" appear on the diagram both on the left side of the chest and the left arm.

  Note: Right chest pain alone does not make the outcome of this questionnaire positive, even if all other previous conditions are met. Left chest pain does not make the outcome of this questionnaire positive unless left arm pain is also marked. Jaw pain alone does not make the outcome of this questionnaire positive.

When all the above conditions are met (Q8 = Positive), staff must complete the Positive Angina screening worksheet.

If all of the above items look acceptable, enter your Staff ID number in the "reviewed by" section at the bottom of page 1.

Additional Instructions

For follow up visits, all physician confirmed angina trigger an AE form (#30).

Positive Angina Worksheet – Screening

This worksheet is to be completed for every participant who is coded as POSITIVE on Q8 of the Rose Questionnaire – Angina **during screening**.

Steps for all participants

- ❑ Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.

  Referral Date: _____

  Physician Name (if known): _____

  Physician Phone (if known): _____

- ❑ Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM

- ❑ Does participant wish to continue in the trial? (circle one) YES / NO
  *(If YES, then go on to the following section. If NO, close the participant out as a "Refusal" on the visit form or on a closeout form if between visit*s).

Steps for participants who wish to continue in the trial:

- ❑ Contact participant's physician to get approval for participation in the study. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. Approval requires a letter indicating that patient has had a negative stress test within the last 6 months, and that the physician approves of their participation in the study.

  Physician Name: _____

  Physician Phone: _____

  Date of contact: _____

  Date of physician contact: _____

  Outcome of contact (circle one): EXCLUDE / OK TO CONTINUE

  Notes: _____

  _____

- ❑ Study clinician reviews study chart

  Study Clinician Name: _____

  Date of Review: _____

  Outcome of review (circle one): EXCLUDE / OK TO CONTINUE

  Study Clinician Signature: _____

  Notes: _____

  _____

(If both the participant's physician and the study clinician say the participant is "OK to continue," enter an outcome of "Eligible" on the Pre-Randomization Checklist. Otherwise, enter an outcome of "Ineligible." To close the participant out prior to completing the Pre-Randomization Checklist, you can enter a closeout form with the reason coded as

Positive Angina Worksheet – Follow Up Visits – Repeat Positives

This worksheet is to be completed for every participant who is coded as POSITIVE on Q8 of the Rose Questionnaire – Angina during a follow up visit, and has previously been POSITIVE.

Steps for repeat positives

- ❑ Study clinician reviews study chart for any signs that participant's condition has changed.
  Study Clinician Name: _____
  Date of Review: _____
  Outcome of review (circle one): NEEDS REFERRAL* / OK TO CONTINUE
  Study Clinician Signature: _____
  Notes: _____
  _____

*If study clinician decides that participant needs referral:

- ❑ Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.
  Referral Date: _____
  Physician Name (if known): _____
  Physician Phone (if known): _____
- ❑ Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM

Positive Angina Worksheet – Follow Up Visits – New Positives

This worksheet is to be completed for every participant who is coded as POSITIVE on Q8 of the Rose Questionnaire – Angina during a follow up visit, and has not previously been POSITIVE.

Steps for new positives

- ❑ Ask participant to refrain from participating in the exercise portion of the intervention until the follow-up has been completed.
- ❑ Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.

  Referral Date: _____

  Physician Name (if known): _____

  Physician Phone (if known): _____
- ❑ Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM
- ❑ Contact participant's physician to get approval for their continued participation in the exercise component of the intervention. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. Approval requires a letter indicating that patient has had a negative stress test within the last 6 months, and that the physician approves of their participation in exercise component of the intervention.

  Physician Name: _____

  Physician Phone: _____

  Date of contact: _____

  Date of physician contact: _____

  Outcome of contact (circle one): STOP EXERCISE / OK TO CONTINUE

  Notes: _____

  _____

- ❑ Study clinician reviews study chart

  Study Clinician Name: _____ Date of Review: _____

  Outcome of review (circle one): STOP EXERCISE / OK TO CONTINUE

  Study Clinician Signature: _____

  Notes: _____

  _____

(If both the participant's physician and the study clinician say the participant is "OK to continue," inform participant that they can resume the exercise component of the intervention. Otherwise, notify participant that it has been decided that they should continue to refrain from the exercise component of the intervention.)

SV1
ID: _____
Date: ____ / ____ / _____

Diet and Physical Activity Change Checklist

Please read the PREMIER SV1/SV2 Activity Fact Sheet (form #106) before completing this checklist. If you join the PREMIER study, you will be placed randomly into one of three groups and you will be asked to make diet and physical activity changes.

Are you willing and able to:	**Yes**	**Maybe**	**No**
1. Attend regular group and individual sessions if asked?	❑	❑	❑
2. Lose weight if you are overweight according to the study recommendations?	❑	❑	❑
3. Reduce your dietary sodium (salt) intake?	❑	❑	❑
4. Limit your alcohol intake to less than two drinks per day? (if you drink) *(one drink = 1 can of beer or 1 glass of wine or 1 shot of liquor)*	❑	❑	❑
5. Participate in regular moderate intensity physical activity? *(moderate intensity is like a brisk walk)*	❑	❑	❑
6. Eat at least 9 servings of fruits and vegetables each day? *(a serving is one piece of fruit, ½ cup of cooked vegetables, or 1 cup of raw vegetables)*	❑	❑	❑
7a. Eat at least 3 servings of dairy foods each day? *(a serving is 8 oz. milk or 1 cup yogurt)*	❑	❑	❑
b. **If no to 7a,** is this because you are lactose intolerant? *(being lactose intolerant means you have problems digesting dairy foods)*	**Yes** ❑		**No** ❑
c. **If yes to 7b,** are you willing to take Lactaid (provided by the study) to help you digest dairy foods?	**Yes** ❑	**Maybe** ❑	**No** ❑

Office use only

Outcome ..... eligible ❑
ineligible ❑

Interventionist signature: _____ Reviewed by (staff ID): _____

Diet and Physical Activity Change Checklist

Overview

This form will typically be completed at the SV1 visit.

The purpose of this self-administered form is to identify the participant's willingness to comply with the study guidelines. It will be used at screening to help determine eligibility by identifying participants who are unwilling to change their diet and/or physical activity for the course of the study.

Administration Instructions

Using a blue or black pen, fill out the visit date on pages 1. Be sure to use a four digit year.

Place ID labels on page 1.

The remaining items can be completed by the participant or by the interviewer. All questions on this form should be completed, except Q7b and Q7c, which depend on the answer to Q7a.

Page	Question	Special Administration Instructions (if any)
1	1-6	If No, get an explanation from the participant and try to clarify their answer. Make sure the participant is clearly understands the question, and knows that by answering No they will be excluded. In particular, it may be necessary to clarify how large a serving size is in order to get an accurate answer to questions 6 and 7.
	7a	If "Yes" or "Maybe", Stop. If No, Q7b should be completed.
	7b	If Q7a = "No", this question may not be left blank. If Yes, Q7c should be completed. If No, get an explanation from the participant and try to clarify their answer. Make sure the participant is clearly understands the question, and knows that by answering No they will be excluded.
	7c	If Q7a = "No", and Q7b = "Yes" this question may not be left blank. If No, get an explanation from the participant and try to clarify their answer. Make sure the participant is clearly understands the question, and knows that by answering No they will be excluded.
	Office Use:	If you have gotten to this point without reaching a "No" response, except for Q7a, enter "eligible". If participant responded "No" to any questions above (except Q7a), and the answer was not recoded after reviewing it with the participant, enter "ineligible".

Coding Instructions

After the form is completed, the interviewer should review all "Maybe" and "No" responses with the participant.

For "No" responses, confirm that they meant to say "No." If so, get an explanation and explain that this response may make the participant ineligible. Then have an interventionist review the form. If possible, this should be done while the participant is still in the clinic. If not, the interventionist can call the participant if needed. This review must be completed before the participant's next visit. If the form is reviewed by the interventionist, they should sign the form in the space provided. Unless the interventionist decides the response should be recoded to "Yes" or "Maybe," the participant will be ineligible.

For "Maybe" responses, find out the reason for the response and note it on the form. This will help the interventionist to prepare for the SV3 Motivational Interview. Remind the participant that they will eventually have to say "Yes" to this question to continue in the study.

Recode the answers as needed following review by the interviewer and interventionist. Add an explanation, and initial and date the revision.

Review Instructions

If the participant is INELIGIBLE (at least one question = No in (Q1-6) or Q7a = "No" and Q7b = "No" or Q7b = "Yes" and Q7c = "No"), enter "ineligible" on the SV1 Visit Form (#03) for the SV1 Diet and Physical Activity Change Checklist outcome.

If the participant is ELIGIBLE (Office use only box is marked eligible), check the following items:

- Page 1 should be dated.
- Page 1 should have correct ID# label.
- Q1-6 = "Yes" or "Maybe"
- Q7a = "Yes" or "Maybe" **OR** if "No", Q7b should ="Yes" and Q7c = "Yes" or "Maybe".
- If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 1, and enter "eligible" on the SV1 Visit Form (#03) for the SV1 Diet and Physical Activity Change Checklist outcome.

Additional Instructions

This form is not entered. The outcome is reported and entered on the SV1 Visit Form.

At the SV3 visit, an interventionist follows up on these same questions via the Motivations Script and Notes (Form #41) and the Diet and Physical Activity Change Questionnaire (Form #40).

SV2
ID: _____
Date: ____ / ____ / _____

SV2 Blood Pressure Form

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Circle Cuff size from SV1: 1 2 3 4

Cuff size used: .....Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____
+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number..... ____ ____

PIL ID: _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value..... __ __ __ / __ __ __

b. Zero value..... __ __

c. Corrected value (a-b)..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value..... __ __ __ / __ __ __

b. Zero value..... __ __

c. Corrected value (a-b)..... __ __ __ / __ __ __

4. COMPUTE SUM

a. Sum of 2 SBPs and 2 DBPs (2c + 3c) __ __ __ / __ __ __

b. Sum of 2 SBPs and 2 DBPs from SV1 BP form (item #4) __ __ __ / __ __ __

c. Sum of 4 SBPs and 4 DBPs (4a + 4b) __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Ineligible: escape level 1 BP ..... Sum of SBPs for this visit (4a) ≥ 359 ❑ 1

Sum of DBPs for this visit (4a) ≥ 219 ❑ 2

If box 1 or 2 is checked: complete form #32 (escape level 1), participant is ineligible

Ineligible: escape level 2 BP .....Cumulative sum of SBPs (4c) ≥ 662 ❑ 5

Cumulative sum of DBPs (4c) ≥ 394 ❑ 6

If box 5 or 6 is checked: complete form #32 (escape level 2), participant is ineligible

Ineligible: BP too low.....Cumulative sum of SBPs (4c) ≤ 473 ❑ 3

Cumulative sum of DBPs (4c) ≤ 313 ❑ 4

If box 3 or 4 is checked: participant is ineligible

Eligible: Cumulative sum of SBPs (4c) 474-661, Cumulative sum of DBPs (4c) 314-393 ❑ 7

Collected by (staff ID): _____
Reviewed by (staff ID): _____
Entered by (staff ID): _____

SV2 Blood Pressure Form and Coding Instructions

Overview

The SV2 Blood Pressure Form is filled out by clinic staff and is used for blood pressure screening to determine eligibility of potential participants.

The SV2 Blood Pressure Form must be filled out during each SV2 visit. ID # labels should be printed and placed on the SV2 forms.

If data collected on this form indicates immediate exclusion, "ineligible" should be checked on the SV2 Visit Form (#10) for the SV2 Blood Pressure Form outcome (at the top). If blood pressure values are too high for eligibility, the BP escape-screening form (#32) should be completed**.**

If item 1c=No, all subsequent questions are left blank, participant is ineligible. If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Use correct version of form. The correct version will always be on the site workstation computer.

Place ID labels on pages 1 and 2.

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Page	Question	Special Administration Instructions
1	1	Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
	a.	Record the time. The participant should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
	b.	In the large box, circle the cuff size used at SV1. Refer to the SV1 Blood Pressure form (#02), item #1b. Mark an "X" on the corresponding line indicating the cuff size used for SV2. The cuff size used at SV2 should be the same as the cuff size used at SV1.
	c.	Indicate here whether or not the cuff fits properly. If the brachial artery is occluded by the cuff, the participant is excluded from participating in PREMIER (see MOP Chapter 17). If this is so, check No, and check "ineligible" on the SV2 Visit Form (Form #10) for the SV2 Blood Pressure Form outcome (at the top). If the cuff fits properly, check Yes.
		WAIT 5 MINUTES SEATED
	d.	Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.

Page	Question	Special Administration Instructions
1	1 e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
	f.	Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
	g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.
2	2 a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
	b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
	c.	Do Items 3a and 3b first. Then follow instructions for Item #3c.
		Wait 30 seconds
	3 a.	Repeat item #2a.
	b.	Repeat item #2b.
	c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values.If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4 a.	Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100.
	b.	Record the sum of the SV1 SBP's and DBP's from the SV1 Blood Pressure form (#02), item #4.
	c.	Add the sums of the SBP's and DBP's from items #4a and #4b and record on line #4c.
	5	Using the sum value from item #4c, check the **first** applicable box. If ineligible, check "ineligible" on the SV2 visit form (#10) for the SV2 Blood Pressure Form outcome (at the top). If eligible, check "eligible" on the SV2 visit form for the SV2 Blood Pressure Form outcome. If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape-screening form (#32) should be filled out. Refer to MOP Chapter 23 for details and complete form #32.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

If the participant is INELIGIBLE (Q1c = No **or** Q5 = ANY box marked EXCEPT 7), mark as ineligible on the SV2 Visit form (#10) for the SV2 Blood Pressure Form outcome.

Check for correct calculations in items 1f, 2c, 3c, 4a, and 4c.

If the participant is ELIGIBLE (Q5 = box #7 marked), check the following items:

- Page 1 should be dated.
- Pages 1-2 should have correct ID# labels.
- Page 1:
  - -items 1a-b and 1d-g should be completed;
  - -item 1c should be coded as Yes;
- Page 2:
  - -items 2 and 3 should be completed;
  - -item 4c should be within the range allowed for blood pressure shown in the last option for item 5, the eligible line;
  - -item 5 should have box 7 marked.
- **All pages:** all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.
- If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2, and enter "eligible" on the SV2 Visit form (#10) for the SV2 Blood Pressure Form outcome (at the top).

Additional Instructions

Use the cuff size obtained at SV1 to record all of a participant's blood pressure measurements during screening.

SV2
ID: _____

SV2 Visit Form

	DONE?
Check visit window	❑
Informed consent (if applicable)	❑
Complete SV2 Blood Pressure Form	**eligible** ❑1 **ineligible** ❑2
Complete Baseline Medication Use Questionnaire (including medications review and clinician review)	**eligible** ❑1 **ineligible** ❑2
Collect non-fasting blood specimen	❑
Distribute 24-hour urine materials	❑
Distribute Food Record and review instructions	❑
Review SV1/SV2 Activity Fact Sheet	❑
Complete Local Lab Worksheet	**eligible** ❑1 **ineligible** ❑2

SV2 Visit Outcome ..... **eligible** ❑1
ineligible ❑2
refused ❑3

SV3 Visit Date: _____

Reviewed by (staff ID): _____
Entered by (staff ID): _____

SV2 Visit Form Training Manual and Coding Instructions

Overview

The SV2 Visit form is filled out by clinic staff and is used to track the progress of the participant through the components that make up the SV2 visit.

As soon as a participant is determined to be ineligible, check the "Ineligible" box under the Visit Outcome and terminate the visit. If a participant refuses to complete the visit, check the "Refused" box under the Visit Outcome and terminate the visit. For eligible participants, all items must be completed.

Do not enter this form until the visit is complete and a final outcome is determined. If visit is incomplete and will not be completed, either enter "Refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

Administration Instructions

Using a blue or black pen, fill out each of the items on page 1. If a participant becomes ineligible at any point, you do not need to complete the remaining items.

Question	**Special Administration Instructions (if any)**
Check visit window	Make sure that at least 7 days have elapsed since the SV1 blood pressure date.
Informed consent	The need for a consent to be done at a specific visit will vary by site. If consent is being done at this visit, check the "Done?" box.
SV2 BP Form	After completing form #9, enter the eligibility outcome. If ineligible, skip to the SV2 Outcome field, check the "ineligible" box, and terminate the visit.
Medication Use	After completing form #11, enter the eligibility outcome. If ineligible, skip to the SV2 Outcome field, check the "ineligible" box, and terminate the visit.
Non-fasting blood	After non-fasting blood sample has been collected, check the "Done?" box.
24-hour urine materials	If you will be collecting 24-hour urines at SV3, distribute the materials and instructions and check the "Done?" box. Otherwise, just put a slash through the box and note that this will take place at a later date.
Review fact sheet	After reviewing form #106 with the participant, check the "Done?" box. If the participant decides after reviewing the fact sheet that they do not wish to continue with the study, skip to the SV2 Outcome field, check the "refusal" box, and terminate the visit.
Local Lab worksheet	After local lab results have been received, fill out the local lab worksheet (form #12) and record the outcome on the visit form.

Question	Special Administration Instructions (if any)
SV2 Visit Outcome	see Coding Instructions below

Coding Instructions

The Local Lab Worksheet can not be completed until local lab results come back, so the visit form can not be finalized until then.

SV2 Visit Outcome: After all other items are complete, enter the visit outcome. If the outcomes for blood pressure, Medication Questionnaire, and Local Lab Worksheet are all "eligible" and the participant wishes to continue, check the "eligible" box. If any item is marked "ineligible," check the "ineligible" box. If the participant refused at any point, check the "refused" box. If visit is incomplete and will not be completed, either enter "refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

Review Instructions

Do not review this form until the visit is complete and a final outcome is determined. If visit is incomplete and will not be completed, either enter "Refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

For all participants:

- Make sure that the ID label has been attached.

For eligible participants:

- Check that all items have been completed.
- Make sure that all of the eligible/ineligible responses have been checked "eligible."

For ineligible participants:

- All items do not have to be completed, but make sure that at least one eligible/ineligible response has been checked "ineligible."

For refusals:

- No other items are required.

Additional Instructions

Do not enter this form until:

- the visit is complete
- a final outcome is determined
- all other forms related to the visit (#9, 11, 12) have been entered.

Visit: SV2
ID: _____

Date: __ __ / __ __ / __ __ __ __

Baseline Medication Use Questionnaire

1. Do you regularly (at least 5 days per month) take any prescription medicines, over the counter medications, or nutritional supplements? ..... **Yes** ❑ **No** ❑

2. **If yes** to question 1, please list the medications: (Use the back of the page if you need more space)

Name of Medication	Date you last took a dose of the medication.	Reason for use:
1._____	_____/_____/_____	_____
2._____	_____/_____/_____	_____
3._____	_____/_____/_____	_____
4._____	_____/_____/_____	_____
5._____	_____/_____/_____	_____
6._____	_____/_____/_____	_____
7._____	_____/_____/_____	_____
8._____	_____/_____/_____	_____
9._____	_____/_____/_____	_____
10._____	_____/_____/_____	_____
11._____	_____/_____/_____	_____
12._____	_____/_____/_____	_____
13._____	_____/_____/_____	_____

ID: _____

	Yes	No
3. Have you taken any medications for pain in the last month?.....	❑ 1	❑ 2

(see attached list of pain medications)

4. **If yes**, how many times did you take it?.....**rarely**	❑ 2
most days	❑ 3
every day	❑ 4

ID: _____

Medication Use Review: (to be completed by clinic staff after reviewing page 1 and the medications brought in by the participant)

5. List all medications and/or supplements used regularly (at least 5 days per month) by the participant:

a. _____

b. _____

c. _____

d. _____

e. _____

f. _____

g. _____

h. _____

6. Is the participant taking any of the following exclusionary medications?	**Yes**	**No**
a. blood pressure medications (see list)	❑ 1	❑ 2
b. weight loss medications (see list)	❑ 1	❑ 2
c. anti-psychotic medications (see list)	❑ 1	❑ 2
d. mood stabilizers (see list)	❑ 1	❑ 2
e. oral steroids, oral breathing medications other than inhalers (see list)	❑ 1	❑ 2
f. insulin or oral hypoglycemics (see list)	❑ 1	❑ 2

7. Is the participant taking any of the following non-exclusionary medications?	**Yes**	**No**
a. lipid lowering medications (see list)	❑ 1	❑ 2
b. oral contraceptive pills (see list)	❑ 1	❑ 2
c. hormone replacement therapy (see list)	❑ 1	❑ 2
d. calcium supplements	❑ 1	❑ 2
e. vitamins	❑ 1	❑ 2
f. minerals	❑ 1	❑ 2

_____ _____

Clinician signature Date

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The purpose of this self/interviewer-administered questionnaire is to identify individuals who are taking medications that would exclude them from further participation in the study. This form is administered during the SV2 Visit. Similar follow-up medication forms are administered before all follow-up blood pressure assessments.

If the participant is eligible to continue and reports taking ***any*** medications, a PREMIER clinician must review and sign the form assuring that the participant is not using any exclusionary products. If the participant is taking a medication that is clearly exclusionary, the form does not need to be reviewed by a clinician.

Administration Instructions

Place ID label on pages 1 – 3.

Fill out the visit date on page 1. Be sure to use a four digit year.

The first two pages of this form should be completed by the participant and the third page should be completed by the interviewer.

Page	Question	Special Administration Instructions (if any)
1	1	If Yes, fill out Q2. If No, skip to Q3.
	2	If Q1 = Yes, this question may not be left blank. Record any medications or nutritional supplements regularly taken by the participant in the space provided.
2	3	If Yes to Q3, fill out Q4.
	4	If Q3 = Yes, this question may not be left blank. Mark only one response with an "X". This question is not exclusionary.
3	**Page 3 to be completed by clinic staff only.**	
	5	Record all medications and/or supplements used by the participant. Refer to page 1 and the medications brought in by the participant. Only list medications that are taken at least 5 times per month.
	6	See Coding Instructions
	7	See Coding Instructions

Coding Instructions

Using the list of medications in Q5, code each item under Q6 as Yes or No. Use the attached lists of medications to identify medications in each category. These lists are extensive, but not exhaustive, so consult a clinician if in doubt about any medication.

Items under Q6 are exclusionary if the answer is Yes. Note that Q6e includes oral steroids taken for any reason, not just as an asthma medication, but does not include topical steroids.

Next, use the list of medications in Q5 to code each item under Q7 as Yes or No. These items are not exclusionary.

If the participant is eligible to continue and reports taking ***any*** medications, a PREMIER clinician (MD, physician assistant, nurse practitioner) must review and sign the form assuring that the participant is not using any exclusionary products. If the participant is taking a medication that is clearly exclusionary, the form does not need to be reviewed by a physician.

Review Instructions

? Page 1 should be dated

? Pages 1 – 3 should have correct ID# labels.

? For all eligible participants with any medications listed under Q5, and no exclusionary medications checked under Q6, the clinician's signature and date should be filled in (at the bottom).

? If the participant is INELIGIBLE (at least one "Yes" response to items 6 a-f), enter "ineligible" on the SV2 Visit Form (#10) for the Baseline Medication Use Questionnaire outcome.

? If the participant is ELIGIBLE (all items 6a-f should be coded NO), enter "ELIGIBLE" on the SV2 Visit Form (#10) for the Medication Use Questionnaire outcome.

Additional Instructions

Only questions 3, 4, 6, and 7 are entered.

Pain Medications List (Question 5)

Generic name	Brand name
Acetaminophen	Tylenol
Aspirin	Bayer, Bufferin, Ecotrin
Aspirin & Bicarbonate	Alka-Seltzer
Aspirin & Caffeine	Anacin
Diclofenac	Cataflam, Voltaren
Diflunisal	Dolobid
Etodolac	Lodine
Fenoprofen	Nalfon
Flurbiprofen	Ansaid
Ibuprofen	Advil, Motrin, Nuprin
Indomethacin	Indocin
Ketoprofen	Actron, Orudis, Oruvail
Ketorolac	Toradol
Mefanamic Acid	Ponstel
Nabumetone	Relafen
Naproxen	Aleve, Anaprox, Naprelan, Naprosyn
Oxaprazosin	Daypro
Piroxicam	Feldene
Salicylate	Trilisate
Salsalate	Disalcid, Salflex
Sulindac	Clinoril
Tolmetin	Tolectin
Tramadol	Ultram

Blood pressure medications (question 8, part a)

Generic name	Brand name
Acebutolol	Sectral
Amiloride	Midamor, Moduretic
Amlodipine	Norvasc
Atenolol	Tenormin
Benazepril	Lotensin, Lotrel
Bepridil	Vascor
Betaxolol	Kerlone
Bisoprolol	Zebeta, Ziac
Bumetanide	Bumex
Candesartan	Atacand
Captopril	Capoten, Capozide
Carteolol	Cartrol
Carvedilol	Coreg
Chlorthalidone	Hygroton
Clonidine	Catapres, Clonidine, Combipres
Diltiazem	Cardizem, Dilacor, Tiazac
Doxazosin mesylate	Cardura
Enalapril maleate	Vasoretic, Vasotec
Ethacrynic Acid	Edecrin
Filodipine	Plendil
Fosinopril sodium	Monopril
Furosemide	Lasix
Hydralazine	Apresoline, Apresazide
Hydrochlorothiazide	Esidrix, Hydrodiuril, Microzide
Indapamide	Lozol
Irbesartan	Avapro
Isradipine	Dynacirc
Labetolol	Normodyne, Trandate
Lisinopril	Prinivil, Prinzide, Zestoretic, Zestril
Losartan potassium	Cozaar, Hyzaar
Methyldopa	Aldoclor, Aldomet, Aldoril
Metoprolol	Lopressor, Toprol

(continued on next page)

Blood pressure medications (question 8, part a, continued)

Generic name	Brand name
Minoxidil	Loniten
Moexipril	Univasc
Nadolol	Corgard, Coroxide
Nicardipine	Cardene
Nifedipine	Adalat, Procardia
Nimodipine	Nimotop
Nisoldipine	Sular
Penbutolol	Levatol
Pindolol	Visken
Prazosin	Minipress, Minizide
Propranolol	Inderide, Inderol
Quinapril	Accupril
Ramipril	Altace
Sotalol	Betapace
Spironolactone	Aldactizide, Aldactone
Telmisartan	Micardis
Terazosin	Hytrin
Timolol	Timolide
Trandolapril	Mavik
Triamterene	Maxzide, Dyazide, Dyrenium
Valsartan	Diovan
Verapamil	Calan, Covera, Isoptin, Verelan

Weight-loss Drugs (Question 8, part b)

Generic name	Brand name
Benzphetamine	Didrex
D-Amphetamine	Dexadrine, Dextrostat
Dexfenfluramine	Redux
Diethylpropion	Tenuate, Tenuate Dospan, Tepanil
Fenfluramine	Pondimin
Mazindol	Mazanor, Sanorex
Methamphetamine	Desoxyn
Orlistat	Xenical
Phendimetrazine	Bontril, Prelu-2, Plegine, X-trozine
Phenmetrazine	Preludin
Phenylpropanolamine	Accutrim, Dexatrim
Phentermine	Adipex, Fastin, Ionamin, Obenix, Oby-Cap, Oby-Trim, Pro-Fast, Zantril
Sibutramine	Meridia

* All weight-loss medications affect blood pressure except for Xenical (Orlistat)

Anti-psychotics (Question 8, part c)

Generic name	Brand name
Chlorpromazine	Thorazine
Chlorprothixene	Taractan
Clozapine	Clozaril
Flupenthioxol	Fluanxol
Fluphenazine	Permitil, Prolixin
Haloperidol	Haldo*
Hydroxyzine	Vistaril*
Loxapine	Loxitane
Mesoridazine	Serentil
Methotrimeprazine	Nozinan
Molindone	Moban
Olanzapine	Zyprexa
Perphenazine	Trilafon
Pimozide	Orap
Pipotiazine	Piportil
Prochlorperazine	Compazine*
Promazine	Sparine
Quetiapine	Seroquel
Resperidone	Risperdal
Sulpiride	
Thioridazine	Mellaril
Thiothixene	Navane
Trifluoperazine	Stelazine

Mood stabilizers (Question 8, part d)

Generic name	Brand name
Carbamazepine	Depakote
Divalproex	Tegretol*
Lithium	Cibalith, Eskalith, Lithobid, Lithonate, Lithotabs

* These drugs may be taken for other purposes besides psychosis or bipolar disorder. Participant should be questioned about the reason these were prescribed before being excluded. If the drug was taken for some other reason, recode 8c or 8d to “No”.

Oral steroids (Question 8, part e)

Generic name	Brand name
Betamethasone*	Celestone*
Dexamethasone	Decadron, Dexone, Hexadrol
Fludrocortisone	Florinef
Hydrocortisone	Cortef, Hydrocortone
Methylprednisolone*	Medrol*
Prednisolone	Delta-Cortef, Prelone
Prednisone	Deltasone, Orasone

Oral breathing medications other than inhalers (Question 8, part e)

Generic name	Brand name
Albuterol sulfate*	Proventil*, Ventolin*, Volmax*
Aminophylline	Amesec, Phyllocontin, Somophyllin
Dyphylline	Dilor, Lufyllin, Neothylline
Guaifenesin/theophylline	Elixophylline
Metaproterenol sulfate*	Alupent*, Metaprel*
Oxtriphylline	Choledyl
Terbutaline sulfate	Brethine
Theophyllin	Ami-Rax, Asbron, Azpan, Bronkolixir, Bronkotabs, Constant-T, Elixophyllin, Hydrophed, Labid, Marax, Quadrinal, Quibron, Respbid, Slo-Bid, Slo-Phyllin, Somophyllin, Tedral, T.E.P., Theo-24, Theochron, Theodrine, Theo-Dur, Theolair, Theophyl, T-Phyl, Uni-Dur, Uniphyl

*Exclusionary only if in oral form (tablet or syrup).

Insulin/oral hypoglycemics (Question 8, part f)

Generic name	Brand name
Acetohexamide	Dymelor
Chlorpropamide	Diabinese
Glemipiride	Amaryl
Glipizide	Glucotrol
Glyburide	Diabeta, Glynase, Micronase
Insulin	Actrapid, Humalog, Humulin, Ilentin, Iletin, Insulatard, Isophane, Lentard, Lente, Mixtard, Monotard, Novolin, Protaphane, Semilente, Semitard, Ultratard, Velosulin
Metformin	
Tolazamide	Tolinase
Tolbutamide	Orinase

Lipid-lowering drugs (Question 9, item a)

Generic name	Brand name
Atorvastatin	Lipitor
Bizafibrate	Bezalip
Cholestyramine	Cholybar, Locholest, Prevalite, Questran
Clofibrate	Atromid-S
Colestipol	Colestid
Dextrothyroxine sodium	Choloxin
Fluvastatin	Lescol
Gemfibrozil	Lopid
Lovostatin	Mevacor
Nicotinic acid	Niacin, Niacinamide, Niacor, Nicobid, Nicotinamide, Slo-Niacin
Pravastatin	Pravachol
Probucol	Lorelco
Simvastatin	Zocor

Oral contraceptives (Question 9, item b)

Generic name	Brand name
Desogestel	Desogen, Mircette, Ortho-Cept
Ethynodiol	Demulen, Ovulen, Zovia
Levonorgestrel	Alesse, Leveln, Levora, Nordette, Tri-Levlen, Tri-Phasil
Medroxyprogesterone	Depo-Provera
Mestranol/norethynodrel	Enovid
Norethin A-ET	Loestrin, Norlestrin
Norethindrone	Brevicon, Enovid, Estrastep, Genora, Jenest, Micronor, Modicon, Necon, Nelova, Norinyl, Nor-Q-D, Ortho-Novum, Ovcon, Tri-Norinyl
Norgestimate	Ortho-Cyclen, Ortho Tri-Cyclen
Norgestrel	Lo/Ovral, Ovral, Ovrette
Progesterone	Progestacert

Hormone replacement therapy (Question 9, part c)

Generic name	Brand name
Chlorotrianesine	Tace
Conjugated estrogens	Premarin, Premphase, Prempro
Diethylstilbestrol	
Esterified estrogens	Estratab, Estratest, Menest, Milprem, PMB
Estradiol	Alora, Climara, Deladumone, Delestrogen, Depo, Estrace, Estraderm, Fempatch, Vivelle
Estrone	Theelin
Estropipate	Ogen, Ortho
Ethinyl estradiol	Estinyl, Feminone
Quinestrol	Estrovis

SV2
ID: _____

Local Lab Worksheet

Renal insufficiency eligibility: follow the steps below. When you reach an outcome of ELIGIBLE or INELIGIBLE in one of the steps **circle it** and then check the appropriate box below.

Males	**Females**
1. If serum creatinine ≤ 1.5 mg/dl then **ELIGIBLE**, Otherwise go to step 2	**1.** If serum creatinine ≤ 1.2 mg/dl then **ELIGIBLE**, Otherwise go to step 2
2. If clinician chooses to reject participant at this point, then **INELIGIBLE**, Otherwise go to step 3	**2.** If clinician chooses to reject participant at this point, then **INELIGIBLE**, Otherwise go to step 3
3. Compute GFR	**3.** Compute GFR
Weight in kg = _____A	Weight in kg = _____A
140 - age in years = _____B	140 - age in years = _____B
72 * serum creatinine mg/dl = _____C	72 * serum creatinine mg/dl= _____C
GFR = (A * B) / C = _____	GFR = ((A * B) / C) * 0.85 = _____
If GFR < 60, then participant is **INELIGIBLE** Otherwise participant is **ELIGIBLE**	If GFR < 60, then participant is **INELIGIBLE** Otherwise participant is **ELIGIBLE**

	eligible	**ineligible**
4. Renal insufficiency eligibility	❑ 1	❑ 2

Blood sugar eligibility: check the appropriate boxes for initial and repeat results. Check the overall outcome below. If a repeat is done, use the repeat result for the overall outcome.

	Non-fasting	Fasting
Initial	❑ <160 = eligible ❑ ≥160 = ineligible	❑ <126 = eligible ❑ ≥126 = ineligible
Repeat	❑ <160 = eligible ❑ ≥160 = ineligible	❑ <126 = eligible ❑ ≥126 = ineligible

	eligible	**ineligible**
Blood sugar eligibility.....	❑ 1	❑ 2

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Local Lab Worksheet

Overview

The Local Lab Worksheet is filled out by clinic staff and is used for renal insufficiency and blood sugar screening to determine eligibility of potential participants.

The Local Lab Worksheet must be filled out during each SV2 visit.

If some data collected on this form indicates immediate exclusion, "ineligible" should be checked on the SV2 Visit Form (#10) for the Local Lab Worksheet outcome. If data requires that participants be referred to a physician for consultation, make sure the Participant Information Sheet (form #100) gives you permission to contact their physician.

Administration/Coding Instructions

Place ID label on Page 1.

This form should be completed by clinic staff after the local lab results have been received.

Local lab tests may be repeated once. If a test was repeated, make a note of this on the form. If a test is repeated, the repeat result must be used.

When an outcome is reached in one of the steps for Renal Insufficiency, be sure to **CIRCLE IT** and then check the appropriate box towards the bottom of page 1.

Page	Question	Special Administration Instructions (if any)
1	1-3	Using the participants lab results follow steps 1-3 listed on the form to determine whether or not the data indicate renal insufficiency. Be certain to use the appropriate gender (male, female).
		Renal insufficiency eligibility: Refer to steps 1-3 above. If ELIGIBLE is circled in steps 1 or 3, mark the "eligible" box. If INELIGIBLE is circled in steps 2 or 3, mark the "ineligible" box.
		Blood sugar eligibility: Refer to 'non-fasting' and 'fasting' eligibility criteria at the bottom of page 1. If only an initial test is done, use the outcome of that test to check the overall blood sugar outcome at the bottom of the page. If a repeat test is done, use the outcome of the repeat test to check the overall blood sugar outcome at the bottom of the page. Once a repeat test is done, the initial outcome may not be used.

Review Instructions

If the participant is INELIGIBLE (Renal insufficiency eligibility **and/or** Blood sugar eligibility is marked "ineligible"), enter "ineligible" on the SV2 Visit Form (#10) for the Local Lab Worksheet outcome.

If the participant is ELIGIBLE (Renal insufficiency eligibility **and** Blood sugar eligibility is marked "eligible"), check the following items:

- Page 1 should have correct ID# labels.
- Make sure one outcome is **circled** in steps 1-3. If step 3 is filled in, check the calculations for accuracy.
- Renal insufficiency eligibility outcome = "eligible" and "eligible" is circled in steps 1 or 3.
- Make sure one box is marked in either the non-fasting or fasting criteria.
- Blood sugar eligibility outcome = "eligible" and one "eligible" box is checked in either the non-fasting or fasting criteria.
- If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 1, and enter "eligible" on the SV2 Visit Form (#10) for the Local Lab Worksheet outcome.

All corrections should be explained, initialed, and dated.

When filling out the "Reviewed by" box, be sure to use the correct staff ID number.

Additional instructions:

This form is not entered. The outcome is reported and entered on the SV2 Visit Form (#10) for the Local Lab Worksheet outcome.

If participant is ineligible due to high blood sugar, and they do not know they are diabetic, refer them to their physician. If any lab value requires immediate medical attention or the study clinician decides for any reason that the participant's physician must be informed of an abnormal lab value, first refer to the Participant Information Form (#100) to be sure you have permission to contact the physician.

Tests can be repeated once at local discretion. Sites can do any of the following combination of blood draws: two non-fasting blood draws, two fasting blood draws, or one non-fasting and one fasting blood draw. Eligibility is based on the repeat specimen.

SV3
ID: _____
Date: ____ / ____ / _____

SV3 Blood Pressure Form

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Circle Cuff size from SV1: 1 2 3 4

Cuff size used.....Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly?…….. Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____
+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number..... ____ ____

PIL ID: _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value..... __ __ __ / __ __ __

b. Zero value..... __ __

c. Corrected value (a-b)..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value..... __ __ __ / __ __ __

b. Zero value..... __ __

c. Corrected value (a-b)..... __ __ __ / __ __ __

4. COMPUTE SUM

a. Sum of 2 SBPs and 2 DBPs (2c + 3c)..... __ __ __ / __ __ __

b. Sum of 4 SBPs and 4 DBPs from SV2 BP form (item #4c) .... __ __ __ / __ __ __

c. Sum of 6 SBPs and 6 DBPs (4a + 4b)..... __ __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Ineligible: escape level 1 BP ..... Sum of SBPs for this visit (4a) ≥ 359 ❑ 1

Sum of DBPs for this visit (4a) ≥ 219 ❑ 2

If box 1 or 2 is checked: complete form #32 (escape level 1), participant is ineligible

Ineligible: escape level 2 BP .....Cumulative sum of SBPs (4c) ≥ 957 ❑ 5

Cumulative sum of DBPs (4c) ≥ 573 ❑ 6

If box 5 or 6 is checked: complete form #32 (escape level 2), participant is ineligible

Ineligible: BP too low.....Cumulative sum of SBPs (4c) ≤ 716 ❑ 3

Cumulative sum of DBPs (4c) ≤ 476 ❑ 4

If box 3 or 4 is checked: participant is ineligible

Eligible: Cumulative sum of SBPs (4c) 717-956, Cumulative sum of DBPs (4c) 477-572 ❑ 7

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

SV3 Blood Pressure Form and Coding Instructions

Overview

The SV3 Blood Pressure Form is filled out by clinic staff and is used for blood pressure screening to determine eligibility of potential participants.

The SV3 Blood Pressure Form must be filled out during each SV3 visit. ID # labels should be printed and placed on the SV3 forms.

If data collected on this form indicates immediate exclusion, "ineligible" should be checked on the SV3 Visit Form (#15) for the SV3 Blood Pressure Form outcome (at the top). If blood pressure values are too high for eligibilty, the BP escape-screening form (#32) should be completed**.**

If item 1c=No, all subsequent questions are left blank, participant is ineligible. If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Use correct version of form. The correct version will always be on the site workstation computer.

Place ID labels on pages 1 and 2.

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Page	Question	Special Administration Instructions
1	1	Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
	a.	Record the time. The participant should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
	b.	In the large box, circle the cuff size used at SV1. Refer to the SV1 Blood Pressure form (#02), item #1b. Mark an "X" on the corresponding line indicating the cuff size used for SV3. The cuff size used at SV3 should be the same the cuff size used at SV1.
	c.	Indicate here whether or not the cuff fits properly. If the brachial artery is occluded by the cuff, the participant is excluded from participating in PREMIER (see MOP Chapter 17). If this is so, check No, and check "ineligible" on the SV3 Visit Form (Form #15) for the SV3 Blood Pressure Form outcome (at the top). If the cuff fits properly, check Yes.
		WAIT 5 MINUTES SEATED
	d.	Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.

Page	Question	Special Administration Instructions
1	1 e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse **obliteration** pressure (the pressure at which the radial pulse can no longer be felt).
	f.	Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
	g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.
2	2 a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
	b.	Record the zero value. If the meniscus is exactly between **the** lines, round up to the nearest **even** number. Use a leading zero if less than 10.
	c.	Do Items 3a and 3b first. Then follow instructions for Item #3c.
		Wait 30 seconds
	3 a.	Repeat item #2a.
	b.	Repeat item #2b.
	c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4 a.	Add the values from lines 2c and 3c together and record the sum on line #4a. The sum should be an even number. Use a leading zero if the value is less than 100.
	b.	Record the sum of the SV2 SBP's and DBP's from the SV2 Blood Pressure form (#09), item #4c.
	c.	Add the sums of the SBP's and DBP's from items #4a and #4b and record on line #4c.
	5	Using the sum value from item #4c, check the **first** applicable box. If ineligible, check "ineligible" on the SV3 visit form (#15) for the SV3 Blood Pressure Form outcome (at the top). If eligible, check "eligible" on the SV3 visit form for the SV3 Blood Pressure Form outcome. If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape-screening form (#32) should be filled out. Refer to MOP Chapter 23 for details and complete form #32.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

If the participant is INELIGIBLE (Q1c = No **or** Q5 = ANY box marked EXCEPT 7), mark as ineligible on the SV3 Visit form (#15) for the SV3 Blood Pressure Form outcome.

Check for correct calculations in items 1f, 2c, 3c, 4a, and 4c.

If the participant is ELIGIBLE (Q5 = box #7 marked), check the following items:

- Page 1 should be dated.
- Pages 1-2 should have correct ID# labels.
- Page 1:
  - -items 1a-b and 1d-g should be completed;
  - -item 1c should be coded as Yes;
- Page 2:
  - -items 2, 3 and 4 should be completed;
  - -item 4c should be within the range allowed for blood pressure shown in the last option for item 5, the eligible line;
  - -item 5 should have box 7 marked.
- **All pages:** all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.
- If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2, and enter "eligible" on the SV3 Visit form (#15) for the SV3 Blood Pressure Form outcome (at the top).

Additional Instructions

Use the cuff size obtained at SV1 to record all of a participant's blood pressure measurements during screening.

SV3
ID: _____

SV3 Visit Form

DONE?

Check visit window..... ❑

Informed consent (if applicable) ..... ❑

Complete SV3 Blood Pressure Form ..... **eligible** ❑1
ineligible ❑2

Complete Baseline Symptoms Questionnaire..... ❑

Review completed SV2 Food Record..... **eligible** ❑1
❑ Needs to be repeated **ineligible** ❑2

Review SV3 Activity Fact Sheet..... ❑

Motivational session with interventionist ..... ❑

Complete Diet and Physical Activity Change Questionnaire ..... **eligible** ❑1
ineligible ❑2

24-hour food interviews:..... review instructions ❑
complete convenient time schedule ❑
fax schedule to Penn State ❑

SV3 Visit Outcome..... **eligible** ❑1
ineligible ❑2
refused ❑3

Treadmill Test Visit Date: _____
Other Interim Visit Date: _____
Randomization Visit Date: _____

Reviewed by (staff ID): _____
Entered by (staff ID): _____

SV3 Visit Form
Overview

The SV2 Visit form is filled out by clinic staff and is used to track the progress of the participant through the components that make up the SV2 visit.

As soon as a participant is determined to be ineligible, check the "Ineligible" box under the Visit Outcome and terminate the visit. If a participant refuses to complete the visit, check the "Refused" box under the Visit Outcome and terminate the visit. For eligible participants, all items must be completed.

Do not enter this form until the visit is complete and a final outcome is determined. If visit is incomplete and will not be completed, either enter "Refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

Administration Instructions

Using a blue or black pen, fill out each of the items on page 1. If a participant becomes ineligible at any point, you do not need to complete the remaining items.

Question	**Special Administration Instructions (if any)**
Check visit window	Make sure that at least 7 days have elapsed since the SV2 blood pressure date.
Informed consent	The need for a consent to be done at a specific visit will vary by site. If consent is being done at this visit, check the "Done?" box.
SV3 BP Form	After completing form #14, enter the eligibility outcome. If ineligible, skip to the SV3 Outcome field, check the "ineligible" box, and terminate the visit.
Symptoms Questionnaire	After the Symptoms Questionnaire has been completed, check the "Done?" box.
SV2 Food Record	The SV2 Food Record needs to be complete and acceptable for the participant to be eligible. If the Food Record is complete and acceptable (at least four foods are listed and an attempt made to write in the amounts), then check "eligible." If the Food Record is not acceptable, and the participant is willing to try again, then check the "needs to be repeated" box. If participant refuses or is unable to complete an acceptable food record, then check "ineligible."
Review fact sheet	After reviewing form #107 with the participant, check the "Done?" box. If the participant decides after reviewing the fact sheet that they do not wish to continue with the study, skip to the SV3 Outcome field, check the "refusal" box, and terminate the visit.
Motivational Session	After the motivational session with the interventionist has been completed, check the "Done?" box.

Question	Special Administration Instructions (if any)
Diet and PA Change Q	After the Diet and Physical Activity Change Questionnaire (Form #40) has been completed, record the outcome.
Food Interviews	Check the "Done?" boxes as each item is completed.
SV3 Visit Outcome	see Coding Instructions below

Coding Instructions

SV3 Visit Outcome: After all other items are complete, enter the visit outcome. If the outcomes for blood pressure, SV2 Food Record, and Diet and Physical Activity Change Questionnaire are all "eligible" and the participant wishes to continue, check the "eligible" box. If any item is marked "ineligible," check the "ineligible" box. If the participant refused at any point, check the "refused" box. If visit is incomplete and will not be completed, either enter "refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

Review Instructions

Do not review this form until the visit is complete and a final outcome is determined. If visit is incomplete and will not be completed, either enter "Refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

For all participants:

- Make sure that the ID label has been attached.

For eligible participants:

- Check that all items have been completed.
- Make sure that all of the eligible/ineligible responses have been checked "eligible."

For ineligible participants:

- All items do not have to be completed, but make sure that at least one eligible/ineligible response has been checked "ineligible."

For refusals:

- No other items are required.

After reviewing the form, enter your staff ID on the "Reviewed by" line.

Additional Instructions

Do not enter this form until:

- the visit is complete
- a final outcome is determined
- all other forms related to the visit (#14, 16, 18, 40) have been entered.

Visit: SV3

ID: _____

Date: ____ / ____ / _____

Baseline Symptoms Questionnaire

Below is a list of problems or complaints people sometimes experience. For each item, if you did not have the problem **during the past month**, please check the box under "symptom did not occur".

If you did experience the problem **during the past month**, please check the box that best describes how bothersome it was for you. Use the key below:

Mild = symptom did not interfere with usual activities
Moderate = symptom interfered somewhat with usual activities
Severe = symptom was so bothersome that usual activities could not be performed.

Symptoms ***(during the last month)***	Symptom did not occur	Symptom occurred and was:		
		Mild	Moderate	Severe
1. Poor appetite	❑ 1	❑ 2	❑ 3	❑ 4
2. Diarrhea/loose stools	❑ 1	❑ 2	❑ 3	❑ 4
3. Constipation	❑ 1	❑ 2	❑ 3	❑ 4
4. Nausea or upset stomach	❑ 1	❑ 2	❑ 3	❑ 4
5. Bloating or excess gas	❑ 1	❑ 2	❑ 3	❑ 4
6. Wheezing or difficulty breathing	❑ 1	❑ 2	❑ 3	❑ 4
7. Heart palpitations	❑ 1	❑ 2	❑ 3	❑ 4
8. Leg/ankle swelling	❑ 1	❑ 2	❑ 3	❑ 4
9. Aches or pains in muscles or joints	❑ 1	❑ 2	❑ 3	❑ 4
10. Fatigue or low energy level	❑ 1	❑ 2	❑ 3	❑ 4
11. Excessive thirst	❑ 1	❑ 2	❑ 3	❑ 4
12. Lightheadedness when standing up	❑ 1	❑ 2	❑ 3	❑ 4
13. Headache	❑ 1	❑ 2	❑ 3	❑ 4
14. Difficulty sleeping	❑ 1	❑ 2	❑ 3	❑ 4

ID: _____

15. Have you had any other symptoms in the past month that have not been noted on this form? Yes ❑1 No ❑2

16. **If yes,** please explain: _____

_____

_____

Office Use:

_____ _____

Clinician signature Date

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The purpose of this self-administered form is to identify individuals who have symptoms that could either interfere with their further participation in the study or are potentially exclusionary items.

This form is administered at SV3. A similar version of this form (Form #78) is administered during follow-up. **Any positive responses** should be brought to the attention of a study clinician, who initiates appropriate action in accordance with the protocol, and then signs the form.

After the form is completed, the interviewer should review the form for completeness with the participant.

Administration Instructions

Place ID labels on pages 1 and 2.

Using a blue or black pen, check the SV# visit box.

Fill out the visit date on page 1. Be sure to use a four digit year.

Page	Question	Special Administration Instructions
1	1-14	Check to make sure only one response is marked for each symptom. If a symptom is left blank or more than one response is marked, review the symptom with the participant and mark one response.
2	15	If Yes, complete Q16.
	16	If Q15 = Yes, this question may not be left blank. Make sure the response is legible and review the other symptoms with the study clinician.

Coding Instructions

Any positive responses should be brought to the attention of a study clinician, who initiates appropriate action in accordance with the protocol, and then signs the form.

Review Instructions

Confirm that pages 1 and 2 have an ID label.

Make sure all items were completed (questions 16 and 18 can be blank if questions 15 and 17 are answered "No."

If participant answered "Yes" to question 15, review the notes in question 16 for completeness.

Pre-randomization
ID: _____
Date: ____ / ____ / _____

Eligibility Review Questionnaire

Please review and answer all of the questions on this form. Indicate your answers by placing an "x" in the appropriate box. Depending upon your answers, some of the questions may be skipped.

Thank you very much for your cooperation.

	Yes	No	Comments
1. Have you ever had any of the following?			
a. Stroke	❑ 1	❑ 2	_____
b. Heart attack	❑ 1	❑ 2	_____
c. Congestive heart failure	❑ 1	❑ 2	_____
d. Coronary bypass surgery or angioplasty	❑ 1	❑ 2	_____
e. Blood vessel surgery to open arteries in your neck or legs	❑ 1	❑ 2	_____
2. Have you ever had cancer? (other than skin cancer)	❑ 1	❑ 2	_____
. 2a. ***If yes,*** was it: Active within the past 2 years or treated with radiation or chemotherapy in the past 2 years?	❑ 1	❑ 2	_____
3. Have you taken any medications to control your blood pressure within the past 3 months?	❑ 1	❑ 2	_____
4. Have you taken any medications to control your weight within the past 3 months? (see attached list)	❑ 1	❑ 2	_____
5. Do you regularly (more than 5 days per month) take any of the following medications?			
a. Steroid or corticosteroid pills? (e.g., prednisone)	❑ 1	❑ 2	_____
b. Oral breathing medications other than inhalers?	❑ 1	❑ 2	_____
c. Insulin or pills for diabetes	❑ 1	❑ 2	_____
d. Lithium?	❑ 1	❑ 2	_____

	Yes	No	Comments
6. In the last 2 years, have you been hospitalized for psychological or emotional problems?	❑ 1	❑ 2	_____

For women only

7. Are you pregnant, planning to become pregnant in the next 18 months, or breast feeding?	❑ 1	❑ 2	_____

Office Use:

Outcome:	Eligible	❑ 1	Reviewed by (staff ID): _____
	Ineligible	❑ 2	Entered by (staff ID): _____

Weight-loss Drugs (Question 4)

This list includes some but not all the prescription and over the counter weight loss products. Please respond "Yes" if you have used any of these products for weight loss within the past 3 months.

Generic name	Brand name
Benzphetamine	Didrex
dexfenfluramine	Redux
diethylpropion	Tenuate, Tepanil
fenfluramine	Pondimin
phentermine	Adipex, Fastin, Ionamin, Obenix, Oby-Cap, Oby-Trim, Pro-Fast, Zantril
fenfluramine/phentermine	Fen/Phen
mazindol	Sanorex, Mazanor
phendimetrazine	Plegine, X-trozine, Bontril, Prelu-2
phenmetrazine	Preludin
phenylpropanolamine	Dexatrim, Accutrim
d-amphetamine	Dexadrine, Dextrostat
methamphetamine	Desoxyn
orlistat	Xenical
sibutramine	Meridia

Eligibility Review Questionnaire

Overview

This Eligibility Review Questionnaire is completed in the 30 days prior to the randomization visit for all participants where more than 30 days will have elapsed between completing the Eligibility Questionnaire and randomization. It is likely that all participants will need to fill out this questionnaire.

Most of the questions are repeated from the Eligibility Questionnaire.

Administration Instructions

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Place ID labels on pages 1 and 2. If an ID# has not yet been assigned, leave blank and fill in later.

The remaining items can be completed by the participant or by the interviewer.

The following information is intended to help you assist participants in providing accurate answers to these questions. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire so that further review may be undertaken by a study clinician.

Page	Question	Special Administration Instructions (if any)
1	1a-e	These questions are intended to screen for cardiovascular disease other than hypertension. An individual with only hypertension should answer NO to each question. If any question is answered YES, participant is ineligible for the study. Note: question 1a does not include heat stroke.
	2	Enter YES if the participant has ever had a diagnosis of cancer. If there is no history of cancer or participant has only had skin cancer, enter NO.
	2a	For Inactive cancers, those which have (1) been in remission for over two years or were removed over two years ago AND (2) have not resulted in any further treatment within the past two years, **ENTER NO**. For Active cancers, those present within the past two years OR which required treatment within the past two years, **ENTER YES.** If Yes, then participant is ineligible.
	3	If YES, participant is ineligible.
	4	If YES, the participant is ineligible for this cohort, but may be screened for a subsequent cohort if they go off the medication. If No, double check if participant reviewed the list of Weight Loss Drugs on page 3.
	5	If YES to any of the items (a, b, c, or d), the participant is ineligible. Note: the 5+ days per month do not have to be consecutive.
2	6	If YES, participant is ineligible.

Page	Question	Special Administration Instructions (if any)
2	7	This question should be completed only by women. If YES, Participant is ineligible.
	Office Use:	If you have gotten to this point and the participant is still eligible, and all comments have been resolved, then enter "eligible".

Coding Instructions

Follow up on any items left blank or where participant wrote in the comments field. Code or recode the answers as appropriate following clinician/interventionist review. Add an explanation of the decision, and initial and date the correction.

When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID number should not be filled in until the form is entered.

Review Instructions

If the participant is INELIGIBLE (at least ONE question = Yes on page 1 or 2, except Q2, mark the outcome as ineligible on this form and on the Pre-Randomization Checklist for the Eligibility Review Questionnaire Outcome.

If the participant is ELIGIBLE, check the following items:

- Page 1 should be dated, pages 1-2 should have correct ID# labels.
- Page 1: items 1a-e, 2a, 3, 4, 5a-d should be coded (or recoded) NO;
- Page 2: item 6 should be coded (or recoded) NO, item 7 should be skipped or coded NO.

If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2, and enter "eligible" on the Pre-Randomization Checklist for the Eligibility Review Questionnaire outcome.

ID: _____

Visit: Pre-Randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

Date: __ __ / __ __ / __ __ __ __

7-Day Physical Activity Recall

1. Day of the week form was completed:.....Sunday ❑ 1
   Monday ❑ 2
   Tuesday ❑ 3
   Wednesday ❑ 4
   Thursday ❑ 5
   Friday ❑ 6
   Saturday ❑ 7

2. What days of the week do you consider to be your weekend or non-work days? (for most people, this would be Saturday or Sunday, but this may be different for you) .....Sunday ❑ 1
   Monday ❑ 1
   Tuesday ❑ 1
   Wednesday ❑ 1
   Thursday ❑ 1
   Friday ❑ 1
   Saturday ❑ 1

ID: _____

		Yesterday						One week ago
Days of the Week		_____	_____	_____	_____	_____	_____	_____
		HRS MIN	**HRS MIN**	**HRS MIN**	**HRS MIN**	**HRS MIN**	**HRS MIN**	**HRS MIN**
Sleep								
		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
MORNING	**Moderate**							
		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
	Hard							
		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
	Very Hard							
		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
AFTNOEORN	**Moderate**							
		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
	Hard							
		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
	Very Hard							
		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
EVENING	**Moderate**							
		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
	Hard							
		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
	Very Hard							
		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __

Was this a typical week in terms of your usual pattern of activity or exercise?..... **Yes** ❑ 1 **No** ❑ 2

If no, were you more or less active in the past week than you usually are?... **More** ❑ 1 **Less** ❑ 2

ID: _____

Types of Activities

Think about the kinds of physical activities you have engaged in during the past 3 months.

A. Which of the following types of activities have you done? Which have you done the most often?

To answer these questions, put a check mark next to all the activities that you have done. Then identify up to three activities you have done most often by putting a number 1 next to the activity you have done most often, a number 2 next to the activity done next most often, and a number 3 next to the activity done third most often, for up to 3 activities. If you haven't done 3 activities, number either the 1 or 2 activities that you have done.

Activity	Check if done	Number up to 3 done most often
1. Aerobics or dance aerobics	❑	
2. Jogging or running, or jogging or running on a treadmill	❑	
3. Riding a bicycle or an exercise bicycle	❑	
4. Stair climbing for exercise or using a stair-stepping machine	❑	
5. Stretching exercises	❑	
6. Swimming for exercise (for example, laps)	❑	
7. Walking for exercise or walking on a treadmill	❑	
8. Weight training	❑	
9. Baseball or softball	❑	
10. Basketball	❑	
11. Bowling	❑	
12. Cross-country skiing or using a skiing machine	❑	
13. Downhill skiing	❑	
14. Football	❑	
15. Golf	❑	
16. Handball, racquetball, or squash	❑	
17. Rowing or using a rowing machine	❑	
18. Soccer	❑	

ID: _____

Activity	Check if done	Number up to 3 done most often
19. Social dancing	❑	
20. Tae Kwon Do, Karate, or similar martial arts	❑	
21. Tai Chi	❑	
22. Tennis or badminton	❑	
23. Volleyball	❑	
24. Water skiing	❑	
25. Active household chores and home maintenance (for example, scrubbing floors or windows, moving boxes or furniture, cleaning gutters, carpentry)	❑	
26. Active gardening (for example, planting shrubs, digging or spading dirt, hauling and spreading mulch)	❑	
27. Active yard work (for example, raking leaves, mowing the lawn, trimming shrubs or trees, shoveling snow)	❑	
28. Other: _____	❑	
29. Other: _____	❑	

B. How often did you use special exercise equipment when you engaged in physical activity? .....

(Exercise equipment includes treadmills, exercise bicycles, stair-stepping machines, rowing machines, skiing machines, weight training machines, free weights, and other equipment used in fitness centers or sold for home use.)

Always ❑ 1
Usually ❑ 2
Occasionally ❑ 3
Seldom ❑ 4
Never ❑ 5

C. Think about your usual activity level. In a typical week, how often do you do vigorous physical activity for at least 20 minutes? .....

(Vigorous activity is about the same intensity as running. Some other Activities that can be vigorous are jogging, stair stepping, aerobics classes, swimming laps, and singles tennis).

Never ❑ 1
Once a week ❑ 2
Twice a week ❑ 3
Three or more times a week ❑ 4

ID: _____

Office use only:

Interviewer Assessment

This page is to be completed by the interviewer after the 7-day physical activity recall is complete.

1. Were there any problems with the 7-day PAR interview?: ..... Yes ❑ 1
   No ❑ 2

   1a. **If yes**, please explain:

   _____

   _____

   _____

   _____

   _____

2. Do you think this was a valid 7-day PAR interview?:..... Yes ❑ 1
   No ❑ 2

3. Please list below any activities reported by the participant that you did not know how to classify:

_____

_____

_____

_____

_____

Interviewer (staff ID):	_____
Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

Overview

This form is designed to capture information about the quantity and type of physical activity done by the participant. The form has two parts: an interview plus a self-administered questionnaire. The interview portion must be completed by a certified interviewer. See MOP chapter 22 for information about the interview process and certification requirements.

Note: in a few cases, the previous week's activity may be extremely atypical (the participant was in the hospital or in bed, or there was a family crisis, work crisis, or travel. It is permissible in these cases to go to the week prior to the previous week. **The coordinating center must be notified when such an exception is made.** Fax the CC a copy of the completed form and a note explaining why the exception was made.

Administration Instructions

Using a blue or black pen, check the appropriate box to designate which visit this form (#18) was administered: Pre-Randomization, 6, or 18 month.

The interviewer should complete question 1 on page 1 and the top of page 2 before the participant arrives. Question 2 on page 1 and the rest of page 2 are completed during the course of the PAR interview. Then the participant can fill out pages 3 and 4 on their own. Pages 3 and 4 could also be interviewer-administered. After the participant is done, the interviewer completes page 5.

Page	Question	Special administration instructions
1	1	Check the current day of the week.
	2	Indicate which days the participant considers their "weekend." If the participant does not work or does not have a "weekend", do not check any of the items, and add a note in the margin to show that the answer is not applicable rather than missing. For each day selected by the participant, place a "W" on page 2 above that day as a reminder.
2	days	Fill out the day names for yesterday through a week ago across the top of the page before the participant arrives. Leave any day/time/activity level sections where no activities took place blank (do not fill out as zero). You can put a line or arrow through these sections from top to bottom as a reminder that they are intentionally left blank. Mark one response for both questions at the bottom of the page.
	grid	See MOP Chapter 22 for instructions. Also see the sample form on page 8.
3-4	A1-29	Participant should check any activity they did even once in the last 3 months. Then participant should indicate their top 3 activities. If participant says that 2 or all 3 of the activities are done equally, push them to see if they can make a decision. If not, code ties as the average of the rankings. If participant does 3 activities equally, each should be coded as a 2. If participant does their top two activities equally, they should each be coded as 1.5. If participant does their 2nd and 3rd activities equally, they should each be coded as 2.5.
4	B	Only one response should be marked.

Page	Question	Special administration instructions
	C	Only one response should be marked. If participants ask about the example activities given, you can use the following information to clarify: Jogging is considered a vigorous activity at any pace, except combination walking/jogging. Aerobics is considered a vigorous activity, except low impact aerobics. Swimming laps, stair-stepping, and singles tennis are considered vigorous activities at any pace. If participants ask about a particular activity, and whether or not it counts as vigorous, use the Compendium of Physical Activities in Chapter 22 of the MOP to look up the METs. Anything above 6.0 counts as vigorous.

Coding Instructions

Interviewer Assessment section (page 5)

Question	Instructions
1	List any and all problems that occurred during the interview. These could include issues like: participant did not understand the questions, participant had trouble quantifying their activity, participant had trouble categorizing activity levels, interview was interrupted or cut short, etc.
2	This asks for the interviewer's subjective impression of whether or not the PAR was valid. This response should be based on the interviewers feelings regarding whether or not the participant was being truthful during the recall and could conceptualize what was being asked during the interview. Sometimes the answer will be obvious. For example, if the participant reports no or little sleep, or they insist that something generally thought of as a light activity was hard or very hard, then the interview is probably not valid. Interviews with problems reported in answer to question 1 may also be invalid. Interviewers should use their overall impression of the interview to reach a decision.
3	List any activities which could not be found in the Compendium reference in MOP Chapter 22. Fax a copy of any form with unclassified activities to the Data Clerk at the coordinating center. Note on the cover sheet what the problem was and ask for a coding decision. The coordinating center will forward these forms to a physical activity expert for a decision.

Review Instructions

Ideally the reviewer should be a person who is certified as a PAR interviewer.

Check the following items:

- Form should be filled out in blue or black pen (including page 2). Corrections should be initialled, dated, and a reason given.
- Page 1 should be dated, and pages 1-5 should have an ID label attached.
- Make sure that the date on page 1, the day indicated on question 1 of page 1, and the days listed across the top of page 2 are consistent.
- All questions on pages 1, 3, 4, and 5 should be answered.
- The two questions at the bottom of page 2 should be answered.
- Review the grid on page 2 to be sure all information is legible.

Additional Instructions

Do not enter this form until all coding issues have been resolved.

On page 2, only enter the items where a number of hours/minutes was indicated, skip over the other fields.

Sample Form

Yesterday W W **One week ago**

Days of the Week		SUN **HRS MIN**	SAT **HRS MIN**	FRI **HRS MIN**	THUR **HRS MIN**	WED **HRS MIN**	TUES **HRS MIN**	MON **HRS MIN**
Sleep		10 P – 7 A 0 9 : 0 0	10:30 P – 8 A 0 9 : 0 0	10:30 P-6:45 A 0 8 : 1 5	10 P – 7 A 0 9 : 0 0	10 P – 7 A 0 9 : 0 0	10 P - 7 A 0 9 : 0 0	10 P – 7 A 0 9 : 0 0
MORNING	**Moderate**	lifting/stacking 0 0 : 2 0	mop 0 0 : 2 0	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	walk 0 0 : 1 0	 __ __ : __ __
	Hard	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __
	Very Hard	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __
AFTER NOON	**Moderate**	lifting/stacking 0 0 : 2 0	 __ __ : __ __	 __ __ : __ __	walk 0 0 : 2 0	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __
	Hard	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __
	Very Hard	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __
EVENING	**Moderate**	walk 0 0 : 2 0	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __
	Hard	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __
	Very Hard	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __	 __ __ : __ __

Was this a typical week in terms of your usual pattern of activity or exercise?..... **Yes** ☒ 1 **No** ❑ 2

If no, were you more or less active in the past week than you usually are?... **More** ☒ 1 **Less** ❑ 2

Pre-randomization
ID: _____

Pre-Randomization Checklist

Items that must be completed **and entered** prior to randomization:

	Eligible	Ineligible	N/A
Complete Eligibility Review Questionnaire (Form #17) ..... *(if more than 30 days between Eligibility Questionnaire and R/I visit)*	❑ 1	❑ 2	❑ 3
Follow up for positive Rose PVD Screener	❑ 1	❑ 2	❑ 3
Follow up for positive Rose Angina Screener	❑ 1	❑ 2	❑ 3
Case conference outcome	❑ 1	❑ 2	

Waist circumference (transfer to Randomization Checklist) .... ____ ____ ____ . ____ cm

____ ____ ____ . ____ cm

Items that must be completed **but do not have to be entered** prior to randomization:

	DONE?
Collect signed medical release form	❑
Complete two 24-hour recalls	❑
Complete Patient History Questionnaire	❑
Complete Physical Activity Recall……..	❑
Collect acceptable 24-hour urine	❑
Collect acceptable fasting blood (CLCS, Storage, CDC) ...	❑
Complete Treadmill Test	❑
Complete Psychosocial Questionnaire Packet ..... *(7 forms: #45-49, 23, 25)*	❑

Outcome ..... **eligible** ❑1
ineligible ❑2
refused ❑3

Randomization Visit Date: _____

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Pre-Randomization Checklist Training Manual and Coding Instructions

Overview

The Pre-Randomization Checklist is used to track the completion of forms and measurements during the time period between the SV3 visit and the R/I visit. This form must be complete before the R/I visit can begin.

It is possible to fill out this form on the day of the R/I visit, but that is not recommended. The form must be entered before the randomization can occur, and this could pose logistical challenges if left until the last minute.

The items on this form are divided into those that must be completed and entered prior to the R/I visit, and those that only need to be completed prior to the R/I visit. It is recommended that sites try to complete and enter all items prior to the R/I visit in order to allow time to resolve any potential data problems before the participant is randomized.

As soon as a participant is determined to be ineligible, check the "Ineligible" box under the Visit Outcome and terminate the visit. If a participant refuses to complete the visit, check the "Refused" box under the Visit Outcome and terminate the visit. For eligible participants, all items must be completed.

Do not enter this form until all pre-randomization activities are complete and a final outcome is determined. If the pre-randomization activities are incomplete and will not be completed, either enter "Refused" (if appropriate), or close out the participant using the closeout form (#30) and do not enter the Pre-Randomization Checklist.

Administration Instructions

Using a blue or black pen, fill out each of the items on page 1. If a participant becomes ineligible at any point, you do not need to complete the remaining items.

Question	**Special Administration Instructions (if any)**
Eligibility Review Q	If more than 30 days will have elapsed between the date the Eligibility Questionnaire was completed and the date of the scheduled R/I visit, complete the Eligibility Review Questionnaire and enter its outcome. Otherwise, enter N/A
Rose Q – PVD	If the participant had a positive Rose Questionnaire – PVD at SV1, enter the outcome of the followup process. Otherwise, enter N/A.
Rose Q – Angina	If the participant had a positive Rose Questionnaire – Angina at SV1, enter the outcome of the followup process. Otherwise, enter N/A.
Case conference	After conducting a case conference to review the participant, enter the outcome. The process for conducting a case conference is flexible and can be determined by each site. The only requirement is that staff have a chance to discuss the appropriateness of each participant for the study.

Question	Special Administration Instructions (if any)
Waist Circumference	Measure waist circumference to the nearest 0.1 cm according to the procedures in MOP Chapter 20. These measurements will be transferred to the Randomization Checklist and entered as a part of the R/I visit at that time.
Medical release	Using the form developed for your site, collect a signed medical release form from each participant. If participant will not sign a medical release, refer to investigator for a decision about whether participant should be excluded.
24-hour food interviews	After Penn State has confirmed that the two food interviews were completed, check the box. If Penn State is unable to complete the two interviews, do not check the box, and enter an outcome of Ineligible.
Patient History	After the Patient History Questionnaire (#24) has been completed and reviewed, check the box. If the form can not be completed, do not check the box, and enter an outcome of Ineligible.
Physical Activity Recall	After the Physical Activity Recall (#18) has been completed and reviewed, check the box. If the form can not be completed, do not check the box, and enter an outcome of Ineligible.
24-hour urine	After an acceptable 24-hour urine has been collected, and the Central Lab Collection Form – 24-Hour Urine (#20) has been completed and reviewed, check the box. If an acceptable sample can not be collected, do not check the box, and enter an outcome of Ineligible.
Fasting blood	After an acceptable fasting blood sample has been collected, and the Central Lab Collection Form – Fasting Blood (#21) and the CDC Lab Collection Form (#77) have been completed and reviewed, check the box. If an acceptable sample can not be collected, do not check the box, and enter an outcome of Ineligible.
Treadmill Test	After an acceptable treadmill test has been completed, and the Fitness Test Form (#26) has been completed and reviewed, check the box. If the test can not be completed, do not check the box, and enter an outcome of Ineligible.
Psychosocial packet	After the psychosocial questionnaires (#45-49, 23, 25) have been completed and reviewed, check the box. If the forms can not be completed, do not check the box, and enter an outcome of Ineligible.
Outcome	see Coding Instructions below

Coding Instructions

Outcome: After all other items are complete, enter the visit outcome. If the outcomes for the Eligibility Review Questionnaire, Rose Questionnaires follow-up, and case conference are all "eligible" or "N/A" and the participant wishes to continue, check the "eligible" box. If any item is marked "ineligible," check the "ineligible" box. If the participant refused at any point, check the "refused" box. If the checklist is incomplete and will not be completed, either enter "refused" (if appropriate), or close out the participant using the closeout form (#30) and do not enter the checklist.

Review Instructions

Do not review this form until all pre-randomization activities are complete and a final outcome is determined. If the pre-randomization activities are incomplete and will not be completed, either enter "Refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

For all participants:

- Make sure that the ID label has been attached.

For eligible participants:

- Check that all items have been completed.
- Make sure that all of the eligible/ineligible responses have been checked "eligible" or "N/A"
- Make sure that no more than 6 months have passed between the SV1 blood pressure date and the scheduled randomization visit.

For ineligible participants:

- All items do not have to be completed, but make sure that at least one eligible/ineligible response has been checked "ineligible" or one "Done?" box has not been checked.

For refusals:

- No other items are required.

After reviewing the form, enter your staff ID on the "Reviewed by" line.

Additional Instructions

Do not enter this form until:

- All pre-randomization activities are complete
- A final outcome is determined
- The eligibility review questionnaire (#17) has been entered.

(Other forms — *#20, 21, 77, 24, 26, 45, 46, 47, 48, 49, 23, 25* — do not have to be entered prior to entering this checklist.)

Pre-Randomization
ID: _____

Central Lab Collection Form – Baseline 24-Hour Urine

Data from worksheet (best of initial sample or repeat)

Collect start date ..... __ __ / __ __ / __ __ __ __

Start time .....__ __ : __ __ AM or PM

Collect stop date ..... __ __ / __ __ / __ __ __ __

Stop time .....__ __ : __ __ AM or PM

Time Sufficient (22-26 hours) ..... Yes ❑ 1
No ❑ 2

Total Volume ..... __ __ __ __ cc

Volume Sufficient (≥500 cc) ..... Yes ❑ 1
No ❑ 2

Sample obtained correctly..... Yes ❑ 1
❑ discarded initial void ❑ ≤1 voiding missed ❑ not menstruating No ❑ 2

Was participant able to refrigerate sample? ..... Yes ❑ 1
No ❑ 2

Sample Collection Outcome.....Ready to ship to lab* ❑ 1
Failed ❑ 2

Extra Collection Outcome..... Ready to ship to storage* ❑ 1
Failed ❑ 2

Collected by (staff ID):	_____
Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

*Includes adequate samples, and also inadequate samples where obtaining an adequate sample was not possible.

ID: _____

Central Lab Collection Form – Baseline 24-Hour Urine – Worksheet

Initial Sample

1. Collect start date __ __ / __ __ / __ __ __ __ **Start time** __ __ : __ __ AM or PM

2. Collect stop date __ __ / __ __ / __ __ __ __ **Stop time** __ __ : __ __ AM or PM

3. Number of hours..... __ __

4. Time Sufficient (22-26 hours)..... Yes ❑ No ❑

5. Total Volume (22-26 hours)..... __ __ __ __ cc

6. Volume Sufficient (≥500 cc)..... Yes ❑ No ❑

7. Sample obtained correctly..... Yes ❑ No ❑
❑ discarded initial void ❑ ≤1 voiding missed ❑ not menstruating

8. Was participant able to refrigerate sample? Yes ❑ No ❑

9. Initial Sample Collection Outcome Adequate (answer is YES to #4, #6, and #7) ❑
Inadequate (do repeat sample) ❑

Repeat Sample

10. Collect start date __ __ / __ __ / __ __ __ __ **Start time** __ __ : __ __ AM or PM

11. Collect stop date __ __ / __ __ / __ __ __ __ **Stop time** __ __ : __ __ AM or PM

12. Number of hours..... __ __

13. Time Sufficient (22-26 hours)..... Yes ❑ No ❑

14. Total Volume (22-26 hours)..... __ __ __ __ cc

15. Volume Sufficient (≥500 cc)..... Yes ❑ No ❑

16. Sample obtained correctly..... Yes ❑ No ❑
❑ discarded initial void ❑ ≤1 voiding missed ❑ not menstruating

17. Was participant able to refrigerate sample? Yes ❑ No ❑

18. Repeat Sample Collection Outcome Adequate (answer is YES to #13, #15, and #16) ❑
Inadequate ❑

Overall Collection Outcome Initial sample was adequate, or was the best of the two ❑
Repeat sample was adequate, or was the best of the two ❑
Failed, neither sample can be sent ❑

Collected by (staff ID):	_____
Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

Overview

This form will be used to track the collection and shipping of 24-hour urine specimens during screening. Use forms 62 and 64 for specimens collected at 6 and 18 months. It is expected that this form will be filled out for each participant at their initial attempt and, if one is necessary, their repeat attempt to collect a 24-hour urine specimen.

Administration Instructions

Fill out the worksheet first. After the initial (and repeat) collection is completed, transfer the data to the first page of the form.

Coding Instructions

Page	Field	Special Instructions
2	1	Record the start date and start time as recorded on the label attached to the urine collection jug. For the date, use leading zeros as appropriate. Be sure to use a four digit year. For the time, use leading zeros as appropriate. Circle AM or PM. Remember that Noon is 12 PM.
	2	Record the stop date and stop time as recorded on the label attached to the urine collection jug.
	3	Subtract stop time from start time. Record answer in hours (rounded to the nearest whole number). This is a two-digit field. Use leading zeros as appropriate.
	4	Mark Yes if number of hours is at least 22 but not more than 26 hours. Mark No if number of hours is fewer than 22 or more than 26.
	5	Record total volume in cubic centimeters of urine as measured using a graduated cylinder. This is a four-digit field. Use leading zeros if necessary.
	6	Mark Yes if total volume is at least 500 cc. Otherwise, mark No.
	7	Mark Yes only if all three boxes below are checked.
	8	Mark Yes if the participant was able to refrigerate the sample. Note that this is *not* a requirement for Q9.
	9	Mark Adequate if answers are Yes to #4, 6, and 7.
	10-18	Only go on to repeat sample if Q9 is coded as inadequate. Instructions for Q10-18 are the same as for Q1-9.
	Overall	Self-explanatory

If there was no repeat sample, or the initial sample was the best of the two, transfer the information from the top section of the worksheet to page 1 of the form. If the repeat sample was the best of the two, transfer the information from the bottom section of the worksheet to

Review Instructions

Make sure that if the sample collection outcome is “ready to ship to lab” that you have two tubes of urine (1 with HCl and 1 without) in the freezer. If the extra collection outcome is “ready to ship to storage”, you should have four additional tubes of urine in the freezer (2 with HCl and 2 without).

Check that the data were correctly transcribed from page 2 to page 1.

Additional Instructions

This form is used to generate the shipping logs for sending specimens to the lab or to storage. Specimens can not be shipped until this form is entered.

Pre-Randomization
ID: _____

Central Lab Collection Form – Baseline Fasting Blood

Data from worksheet (best of initial sample or repeat)

Collect date..... __ __ / __ __ / __ __ __ __

Collect time ..... __ __ : __ __ AM or PM

Fasting time..... __ __ hours

Fasting time sufficient (12+ hours) ..... Yes ❑ 1
No ❑ 2

Serum Vial Collection Outcome (red)..... Ready to ship to lab* ❑ 1
Failed ❑ 2

Plasma Vial Collection Outcome (purple)..... Ready to ship to lab* ❑ 1
Failed ❑ 2

Buffy Vial Collection Outcome (purple) .....Ready to ship to storage* ❑ 1
Failed ❑ 2

Extra Serum Vials Collection Outcome (red).....Ready to ship to storage* ❑ 1 _____
Failed ❑ 2 # vials

Extra Plasma Vials Collection Outcome (clear).....Ready to ship to storage* ❑ 1 _____
Failed ❑ 2 # vials

*Includes adequate samples, and also inadequate samples where obtaining an adequate sample was not possible.

Collected by (staff ID): _____
Reviewed by (staff ID): _____
Entered by (staff ID): _____

ID: _____

Central Lab Collection Form – Baseline Fasting Blood – Worksheet

Initial Sample

1. Collect date __ __ / __ __ / __ __ __ __ **Collect time** __ __ : __ __ AM or PM

2. Fasting time.....__ __ hours

3. Time Sufficient (12+ hours)..... Yes ❑ No ❑

4. Serum Vial Collected (red)..... Yes ❑ No ❑ Hemolyzed ❑

5. Plasma Vial Collected (clear)..... Yes ❑ No ❑ Hemolyzed ❑

6. Buffy Vial Collected (purple) ..... Yes ❑ No ❑ Hemolyzed ❑

7. Extra Serum Vials Collected (red) .....Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

8. Extra Plasma Vials Collected (clear).....Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

9. Initial Sample Collection Outcome Adequate (answer is YES to #3-8) ❑
Inadequate, repeat the sample ❑

Repeat Sample

10. Collect date __ __ / __ __ / __ __ __ __ **Collect time** __ __ : __ __ AM or PM

11. Fasting time.....__ __ hours

12. Time Sufficient (12+ hours)..... Yes ❑ No ❑

13. Serum Vial Collected (red)..... Yes ❑ No ❑ Hemolyzed ❑

14. Plasma Vial Collected (clear)..... Yes ❑ No ❑ Hemolyzed ❑

15. Buffy Vial Collected (purple) ..... Yes ❑ No ❑ Hemolyzed ❑

16. Extra Serum Vials Collected (red) .....Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

17. Extra Plasma Vials Collected (clear).....Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

18. Initial Sample Collection Outcome Adequate (answer is YES to #12-17) ❑
Inadequate ❑

Overall Collection Outcome Initial draw was adequate, or was the best of the two ❑
Repeat draw was adequate, or was the best of the two ❑
Failed (neither draw can be sent to the lab) ❑

Collected by (staff ID): _____
Reviewed by (staff ID): _____

Overview

This form will be used to track the collection and shipping of fasting blood specimens collected during screening. Use forms 63 and 65 for specimens collected at 6 and 18 months. It is expected that this form will be filled out for each participant at their initial attempt and, if one is necessary, their repeat attempt to collect a fasting blood specimen.

Administration Instructions

Fill out the worksheet first. After the initial (and repeat) collection is completed, transfer the data to the first page of the form.

Coding Instructions

Page	Field	Special Instructions
2	1	Record the collect date and collect time of the draw. For the date, use leading zeros as appropriate. For the time, use leading zeros as appropriate. Circle AM or PM. Remember that noon is 12 PM.
	2	Round answer, in hours, to the nearest whole number.
	3	Mark Yes if number of hours is at least 12. Otherwise, mark No.
	5-8	Mark Yes if the sample was collected. Mark No if the sample was not collected. Mark Hemolyzed if the sample was hemolyzed.
	9	Mark Adequate if answers are Yes to #3-8.
	10-18	Only go on to repeat sample if Q9 is coded as inadequate. Instructions for Q10-18 are the same as for Q1-9.
	Overall	Self-explanatory

If there was no repeat sample, or the initial sample was the best of the two, transfer the information from the top section of the worksheet to page 1 of the form. If the repeat sample was the best of the two, transfer the information from the bottom section of the worksheet to page 1 of the form.

Review Instructions

Make sure that if the sample collection outcome is “ready to ship to lab” or “ready to ship to storage” that you have the matching tube(s) in the freezer.

Check that the data were correctly transcribed from page 2 to page 1.

Additional Instructions

This form is used to generate the shipping logs for sending specimens to the lab or to storage. Specimens can not be shipped until this form is entered.

ID: _____

Visit
6 month ❑ 08
18 month ❑ 10

Date: ____ / ____ / _____

Alcohol Intake Questionnaire

1. On average, how many drinks of alcohol do you have in a week? (1 drink=1 can of beer or 1 glass of wine or 1 shot of liquor. If you don't drink alcohol, enter 0.)..... ____ ____ . ____ drinks per week

1a. **If you drink alcohol,** how often do you have six or more drinks on one occasion?.....

- Never ❑ 1
- Less than monthly ❑ 2
- Monthly ❑ 3
- Weekly ❑ 4
- 2-3 days/week ❑ 5
- 4-7 days/week ❑ 6

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This questionnaire is designed to capture information about alcohol consumption and binge drinking.

Administration Instructions

This form is designed to be self administered. It can be completed at the clinic, or handed out to be completed at home.

Question	Special Administration Instructions (if any)
1	Participants who do not drink alcohol should enter zero. If the participant asks, a drink is defined as 12 oz. of beer, 5 oz. of wine, or a 1 oz. shot of liquor. If participant gives a range use the mid-range or higher number. For example, code "5-6" as "5.5", code "0.5 to 1" as 1, and code "4 to 6" as "5".
1a	Participants who do not drink alcohol should skip this question.

Coding Instructions

No coding is required.

Review Instructions

Make sure question 1 was answered, and the skip pattern was followed correctly.

ID: _____

Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

Quality of Life Questionnaire

Date: ____ / ____ / _____

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by checking the appropriate box. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: ..... Excellent ❑ 1
   Very Good ❑ 2
   Good ❑ 3
   Fair ❑ 4
   Poor ❑ 5

2. Compared to four weeks ago, how would you rate your health in general now? ..... Much better now than four weeks ago ❑ 1
   Somewhat better now than four weeks ago ❑ 2
   About the same now as four weeks ago ❑ 3
   Somewhat worse now than four weeks ago ❑ 4
   Much worse now than four weeks ago ❑ 5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Activities	**Yes, limited a lot**	**Yes, limited a little**	**Not limited at all**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	❑ 1	❑ 2	❑ 3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	❑ 1	❑ 2	❑ 3
c. Lifting or carrying groceries	❑ 1	❑ 2	❑ 3
d. Climbing several flights of stairs	❑ 1	❑ 2	❑ 3
e. Climbing one flight of stairs	❑ 1	❑ 2	❑ 3
f. Bending, kneeling or stooping	❑ 1	❑ 2	❑ 3
g. Walking more than a mile	❑ 1	❑ 2	❑ 3
h. Walking several blocks	❑ 1	❑ 2	❑ 3
i. Walking one block	❑ 1	❑ 2	❑ 3
j. Bathing or dressing yourself	❑ 1	❑ 2	❑ 3

ID: _____

4. During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
a. Cut down on the amount of time you spent on work or other activities	❑ 1	❑ 2
b. Accomplished less than you would like	❑ 1	❑ 2
c. Were limited in any kind of work or other activities	❑ 1	❑ 2
d. Had difficulty performing the work or other activities (for example, it took extra effort)	❑ 1	❑ 2

5. During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
a. Cut down the amount of time you spent on work or other activities	❑ 1	❑ 2
b. Accomplished less than you would like	❑ 1	❑ 2
c. Didn't do work or other activities as carefully as usual	❑ 1	❑ 2

6. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? ..... Not at all ❑ 1
Slightly ❑ 2
Moderately ❑ 3
Quite a bit ❑ 4
Extremely ❑ 5

7. How much bodily pain have you had during the past four weeks? ..... None ❑ 1
Very mild ❑ 2
Moderate ❑ 3
Severe ❑ 4
Very severe ❑ 5

8. During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?..... Not at all ❑ 1
A little bit ❑ 2
Moderately ❑ 3
Quite a bit ❑ 4
Extremely ❑ 5

ID: _____

9. These questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past four weeks:

	All of the time	**Most of the time**	**A good bit of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Did you feel full of pep?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6
b. Have you been a very nervous person?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6
c. Have you felt so down in the dumps that nothing could cheer you up?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6
d. Have you felt calm and peaceful?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6
e. Did you have a lot of energy?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6
f. Have you felt downhearted and blue?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6
g. Did you feel worn out?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6
h. Have you been a happy person?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6
i. Did you feel tired?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6

10. During the past four weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?..... All of the time ❑ 1
Most of the time ❑ 2
Some of the time ❑ 3
A little of the time ❑ 4
None of the time ❑ 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
a. I seem to get sick a little easier than other people	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
b. I am as healthy as anybody I know	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
c. I expect my health to get worse	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
d. My health is excellent	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Overview

This self-administered questionnaire is designed to capture information about the participant‘s quality of life. It is administered at baseline (any time prior to randomization) and at the 6 and 18 month follow-up visits.

This form will eventually be scored using the standard SF-36 methodology.

Administration Instructions

Instruct participant to fill out the form in blue or black pen. Participants should be encouraged to answer every question.

Coding Instructions

No coding is required.

Review Instructions

Check to be sure all items were completed. If any items were not completed, confirm with participant that they meant to skip the item. Participants are allowed to decline to answer any of the questions.

Pre-randomization
ID: _____

Patient History Questionnaire

This form asks you a variety of questions about your background and habits that may affect or relate to your health. It should take about 10 minutes to complete. Please fill in the information requested, or place a check in the appropriate space. A few questions may be similar to ones you have answered before, but please do not skip any questions. If you are not sure about an answer, please estimate.

If you have questions or would like help filling it out, please call _____ at _____. Please return this questionnaire by _____. We thank you for your time and your contribution to this research.

PERSONAL INFORMATION AND HABITS

1. How much formal or academic education have you had?..... Grade school ❑ 1
   (Check the highest level completed)
   Some High School ❑ 2
   Completed High School ❑ 3
   Some College (including community or technical college) ❑ 4
   Completed college degree (BA, BS) ❑ 5
   Post graduate work ❑ 6

2. What is your marital status?..... Single ❑ 1
   Married ❑ 2
   Widowed ❑ 3
   Divorced/Separated ❑ 4

3. What is your current employment status?..... Employed full-time ❑ 1
   (Check the one that applies to the greatest percentage of your time)
   Employed part-time ❑ 2
   Homemaker ❑ 3
   Retired ❑ 4
   Disabled, unable to work ❑ 5
   Unemployed ❑ 6
   Student ❑ 7

ID#_____

4. What is your total annual household income? ..... Less than $29,999 ❑ 1
   (Please give the best approximation of the total income from all sources within your household in the past year)
   $30,000 to $44,999 ❑ 2
   $45,000 to $59,999 ❑ 3
   $60,000 to $74,999 ❑ 4
   $75,000 to $89,999 ❑ 5
   $90,000 or more ❑ 6

5. Have you smoked at least 100 cigarettes in your entire life? ..... Yes ❑ 1
   No ❑ 2

If Yes,

a. How old were you when you first started smoking? ..... _____ years

b. Do you smoke cigarettes now? ..... Yes ❑ 1
   No ❑ 2

If Yes, how many cigarettes do you smoke per day now? ..... _____ cigarettes

If No, how old were you when you stopped? ..... _____ years

c. On the average of the entire time you smoked, how many cigarettes did you smoke per day? ..... _____ cigarettes

6. Have you ever smoked a pipe or cigars regularly? ..... Yes ❑ 1
   No ❑ 2

If Yes, Do you currently smoke a pipe or cigars? Yes ❑ 1
No ❑ 2

7. Has a doctor ever told you that you might have high blood pressure? ..... Yes ❑ 1
   No ❑ 2

If Yes, Have you ever taken medication in order to control your blood pressure? Yes ❑ 1
No ❑ 2

ID#_____

Family Medical History	**Yes**	**No**	**Don't Know**
8. Has your biological father ever had high blood pressure?	❑ 1	❑ 2	❑ 3
9. Has your biological father ever had kidney failure?	❑ 1	❑ 2	❑ 3
10. Has your biological father ever had diabetes?	❑ 1	❑ 2	❑ 3
11. Has your biological mother ever had high blood pressure?	❑ 1	❑ 2	❑ 3
12. Has your biological mother ever had kidney failure?	❑ 1	❑ 2	❑ 3
13. Has your biological mother ever had diabetes?	❑ 1	❑ 2	❑ 3
14. Do you have any biological brothers or sisters?	❑ 1	❑ 2	❑ 3

If yes,	**Yes**	**No**	**Don't Know**
Have any of your brothers or sisters ever had high blood pressure?	❑ 1	❑ 2	❑ 3
Have any of your brothers or sisters ever had kidney failure?	❑ 1	❑ 2	❑ 3
Have any of your brothers or sisters ever had diabetes?	❑ 1	❑ 2	❑ 3

	Yes	**No**
15. Do you have any biological children?	❑ 1	❑ 2

If yes,	**Yes**	**No**	**Don't Know**
Have any of your children ever had high blood pressure?	❑ 1	❑ 2	❑ 3
Have any of your children ever had kidney failure?	❑ 1	❑ 2	❑ 3
Have any of your children ever had diabetes?	❑ 1	❑ 2	❑ 3

	Yes	**No**	**Don't Know**
16. Have any of your biological relatives (parents, brothers, sisters, children) suffered a stroke or heart attack before age 60?	❑ 1	❑ 2	❑ 3

ID#_____

	Yes	No
17. Have you ever tried to reduce your sodium (e.g., salt) intake?	❑ 1	❑ 2
18. Have you ever tried to lose weight?	❑ 1	❑ 2
19. Have you ever tried the DASH diet?	❑ 1	❑ 2
20. Have you ever tried any other special diet?	❑ 1	❑ 2
21. Have you ever tried to increase your physical activity (or exercise)?	❑ 1	❑ 2
22. Have you ever tried to reduce your alcohol intake?	❑ 1	❑ 2

Reviewed by (staff ID) _____
Entered by (staff ID)_____

Overview

This self-administered questionnaire is designed to capture demographic and medical history data. It can be administered at any time prior to randomization.

Administration Instructions

Place ID labels on pages 1-4.

Instruct participant to fill out the form in blue or black pen. Participants should be encouraged to answer every question, but this is not required.

Page	Question	Special administration instructions
1	1-3	Only one item in each question should be checked.
2	4	Only one item should be checked.
	5	This skip pattern is complex. Go over it with the participant before they fill out the questionnaire. Highlighting the skips may be helpful to participants.
	6-7	Each question has a skip pattern. Highlighting the skips may be helpful to participants.
3	8-13	Self explanatory
	14	Include half-brothers and half-sisters as biological relatives.
	15	Self explanatory
	16	Include half-brothers and half-sisters as biological relatives.
4	17	Self explanatory
	18	Include weight loss via diet or exercise.
	19-22	Self explanatory

Coding Instructions

No coding is required.

Review Instructions

Check to be sure all items were completed. If any items were not completed, confirm with participant that they meant to skip the item. Participants are allowed to decline to answer any of the questions.

Check the skip pattern on question 5.

Check the skip pattern on questions 6-7.

ID: _____

Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

Perceived Stress Questionnaire

Date: ____ / ____ / _____

The questions in this scale ask you about your feelings and thoughts **during the last month**. In each case, please check the item for how often you felt or thought a certain way.

1. In the last month, how often have you felt that you were unable to control the important things in your life?..... never ❑ 0
   almost never ❑ 1
   sometimes ❑ 2
   fairly often ❑ 3
   very often ❑ 4

2. In the last month, how often have you felt confident about your ability to handle your personal problems? ..... never ❑ 0
   almost never ❑ 1
   sometimes ❑ 2
   fairly often ❑ 3
   very often ❑ 4

3. In the last month, how often have you felt that things were going your way? ..... never ❑ 0
   almost never ❑ 1
   sometimes ❑ 2
   fairly often ❑ 3
   very often ❑ 4

4. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?..... never ❑ 0
   almost never ❑ 1
   sometimes ❑ 2
   fairly often ❑ 3
   very often ❑ 4

Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

Perceived Stress Questionnaire
Overview

This self-administered questionnaire is designed to capture information about the participant's perceived stress level. It is administered at baseline (any time prior to randomization) and at the 6 and 18 month follow-up visits.

Administration Instructions

Using a blue or black pen, check the appropriate box to designate which visit this form (#25) was administered: Pre-randomization, 6, or 18 month. Only one box should be marked.

Instruct participant to fill out the form in blue or black pen. Participants should be encouraged to answer every question.

Participants may need clarification on what type of stress to report. The questions do not refer just to stress related to the PREMIER screening or intervention. Answers should include stress from work, relationships, or life in general.

Coding Instructions

No coding is required.

Review Instructions

Page 1 should be dated and have an ID label attached.

Check to be sure all items were completed. If any items were not completed, confirm with participant that they meant to skip the item. Participants are allowed to decline to answer any of the questions.

PREMIER

Fitness Test Form

ID: _____

Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

Date: ____ / ____ / _____

AGE: _____ | GENDER: M / F

1. Compute predicted maximal heart rate (220 – age in years) ..... __ __ __
   x 0 . 8 5
2. Compute 85% predicted maximal heart rate..... __ __ __
3. Measure pre-exercise blood pressure..... __ __ __ / __ __ __
4. Measure pre-exercise heart rate ..... __ __ __
5. Conduct Treadmill Test

Time	Stage	Speed/Grade	Heart Rate	BP	RPE
0 min.	Warm Up	2 MPH / 0% grade			
1 min.		↓			
2 min.	Stage 1	___ MPH / 2% grade			
3 min.		↓	2:50 __ __ __[1]		
4 min.		↓	3:50 __ __ __[1]		
5 min.	Stage 2	___ MPH / 7% grade	4:50 __ __ __[1]	4:20 __ __ __ / __ __ __[2]	4:20 __ __[3]
6 min.		↓	5:50 __ __ __[1]		
7 min.		↓	6:50 __ __ __[1]		
8 min.	Cool Down	2 MPH / 0% grade	7:50 __ __ __[1]	7:20 __ __ __ / __ __ __[2]	7:20 __ __[3]
9 min.		↓			
10 min.		↓	9:50 __ __ __		

6. Measure post-exercise blood pressure (after 3 mins.)..... __ __ __ / __ __ __
7. Measure post-exercise heart rate (after 3 mins.)..... __ __ __
8. Fitness Test Outcome..... **terminated**[1,2,3] ❑1
   completed ❑2

Collected by (staff ID): _____
Reviewed by (staff ID): _____
Entered by (staff ID): _____

[1] If heart rate greater than 85% of max (item 2 above) then terminate test.
[2] If SBP>240 or DBP>115 then terminate test.
[3] If RPE>17 then terminate test.

Overview

The fitness test form is filled out by the treadmill technician. Part of the form is complete before the participant arrives, the rest is completed during the test.

Administration Instructions

Attach an ID label to the form. Using a blue or black pen, check the appropriate box to designate the appropriate visit: Pre-randomization, 6, or 18 month. Only one box should be marked.

Before participant arrives, fill out his/her age and gender in the boxes at the top of the page. Then complete items 1 and 2 (compute 85% max heart rate). Round off all decimals for the 85% max heart rate (150.4 rounds to 150, 150.5 rounds to 151). Finally, use participant's age at baseline and gender to fill in the appropriate speed for the treadmill for stages 1 and 2. Enter the appropriate speeds in the table for item 5.

Complete the remainder of the form as the participant does the test. Consult MOP chapter 18 for information on how to conduct the test.

Coding Instructions

No coding is required.

Review Instructions

Page 1 should have an ID label and be dated.

Make sure the form is legible. Because the form is completed in a hurry while the test is ongoing, it may be necessary to go back and clarify some of the notations. In this case, do not mark over the original values, just add a clarifying notation in the margin (date and initial it).

If test was terminated:

- Make sure questions 1, 2, 3, 4, 6, 7, and 8 were completed.

If test was not terminated:

- Make sure all questions were completed.
- Check to be sure participant's heart rate, BP, and Rating of Perceived Exertion (RPE) stayed below the termination levels throughout the test. Termination levels are 85% max (from item #2) for heart rate, SBP>240 or DBP>115 for blood pressure, or a RPE>17. If levels were exceeded and the test was not terminated, refer this case to the clinician, investigator, and clinic coordinator for immediate review. Also notify the coordinating center of the safety violation.
- If the test was terminated due to heart rate, record the heart rate in the next available heart rate space.

Additional Instructions

Age and gender are not entered.

Pre-randomization
ID: _____
Date: ____ / ____ / _____

4th Baseline Blood Pressure Form

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Cuff size from SV1 _____

Cuff size used: .....Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____

\+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number..... ____ ____

PIL ID: _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value..... __ __ __ / __ __ __

b. Zero value..... __ __

c. Corrected value (a-b)..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value..... __ __ __ / __ __ __

b. Zero value..... __ __

c. Corrected value (a-b)..... __ __ __ / __ __ __

4. COMPUTE SUM

a. Sum of 2 SBPs and 2 DBPS (2c + 3c) __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Ineligible: escape-level BP .....Sum of SBPs for this visit ≥ 359 ❑ 1

Sum of DBPs for this visit ≥ 219 ❑ 2

If box 1 or 2 is checked: complete form #32 (escape level 1), participant is ineligible

Eligible .....Sum of SBPs ≤ 358, Sum of DBPs ≤ 218 ❑ 7

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The 4th Baseline Blood Pressure Form is filled out by clinic staff and is used for blood pressure screening to determine eligibility of potential participants.

The 4th Baseline Blood Pressure must be done at some point between the SV3 blood pressure and the R/I visit. The 4th Baseline Blood Pressure may be done on the day of the R/I visit.

This is not an eligibility measure except that if the blood pressure reaches escape level 1, the participant will be excluded. There is no lower limit, and no exclusion for high blood pressures so long as they are below escape level 1.

If item 1c=No, all subsequent questions are left blank and the participant is ineligible. If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Use correct version of form. The correct version will always be on the site workstation computer.

Place ID labels on pages 1 and 2. Check for accuracy.

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Page	Question	Special Administration Instructions
1	1	Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
	a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
	b.	Measure the participant's arm circumference. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). Record the rounded arm circumference. Based on the arm circumference obtained, mark an "X" on the corresponding line indicating proper cuff size for the measurement. Use the cuff size obtained at SV1 for all of the participant's blood pressure measurements during screening.
	c.	Indicate here whether or not the cuff fits properly. If the brachial artery is occluded by the cuff, the participant is excluded from participating in PREMIER (see MOP Chapter 17). If this is so, check No, and check "ineligible" on the Randomization Checklist Visit Form (Form #60) for the 4th Baseline Blood Pressure Form outcome. If the cuff fits properly, check Yes.

Page	Question	Special Administration Instructions
1		**WAIT 5 MINUTES SEATED**
	1 d.	Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.
	e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
	f.	Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
	g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.
2	2 a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
	b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
	c.	Do Items 3a and 3b first. Then follow instructions for Item #3c.
		Wait 30 seconds
	3 a.	Repeat item #2a.
	b.	Repeat item #2b.
	c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4	Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100.
	5	Using the sum value from item #4, check the **first** applicable box . If ineligible, check "ineligible" on the Randomization Checklist (#60) for the 4th Baseline Blood Pressure Form outcome. If eligible, check "eligible" on the Randomization Checklist (#60) for the 4th Baseline Blood Pressure Form outcome. If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#32) should be filled out. Refer to MOP Chapter 23 for details and complete form #32.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

Check for correct calculations in items 1f, 2c, 3c, and 4.

If the participant is ELIGIBLE (Q5= box #3 marked), check the following items:

- Page 1 should be dated.
- Pages 1-2 should have correct ID# labels.
- Page 1:
  - -items 1a-b and 1d-g should be completed;
  - -item 1c should be coded as Yes;
- Page 2:
  - -items 2 and 3 should be completed;
  - -item 4 should be within the range allowed for blood pressure shown in the last option for item 5, the eligible line;
  - -item 5 should have box 3 marked.
- All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

Additional Instructions

Use the cuff size obtained at SV1 to record all of a participant's blood pressure measurements during screening.

ID: _____

Date: ____ / ____ / _____

Participant Closeout Form

Complete this form for all participants who decline to participate or who are found to be ineligible **prior to randomization**. This form is to be used **between visits**. Use the visit forms for closeouts during a visit.

Reason for closeout (select one):

Local lab – renal insufficiency ..... ❑ 11

Local lab – blood sugar ..... ❑ 12

Eligibility review questionnaire ineligible ..... ❑ 14

Time limit exceeded ..... ❑ 19

Investigator discretion for safety ..... ❑ 18

Not willing to stop exclusionary medications ..... ❑ 20

Transportation problems ..... ❑ 21

Started BP medication ..... ❑ 22

Started other exclusionary medication ..... ❑ 23

Physician's orders ..... ❑ 24

Illness ..... ❑ 25

Death ..... ❑ 26

Moved ..... ❑ 27

Schedule/time conflict ..... ❑ 28

Refused ..... ❑ 88

Other (contact the coordinating center for an appropriate code) ..... ❑ ___

Description: _____

_____

_____

_____

_____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This form is used by clinic staff to close out a participant who drops out or is excluded **between visits** and **prior to randomization.**

Coding Instructions

Before completing the form, check to be sure that the participant can not be closed out using a visit form. Also check to be sure the participant is not randomized. If the participant is already randomized, use a Premature Termination Form (#37) to close out the participant.

Reason: When selecting the reason for the closeout, be sure to review all of the choices before making a selection. If the situation does not fit any of the choices, note the reason at the bottom of the form or on an attached sheet and fax the form to the Data Clerk at the Coordinating Center for a coding decision.

See the attached list of Closeout Reason Codes for a detailed explanation of when to use each code. If there is a reason that is even close to the situation you are trying to code, use that reason instead of requesting a new code.

Do not code as "Other" without first consulting the Coordinating Center.

Description: Briefly describe the reason for the closeout. Include as much detail as possible.

Review Instructions

Make sure the ID, date, and reason for closeout have been completed.

Only one reason should be checked.

Review the notes and make sure the reason has been correctly coded.

Additional Instructions

Do not enter this form until all other forms for the participant has been entered. Once the participant is closed out, you will not be able to enter any new forms. Also be sure any edits to the participant's data have been completed. Once the participant is closed out, many of the restricted edits will no longer be allowed.

Explanations of Closeout Reason Codes

Category	When to use this category
Local lab – renal insuf.	Participant becomes ineligible due to renal insufficiency on the local lab results and needs to be closed out before the next visit.
Local lab – blood sugar	Participant becomes ineligible due to blood sugar on the local lab results and needs to be closed out before the next visit.
Eligibility review Q	Eligibility Review Questionnaire is completed after the Pre-randomization Checklist has already been entered, and participant is ineligible. (This would happen only if the participant's randomization visit date changes after the Pre-Randomization Checklist has been entered, and the new date requires that the Eligibility Review Questionnaire be completed.)
Time limit exceeded	More than 4 months has elapsed between PSV and SV1, or more than 6 months has elapsed between SV1 and the projected randomization date, or participant could not be randomized within the randomization window.
Investigator discretion	Any time the PI decides a participant should be excluded (when their data otherwise makes them eligible). This can be used to close out participants with positive Rose Questionnaires where the project clinician does not give permission for them to continue in the trial.
Exclusionary medications	A participant agrees to stop taking one of the exclusionary medications, the Medication Questionnaire or Eligibility Questionnaire is coded as eligible, and then the participant later refuses to stop taking the medication.
Transportation problems	Participant is unable to make their next visit due to transportation problems. This code should only be used if transportation issues come up between visits. If this comes up at a visit, code it as a refusal on the visit form.
Started BP medication	A participant starts taking BP medication and it is not caught on the Medication Questionnaire, Eligibility Questionnaire, or Eligibility Review Questionnaire.
Started other medication	A participant starts taking an exclusionary medication other than BP medication, and it is not caught on the Medication Questionnaire, Eligibility Questionnaire, or Eligibility Review Questionnaire.
Physician's orders	The participant's personal physician decides that the participant should not take part in the trial. This can be used to close out participants with positive Rose Questionnaires who do not get physician approval (alternative to the Pre-Randomization Checklist).
Illness	Participant illness (code family illness as schedule/time conflict).
Death	Participant death (code death in family as a schedule/time conflict)

(continued on next page)

Explanations of Closeout Reason Codes

Category	When to use this category
Schedule/time conflict	Participant is unable to make their screening visits due to a scheduling problem or time conflict. This includes work schedule conflicts, inability to get day care, and vacations. Also can be used if participant will be unable to attend all of the intervention sessions due to a scheduling problem or time conflict.
Refusal	Participant refused to complete a clinic visit or complete a required study measure, or repeatedly misses scheduled appointments (passive refusal). Use only if none of the above reasons apply.

ID: _____

Event Date: ____ / ____ / _____

Adverse Events Form

Site Event Summary (to be completed by clinic staff at the site)

1. Visit (code current visit/last visit completed): ..... randomization visit ❑ 06
3 month visit ❑ 07
6 month visit ❑ 08
12 month visit ❑ 09
18 month visit ❑ 10

2. Source of adverse event: .....Symptoms Form (3, 6, 12, or 18 month) ❑ 2
Physician Confirmed Angina (3, 6, 12, or 18 month) ❑4

3. Describe event (Brief overview of event. Indicate whether it is ongoing or resolved):

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

ID: _____

Site Event Summary (to be completed by unblinded clinician at the site)

	Yes	No	DK
4. Study-related consequences of event ..... change in diet	❑ 1	❑ 2	❑ 3
change in exercise pattern	❑ 1	❑ 2	❑ 3
started on BP medications	❑ 1	❑ 2	❑ 3
interrupted intervention attendance	❑ 1	❑ 2	❑ 3

5. Site clinician notes (Optional):

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____ _____

Site clinician signature Date

Reviewed by (staff ID): _____

Entered by (staff ID): _____

AFTER SITE REVIEW AND DATA ENTRY, FAX FORM TO THE CC FOR BLINDED CLINICIAN REVIEW

ID: _____

Event Summary (to be completed by clinician at coordinating center)

1. Date of event .....__ __ / __ __ / __ __ __ __

2. Category of event ..... gastrointestinal ❑ 1
cardiovascular (cardiac or neurologic) ❑ 2
musculoskeletal ❑ 3
other: _____ ❑ 4

3. CC clinician notes:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____ _____

CC clinician signature Date

CC entered by (staff ID): _____

Adverse Event Form Coding Instructions

Overview

Pages 1-2 are reviewed and entered at site. Then pages 1-3 are faxed to CC for blinded clinician review. Following clinician review, the CC enters page 3 and faxes a copy of pages 1-3 back to site. Sites should file both the original and the coded copy.

The master copy of the data from pages 1-2 will reside at the sites. The master copy of the data form page 3 will reside at the CC.

All data (including text descriptions) will be entered and available for use in reporting.

Adverse Events are specifically defined as a) a "yes" answer to Q#15 on the Symptoms Questionnaire, b) a "yes" answer to Q#17 on the Symptoms Questionnaire that upon examination, a clinician feels could be recoded into one of the categories in Q#15 or c) an instance of physician-confirmed angina. An event is therefore not counted as an AE until one of the previous instances occur. Once one of these instances has been determined to occur, this form should be completed and sent to the CC. Ideally, the form should be faxed to the CC once all pertinent information has been entered on the form.

Administration Instructions

This form is completed by site personnel.

Place ID labels on pages one through three.

Enter the date of the event on page one. Be sure to use a four digit year.

Page	Question	Special Administration Instructions
1	1	Check the appropriate time frame in which the AE occurred. AE's may only occur after randomization; AE's may not occur during screening.
	2	Check the appropriate source of the AE, i.e. how the AE was originally identified.
	3	Briefly describe the circumstances surrounding the AE. Be sure to indicate whether it is ongoing or resolved.
2	4-5	An unblinded site study clinician should complete these questions. Further notes are optional.
3	1-3	A CC clinician should complete these questions.

ID: _____

Date: ____ / ____ / _____

Safety Review Form

This form should be filled out by clinic or intervention staff if the participant calls in to report a medical problem, or mentions a medical problem at an intervention visit. The form should then be reviewed by the site clinician to determine whether any follow-up with the participant needs to occur.

Briefly describe event (Indicate whether it is ongoing or resolved):

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Clinician Review:	**Yes**	**No**	**N/A**
Does this condition require that the participant's intervention participation be modified? (*If "yes", complete next page)*	❑	❑	❑

_____ _____

Clinician signature Date

Reviewed by (staff ID): _____

To be completed by site clinician if participant's intervention participation is modified:

	Yes	No	DK
1. Study-related consequences of event.....change in diet	❑	❑	❑
change in current exercise pattern	❑	❑	❑
started on BP medications	❑	❑	❑
interrupted intervention attendance	❑	❑	❑

	Yes	No
2. Has the participant seen their physician as a result of this event?	❑	❑
If No: Was participant referred to their physician as a result of this event?.....	❑	❑

3. Site clinician notes (Optional):

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

ID: _____

Date of BP Escape: ____ / ____ / _____

Blood Pressure Escape Form – Screening

ESCAPE INFORMATION:

1. Visit ..... SV1, SV2, or SV3 ❑ 1
   4th baseline BP ❑ 2

2. Escape Level..... Level 1 ❑ 1
   Level 2 ❑ 2

FOLLOW UP ACTIONS:

3. Exclude from study (by entering the Visit Form or the Baseline BP form)

4. Refer to physician* (Level 1: within 1 week, Level 2: within 1 month)

Date referred: __ __ / __ __ / __ __ __ __

Notes: _____

_____

_____

*Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician.

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This form is used track the process of following up on an escape-level blood pressure **during screening**. Complete this form whenever a SV1, SV2, SV3, or 4th baseline BP form escape outcome is reached.

Start completing this form immediately after the escape-level BP is reached. You will need to have the BP form available as you complete this form.

Coding Instructions

Question	**Instructions**
Date of BP escape	Enter the date from the BP form.
1. Visit	Code the appropriate visit from the BP form.
2. Escape level	Escapes are either level 1 (requiring more immediate follow-up) or level 2. The escape level is indicated on the BP form outcome.
Date referred	Enter the date the participant was referred to their physician. This is the date the participant was told to see their physician. Some participants may need assistance in finding a physician. Make sure the date is within the time frame allowed (1 week for level 1, 1 month for level 2).
Notes	Describe the referral process in detail. Important information to include: any difficulty you had in contacting the participant, any participant comments/feedback, whether participant required assistance in finding a physician, any further contacts with the participant or their physician. When describing additional follow-up, be sure to include the date and the staff ID of the person involved.

Review Instructions

- Make sure ID label was attached and all items were completed.
- Check that referral happened within the allowed time window (1 week or 1 month).
- Review the Notes section to be sure it adequately explains the follow-up. ("Referred" is not an adequate explanation.)

Additional Instructions

Once form has been reviewed and entered, fax a copy to the Data Clerk at the coordinating center). Be sure to use a shipping log (Form #316).

File the original form in the participant's chart.

3 Month
ID: _____
Date: ____ / ____ / _____

3 Month Visit Blood Pressure Form

	Yes	No
Has the participant's medication list changed since their last visit?……..	❑	❑

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Arm circumference (cm, round all fractions up)..... _____ _____

Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____

\+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number ..... ____ ____

PIL ID: _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

4. COMPUTE SUM

Sum of 2 SBPs and 2 DBPs (2c + 3c)..... __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Escape-level 1 BP ..... Sum of SBPs ≥ 319 ❑ 1

Sum of DBPs ≥ 199 ❑ 2

If box 1 or 2 is checked: complete form #83

Non-escape BP ..... Sum of SBPs <319, Sum of DBPs <199 ❑ 7

Collected by (staff ID):	_____
Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

Overview

The 3 Month Visit Blood Pressure Form is filled out by clinic staff and is used to measure participant's blood pressure to make sure it does not exceed safety limits.

If blood pressure values reach escape level 1, the BP Escape Form – 3 Month Visits (#83) should be completed**.**

If item 1c=No, all subsequent questions are left blank. Before entering the form, contact the coordinating center for a decision on what follow up action should be taken.

If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Place ID labels on pages 1 and 2. Check for accuracy.

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Page	Question		Special Administration Instructions
1	1		Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17. Be sure to ask the participant whether their medication list has changed. A Form #79 MUST be completed for each PREMIER BP taken.
		a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
		b.	Measure the participant's arm circumference. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). Record the rounded arm circumference. Based on the arm circumference obtained, mark an "X" on the corresponding line indicating proper <u>cuff size</u> for the measurement.
		c.	Indicate here whether or not the cuff fits properly. If the answer is Yes, go on. If the answer is No, contact the coordinating center for a decision on what follow up action should be taken..
1			**WAIT 5 MINUTES SEATED**
	1	d.	Obtain and record the <u>resting 30-second</u> pulse (radial artery) by counting the number of beats in 30 seconds.
		e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
		f.	Add 60 to the pulse obliteration pressure to obtain the <u>random zero peak inflation level</u> (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
		g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.

Page	Question		Special Administration Instructions
2	2	a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
		b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
		c.	Do Items 3a and 3b first. Then follow instructions for Item #3c.
			Wait 30 seconds
	3	a.	Repeat item #2a.
		b.	Repeat item #2b.
		c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4		Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100.
	5		Using the sum value from item #4, check the **first** applicable box . If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#83) should be filled out. Refer to MOP Chapter 23 for details and complete form #83.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

? Page 1 should be dated.

? Pages 1-2 should have correct ID# labels.

? Page 1:

-items 1a-b and 1d-g should be completed.

-check for correct addition in item 1f.

-item 1c should be coded as Yes, or if No, there should be a note explaining the follow up plan or other outcome for this participant.

? Page 2:

-items 2 and 3 should be completed.

-check for correct addition in items 2c, 3c, and 4.

-item 4 should match the outcome selected in item 5

? All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

? If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2.

Additional Instructions

A Form #79 (Follow-up Medication Use Questionnaire) MUST be completed on the same day as the BP measurement.

ID: _____

Visit
3 month ❑ 07
12 month ❑ 09

Date: ____ / ____ / _____

Brief Medication Use Questionnaire

	Yes	No	Comments
1. Have you taken any medications to control your blood pressure within the past 3 months? *(see attached list)*	❑ 1	❑ 2	_____
2. Have you taken any medications to control your weight within the past 3 months? *(see attached list of commonly-used medications)*.....	❑ 1	❑ 2	_____
3. Do you regularly (more than 5 days per month) take any of the following medications? *(see attached lists for each medication)*			
a. Anti-psychotic medications?.....	❑ 1	❑ 2	_____
b. Mood stabilizers?.....	❑ 1	❑ 2	_____
c. Steroid or corticosteroid pills? (prednisone).....	❑ 1	❑ 2	_____
d. Breathing medications other than inhalers?.....	❑ 1	❑ 2	_____
e. Insulin or oral hypoglycemics?.....	❑ 1	❑ 2	_____

	Yes	No
4. Have you taken any medications for pain in the last month?..... *(see attached list of pain medications)*	❑ 1	❑ 2

5. **If yes**, how many times did you take it? ..... **never** ❑ 1
rarely ❑ 2
most days ❑ 3
every day ❑ 4

6. For staff use only: If there is a "yes" response to Question 2, is it a medication that affects blood pressure?……... **Yes** ❑ 1 **No** ❑ 2

_____ _____
Clinician signature Date

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Overview

The purpose of this self/interviewer-administered questionnaire is to identify individuals who are taking medications of interest during the study follow-up period. This form is administered during follow up at the 3 month and 12 month visits.

If the participant reports taking ***any*** medications, a PREMIER clinician must review and sign the form.

Administration Instructions

Place ID label on page 1.

Using a blue or black pen, check the appropriate box to designate the visit: 3 or 12 month.

Fill out the visit date on page 1. Be sure to use a four digit year.

The remainder of the first page of this form should be completed by the participant.

Page	Question	Special Administration Instructions (if any)
1	1	If Yes, follow up and get the name of the medication, the dosage, and when they started taking the medication. Attach another page if needed.
	2	If Yes, follow up and get the name of the medication, the dosage, and when they started taking the medication. These should only be *prescription* medications. Attach another page if needed. Use Form 201 if necessary to identify weight-loss medications not covered on Page 4 of this form. If yes, the staff member should complete Question 6.
	3	If any item is Yes, follow up and get the name of the medication(s), the dosage, and when they started taking the medication. Attach another page if needed.
	4	If Yes, fill out Q5.
	5	Mark only one response.
	6	If the participant has taken weight-loss medications in the past three months ("Yes" in Question 2), review the weight-loss medication list (Pages 5-6 on this form) to see if the medication has blood pressure effects. Most weight-loss medications **do** have BP effects; those that do not are marked with an asterisk (*). If the medication is not listed on this form, consult Form 201 for a more complete list of weight-loss medications. If the medication has BP effects, check "Yes", if not, then check "No".

Review Instructions

If participant answered Yes to Q1, Q2, or Q3, make sure the details have been noted, and forward the form to a clinician for review. These forms must be signed by a clinician.

Check to see that form has an ID label and date, and that the correct visit was checked.

Check that all questions were answered (except Q5 if Q4=No)

Check to be sure that if Q2 was answered "Yes", that Q6 is completed by staff.

Additional Instructions

Consult a clinician regarding what to tell participants who answer yes to Q2 or any part of Q3. The clinician may wish to contact the participant's personal physician (with permission from the participant) to see if it is possible for the participant to stop taking the medication. Staff should not tell a participant to stop taking a prescription medication, but may wish to discourage them from taking non-prescription medications.

Consult MOP Chapter 24 (Study Outcomes and Adjudication) for instructions on handling a Yes answer to Q1.

Blood pressure medications (question 1)

Generic name	Brand name
Acebutolol	Sectral
Amiloride	Midamor, Moduretic
Amlodipine	Norvasc
Atenolol	Tenormin
Benazepril	Lotensin, Lotrel
Bepridil	Vascor
Betaxolol	Kerlone
Bisoprolol	Zebeta, Ziac
Bumetanide	Bumex
Candesartan	Atacand
Captopril	Capoten, Capozide
Carteolol	Cartrol
Carvedilol	Coreg
Chlorthalidone	Hygroton
Clonidine	Catapres, Clonidine, Combipres
Diltiazem	Cardizem, Dilacor, Tiazac
Doxazosin mesylate	Cardura
Enalapril maleate	Vasoretic, Vasotec
Ethacrynic Acid	Edecrin
Filodipine	Plendil
Fosinopril sodium	Monopril
Furosemide	Lasix
Hydralazine	Apresoline, Apresazide
Hydrochlorothiazide	Esidrix, Hydrodiuril, Microzide
Indapamide	Lozol
Irbesartan	Avapro
Isradipine	Dynacirc
Labetolol	Normodyne, Trandate
Lisinopril	Prinivil, Prinzide, Zestoretic, Zestril
Losartan potassium	Cozaar, Hyzaar
Methyldopa	Aldoclor, Aldomet, Aldoril
Metoprolol	Lopressor, Toprol

(continued on next page)

Blood pressure medications (Con't)

Generic name	Brand name
Minoxidil	Loniten
Moexipril	Univasc
Nadolol	Corgard, Coroxide
Nicardipine	Cardene
Nifedipine	Adalat, Procardia
Nimodipine	Nimotop
Nisoldipine	Sular
Penbutolol	Levatol
Pindolol	Visken
Prazosin	Minipress, Minizide
Propranolol	Inderide, Inderol
Quinapril	Accupril
Ramipril	Altace
Sotalol	Betapace
Spironolactone	Aldactizide, Aldactone
Telmisartan	Micardis
Terazosin	Hytrin
Timolol	Timolide
Trandolapril	Mavik
Triamterene	Maxzide, Dyazide, Dyrenium
Valsartan	Diovan
Verapamil	Calan, Covera, Isoptin, Verelan

Weight-loss Drugs (Question 2)

Generic name	Brand name
Benzphetamine	Didrex
D-Amphetamine	Dexadrine, Dextrostat
Dexfenfluramine	Redux
Diethylpropion	Tenuate, Tenuate Dospan, Tepanil
Fenfluramine	Pondimin
Mazindol	Mazanor, Sanorex
Methamphetamine	Desoxyn
Orlistat*****	Xenical*****
Phendimetrazine	Bontril, Prelu-2, Plegine, X-trozine

Weight-loss Drugs (Con't)

Phenmetrazine	Preludin
Phenylpropanolamine	Accutrim, Dexatrim
Phentermine	Adipex, Fastin, Ionamin, Obenix, Oby-Cap, Oby-Trim, Pro-Fast, Zantril
Sibutramine	Meridia

Anti-psychotics (Question 3, part a)

Generic name	**Brand name**
Chlorpromazine	Thorazine
Chlorprothixene	Taractan
Clozapine	Clozaril
Flupenthioxol	Fluanxol
Fluphenazine	Permitil, Prolixin
Haloperidol	Haldol
Hydroxyzine	Vistaril
Loxapine	Loxitane
Mesoridazine	Serentil
Methotrimeprazine	Nozinan
Molindone	Moban
Olanzapine	Zyprexa
Perphenazine	Trilafon
Pimozide	Orap
Pipotiazine	Piportil
Prochlorperazine	Compazine
Promazine	Sparine
Quetiapine	Seroquel
Resperidone	Risperdal
Sulpiride	
Thioridazine	Mellaril
Thiothixene	Navane
Trifluoperazine	Stelazine

Mood stabilizers (Question 3, part b)

Generic name	Brand name
Carbamazepine	Depakote
Divalproex	Tegretol
Lithium	Cibalith, Eskalith, Lithobid, Lithonate, Lithotabs

Oral steroids (Question 3, part c)

Generic name	Brand name
Betamethasone*	Celestone*
Dexamethasone	Decadron, Dexone, Hexadrol
Fludrocortisone	Florinef
Hydrocortisone	Cortef, Hydrocortone
Methylprednisolone*	Medrol*
Prednisolone	Delta-Cortef, Prelone
Prednisone	Deltasone, Orasone

Oral breathing medications other than inhalers (Question 3, part d)

Generic name	Brand name
Albuterol sulfate*	Proventil*, Ventolin*, Volmax*
Aminophylline	Amesec, Phyllocontin, Somophyllin
Dyphylline	Dilor, Lufyllin, Neothylline
Guaifenesin/theophylline	Elixophylline
Metaproterenol sulfate*	Alupent*, Metaprel*
Oxtriphylline	Choledyl
Terbutaline sulfate	Brethine
Theophyllin	Ami-Rax, Asbron, Azpan, Bronkolixir, Bronkotabs, Constant-T, Elixophyllin, Hydrophed, Labid, Marax, Quadrinal, Quibron, Respbid, Slo-Bid, Slo-Phyllin, Somophyllin, Tedral, T.E.P., Theo-24, Theochron, Theodrine, Theo-Dur, Theolair, Theophyl, T-Phyl, Uni-Dur, Uniphyl

*Include only if in oral form (tablet or syrup).

Insulin/oral hypoglycemics (Question 3, part e)

Generic name	Brand name
Acetohexamide	Dymelor
Chlorpropamide	Diabinese
Glemipiride	Amaryl
Glipizide	Glucotrol
Glyburide	Diabeta, Glynase, Micronase
Insulin	Actrapid, Humalog, Humulin, Ilentin, Iletin, Insulatard, Isophane, Lentard, Lente, Mixtard, Monotard, Novolin, Protaphane, Semi-lente, Semitard, Ultratard, Velosulin
Metformin	
Tolazamide	Tolinase
Tolbutamide	Orinase

Pain Medications List (Question 4)

Generic name	Brand name
Acetaminophen	Tylenol
Aspirin	Bayer, Bufferin, Ecotrin
Aspirin & Bicarbonate	Alka-Seltzer
Aspirin & Caffeine	Anacin
Diclofenac	Cataflam, Voltaren
Diflunisal	Dolobid
Etodolac	Lodine
Fenoprofen	Nalfon
Flurbiprofen	Ansaid
Ibuprofen	Advil, Motrin, Nuprin
Indomethacin	Indocin
Ketoprofen	Actron, Orudis, Oruvail
Ketorolac	Toradol
Mefanamic Acid	Ponstel
Nabumetone	Relafen
Naproxen	Aleve, Anaprox, Naprelan, Naprosyn

Pain Medications List (con't)

Oxaprazosin	Daypro
Piroxicam	Feldene
Salicylate	Trilisate

Salsalate	Disalcid, Salflex
Sulindac	Clinoril
Tolmetin	Tolectin
Tramadol	Ultram

ID: _____
Date: __ __ / __ __ / __ __ __ __

Vigorous Exercise Worksheet

	Yes	No
1. Is the participant currently doing vigorous exercise?	❑1 ELIG	❑2 go to Q2

	Yes	No
2. **If No to Q1,** is the participant a male > 40 or a female >50 years of age? ...	❑1 go to Q4	❑2 go to Q3

3. **If No to Q2,** then count risk factors:

- ❑ Total cholesterol >240 (from local lab results, repeat test at 6 months if needed)
- ❑ Blood pressure > 140/90 (from last cluster of BP measures: baseline or 6 month)
- ❑ Daily use of tobacco products (from patient history questionnaire)
- ❑ Family history of heart attack or angina before age 60 (from Patient History Questionnaire, Q16)

	Yes	No
_____ Total ⟶ Is the total >= 2?	❑1 go to Q4	❑2 ELIG

Physician Approval

	Yes	No
4. **If Yes to Q2 or Q3,** did the participant have a negative stress test within the last 6 months and did the physician approve?	❑1 go to Q5	❑2 INELIG
5. **If Yes to Q4,** did the PREMIER clinician review the chart and also approve?	❑1 ELIG	❑2 INELIG

_____ _____
Clinician signature Date

Overview

This worksheet is used to track the process of approving a participant to do vigorous physical activity. The worksheet is initiated when the participant asks to be allowed to do vigorous physical exercise. The form is not entered, but must be filed in a separate place in each clinic as a record of the approval or disapproval. (Note: Do not file in the participant's clinic chart, as these will ultimately only be completed for Premier B or C participants. Do not file in the intervention chart since BP/cholesterol data are stored on the form.)

Note: the risk factors follow JNC guidelines with one exception: the risk factor for diabetes has been dropped because participants with diabetes have been screened out.

Administration/Coding Instructions

The form is completed based on information already in the participant's chart.

Based on the answers to questions 1-4, two outcomes are possible. The participant may be eligible, or need physician approval.

Place an ID label on page #1 and date the form.

Page	Question	Special Administration Instructions (if any)
1	1	The self-report answer may be found on Form 18 (PAR, Page 4, Question C). If the participant answered #3 or #4, then code the form as "Yes". If Yes, then participant is eligible for vigorous physical activity. If No, go on to Q2.
	2	Use the participant's date of birth from the Prescreen Eligibility Form (#1) to answer the question. If No, then go on to Q3. If Yes, go on to Q2.
	3	Use the indicated forms to check the appropriate boxes and then count the checked boxes to compute the total. Use the total to answer the question. If No, then participant is eligible for vigorous physical activity. If Yes, go on to Q4.
	4	If physician approves vigorous physical activity, check Yes, attach the letter from the physician and go on to Q5. If the physician does not approve or can not be contacted, or the participant does not wish to contact the physician or take the stress test, then the participant is not eligible for vigorous physical activity. The participant should be advised not to do vigorous physical activity.
	5	If the PREMIER clinician also approves vigorous physical activity, check Yes. The participant is then eligible for vigorous physical activity. If the PREMIER clinician does not approve, then the participant is not eligible for vigorous physical activity. The participant should be advised not to do vigorous physical activity. If the PREMIER clinician is asked to review the

Review Instructions

Check the following items:

- ID label is attached
- Form is dated
- Skip pattern is correctly followed
- Physician's letter is attached (if Q4=Yes)
- Clinician has signed form if Q5 is answered (Yes or No)

Additional Instructions

If participant needs physician approval, this requires a letter from the physician stating that the participant has had a negative stress test within the last 6 months and that the physician approves of the participant doing vigorous exercise. Then, the PREMIER clinician must also review the participant's study chart and agree that vigorous exercise is appropriate.

ID: _____

Date: ____ / ____ / _____

Premature Termination Form

Complete this form for all **randomized** participants who terminate study participation **after randomization**.

Reason for termination (select one):

Started on blood pressure medication ..... ❑ 31

Physician's orders ..... ❑ 32

Illness ..... ❑ 33

Injury ..... ❑ 34

Pregnancy ..... ❑ 35

Death ..... ❑ 36

Moved out of area ..... ❑ 37

Schedule/time conflict ..... ❑ 38

Transportation problems ..... ❑ 39

Refused to continue ..... ❑ 40

Reason:_____

Other (contact the coordinating center for an appropriate code) ..... ❑ ___

Cause of death:	Yes	No
Was the cause of death due to a CV Event? (see coding instructions)……..	❑ 1	❑ 2

Description:

_____

_____

_____

_____

_____

_____ _____

Principal Investigator Signature Date

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This form is used by clinic staff to close out a participant who drops out or is excluded **after randomization.** If participant is still coming in for minimal study measures, do not complete this form.

Coding Instructions

Before completing the form, check to be sure the participant is has been randomized. If the participant is not yet randomized, use a Participant Closeout Form (#28) to close out the participant.

Date: Enter the date of the participant's **last** contact with the study.

Reason: When selecting the reason for the termination, be sure to review all of the choices before making a selection. If the situation does not fit any of the choices, note the reason at the bottom of the form or on an attached sheet and fax the form to the Data Clerk at the Coordinating Center for a coding decision.

See the attached list of Termination Reason Codes for a detailed explanation of when to use each code. If there is a reason that is even close to the situation you are trying to code, use that reason instead of requesting a new code.

Do not code as "Other" without first consulting the Coordinating Center.

Cause of Death: Complete this question only if the participant has died. Indicate the cause of death as being CV-related or non-CV related. CV-related deaths include: Myocardial Infarct (heart attack), Stroke, Heart Failure, or Arrhythmia. If you are unsure whether a death is CV-related or not, call the coordinating center.

Description: Briefly describe the reason for the termination. Include as much detail as possible.

PI Signature: PI must sign and date the form for the termination to take effect.

Review Instructions

Make sure the ID, date, and reason for termination have been completed.

Only one reason should be checked.

Review the notes and make sure the reason has been correctly coded.

Additional Instructions

Do not enter this form until all other forms for the participant has been entered. Once the participant is terminated, you will not be able to enter any new forms. Also be sure any edits to the participant's data have been completed. Once the participant is terminated, many of the restricted edits will no longer be allowed.

Explanations of Termination Reason Codes

Category	When to use this category
Started on BP meds	If participant reports going on BP medications. This could come up on a Medication Use Questionnaire, or may be mentioned by the participant during another contact.
Physician's orders	If the participant's physician or the study clinician request that the participant stop participating in the study. If the participant is also put on BP medication, use that code instead.
Illness	Participant illness (code family illness as schedule/time conflict).
Injury	Participant injury. Do not code as termination reason unless participant stops all study activities due to the injury. Do not terminate if participant merely stops doing the physical activity portion of the intervention.
Pregnancy	Participant pregnancy.
Death	Participant death (code death in family as a schedule/time conflict)
Moved out of area	Participant has left the area permanently. Do not code if participant will be coming back later during the follow up period, or if the participant will be returning for follow up measures.
Schedule/time conflict	Participant is unable to make their clinic and intervention visits due to a scheduling problem or time conflict. This includes work schedule conflicts, inability to get day care, and vacations.
Transportation problems	Participant is unable to get to their clinic and intervention visits due to transportation problems. If transportation arrangements can be made to get the participant to at least their clinic visits, do not terminate.
Refusal	Participant refused to complete any further clinic or intervention visits. Use only if none of the above reasons apply.

SV3
ID: _____

Diet and Physical Activity Change Questionnaire

Please review the PREMIER study activity fact sheet before completing this questionnaire.

If you join the PREMIER study, you will be placed randomly into one of three groups. You will be asked to make diet and lifestyle changes.

If asked, are you willing and able to:

- Attend the regular group and individual sessions as scheduled?
- Lose weight if you are overweight according to the study recommendations?
- Reduce your dietary sodium (salt) intake?
- Limit your alcohol intake to less than 2 drinks per day (if you drink)?
- Participate in regular moderate intensity physical activity?
  (moderate intensity is like a brisk walk)
- Eat at least 9 servings of fruits and vegetables each day?
  (a serving is one piece of fruit, ½ cup of cooked vegetables, or 1 cup of raw vegetables)
- Eat at least 3 servings of dairy foods each day?
  (a serving is 8 oz. milk or 1 cup yogurt)

Yes ❑
No ❑

Reviewed by (staff ID): _____

Overview

This form is not completed until after the participant has reviewed the SV3 Activity Fact Sheet and completed the Screening Motivational Session. This form serves as a summary of the discussion during the motivational session.

Administration Instruction

The interventionist reads to the participant each of the items, and then enters Yes or No at the end as appropriate.

Coding Instructions

No coding is required

Review Instructions

Make sure an ID label was attached and the question was answered.

Additional Instructions

This form is not entered. The outcome is reported and entered on the SV3 Visit Form.

SV3

ID: _____

Screening Motivational Session Notes

Purpose

Explore the participant's motivation and strengthen commitment to participating in the study.

Prior to Meeting with Participant

To prepare for the interview review the Diet and Physical Activities Checklist (Form #8) completed at the SV1 visit.

Process

Use the following questions or others that you come up with to explore the participant's motivation. Your job is to listen and elicit what is important to the participant about being in the study and not solve the participant's problem. Summarize back to the participant and make sure you understand the full picture. Document the key points in the note section below.

- What are your main reasons for participating in PREMIER?
- What about the study makes it important for you?
- What challenges do you anticipate by participating?
- How do other family and significant others feel about your participation?

Notes:

_____

_____

_____

_____

_____

_____

_____

_____

_____

SV3: After completion of this motivation session, fill out the Diet and Physical Activity Change Questionnaire (Form #40) with the participant to get a final commitment from the participant.

Overview

At the SV3 visit and before randomization, a trained interventionist meets with the participant to explore and help the participant resolve ambivalence or uncertainty about participating in the study. The interview should take about 15 minutes.

The purpose of the interaction is to give the participant the opportunity to reflect on their reasons for participation in the study. When the participant is taken through this process it can help them be more likely to give accurate answers to questions. It is the participant's task and not the interventionist to articulate and resolve any misgivings about participating. It is not the interventionist's role to help the participant solve the challenge or problem, but to summarize and state back to the participant's his/her ambivalence and/or reasons for participating.

At the end of the discussion the participant is able to answer the commitment questions listed on the Diet and Physical Activity Change Questionnaire (Form #40) comfortably and honestly.

Administration Instructions

Prior to the Interview

To prepare for the meeting with the participant review the Diet and Physical Activity Checklist (Form #8) completed at the SV1 visit to develop a picture of the participant's ability and interest in making the lifestyle changes. Pay attention to the questions on the Diet and Physical Activity Checklist that are answered with "maybe," in addition to alcohol consumption from the Eligibility Questionnaire, Form #4. Seek out more information for these behaviors. See below for more detail.

Use Reflective Listening Techniques

Ask the participant the questions allowing them time to answer each question before going on to the next question. Use reflective listening techniques. Listen without judgement, interruption. Use attentive silence and encouragement with words like

- mm-hmm
- tell me more
- for instance
- I see
- Oh?
- Go on
- and
- What else?

Summarize. Reflect back with your own words what you heard the participant say. For example,

"Let me see if I understand exactly what you said…"

When asking the questions, make them open ended with words like what, how, etc. instead of words like do or does. This softens the question and helps the participant feel more comfortable.

To begin the questions

Begin the questions with the statement:

"We would like to ask you some questions to help us understand better why you are considering participating in the PREMIER study. We recognize that participating in a clinical trial can be a burden and want to make sure you are comfortable with your decision."

Follow with a question asking the participant for permission to probe further.

"Is it OK for me to ask you a few questions about this?"

If the participant says no, ask them why?

"You don't want to talk about your interest in the study. Tell me more or tell me more why this is a problem."

Continuing with the questions:

If the participant says yes, continue. Ask one question at a time. Reflect back the participant's statements. Reflect with a statement and not a question. This demonstrates empathy and helps the participant feel they are being heard and makes them more comfortable. For example,

Statement: You have concerns about the study.

Question: You are concerned about the study?

What are your main reasons for participating in the PREMIER study?

What about the study makes it important for you?

What are the advantages and disadvantages participating in the study?

What challenges do you anticipate by participating?

How do you see your life will be different both while a participant and after the study is over?

As the participant gives you feedback, summarize both sides. State back the reasons for participating, along with the reasons for not participating. Refrain from solving the participant's barriers to participating.

On one side you are feeling that you really want to participate, but at the same time, you are uncomfortable about … and concerned that it may interfere with your participation.

"Maybe" Questions and Excessive Alcohol

Use the information from the Diet and Physical Activity Checklist (Form #8) and the alcohol question from the Eligibility Questionnaire (Form #4) to help guide the interaction with the participant. Use receptive open-ended questions to seek out more information about questions answered with a "maybe" and for excessive alcohol. Open-ended questions help the participant feel less defensive. Examples are:

How ready are you to consider eating 9 to 12 servings of fruits and vegetables each day?

How might your life be different if you drink less alcohol?

I'm wondering if we can spend a few minutes talking about dairy foods.

Ability to attend group sessions

Show the participant the schedules for **all three intervention arms**. Ask them if they have any planned trips or other commitments that would prevent their attending any of the sessions. Have them X out any sessions they could not attend.

If they would miss three or more group sessions in phase 1 for any one arm, ask if it is possible that they could reschedule their activities so that they could make the sessions. If not, exclude. If yes, they are eligible to continue.

If they would miss one or two group sessions in phase 1, ask if they would be able to reschedule their activities so that they could make the sessions. If Yes, they are eligible to continue. If no, ask if they would be able to schedule a makeup session around the time of each of the missed sessions. If No, exclude. If yes, they are eligible to continue.

If they would not miss any sessions, probe to be sure they've looked at the dates carefully. Ask about vacation plans.

Also, review phase 2 just to be sure they don't have any major absences, recognizing that the participant may not know their schedule this far out.

Summarize the Interaction

Ask a summary question

How are you feeling about your participation now?

Respect and affirm the participant's response with supportive statements. For a negative

response about participating statements can be:

Even though I would like you to participate in the study, I support and respect your decision to not do so.

It sounds like you've pondered over this decision. I understand (respect) your decision.

I applaud your decision and really appreciate your honesty.

For a positive response from the participant the statement can be

That is great! We would love to have you participate.

When a participant responds that they feel they can participate, but they have some misgivings or challenges, a response can be

I am delighted that you want to participate and am confident we can find away around the challenge (state the challenge).

Concluding the interview

After completing the questions ask if there is anything else the participant wants to say.

Is this all? Do you have any further comments?

Administer the Diet and Physical Activity Change Questionnaire (Form #40) following the form's instructions, regardless of the participant's response. The participant should now be ready to answer the questions on the form comfortably and honestly.

Document the Interaction

After the interview is over, record the participant's comments on this form, the Motivational Session Notes (Form #041), and file in the participant's record. If the participant answered no to the final question, they are ineligible to continue in they study.

Coding Instructions

No coding is required.

Review Instructions

No review is required.

Additional Instructions

This form is not entered. The outcome from form #40 is recorded on the SV3 Visit Form.

Participant ID: _____

Intervention Data Collection Form
PREMIER A

Session Session Number: _____

Date of Session.....___/___/___

Attended Session.....Yes ❑ 1

No ❑ 2

Form Completed by (Staff ID):	_____
Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

Premier A Intervention Data Collection Form

Overview

This form will be completed for each participant at, or immediately after, each scheduled individual intervention session. For PREMIER A participants, this will be at the R/I visit, and at the six month advice session. This form should be completed regardless of participant attendance at the six-month session.

Administration Instructions

Place an ID label at the top of Page 1.

Use correct version of the form. The correct version will always be on the site workstation computer.

Using a blue or black pen, complete the form as outlined below:

Question	**Special Administration Instructions**
Session Number	Record the session number. For the R/I visit, the session number is "1". For the six-month advice session, the session number is "2".
Date of Session	Date of the scheduled session should be recorded as month/day/year in the format mm/dd/yyyy. Remember to use a four digit year.
Attended Session	This field indicates if the participant was present at the session. As a last resort, short of doing nothing at all, the visit can be conducted on the phone. A phone visit is considered the "session" and the participant can be marked as "attended".

After completing the form record your PREMIER Staff ID number in the "form completed by" section at the bottom of the page and send the form to data entry. Note: all forms should be completed within seven days of the scheduled visit.

Participant ID: _____

Intervention Data Collection Form
PREMIER B

Session Type ……Group ❑ 1

Individual ❑ 2

Session Number: ___ ___

Session Attendance

Date of Scheduled Session: __ __ / __ __ / __ __ __ __

Attended Scheduled Session……..……..Yes ❑ 1

No ❑ 2

Weight……. ___ ___ ___ . ___ ___ lbs.

If the participant did not attend the session:	
Reason for Missed Session:	**Was this a planned absence?** Yes ❑ 1 No ❑ 2
	Follow-up Intervention Contacts: Face to Face ❑1 Telephone ❑ 2 Mail ❑ 3 Other ❑ 4 Unable to Contact/Schedule ❑ 5 Chose Not to Contact ❑ 6
	Follow-up Contact Date: __ __ / __ __ / __ __

Food Record Completed ..... Yes ❑ 1

No ❑ 2

Number of Days of Food Records since the last time records were recorded .....___ ___

Day of Week	Calories (Kcal)	Sodium (mg)
Day 1	___ ___ ___ ___	___ ___ ___ ___
Day 2	___ ___ ___ ___	___ ___ ___ ___
Day 3	___ ___ ___ ___	___ ___ ___ ___

Physical Activity Record Completed ……..Yes ❑ 1

No ❑ 2

Number of Days of Exercise since the last time records were recorded..……...___ ___

Total Physical Activity Points for one week..... ___ ___ ___ ___

Completed by (Staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

PREMIER B Intervention Data Collection Form

Overview

This form will be completed for each participant regardless of attendance after each scheduled group and individual intervention session. For PREMIER B participants, this will be at the R/I visit and the conclusion of each subsequent group or individual session.

Windows for Completion:
Phase I and II: Complete and turn in form within 2 weeks or by the next scheduled visit (I or G) whichever occurs first.

Phase III: Complete and turn in this form within 4 weeks or by the next scheduled visit (I or G) whichever occurs first.

Follow-up contacts can occur outside of the visit window, however, attendance, weight, and follow-up visit information cannot be edited after the visit window has passed. Nutrient and physical activity data can be edited at any time.

Administration Instructions

Place an ID label at the top of Page 1.
Using a blue or black pen, complete the form as outlined below:

Question	**Special Administration Instructions**
Session Type	Check one box. Check "Group' if the session was a scheduled group session or "Individual" if the visit was a scheduled individual visit.
Session Number	Use two digits (01, 02, 03, etc.) for individual visits and group sessions. Use the numbering system from the Intervention Contact Schedule in the Protocol. Example: "01" for the R/I visit, "02" for the second individual visit, "01" for the first group session, "02" for the second group session.
Date of Scheduled Session	Using the format mm/dd/yyyy, fill in the date the scheduled session occurred. Remember to use a four digit year.
Attended Scheduled Session	Check one box. Check "YES" if the participant attended the scheduled session or "NO" if the participant did not attend the scheduled session.
Weight	Record weight using a calibrated scale with participant wearing indoor clothing, but without shoes. Use decimals and round to the nearest .25 pound.
If the participant did not attend the session:	
Was this a planned Absence?	Check one box. Check "yes" if the participant informed the interventionist before the scheduled group session of their plans to miss the session. Check "no" if the participant did not contact the interventionist prior to the scheduled session.

Question	Special Administration Instructions
Reason for missed session	Write a brief description of why the visit was missed.
Follow-up Intervention Contact	Note: This section is to be completed for participants who did not attend the scheduled session, but for whom there is a follow-up intervention contact scheduled within the visit window. Complete the form after the follow-up intervention contact has occurred or by the next scheduled session (if the scheduled follow-up contact is missed), whichever occurs first. Follow-up intervention contacts (especially "Face to Face" and "Telephone") should include some behavior change aspects of the intervention (progress check, problem solving, goal setting, action planning, and self-monitoring). Check one box. Check "**Face to Face**" if the intervention contact is made in person with the participant. Check "**Telephone**" if an intervention contact is made by having a conversation with the participant over the telephone. Do not count telephone messages or telephone calls to set up Face to Face intervention contacts as "Telephone" intervention contacts. Check "**Mail**" if the intervention contact consisted of mailing the session materials. Check "**Other**" if any other means was used to made an intervention contact. E-mail falls under this category. Check "**Unable to Contact/Schedule**" if the participant has not responded to contact attempts or the follow-up intervention contact cannot be scheduled within the visit window (the visit can still occur, however). Check "**Chose not to contact**" if the decision was made not to contact the participant about the missed session.
Follow-up Contact Date:	Fill in mm/dd/yyyy of the *actual* date the intervention follow-up contact occurred. (Leave blank if checked "unable to contact" or "chose not to contact".
For the Remaining Items refer to the participants Food & Fitness Diary	
Food Record Completed	Check one box, either "YES" if at least one completed food record is turned in since the last session for which food records were recorded. Check "NO" if incomplete or no records were kept. Note: A completed food record is one that lists all foods eaten in at least one day, regardless of whether nutrient records or calculations were listed.
Days of Food Records	Record the number of complete days Food Records were logged. This is the number of food records completed since the last session for which food records were recorded. Use two digits (01, 02, 03, etc.).

Question	Special Administration Instructions
Dietary Measures	If no food records were kept, leave blank. If food records were kept, fill in the data using whole numbers for up to the first three days food records were kept.
Physical Activity Records Completed	Check one box. Check "YES" if at least one day of physical activity records were recorded since the last session for which physical activity records were recorded. Check "NO" if incomplete of no records were kept.
Days of Exercise	Record the number of complete days physical activity was logged. This is the number of days of activity completed since the last session for which physical activity was recorded. Use two digits (01, 02, 03, etc.).
Total Physical Activity Points	Complete using two digits (01, 02, 03, etc.). Record the number of physical activity points recorded for the *first week* of records turned in at this session.

After completing the form record your PREMIER Staff ID number in the "form completed by" section at the bottom of the page and send the form to data entry.

Participant ID: _____

Intervention Data Collection Form
PREMIER C

Session Type ……Group ❑ 1

Individual ❑ 2

Session Number: ___ ___

Date of Scheduled Session: __ __ / __ __ / __ __ __ __

Session Attendance

Attended Scheduled Session……...……..Yes ❑ 1

No ❑ 2

Weight……. ___ ___ ___ . ___ ___ lbs.

If the participant did not attend the session:	
Reason for Missed Session:	**Was this a planned absence?** Yes ❑ 1 No ❑ 2
	Follow-up Intervention Contacts: Face to Face ❑1 Telephone ❑ 2 Mail ❑ 3 Other ❑ 4 Unable to Contact/Schedule ❑ 5 Chose Not to Contact ❑ 6
	Follow-up Contact Date: __ __ / __ __ / __ __

Food Record Completed.....Yes ❑ 1

No ❑ 2

Number of Days of Food Records since the last time records were recorded..... ___ ___

Day of Week	Calories (Kcal)	Fat (grams)	Sodium (mg)	F&V Servings	Dairy Servings
Day 1	___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___
Day 2	___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___
Day 3	___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___

Physical Activity Record Completed ……..…Yes ❑ 1

No ❑ 2

Number of Days of Exercise since the last time records were recorded ..... ___ ___

Total Physical Activity Points for one week ..... ___ ___ ___ ___

Completed by (Staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

PREMIER C Intervention Data Collection Form

Overview

This form will be completed for each participant regardless of attendance after each scheduled group and individual intervention session. For PREMIER B participants, this will be at the R/I visit and the conclusion of each subsequent group or individual session.

Windows for Completion:
Phase I and II: Complete and turn in form within 2 weeks or by the next scheduled visit (I or G) whichever occurs first.

Phase III: Complete and turn in this form within 4 weeks or by the next scheduled visit (I or G) whichever occurs first.

Follow-up contacts can occur outside of the visit window, however, attendance, weight, and follow-up visit information cannot be edited after the visit window has passed. Nutrient and physical activity data can be edited at any time.

Administration Instructions

Place an ID label at the top of Page 1.
Using a blue or black pen, complete the form as outlined below:

Question	**Special Administration Instructions**
Session Type	Check one box. Check "Group' if the session was a scheduled group session or "Individual" if the visit was a scheduled individual visit.
Session Number	Use two digits (01, 02, 03, etc.) for individual visits and group sessions. Use the numbering system from the Intervention Contact Schedule in the Protocol. Example: "01" for the R/I visit, "02" for the second individual visit, "01" for the first group session, "02" for the second group session.
Date of Scheduled Session	Using the format mm/dd/yyyy, fill in the date the scheduled session occurred. Remember to use a four digit year.
Attended Scheduled Session	Check on box. Check "YES" if the participant attended the scheduled session or "NO" if the participant did not attend the scheduled session.
Weight	Record weight using a calibrated scale with participant wearing indoor clothing, but without shoes. Use decimals and round to the nearest .25 pound.
If the participant did not attend the session:	
Was this a planned Absence?	Check one box. Check "yes" if the participant informed the interventionist before the scheduled group session of their plans to miss the session. Check "no" if the participant did not contact the interventionist prior to the scheduled session.

Question	Special Administration Instructions
Reason for missed session	Write a brief description of why the visit was missed.
Follow-up Intervention Contact	Note: This section is to be completed for participants who did not attend the scheduled session, but for whom there is a follow-up intervention contact scheduled within the visit window. Complete the form after the follow-up intervention contact has occurred or by the next scheduled session (if the scheduled follow-up contact is missed), whichever occurs first. Follow-up intervention contacts (especially "Face to Face" and "Telephone") should include some behavior change aspects of the intervention (progress check, problem solving, goal setting, action planning, and self-monitoring). Check one box. Check "**Face to Face**" if the intervention contact is made in person with the participant. Check "**Telephone**" if an intervention contact is made by having a conversation with the participant over the telephone. Do not count telephone messages or telephone calls to set up Face to Face intervention contacts as "Telephone" intervention contacts. Check "**Mail**" if the intervention contact consisted of mailing the session materials. Check "**Other**" if any other means was used to made an intervention contact. E-mail falls under this category. Check "**Unable to Contact/Schedule**" if the participant has not responded to contact attempts or the follow-up intervention contact cannot be scheduled within the visit window (the visit can still occur, however). Check "**Chose not to contact**" if the decision was made not to contact the participant about the missed session.
Follow-up Contact Date:	Fill in mm/dd/yyyy of the *actual* date the intervention follow-up contact occurred. (Leave blank if checked "unable to contact" or "chose not to contact".
For the Remaining Items refer to the participants Food & Fitness Diary	
Food Record Completed	Check one box, either "YES" if at least one completed food record is turned in since the last session for which food records were recorded. Check "NO" if incomplete or no records were kept. Note: A completed food record is one that lists all foods eaten in at least one day, regardless of whether nutrient records or calculations were listed.
Days of Food Records	Record the number of complete days Food Records were logged. This is the number of food records completed since the last session for which food records were recorded. Use two digits (01, 02, 03, etc.).

Question	Special Administration Instructions
Dietary Measures	If no food records were kept, leave blank. If food records were kept, fill in the data using whole numbers for up to the first three days food records were kept.
Physical Activity Records Completed	Check one box. Check "YES" if at least one day of physical activity records were recorded since the last session for which physical activity records were recorded. Check "NO" if incomplete of no records were kept.
Days of Exercise	Record the number of complete days physical activity was logged. This is the number of days of physical activity records completed since the last session for which physical activity was recorded. Use two digits (01, 02, 03, etc.).
Total Physical Activity Points	Complete using two digits (01, 02, 03, etc.). Record the number of physical activity points recorded for the *first week* of records turned in at this session.

After completing the form record your PREMIER Staff ID number in the "form completed by" section at the bottom of the page and send the form to data entry.

PREMIER

Exercise Confidence Questionnaire

ID: _____

Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

Date: ____ / ____ / _____

Below is a list of things people might do while trying to increase or continue regular exercise. We are interested in exercises like running, swimming, brisk walking, bicycle riding, or aerobics classes.

Whether you exercise or not, please rate how confident you are that you could *really motivate* yourself to do things like these consistently for *at least six months*. Please ***circle one number for each item.***

How sure are you that you can do these things?	**I know I cannot**		**Maybe I can**		**I know I can**	**Does not apply**
1. Get up early, even on weekends, to exercise.	1	2	3	4	5	9
2. Stick to your exercise program after a long, tiring day at work.	1	2	3	4	5	9
3. Exercise even though you are feeling depressed.	1	2	3	4	5	9
4. Set aside time for a physical activity program; that is, walking, jogging, swimming, biking, or other continuous activities for at least 30 minutes, 3 times per week.	1	2	3	4	5	9
5. Continue to exercise with others even though they seem too fast or too slow for you.	1	2	3	4	5	9
6. Stick to your exercise program when undergoing a stressful life change (e.g., divorce, death in the family, moving).	1	2	3	4	5	9
7. Attend a party only after exercising.	1	2	3	4	5	9
8. Stick to your exercise program when your family is demanding more time from you.	1	2	3	4	5	9
9. Stick to your exercise program when you have household chores to attend to.	1	2	3	4	5	9
10. Stick to your exercise program even when you have excessive demands at work.	1	2	3	4	5	9
11. Stick to your exercise program even when social obligations are very time consuming.	1	2	3	4	5	9
12. Read or study less in order to exercise more.	1	2	3	4	5	9

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This self-administered questionnaire is designed to capture information about the participant‘s confidence in their ability to increase their physical activity level. It is administered at baseline (any time prior to randomization) and at the 6 and 18 month follow-up visits.

Administration Instructions

Using a blue or black pen, check the appropriate box to designate which visit this form (#45) was administered: Pre-randomization, 6, or 18 month.

Instruct participant to fill out the form in blue or black pen. Participants should be encouraged to answer every question.

Coding Instructions

No coding is required.

Review Instructions

Page 1 should have an ID label attached.

Make sure that each circle is on a number (not around two numbers or marked between two numbers).

Check to be sure all items were completed. If any items were not completed, confirm with participant that they meant to skip the item. Participants are allowed to decline to answer any of the questions.

Also follow up with participant on forms where “does not apply” was checked frequently.

PREMIER

Eating Habits Confidence Questionnaire

ID: _____

Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

Date: ____ / ____ / _____

Below is a list of things people might do while trying to change their eating habits.

Whether you are trying to change your eating habits or not, please rate how confident you are that you could *really motivate* yourself to do things like these consistently for *at least six months*. Please ***circle one number for each item.***

How sure are you that you can do these things?	**I know I cannot**		**Maybe I can**		**I know I can**	**Does not apply**
1. Drink low or non-fat milk every day.	1	2	3	4	5	9
2. Stick to low fat, low salt foods when dining with friends or co-workers.	1	2	3	4	5	9
3. Cut down on gravies and cream sauces.	1	2	3	4	5	9
4. Eat poultry and fish instead of red meat at dinner.	1	2	3	4	5	9
5. Keep the salt shaker off the kitchen table.	1	2	3	4	5	9
6. Stick to low fat, low salt foods when there is high fat, high salt food readily available at a party.	1	2	3	4	5	9
7. Eat smaller portions of food at a party.	1	2	3	4	5	9
8. Eat fruit or vegetables for a snack.	1	2	3	4	5	9
9. Cook smaller portions so there are no leftovers.	1	2	3	4	5	9
10. Stick to low fat, low salt foods when you feel depressed, bored, or tense.	1	2	3	4	5	9
11. Eat fruit or drink fruit juice with breakfast.	1	2	3	4	5	9
12. Avoid ordering red meat (beef, pork, ham, lamb) at a restaurant.	1	2	3	4	5	9
13. Eat fruit or vegetables at every meal.	1	2	3	4	5	9
14. Substitute low or non-fat milk for whole milk at breakfast.	1	2	3	4	5	9
15. Eat salads for lunch.	1	2	3	4	5	9

ID: _____

How sure are you that you can do these things?	I know I cannot		Maybe I can		I know I can	Does not apply
16. Eat smaller portions at dinner.	1	2	3	4	5	9
17. Eat meatless (vegetarian) entrees for dinner.	1	2	3	4	5	9
18. Stick to low fat, low salt foods when you are alone, and there is no one to watch you.	1	2	3	4	5	9
19. Eat unsalted peanuts, chips, crackers, and pretzels.	1	2	3	4	5	9
20. Stick to low fat, low salt foods when the only snack close by is available from a vending machine.	1	2	3	4	5	9
21. Drink fruit juice instead of soda.	1	2	3	4	5	9
22. Eat unsalted, unbuttered popcorn.	1	2	3	4	5	9
23. Avoid adding salt at the table.	1	2	3	4	5	9
24. Eat more vegetables at restaurants.	1	2	3	4	5	9
25. Eat lunch as your main meal of the day, rather than dinner.	1	2	3	4	5	9
26. Eat yogurt, low fat cottage cheese or low fat cheese most days.	1	2	3	4	5	9
27. Add less salt than the recipe calls for.	1	2	3	4	5	9

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Eating Habits Confidence Questionnaire
Overview

This self-administered questionnaire is designed to capture information about the participant‘s confidence in their ability to change their eating habits. It is administered at baseline (any time prior to randomization) and at the 6 and 18 month follow-up visits.

Administration Instructions

Using a blue or black pen, check the appropriate box to designate which visit this form (#46) was administered: Pre-randomization, 6, or 18 month. Only one box should be marked.

Instruct participant to fill out the form in blue or black pen. Participants should be encouraged to answer every question.

Coding Instructions

No coding is required.

Review Instructions

Page 1 and 2 should have ID labels attached.

Make sure that each circle is on a number (not around two numbers or marked between two numbers).

Check to be sure all items were completed. If any items were not completed, confirm with participant that they meant to skip the item. Participants are allowed to decline to answer any of the questions.

Also follow up with participant on forms where “does not apply” was checked frequently.

ID: _____

Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

Date: ____ / ____ / _____

Social Support and Eating Habits Questionnaire

Below is a list of things people might do or say to someone who is trying to improve their eating habits. If you not trying to change your eating habits, then some of the questions may not apply to you., but please read and give an answer to every question.

Please rate each question ***twice***. Under ***family***, rate how often anyone living in your household has said or done what is described during the last three months. Under ***friends***, rate how often your friends, acquaintances, or coworkers have said or done what is described during the last three months.

Please write one number from the following rating scale in each space:

none	rarely	a few times	often	very often	does not apply
1	2	3	4	5	9

During the past three months, my family or friends:	**Family**	**Friends**
1. Refused to eat the same foods I eat.	_____	_____
2. Discussed my eating habit changes with me (asked me how I'm doing with my eating changes).	_____	_____
3. Reminded me to drink low or non-fat milk.	_____	_____
4. Brought home foods I'm trying not to eat.	_____	_____
5. Commented if I went back to my old eating habits.	_____	_____
6. Reminded me not to eat high fat, high salt foods.	_____	_____
7. Got angry when I encouraged them to eat low salt, low fat foods.	_____	_____
8. Encouraged me not to eat "unhealthy foods" (cake, salted chips) when I'm tempted to do so.	_____	_____
9. Reminded me to eat fruits and vegetables.	_____	_____
10. Got angry when I encouraged them to eat fruits and vegetables.	_____	_____
11. Complimented me on changing my eating habits ("Keep it up," "We are proud of you").	_____	_____
12. Offered me food I'm trying not to eat.	_____	_____
13 Got angry when I encouraged them to drink low or non-fat milk.	_____	_____
14 Ate high fat or high salt foods in front of me.	_____	_____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Social Support and Eating Habits Questionnaire
Overview

This self-administered questionnaire is designed to capture information about the social support the participant has to help them change their eating habits. It is administered at baseline (any time prior to randomization) and at the 6 and 18 month follow-up visits.

Administration Instructions

Using a blue or black pen, check the appropriate box to designate which visit this form (#47) was administered: Pre-randomization, 6, or 18 month. Only one box should be marked.

Instruct participant to fill out the form in blue or black pen. Participants should be encouraged to answer every question.

Explain how the two columns for "family" and "friends" are to be used. Each question should be answered twice: once for family members and once for friends. Some participants may find it easier to go through the questions once thinking about family members and filling out the first column, and then go through the questions again thinking about friends and filling out the second column.

Be sure to stress the fact that the "friends" category also includes co-workers.

Coding Instructions

No coding is required.

Review Instructions

Page 1 should have an ID label attached.

Check to be sure only the numbers 1, 2, 3, 4, 5, and 9 were used. (no answers like "1.5" or "1-2").

Check to be sure all items were completed. Make sure that each item is filled out for both friends and family. If any items were not completed, confirm with participant that they meant to skip the item. Participants are allowed to decline to answer any of the questions.

Also follow up with participant for any form where "does not apply" was coded frequently.

ID: _____

Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

Date: ____ / ____ / _____

Social Support and Exercise Questionnaire

Below is a list of things people might do or say to someone who is trying to exercise regularly. If you not trying to exercise, then some of the questions may not apply to you., but please read and give an answer to every question.

Please rate each question ***twice***. Under ***family***, rate how often anyone living in your household has said or done what is described during the last three months. Under ***friends***, rate how often your friends, acquaintances, or coworkers have said or done what is described during the last three months.

Please write one number from the following rating scale in each space:

none	rarely	a few times	often	very often	does not apply
1	2	3	4	5	9

During the past three months, my family or friends:

		Family	**Friends**
1.	Exercised with me.....	_____	_____
2.	Offered to exercise with me.....	_____	_____
3.	Gave me helpful reminders to exercise ("Are you going to exercise tonight?")	_____	_____
4.	Gave me encouragement to stick with my exercise program.	_____	_____
5.	Changed their schedule so we could exercise together.....	_____	_____
6.	Discussed exercise with me.	_____	_____
4.	Complained about the time I spend exercising.	_____	_____
8.	Criticized me or made fun of me for exercising.	_____	_____
9.	Gave me rewards for exercising (bought me something or gave me something I like).	_____	_____
10.	Planned for exercise on recreational outings.	_____	_____
11.	Helped plan activities around my exercise.	_____	_____
12.	Asked me for ideas on how *they* can get more exercise.	_____	_____
13	Talked about how much they liked to exercise.....	_____	_____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Social Support and Exercise Questionnaire
Overview

This self-administered questionnaire is designed to capture information about the social support the participant has to help them increase their physical activity level. It is administered at baseline (any time prior to randomization) and at the 6 and 18 month follow-up visits.

Administration Instructions

Using a blue or black pen, check the appropriate box to designate which visit this form (#48) was administered: Pre-randomization, 6, or 18 month. Only one box should be marked.

Instruct participant to fill out the form in blue or black pen. Participants should be encouraged to answer every question.

Explain how the two columns for "family" and "friends" are to be used. Each question should be answered twice: once for family members and once for friends. Some participants may find it easier to go through the questions once thinking about family members and filling out the first column, and then go through the questions again thinking about friends and filling out the second column.

Stress the fact that the "friends" category also includes co-workers.

Coding Instructions

No coding is required.

Review Instructions

Page 1 should have an ID label attached.

Check to be sure only the numbers 1, 2, 3, 4, 5, and 9 were used. (no answers like "1.5" or "1-2").

Check to be sure all items were completed. Make sure that each item is filled out for both friends and family. If any items were not completed, confirm with participant that they meant to skip the item. Participants are allowed to decline to answer any of the questions.

Also follow up with participant for any form where "does not apply" was coded frequently.

ID: _____

Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

Date: ____ / ____ / _____

Perceived Body Image Questionnaire – Women

These questions ask about how you **look now**, and how you would **best like to look**. Please check the box under the figure that best answers the following:

1. Right **now** I look like:

❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8 ❑ 9

2. I would like it best if I now looked like:

❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8 ❑ 9

Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

ID: _____

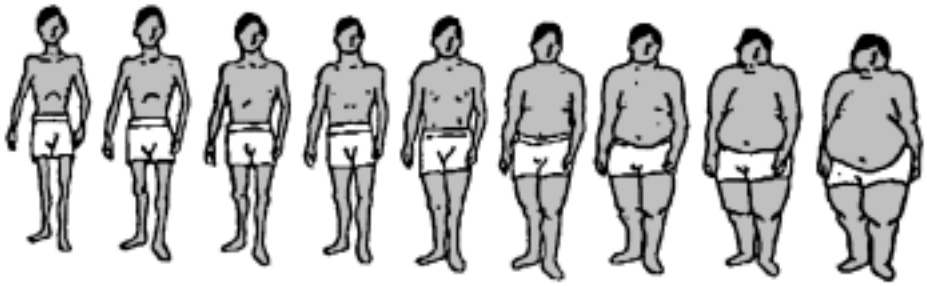
Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

Date: ____ / ____ / _____

Perceived Body Image Questionnaire – Men

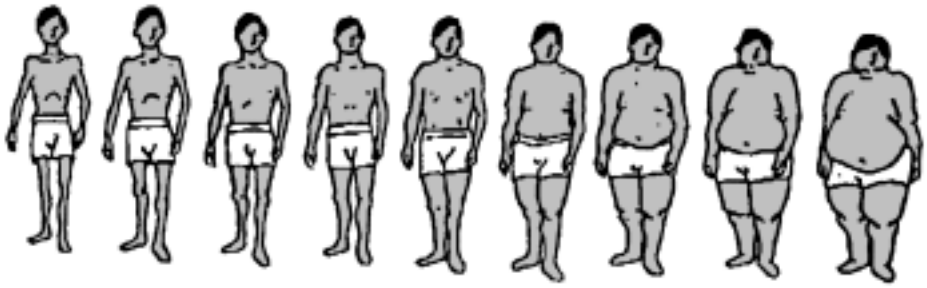
These questions ask about how you **look now**, and how you would **best like to look**. Please check the box under the figure that best answers the following:

1. Right **now** I look like:



❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8 ❑ 9

2. I would like it best if I now looked like:



❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8 ❑ 9

Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

Overview

This self-administered questionnaire is designed to capture information about the participant's perceived and ideal body images. It is administered at baseline (any time prior to randomization) and at the 6 and 18 month follow-up visits. There is a separate form for men and women.

Administration Instructions

Using a blue or black pen, check the appropriate box to designate which visit this form (#49) was administered: Pre-randomization, 6, or 18 month. Only one box should be marked.

Fill out the visit date on page 1 and 2. Be sure to use a four digit year.

Give each participant the form appropriate for their gender. Instruct participant to fill out the form in blue or black pen. Participants should be encouraged to answer both questions.

Coding Instructions

No coding is required.

Review Instructions

Page 1 and 2 should be dated and have ID labels attached.

Check to be sure that a box is marked for each item (no checks between two boxes).

Check to be sure both items were completed. If any items were not completed, confirm with participant that they meant to skip the item. Participants are allowed to decline to answer any of the questions.

Site Number: ____
Cohort: _____
Week ending Friday:
__ __ / __ __ / __ __ __ __

Recruitment Activity Form

Please fill this report out on Friday for each week of recruitment.

I. NEW RECRUITMENT EFFORTS (if none, check here ❑)

Type of activity	Description	Quantity*
Mailed letter/brochure/flier		_____ items (round to nearest 100)
Coupon pack		_____ coupons (round to nearest 100)
Other mass distribution		_____ items (round to nearest 100)
Print article/story		_____ stories
Print advertisement		_____ spots aired
Radio story		_____ stories
Radio advertisement		_____ spots aired
TV story		_____ stories
TV advertisement		_____ spots aired
E-mail distribution list		_____ messages (round to nearest 100)
Screening event/health fair		_____ events (not persons)
Presentation		_____ events (not persons)

II. RECRUITMENT VISITS

Visit	Number currently scheduled
SV1	
SV2	
SV3	
R/I	

Projected Intervention Start Date:

__ __ / __ __ / __ __ __ __

Completed by (staff ID): _____
Entered by (staff ID): _____

Overview

This form is used to capture information about recruitment efforts in order to compute recruitment yields. It also collects information about current numbers of scheduled visits in order to compute recruitment projections. The information gathered each week is used to update several recruitment reports that are then available on the PREMIER web site. If more than one cohort is being recruited at a time, a separate form needs to be completed for each cohort.

The form should be filled out by the Recruitment Coordinator once a week during recruitment. **The form should always be filled out on Friday**. If possible, the data should be entered on Friday. If not, the form should be entered by Monday or Tuesday at the latest.

Coding Instructions

Question	**Instructions**
Header:	Enter the site number (1=Baltimore, 2=Baton Rouge, 4=Durham, 9=Portland), the cohort, and the date at the top of the form.
I. Recruitment Efforts	If no mailings, advertisements, stories, events, or presentations have occurred in the last week (last Saturday through today) check the box and go on to II. Otherwise, complete the remaining items. List any activities you did **during that week**. Skip any items you did not do.
Mailed letter/ brochure/flier	This refers to any mass mailing of PREMIER information that requests a mail or phone response. This does not include calls or cards returned as a result of distributing brochures by other means (e.g. hand distribution at stores, malls). Round numbers off to the nearest 100. For example, 13,550 brochures would be rounded to 13600.
Coupon pack	Any mass mailing of through companies which include PREMIER information or coupons with other coupons. (e.g. Valpack). Round numbers off to the nearest 100
Other mass distribution	This includes brochures left on display at sites, libraries, grocery stores, and pharmacies. Round numbers off to the nearest 100
Print article/story	Any **free** local or national newspaper or magazine article or public service announcement or newsletter (church, work site, hospital, HMO, MCO, and professional organization) that gives information about PREMIER. This would also include payroll stuffers that are placed without a fee. List the number of stories that appeared. For example, if a newspaper ran a series of articles, each day it appeared would count as one story.

Question	Instructions
Print advertisement	Any print (newspaper, circular, magazine, etc.) advertisement that is **paid** for by a PREMIER site. This would include inserts in newspapers or utility bills (if it was paid to be inserted). List the total number of spots aired. For example, two advertisements aired three times each would be 6 spots aired.
Radio story	Any **free** radio announcement, advertisement, interview, or program that gives information about PREMIER. List the number of stories that aired.
Radio advertisement	Any radio advertisement or announcement that is **paid** for by a PREMIER site. List the number of spots that aired.
TV story	Any **free** TV announcement, advertisement, interview, or program that gives information about PREMIER. List the number of stories that aired.
TV advertisement	Any TV advertisement or announcement that is **paid** for by a PREMIER site. List the number of spots that aired.
E-mail distribution list	Any information distributed through e-mail. Round off to the nearest 100.
Screening event/health fair	Any screening at a gathering or event that occurs outside a PREMIER clinic. Count the number of events, not the number of persons attending.
Presentation	Any presentations other than screening done outside a PREMIER clinic. Count the number of events, not the number of persons attending.
II. Recruitment Visits	Enter the number of **future** visits currently on your books for the current cohort.
Intervention Start Date	Enter the date you plan to hold your first intervention **group** session.
Completed by	Enter the staff ID of the person who completed the form.

Review Instructions

- Make sure the date recorded is a Friday.
- Confirm that the intervention start date matches the projected date of the first **group** session for the cohort.

ID: _____

Date of BP Escape: ____ / ____ / _____

Blood Pressure Escape Form – 3, 12 month visits

ESCAPE INFORMATION:

1. Visit ..... 3 month ❑ 7
   12 month ❑ 9

2. Escape Level..... Level 1 ❑ 1
   Level 2 ❑ 2

FOLLOW UP ACTIONS:

3. Obtain additional RZ BP within 1 week .....Date obtained: __ __ / __ __ / __ __ __ __

4. Sum of 2 BP readings for the original visit:..... __ __ __ / __ __ __

5. Sum of additional 2 BP readings:..... __ __ __ / __ __ __

6. Cumulative sum of original and repeat BP readings (4+5):..... __ __ __ / __ __ __

7a. Escape Level 1 Outcome:.....≤637/397 (no referral needed) ❑ 1
≥718/438 (refer to physician* within 1 week) ❑ 2
≥638/398 (refer to physician* within 1 month) ❑ 3

7b. Escape Level 2 Outcome:.....≤557/357 (no referral needed) ❑ 4
≥638/398 (refer to physician* within 1 month) ❑ 5
≥558/358 (refer to physician* within 2 months) ❑ 6

Date referred: __ __ / __ __ / __ __ __ __

Date referral confirmed: __ __ / __ __ / __ __ __ __

Notes: _____

_____

_____

*Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician.

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This form is used to track the process of following up on an escape-level blood pressure **during the 3 month or 12 month visits.** Complete this form whenever the 3 or 12 Month Visit BP Form escape outcomes are reached.

Start completing this form immediately after the escape-level BP is reached. You will need to have the BP form available as you complete this form.

Coding Instructions

Question	**Instructions**
Date of BP escape	Enter the date from the BP form.
1. Visit	Code the appropriate visit from the BP form.
2. Escape level	Escapes are either level 1 (requiring more immediate follow-up) or level 2. Level 1 is the only option at the 3 month visit. The escape level is indicated on the BP form outcome.
3. Date of repeat	Enter the date the repeat measurement was obtained. Make sure this is within 1 week of the escape.
4. Previous BP	Enter the BP sum from the previous visit (the visit where the escape happened)
5. Repeat BP	Enter the sum of the two BP readings from the repeat reading.
6. Sum	Add items 4+5.
7a-b. Outcome	If the escape was a Level 1, complete item 7a. If the escape was a Level 2, complete item 7b.
Referral date	Enter the date the participant was referred. This is the date the participant was told to contact their physician for a follow-up appointment.
Confirmation date	During the following seven days, attempt to confirm with the participant that a follow-up appointment was made. If able to confirm, enter the date of confirmation. Write the date of the appointment in the "Notes" section. If unable to confirm after seven days, enter the date of the last attempt to confirm.

Notes: Indicate any issues, problems, or special circumstances. If referral could not be confirmed, be sure to indicate that in the notes.

Review Instructions

- Make sure ID label was attached and all items were completed.
- Make sure that Level 1 escapes have item 7a completed and Level 2 escapes have item 7b completed.
- Check that referral happened within the allowed time window (based on 7a or 7b).
- Review the Notes section to be sure it adequately explains the follow-up. ("Referred" is not an adequate explanation.)

Additional Instructions

Once form has been reviewed and entered, fax a copy to the Data Clerk at the coordinating center). Be sure to use a shipping log (Form #316).

File the original form in the participant's chart.

ID: _____

Date of BP Escape: ____ / ____ / _____

Blood Pressure Escape Form – 6, 18 Month Visit Clusters

ESCAPE INFORMATION:

1. Visit — 6 month ❑ 8; 18 month ❑ 10

2. Escape Level ..... Level 1 ❑ 1; Level 2 ❑ 2

FOLLOW UP ACTIONS:

Escape Level 1

3. Obtain additional RZ BP within 1 week ..... Date obtained: __ __ / __ __ / __ __ __ __

4. Sum of 2 BP readings for the original visit: ..... __ __ __ / __ __ __

5. Sum of additional 2 BP readings: ..... __ __ __ / __ __ __

6. Cumulative sum of original and repeat BP readings (4+5): ..... __ __ __ / __ __ __

7. Outcome: ..... ≤637/397 (no referral needed)* ❑ 1; ≥718/438 (refer to physician within 1 week) ❑ 2; ≥638/398 (refer to physician within 1 month) ❑ 3

Escape Level 2: *Refer to physician within 2 months*

Date referred: __ __ / __ __ / __ __ __ __

Date referral confirmed: __ __ / __ __ / __ __ __ __

Notes: _____

_____

_____

*Be sure to confirm participant's Escape Level 2 status at their Cluster Visit 3 if the escape took place then. If the participant is an Escape Level 2, then they still need to be referred to their physician.

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This form is used track the process of following up on an escape-level blood pressure **during the 6 month or 18 month visit clusters.** Complete this form whenever an escape outcome is reached on one of the 6 or 18 Month Visit BP Forms.

Start completing this form immediately after the escape-level BP is reached. You will need to have the BP form available as you complete this form. Note that no additional BP's need be taken if the participant has reached escape level 2, but this form must be completed and entered.

Coding Instructions

Question	**Instructions**
Date of BP escape	Enter the date from the BP form.
1. Visit	Code the appropriate visit from the BP form.
2. Escape level	Escapes are either level 1 (requiring more immediate follow-up) or level 2. The escape level is indicated on the BP form outcome.
3. Date of repeat	Enter the date the repeat measurement was obtained. Make sure this is within 1 week of the escape.
4. Previous BP	Enter the BP sum from the previous visit (the visit where the escape happened)
5. Repeat BP	Enter the sum of the two BP readings from the repeat reading.
6. Sum	Add items 4+5.
7. Outcome	Check the appropriate outcome. **Note**: If the participant has a Level 1 escape that occurred at Cluster Visit #3, then the participant's Level 2 escape status should be assessed at this time if their Level 1 outcome is "No Referral Needed". If they qualify also for an Escape Level 2 at their Cluster Visit #3, then they should be referred appropriately.
Referral date	Enter the date the participant was referred for either a Level 1 or Level 2 escape. This is the date the participant was told to contact their physician for a follow-up appointment.
Confirmation date	During the following seven days, attempt to confirm with the participant that a follow-up appointment was made. If able to confirm, enter the date of confirmation. Write the date of the appointment in the "Notes" section. If unable to confirm after seven days, enter the date of the last attempt to confirm.
Notes:	Indicate any issues, problems, or special circumstances. If referral could not be confirmed, be sure to indicate that in the notes.

Review Instructions

- Make sure ID label was attached and all items were completed.
- Make sure that Level 1 escapes have item 7a completed and Level 2 escapes have item 7b completed.
- If an Escape Level 1 occurred at a Cluster Visit #3, be sure to assess their Escape Level 2 status if their Level 1 outcome is "No Referral Needed".
- Check that referral happened within the allowed time window (based on #7).
- Review the Notes section to be sure it adequately explains the follow-up. ("Referred" is not an adequate explanation.)

Additional Instructions

Once form has been reviewed and entered, fax a copy to the Data Clerk at the coordinating center). Be sure to use a shipping log (Form #316).

File the original form in the participant's chart.

12 Month
ID: _____
Date: ____ / ____ / _____

12 Month Visit Blood Pressure Form

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Arm circumference (cm, round all fractions up)..... _____ _____

Small adult (< 24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____

\+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number ..... ____ ____

PIL ID: _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

4. COMPUTE SUM

Sum of 2 SBPs and 2 DBPs (2c + 3c)..... __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Escape-level 1 BP ..... Sum of SBPs ≥ 319 ❑ 1

Sum of DBPs ≥ 199 ❑ 2

If box 1 or 2 is checked: complete form #84 (escape level 1)
*Schedule participant for return BP within **1 week***

Escape-level 2 BP ..... Sum of SBPs ≥ 279 ❑ 5

Sum of DBPs ≥ 179 ❑ 6

If box 5 or 6 is checked: complete form #84 (escape level 2)
*Schedule participant for return BP within **1 month***

Non-escape BP ..... Sum of SBPs < 279, Sum of DBPs < 179 ❑ 7

Collected by (staff ID): _____
Reviewed by (staff ID): _____
Entered by (staff ID): _____

Overview

The 12 Month Visit Blood Pressure Form is filled out by clinic staff and is used to measure participant's blood pressure to make sure it does not exceed safety limits.

If blood pressure values reach escape level 1 or 2, the BP Escape Form – 12 Month Visits (#84) should be completed**.**

If item 1c= No, all subsequent questions are left blank. Before entering the form, contact the coordinating center for a decision on what follow up action should be taken.

If item 1c= Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Place ID labels on pages 1 and 2. Check for accuracy.

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Page	Question	Special Administration Instructions
1	1	Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
	a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
	b.	Measure the participant's arm circumference. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). Record the rounded arm circumference. Based on the arm circumference obtained, mark an "X" on the corresponding line indicating proper cuff size for the measurement.
	c.	Indicate here whether or not the cuff fits properly. If the answer is Yes, go on. If the answer is No, contact the coordinating center for a decision on what follow up action should be taken..
		WAIT 5 MINUTES SEATED
	d.	Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.
	e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
	f.	Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
	g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.

Page	Question		Special Administration Instructions
2	2	a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
		b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
		c.	Do Items 3a and 3b first. Then follow instructions for Item #3c.
			Wait 30 seconds
	3	a.	Repeat item #2a.
		b.	Repeat item #2b.
		c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4		Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100.
	5		Using the sum value from item #4, check the **first** applicable box . If the BP escape levels are reached, the participant needs to have a follow-up BP scheduled. Schedule participant for return BP within 1 week for escape level 1 or within 1 month for escape level 2. Refer to MOP Chapter 23 for details and complete form #84 after follow-up appt. is completed.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

? Page 1 should be dated.

? Pages 1-2 should have correct ID# labels.

? Page 1:

-items 1a-b and 1d-g should be completed.

-check for correct addition in item 1f.

-item 1c should be coded as Yes, or if No, there should be a note explaining the follow up plan or other outcome for this participant.

? Page 2:

-items 2 and 3 should be completed.

-check for correct addition in items 2c, 3c, and 4.

-item 4 should match the outcome selected in item 5

? All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

? If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2.

Additional Instructions

3 Month
ID: _____
Date: __ __ / __ __ / __ __ __ __

3 Month Visit Form

	DONE?
Check visit window	❑
Informed consent (if applicable)	❑
Complete Follow-Up Symptoms Questionnaire	❑
Complete Follow-Up Medication Use Questionnaire	❑
Complete Follow-Up Rose Questionnaire – Angina	❑
Complete 3 Month Visit Blood Pressure Form	❑
Update Participant Contact Form	❑

Measure weight ..... ___ ___ ___ . ___ ___ lbs

If using a balance beam scale, record beam measurements here:

Fifty pound beam measurement: ___ ___ ___
One pound beam measurement: ___ ___ . ___ ___

Total weight measurement: ___ ___ ___ . ___ ___ Record weight on line above

3 Month Visit Outcome ..... **all data collected** ❑1
partial data collected* ❑2
no data collected* ❑3

**Do not select either of these outcomes until the visit window has expired and it is confirmed that no further data for this visit will be collected.*

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Overview

This form is completed at the 3 month safety visit. It is used to track the completion of each of the items that comprise this visit. Generally, this visit is completed in a single clinic appointment. This form must be completed for every randomized participant, regardless of whether they complete any part of the 3 month visit. Only terminated participants do not need to have this form completed.

Administration Instructions

Using a blue or black pen, fill out each of the items on page 1.

Question	**Special Administration Instructions (if any)**
Date	Use the date the last item in the visit was completed.
Visit window	Check to be sure the visit is taking place within two weeks of the participant's 3-month anniversary date. Use the Clinic Visit Windows Report (#17) from the data management system to find the visit window for each participant. If the visit is outside the target window, but within the allowed window, it can still be entered. If visit is outside both the target window and the allowed window, it can not be entered (contact the coordinating center for a decision on what to do with the data).
Informed consent	If the local IRB requires a visit-specific consent, check it off once it has been obtained. Otherwise, cross this item out.
Follow-Up Symptoms Q	Check this off once the form has been completed. Note: his form can trigger an Adverse Events Form and additional follow up may be required.
Follow-Up Medication Use Q	Check this off once the form has been completed. Note: if participant reports going on BP medications, this form can trigger additional follow up.
Follow-Up Rose Angina Q	Check this off once the form has been completed. Note: this form can trigger an Adverse Events Form and additional follow up may be required.
Blood Pressure	Check this off once the 3 Month Visit BP Form has been completed. Note: this form can trigger a BP Escape Form and additional follow up may be required.
Participant Contact	Verify Participant Contact information.
Weight	Measure weight in pounds and record result (to the nearest quarter pound) If using a balance beam scale, record the measurement of each beam on the form. The sum of these two measurements should equal the recorded weight (after rounding to the nearest quarter pound). Record weight on the "Measure Weight line".

Question	**Special Administration Instructions (if any)**
Outcome	If all forms and measures were completed, check "all data collected." If at least one of the forms or measures was completed, the allowed visit window has expired, and no further data for this visit will be collected, check "partial data collected." If the allowed visit window has expired and no data has been collected, check "no data collected." Do not check "partial data" or "no data" until it is definite that no further data will be collected for this visit and the visit window has expired.

Review Instructions

Check to be sure that each of the required forms has been completed.

If using a balance beam scale, check to see that the calculated weight is the same weight that is recorded on the "Measure Weight" line.

If "all data collected" is checked, all boxes should be checked (or crossed out, in the case of the informed consent) and the weight should be completed.

If "partial data collected" is checked, at least one of the four questionnaire boxes should be checked or the weight should be completed.

If "no data collected" is checked, none of the questionnaire boxes should be checked and the weight should be blank.

If any of the forms triggered an Adverse Event Form or a BP Escape Form, make sure those forms have been completed.

Additional Instructions

Do not enter this form until all other data from the visit has been entered.

PREMIER

6 Month
ID: _____
Date: __ __ / __ __ / __ __ __ __

6 Month Visit Form

DONE?

Check visit window..... ❑

Informed consent (if applicable)..... ❑

Complete Follow-Up Symptoms Questionnaire ..... ❑

Complete Follow-Up Medication Use Questionnaire (one for each BP) ..... ❑

Complete Follow-Up Rose Questionnaire – Angina ..... ❑

Complete 7-Day Physical Activity Recall ..... ❑

Complete psychosocial questionnaire packet and alcohol questionnaire ..... ❑
(forms 23, 25, 45, 46, 47, 48, 49, 22)

Collect 24-hour urine ..... ❑

Collect fasting blood (CLCS, Storage, CDC) ..... ❑

Complete treadmill fitness test..... ❑

Complete 6 Month Visit Blood Pressure Form – Cluster Visit 1 ..... ❑

Complete 6 Month Visit Blood Pressure Form – Cluster Visit 2 ..... ❑

Complete 6 Month Visit Blood Pressure Form – Cluster Visit 3 ..... ❑

Complete 6 Month Visit Blood Pressure Form – Cluster Visit 4 ..... ❑

24-hour food interviews:.....review instructions ❑
complete convenient time schedule, fax to Penn State ❑
interviews completed (notification received from Penn State) ❑

Update Participant Contact Form..... ❑

Measure waist circumference..... ____ ____ ____ . ____ cm

____ ____ ____ . ____ cm

Measure weight (should be done at the first cluster visit) .....___ ___ ___ . ___ ___ lbs

If using a balance beam scale, record beam measurements here:

Fifty pound beam measurement: ___ ___ ___
One pound beam measurement: ___ ___ . ___ ___

Total weight measurement: ___ ___ ___ . ___ ___ Record weight on line above

Six-Month Outcome

6 Month Visit Outcome ..... **all data collected** ❑1

partial data collected* ❑2

no data collected* ❑3

**Do not select either of these outcomes until the visit window has expired and it is confirmed that no further data for this visit will be collected.*

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This form is completed at the 6 month visit. It is used to track the completion of each of the items that comprise this visit. This form must be completed for every randomized participant, regardless of whether they complete any part of the 6 month visit. Only terminated participants do not need to have this form completed.

Administration Instructions

Using a blue or black pen, fill out each of the items on page 1.

Question	**Special Administration Instructions (if any)**
Date	Use the date the last item for the visit cluster was completed.
Visit window	Check to be sure clinic visit(s) are taking place within three weeks of the participant's 7-month anniversary date. Also check that the blood pressures were measured between 5 1/2 months and 8 1/2 months and no closer than two weeks apart. Use the Clinic Visit Windows Report (#17) from the data management system to find the visit windows for each participant. If the visits are outside the target window, but within the allowed window, they can still be entered. If visits are outside both the target window and the allowed window, it can not be entered (contact the coordinating center for a decision on what to do with the data).
Informed consent	If the local IRB requires a visit-specific consent, check it off once it has been obtained. Otherwise, cross this item out.
Follow-Up Symptoms Q	Check this off once the form has been completed. Note: this form can trigger an Adverse Events Form and additional follow up may be required.
Follow-Up Medication Use Q	Check this off once the form has been completed. Note: if participant reports going on BP medications, this form can trigger additional follow up.
Follow-Up Rose Angina Q	Check this off once the form has been completed. Note: this form can trigger an Adverse Events Form and additional follow up may be required.
Physical Activity Recall	Check this off once the form has been completed.
Psychosocial Packet	Check this off once all of the forms in the packet plus the Alcohol Intake Questionnaire have been completed.
24-hour urine	Check this off once the 24-hour urine specimen has been successfully collected and form #62 has been completed.
Fasting blood	Check this off once the fasting blood specimen has been successfully collected and forms #63 & #77 have been completed.

Question	Special Administration Instructions (if any)
Food Interviews	Have the participant complete the convenient times schedule and fax it to Penn State. Confirm that the participant still has their poster. Check this off once you have been notified by Penn State that the two diet interviews have been completed.
Participant Contact	Review the Participant Contact Form and update as needed.
Treadmill	Check this off once the treadmill test has been completed.
Blood Pressures	Check off each of these items as the four 6 Month Visit BP Forms are completed. Note: these forms can trigger a BP Escape Form and additional follow up may be required.
Waist circumference	Measure the two waist circumference measures in centimeters and record the results.
Weight	Measure weight in pounds and record result (to the nearest quarter pound) If using a balance beam scale, record the measurement of each beam on the form. The sum of these two measurements should equal the recorded weight (after rounding to the nearest quarter pound). Record weight on the "Measure Weight line".
Outcome	If all forms and measures were completed, check "all data collected." If at least one of the forms or measures was completed, the allowed visit window has expired, and no further data for this visit will be collected, check "partial data collected." If the allowed visit window has expired and no data has been collected, check "no data collected." Do not check "partial data" or "no data" until it is definite that no further data will be collected for this visit and the visit window has expired.

Review Instructions

Check to be sure that each of the required forms has been completed.

If "all data collected" is checked, all boxes should be checked (or crossed out, in the case of the informed consent) and the weight and waist circumference should be completed.

If using a balance beam scale, check to see that the calculated weight is the same weight that is recorded on the "Measure Weight" line.

If "partial data collected" is checked, at least one box should be checked or the weight or waist circumference should be completed.

If "no data collected" is checked, none of the boxes should be checked and the weight and waist circumference should be blank.

If any of the forms triggered an Adverse Event Form or a BP Escape Form, make sure those forms have been completed.

Additional Instructions

Do not enter this form until all data from the visit has been entered.

12 Month
ID: _____
Date: __ __ / __ __ / __ __ __ __

12 Month Visit Form

	DONE?
Check visit window	❑
Informed consent (if applicable)	❑
Complete Follow-Up Symptoms Questionnaire	❑
Complete Follow-Up Medication Use Questionnaire	❑
Complete Follow-Up Rose Questionnaire – Angina	❑
Complete 12 Month Visit Blood Pressure Form	❑
Update Participant Contact Form	❑

Measure weight ..... ___ ___ ___ . ___ ___ lbs

If using a balance beam scale, record beam measurements here:

Fifty pound beam measurement: ___ ___ ___
One pound beam measurement: ___ ___ . ___ ___

Total weight measurement: ___ ___ ___ . ___ ___ Record weight on line above

12 Month Visit Outcome ..... **all data collected** ❑1
partial data collected* ❑2
no data collected* ❑3

**Do not select either of these outcomes until the visit window has expired and it is confirmed that no further data for this visit will be collected.*

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Overview

This form is completed at the 12 month safety visit. It is used to track the completion of each of the items that comprise this visit. Generally, this visit is completed in a single clinic appointment. This form must be completed for every randomized participant, regardless of whether they complete any part of the 12 month visit. Only terminated participants do not need to have this form completed.

Administration Instructions

Using a blue or black pen, fill out each of the items on page 1.

Question	**Special Administration Instructions (if any)**
Date	Use the date the last item in the visit was completed.
Visit window	Check to be sure the visit is taking place within two weeks of the participant's 12-month anniversary date. Use the Clinic Visit Windows Report (#17) from the data management system to find the visit window for each participant. If the visit is outside the target window, but within the allowed window, it can still be entered. If visit is outside both the target window and the allowed window, it can not be entered (contact the coordinating center for a decision on what to do with the data).
Informed consent	If the local IRB requires a visit-specific consent, check it off once it has been obtained. Otherwise, cross this item out.
Follow-Up Symptoms Q	Check this off once the form has been completed. Note: this form can trigger an Adverse Events Form and additional follow up may be required.
Follow-Up Medication Use Q	Check this off once the form has been completed. Note: if participant reports going on BP medications, this form can trigger additional follow up and exclusion from further participation.
Follow-Up Rose Angina Q	Check this off once the form has been completed. Note: this form can trigger an Adverse Events Form and additional follow up may be required.
Blood Pressure	Check this off once the 12 Month Visit BP Form has been completed. Note: this form can trigger a BP Escape Form and additional follow up may be required.
Participant Contact	Verify Participant Contact information.
Weight	Measure weight in pounds and record result (to the nearest quarter pound) If using a balance beam scale, record the measurement of each beam on the form. The sum of these two measurements should equal the recorded weight (after rounding to the nearest quarter pound). Record weight on the "Measure Weight line".

Question	Special Administration Instructions (if any)
Outcome	If all forms and measures were completed, check "all data collected." If at least one of the forms or measures was completed, the allowed visit window has expired, and no further data for this visit will be collected, check "partial data collected." If the allowed visit window has expired and no data has been collected, check "no data collected." Do not check "partial data" or "no data" until it is definite that no further data will be collected for this visit and the visit window has expired.

Review Instructions

Check to be sure that each of the required forms has been completed.

If using a balance beam scale, check to see that the calculated weight is the same weight that is recorded on the "Measure Weight" line.

If "all data collected" is checked, all boxes should be checked (or crossed out, in the case of the informed consent) and the weight should be completed.

If "partial data collected" is checked, at least one box should be checked or the weight should be completed.

If "no data collected" is checked, none of the boxes should be checked and the weight should be blank.

If any of the forms triggered an Adverse Event Form or a BP Escape Form, make sure those forms have been completed.

Additional Instructions

Do not enter this form until all data from the visit has been entered. Run the 12 Month Visit Completeness Report (#11) in the data management system to confirm that data entry for the other forms is complete.

18 Month
ID: _____
Date: __ __ / __ __ / __ __ __ __

18 Month Visit Form

DONE?

Check visit window..... ❑

Informed consent (if applicable)..... ❑

Complete Follow-Up Symptoms Questionnaire..... ❑

Complete Follow-Up Medication Use Questionnaire (one for each BP) ..... ❑

Complete Follow-Up Rose Questionnaire – Angina ..... ❑

Complete 7-Day Physical Activity Recall ..... ❑

Complete psychosocial questionnaire packet and alcohol questionnaire ..... ❑
(forms 23, 25, 45, 46, 47, 48, 49, 22)

Collect 24-hour urine ..... ❑

Collect fasting blood (CLCS, Storage, CDC)..... ❑

Complete treadmill fitness test..... ❑

Complete 18 Month Visit Blood Pressure Form – Cluster Visit 1 ..... ❑

Complete 18 Month Visit Blood Pressure Form – Cluster Visit 2 ..... ❑

Complete 18 Month Visit Blood Pressure Form – Cluster Visit 3 ..... ❑

24-hour food interviews:..... review instructions ❑
complete convenient time schedule, fax to Penn State ❑
interviews completed (notification received from Penn State) ❑

Update Participant Contact Form..... ❑

Measure waist circumference..... ____ ____ ____ . ____ cm

____ ____ ____ . ____ cm

Measure weight..... ___ ___ ___ . ___ ___ lbs

If using a balance beam scale, record beam measurements here:

Fifty pound beam measurement: ___ ___ ___
One pound beam measurement: ___ ___ . ___ ___

Total weight measurement: ___ ___ ___ . ___ ___ Record weight on line above

18-Month Outcome

18 Month Visit Outcome ..... **all data collected** ❑1

partial data collected* ❑2

no data collected* ❑3

**Do not select either of these outcomes until the visit window has expired and it is confirmed that no further data for this visit will be collected.*

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This form is completed at the 18 month visit. It is used to track the completion of each of the items that comprise this visit. This form must be completed for every randomized participant, regardless of whether they complete any part of the 18 month visit. Only terminated participants do not need to have this form completed.

Administration Instructions

Using a blue or black pen, fill out each of the items on page 1.

Question	**Special Administration Instructions (if any)**
Date	Use the date the last item in the visit was completed.
Visit window	Check to be sure clinic visit(s) are taking place within three weeks of the participant's 17-month anniversary date. Also check that the blood pressures were measured between 15 1/2 months and 18 1/2 months and no closer than two weeks apart. Use the Clinic Visit Windows Report (#17) from the data management system to find the visit windows for each participant. If the visits are outside the target window, but within the allowed window, they can still be entered. If visits are outside both the target window and the allowed window, it can not be entered (contact the coordinating center for a decision on what to do with the data).
Informed consent	If the local IRB requires a visit-specific consent, check it off once it has been obtained. Otherwise, cross this item out.
Follow-Up Symptoms Q	Check this off once the form has been completed. Note: this form can trigger an Adverse Events Form and additional follow up may be required.
Follow-Up Medication Use Q	Check this off once the form has been completed. Note: if participant reports going on BP medications, this form can trigger additional follow up and exclusion from further participation.
Follow-Up Rose Angina Q	Check this off once the form has been completed. Note: this form can trigger an Adverse Events Form and additional follow up may be required.
Physical Activity Recall	Check this off once the form has been completed.
Psychosocial Packet	Check this off once all of the forms in the packet plus the Alcohol Intake Questionnaire have been completed.
24-hour urine	Check this off once the 24-hour urine specimen has been successfully collected and form #20 has been completed.
Fasting blood	Check this off once the fasting blood specimen has been successfully collected and form #21 & #77 have been completed.
Treadmill	Check this off once the treadmill test has been completed.

Question	Special Administration Instructions (if any)
Blood Pressures	Check off each of these items as the three 18 Month Visit BP Forms are completed. Note: these forms can trigger a BP Escape Form and additional follow up may be required
Food Interviews	Have the participant complete the convenient times schedule and fax it to Penn State. Confirm that the participant still has their poster. Check this off once you have been notified by Penn State that the two food interviews have been completed.
Participant Contact	Verify Participant Contact information.
Waist circumference	Measure the two waist circumference measures in centimeters and record the results.
Weight	Measure weight in pounds and record result (to the nearest quarter pound) If using a balance beam scale, record the measurement of each beam on the form. The sum of these two measurements should equal the recorded weight (after rounding to the nearest quarter pound). Record weight on the "Measure Weight line".
Outcome	If all forms and measures were completed, check "all data collected." If at least one of the forms or measures was completed, the allowed visit window has expired, and no further data for this visit will be collected, check "partial data collected." If the allowed visit window has expired and no data has been collected, check "no data collected." Do not check "partial data" or "no data" until it is definite that no further data will be collected for this visit and the visit window has expired.

Review Instructions

Check to be sure that each of the required forms has been completed.

If "all data collected" is checked, all boxes should be checked (or crossed out, in the case of the informed consent) and the weight and waist circumference should be completed.

If using a balance beam scale, check to see that the calculated weight is the same weight that is recorded on the "Measure Weight" line.

If "partial data collected" is checked, at least one box should be checked or the weight or waist circumference should be completed.

If "no data collected" is checked, none of the boxes should be checked and the weight and waist circumference should be blank.

If any of the forms triggered an Adverse Event Form or a BP Escape Form, make sure those forms have been completed.

Additional Instructions

Do not enter this form until all data from the visit has been entered. Run the 18 Month Visit Completeness Report (#12) in the data management system to confirm that data entry for the other forms is complete.

R/I

ID: _____

Randomization Visit Date: __ __ / __ __ / __ __ __ __

Randomization Checklist

Should be completed in advance of the randomization visit:

DONE?

Complete and enter Pre-Randomization Checklist (Form #19) ..... ❑

Can be completed in advance of the randomization visit:

Obtain randomization consent ..... **signed** ❑1
refused ❑2

Measure 4th Baseline Blood Pressure ..... **eligible** ❑1
(if escape level, or a valid BP cannot be obtained, then ineligible) **ineligible*** ❑2

Waist circumference (from pre-randomization visit) ..... ____ ____ ____ . ____ cm

____ ____ ____ . ____ cm

Must be completed on the day of the randomization visit:

DONE?

Check visit window ..... ❑

	Yes	**No**
Have there been any important recent changes in the participant's health status, such as major illness, injury or surgery, that may affect their ability to participate in the study at this time?	❑	❑
If Yes: Has the participant been cleared for randomization at this time? (Complete Form 28 if the participant is not cleared)	❑	❑

Weight (in lbs) ..... ____ ____ ____ . ____ ____ lbs

Outcome ..... **eligible** ❑1
ineligible ❑2
refused ❑3

If ineligible, 4th baseline BP form must be entered prior to entering the Randomization Checklist.

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Randomization Checklist Training Manual and Coding Instructions

Overview

The Randomization Checklist is used to track the completion of forms and measurements during the time period between completing the Pre-Randomization Checklist and randomizing the participant and beginning the intervention at the R/I visit. This form must be complete before the participant can be randomized.

Some items on this form can be done ahead of the R/I visit, and some must be done on the day of the visit. Of the items that can be done ahead of time, some must be entered prior to randomization, others only need to be completed prior to randomization.

To randomize a participant, the Randomization Checklist must first be entered. Then, for those participants with a Randomization Checklist outcome of "eligible," a randomization assignment can be made and a randomization report is printed. At this point, the intervention portion of the visit can begin.

As soon as a participant is determined to be ineligible, check the "Ineligible" box under the Outcome and terminate the visit. If a participant refuses to complete the visit, check the "Refused" box under Outcome and terminate the visit. For eligible participants, all items must be completed.

Administration Instructions

Using a blue or black pen, fill out each of the items on page 1. If a participant becomes ineligible at any point, you do not need to complete the remaining items.

Question	**Special Administration Instructions (if any)**
Pre-Rand. Checklist	Make sure the Pre-Randomization Checklist has been completed **and entered**. If not, complete that form first and then come back to the Randomization Checklist. Both forms can be completed in one visit if necessary, but this is not recommended.
Randomization consent	If the randomization (intervention) consent has not yet been obtained, do it at the R/I visit and record the outcome. If the randomization consent was already obtained, confirm that it is on file and enter the outcome.
4th blood pressure	Enter the outcome from the 4th Baseline Blood Pressure Form (#23). Participant is only ineligible if their blood pressure reaches escape levels as defined in Form #23 or a blood pressure could not be obtained (cuff did not fit properly). If participant does hit escape, be sure that form #23 is entered before entering this form, and that the BP Escape Form – Screening (#32) is completed.

Question	Special Administration Instructions (if any)
Visit window	Make sure no more than 6 months have elapsed between the SV1 blood pressure date and the date of the R/I visit.
Recent changes	Ask whether the participant has had any important recent changes in their health status. If so, and this makes them ineligible for randomization, close them out by completing a Form 28.
Waist circumference	Exactly copy the waist circumference measurements taken at the pre-randomization visit onto this form. The data are entered from this form into the Data Entry system.
Weight	This measure must be completed on the day of the R/I visit. Measure weight to the nearest 0.25 pound according to the procedures in MOP Chapter 20.
Outcome	see Coding Instructions below

Coding Instructions

Outcome: After all other items are complete, enter the visit outcome. If the outcome for the randomization consent is "signed," the outcome for blood pressure is "eligible," all "Done?" items have been checked, and the participant wishes to continue, check the "eligible" box. If the blood pressure is marked "ineligible," check the "ineligible" box. If the participant refused at any point, check the "refused" box. If the checklist is incomplete and will not be completed, either enter "refused" (if appropriate), or close out the participant using the closeout form (#28).

Review Instructions

Do not review this form until all randomization visit activities (except the intervention session) are complete and a final outcome is determined.

For all participants:

- Make sure that the ID label has been attached.

For eligible participants:

- Check that all items have been completed.
- Make sure that no more than 6 months have passed between the SV1 blood pressure date and the scheduled randomization visit.

For ineligible participants:

- All items do not have to be completed, but make sure that at least one eligible/ineligible response has been checked "ineligible" or one "Done?" box has not been checked.

For refusals:

- No other items are required.

After reviewing the form, enter your staff ID on the "Reviewed by" line.

Additional Instructions

Do not enter this form until:

- The pre-randomization checklist has been entered
- All randomization activities are complete
- A final outcome is determined

(The 4th Baseline Blood Pressure Form does not have to be entered prior to entering this form or randomizing the participant, unless the participant is ineligible due to that blood pressure result)

This form will be entered on the day of the visit (with the participant waiting). It is entered into the intervention system, not the data entry system. Once it has been successfully entered, a randomization assignment can be made and a randomization report can be printed. Then the participant's first intervention session can begin.

Because the data entry screen is in the intervention system, this form can only be entered by an unblinded data entry technician.

Six Month
ID: _____

Central Lab Collection Form – 6 Month 24-Hour Urine

Data from worksheet (best of initial sample or repeat)

Collect start date ..... __ __ / __ __ / __ __ __ __

Start time ..... __ __ : __ __ AM or PM

Collect stop date ..... __ __ / __ __ / __ __ __ __

Stop time ..... __ __ : __ __ AM or PM

Time Sufficient (22-26 hours) ..... Yes ❑ 1
No ❑ 2

Total Volume ..... __ __ __ __ cc

Volume Sufficient (=500 cc) ..... Yes ❑ 1
No ❑ 2

Sample obtained correctly ..... Yes ❑ 1
❑ discarded initial void ❑ ≤1 voiding missed ❑ not menstruating No ❑ 2

Was participant able to refrigerate sample? ..... Yes ❑ 1
No ❑ 2

Sample Collection Outcome ..... Ready to ship to lab* ❑ 1
Failed ❑ 2

Extra Collection Outcome ..... Ready to ship to storage* ❑ 1
Failed/Not Attempted ❑ 2

Collected by (staff ID): _____
Reviewed by (staff ID): _____
Entered by (staff ID): _____

*Includes adequate samples, and also inadequate samples where obtaining an adequate sample was not possible.

PREMIER

ID: _____

Central Lab Collection Form – 6 Month 24-Hour Urine – Worksheet

Initial Sample

1. Collect start date __ __ / __ __ / __ __ __ __ **Start time** __ __ : __ __ AM or PM

2. Collect stop date __ __ / __ __ / __ __ __ __ **Stop time** __ __ : __ __ AM or PM

3. Number of hours .....__ __

4. Time Sufficient (22-26 hours) .....Yes ❑ No ❑

5. Total Volume (22-26 hours) ..... __ __ __ __ cc

6. Volume Sufficient (=500 cc) .....Yes ❑ No ❑

7. Sample obtained correctly.....Yes ❑ No ❑
❑ discarded initial void ❑ ≤1 voiding missed ❑ not menstruating

8. Was participant able to refrigerate sample? Yes ❑ No ❑

9. Initial Sample Collection Outcome Adequate (answer is YES to #4, #6, and #7) ❑
Inadequate (do repeat sample) ❑

Repeat Sample

10. Collect start date __ __ / __ __ / __ __ __ __ **Start time** __ __ : __ __ AM or PM

11. Collect stop date __ __ / __ __ / __ __ __ __ **Stop time** __ __ : __ __ AM or PM

12. Number of hours .....__ __

13. Time Sufficient (22-26 hours) .....Yes ❑ No ❑

14. Total Volume (22-26 hours) ..... __ __ __ __ cc

15. Volume Sufficient (=500 cc) .....Yes ❑ No ❑

16. Sample obtained correctly.....Yes ❑ No ❑
❑ discarded initial void ❑ ≤1 voiding missed ❑ not menstruating

17. Was participant able to refrigerate sample? Yes ❑ No ❑

18. Repeat Sample Collection Outcome Adequate (answer is YES to #13, #15, and #16) ❑
Inadequate❑

Overall Collection Outcome

Initial sample was adequate, or was the best of the two ❑
Repeat sample was adequate, or was the best of the two ❑
Failed, neither sample can be sent ❑

Collected by (staff ID): _____
Reviewed by (staff ID): _____

Overview

This form will be used to track the collection and shipping of 24-hour urine specimens during the six month follow-up visit. Use form 64 for specimens collected at 18 months. It is expected that this form will be filled out for each participant at their initial attempt and, if one is necessary, their repeat attempt to collect a 24-hour urine specimen.

Administration Instructions

Fill out the worksheet first. After the initial (and repeat) collection is completed, transfer the data to the first page of the form.

Coding Instructions

Page	Field	Special Instructions
2	1	Record the start date and start time as recorded on the label attached to the urine collection jug. For the date, use leading zeros as appropriate. Be sure to use a four digit year. For the time, use leading zeros as appropriate. Circle AM or PM. Remember that Noon is 12 PM.
	2	Record the stop date and stop time as recorded on the label attached to the urine collection jug.
	3	Subtract stop time from start time. Record answer in hours (rounded to the nearest whole number). This is a two-digit field. Use leading zeros as appropriate.
	4	Mark Yes if number of hours is at least 22 but not more than 26 hours. Mark No if number of hours is fewer than 22 or more than 26.
	5	Record total volume in cubic centimeters of urine as measured using a graduated cylinder. This is a four-digit field. Use leading zeros if necessary.
	6	Mark Yes if total volume is at least 500 cc. Otherwise, mark No.
	7	Mark Yes only if all three boxes below are checked.
	8	Mark Yes if the participant was able to refrigerate the sample. Note that this is *not* a requirement for Q9.
	9	Mark Adequate if answers are Yes to #4, 6, and 7.
	10-18	Only go on to repeat sample if Q9 is coded as inadequate. Instructions for Q10-18 are the same as for Q1-9.
	Overall	Self-explanatory

If there was no repeat sample, or the initial sample was the best of the two, transfer the information from the top section of the worksheet to page 1 of the form. If the repeat sample was the best of the two, transfer the information from the bottom section of the worksheet to

Review Instructions

Make sure that if the sample collection outcome is “ready to ship to lab” that you have two tubes of urine (1 with HCl and 1 without) in the freezer. If the extra collection outcome is “ready to ship to storage”, you should have four additional tubes of urine in the freezer (2 with HCl and 2 without).

Check that the data were correctly transcribed from page 2 to page 1.

Additional Instructions

This form is used to generate the shipping logs for sending specimens to the lab or to storage. Specimens can not be shipped until this form is entered.

6 Month
ID: _____

Central Lab Collection Form – 6 Month Fasting Blood

Data from worksheet (best of initial sample or repeat)

Collect date ..... __ __ / __ __ / __ __ __ __

Collect time ..... __ __ : __ __ AM or PM

Fasting time ..... __ __ hours

Fasting time sufficient (12+ hours) ..... Yes ❑ 1

No ❑ 2

Serum Vial Collection Outcome (red) ..... Ready to ship to lab* ❑ 1

Failed ❑ 2

Plasma Vial Collection Outcome (purple) ..... Ready to ship to lab* ❑ 1

Failed ❑ 2

Extra Serum Vials Collection Outcome (red) ..... Ready to ship to storage* ❑ 1 _____

Failed ❑ 2 # vials

Extra Plasma Vials Collection Outcome (clear) ..... Ready to ship to storage* ❑ 1 _____

Failed ❑ 2 # vials

*Includes adequate samples, and also inadequate samples where obtaining an adequate sample was not possible.

Collected by (staff ID):	_____
Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

ID: _____

Central Lab Collection Form – 6 Month Fasting Blood – Worksheet

Initial Sample

1. Collect date __ __ / __ __ / __ __ __ __ **Collect time** __ __ : __ __ AM or PM

2. Fasting time .....__ __ hours

3. Time Sufficient (12+ hours) ..... Yes ❑ No ❑

4. Serum Vial Collected (red) ..... Yes ❑ No ❑ Hemolyzed ❑

5. Plasma Vial Collected (clear) ..... Yes ❑ No ❑ Hemolyzed ❑

6. Extra Serum Vials Collected (red)..... Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

7. Extra Plasma Vials Collected (clear) ..... Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

8. Initial Sample Collection Outcome Adequate (answer is YES to #3-7) ❑

Inadequate, repeat the sample ❑

Repeat Sample

10. Collect date __ __ / __ __ / __ __ __ __ **Collect time** __ __ : __ __ AM or PM

11. Fasting time .....__ __ hours

12. Time Sufficient (12+ hours) ..... Yes ❑ No ❑

13. Serum Vial Collected (red) ..... Yes ❑ No ❑ Hemolyzed ❑

14. Plasma Vial Collected (clear) ..... Yes ❑ No ❑ Hemolyzed ❑

15. Extra Serum Vials Collected (red)..... Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

16. Extra Plasma Vials Collected (clear) ..... Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

17. Initial Sample Collection Outcome Adequate (answer is YES to #12-16) ❑

Inadequate ❑

Overall Collection Outcome

Initial draw was adequate, or was the best of the two ❑

Repeat draw was adequate, or was the best of the two ❑

Failed (neither draw can be sent to the lab) ❑

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Overview

This form will be used to track the collection and shipping of fasting blood specimens collected at the six-month visit. Use form 65 for specimens collected at 18 months. It is expected that this form will be filled out for each participant at their initial attempt and, if one is necessary, their repeat attempt to collect a fasting blood specimen.

Administration Instructions

Fill out the worksheet first. After the initial (and repeat) collection is completed, transfer the data to the first page of the form.

Coding Instructions

Page	Field	Special Instructions
2	1	Record the collect date and collect time of the draw. For the date, use leading zeros as appropriate. For the time, use leading zeros as appropriate. Circle AM or PM. Remember that noon is 12 PM.
	2	Round answer, in hours, to the nearest whole number.
	3	Mark Yes if number of hours is at least 12. Otherwise, mark No.
	4-7	Mark Yes if the sample was collected. Mark No if the sample was not collected.
	8	Mark Adequate if answers are Yes to #3-7.
	10-17	Only go on to repeat sample if Q8 is coded as inadequate. Instructions for Q10-17 are the same as for Q1-8.
	Overall	Self-explanatory

If there was no repeat sample, or the initial sample was the best of the two, transfer the information from the top section of the worksheet to page 1 of the form. If the repeat sample was the best of the two, transfer the information from the bottom section of the worksheet to

Review Instructions

Make sure that if the sample collection outcome is “ready to ship to lab” or “ready to ship to storage” that you have the matching tube(s) in the freezer.

Check that the data were correctly transcribed from page 2 to page 1.

Additional Instructions

This form is used to generate the shipping logs for sending specimens to the lab or to storage. Specimens can not be shipped until this form is entered.

18 Month
ID: _____

Central Lab Collection Form – 18 Month 24-Hour Urine

Data from worksheet (best of initial sample or repeat)

Collect start date .....__ __ / __ __ / __ __ __ __

Start time ..... __ __ : __ __ AM or PM

Collect stop date .....__ __ / __ __ / __ __ __ __

Stop time ..... __ __ : __ __ AM or PM

Time Sufficient (22-26 hours) .....Yes ❑ 1
No ❑ 2

Total Volume .....__ __ __ __ cc

Volume Sufficient (=500 cc) .....Yes ❑ 1
No ❑ 2

Sample obtained correctly .....Yes ❑ 1
❑ discarded initial void ❑ ≤1 voiding missed ❑ not menstruating No ❑ 2

Was participant able to refrigerate sample?.....Yes ❑ 1
No ❑ 2

Sample Collection Outcome .....Ready to ship to lab* ❑ 1
Failed ❑ 2

Extra Collection Outcome ..... Ready to ship to storage* ❑ 1
Failed/Not Attempted ❑ 2

Collected by (staff ID):	_____
Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

*Includes adequate samples, and also inadequate samples where obtaining an adequate sample was not possible.

ID: _____

Central Lab Collection Form – 18 Month 24-Hour Urine – Worksheet

Initial Sample

1. Collect start date __ __ / __ __ / __ __ __ __ **Start time** __ __ : __ __ AM or PM

2. Collect stop date __ __ / __ __ / __ __ __ __ **Stop time** __ __ : __ __ AM or PM

3. Number of hours .....__ __

4. Time Sufficient (22-26 hours) .....Yes ❑ No ❑

5. Total Volume (22-26 hours) ..... __ __ __ __ cc

6. Volume Sufficient (=500 cc) .....Yes ❑ No ❑

7. Sample obtained correctly.....Yes ❑ No ❑
❑ discarded initial void ❑ ≤1 voiding missed ❑ not menstruating

8. Was participant able to refrigerate sample? Yes ❑ No ❑

9. Initial Sample Collection Outcome Adequate (answer is YES to #4, #6, and #7) ❑
Inadequate (do repeat sample) ❑

Repeat Sample

10. Collect start date __ __ / __ __ / __ __ __ __ **Start time** __ __ : __ __ AM or PM

11. Collect stop date __ __ / __ __ / __ __ __ __ **Stop time** __ __ : __ __ AM or PM

12. Number of hours .....__ __

13. Time Sufficient (22-26 hours) .....Yes ❑ No ❑

14. Total Volume (22-26 hours) ..... __ __ __ __ cc

15. Volume Sufficient (=500 cc) .....Yes ❑ No ❑

16. Sample obtained correctly.....Yes ❑ No ❑
❑ discarded initial void ❑ ≤1 voiding missed ❑ not menstruating

17. Was participant able to refrigerate sample? Yes ❑ No ❑

18. Repeat Sample Collection Outcome Adequate (answer is YES to #13, #15, and #16) ❑
Inadequate❑

Overall Collection Outcome

Initial sample was adequate, or was the best of the two ❑
Repeat sample was adequate, or was the best of the two ❑
Failed, neither sample can be sent ❑

Collected by (staff ID): _____
Reviewed by (staff ID): _____

Overview

This form will be used to track the collection and shipping of 24-hour urine specimens during the eighteen month follow-up visit. It is expected that this form will be filled out for each participant at their initial attempt and, if one is necessary, their repeat attempt to collect a 24-hour urine specimen.

Administration Instructions

Fill out the worksheet first. After the initial (and repeat) collection is completed, transfer the data to the first page of the form.

Coding Instructions

Page	Field	Special Instructions
2	1	Record the start date and start time as recorded on the label attached to the urine collection jug. For the date, use leading zeros as appropriate. Be sure to use a four digit year. For the time, use leading zeros as appropriate. Circle AM or PM. Remember that Noon is 12 PM.
	2	Record the stop date and stop time as recorded on the label attached to the urine collection jug.
	3	Subtract stop time from start time. Record answer in hours (rounded to the nearest whole number). This is a two-digit field. Use leading zeros as appropriate.
	4	Mark Yes if number of hours is at least 22 but not more than 26 hours. Mark No if number of hours is fewer than 22 or more than 26.
	5	Record total volume in cubic centimeters of urine as measured using a graduated cylinder. This is a four-digit field. Use leading zeros if necessary.
	6	Mark Yes if total volume is at least 500 cc. Otherwise, mark No.
	7	Mark Yes only if all three boxes below are checked.
	8	Mark Yes if the participant was able to refrigerate the sample. Note that this is *not* a requirement for Q9.
	9	Mark Adequate if answers are Yes to #4, 6, and 7.
	10-18	Only go on to repeat sample if Q9 is coded as inadequate. Instructions for Q10-18 are the same as for Q1-9.
	Overall	Self-explanatory

If there was no repeat sample, or the initial sample was the best of the two, transfer the information from the top section of the worksheet to page 1 of the form. If the repeat sample was the best of the two, transfer the information from the bottom section of the worksheet to page 1 of the form.

Review Instructions

Make sure that if the sample collection outcome is “ready to ship to lab” that you have two tubes of urine (1 with HCl and 1 without) in the freezer. If the extra collection outcome is “ready to ship to storage”, you should have four additional tubes of urine in the freezer (2 with HCl and 2 without).

Check that the data were correctly transcribed from page 2 to page 1.

Additional Instructions

This form is used to generate the shipping logs for sending specimens to the lab or to storage. Specimens can not be shipped until this form is entered.

18 Month
ID: _____

Central Lab Collection Form – 18 Month Fasting Blood

Data from worksheet (best of initial sample or repeat)

Collect date ..... __ __ / __ __ / __ __ __ __

Collect time .....__ __ : __ __ AM or PM

Fasting time .....__ __ hours

Fasting time sufficient (12+ hours).....Yes ❑ 1
No ❑ 2

Serum Vial Collection Outcome (red) .....Ready to ship to lab* ❑ 1
Failed ❑ 2

Extra Serum Vials Collection Outcome (red) .....Ready to ship to storage* ❑ 1 _____
Failed ❑ 2 # vials

Extra Plasma Vials Collection Outcome (clear) .....Ready to ship to storage* ❑ 1 _____
Failed ❑ 2 # vials

*Includes adequate samples, and also inadequate samples where obtaining an adequate sample was not possible.

Collected by (staff ID): _____
Reviewed by (staff ID): _____
Entered by (staff ID): _____

ID: _____

Central Lab Collection Form – 18 Month Fasting Blood – Worksheet

Initial Sample

1. Collect date __ __ / __ __ / __ __ __ __ **Collect time** __ __ : __ __ AM or PM

2. Fasting time .....__ __ hours

3. Time Sufficient (12+ hours) .....Yes ❑ No ❑

4. Serum Vial Collected (red) .....Yes ❑ No ❑ Hemolyzed ❑

5. Plasma Vial Collected (clear).....Yes ❑ No ❑ Hemolyzed ❑

6. Extra Serum Vials Collected (red) .....Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

7. Extra Plasma Vials Collected (clear) .....Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

8. Initial Sample Collection Outcome Adequate (answer is YES to #3-7) ❑
Inadequate, repeat the sample ❑

Repeat Sample

10. Collect date __ __ / __ __ / __ __ __ __ **Collect time** __ __ : __ __ AM or PM

11. Fasting time .....__ __ hours

12. Time Sufficient (12+ hours) .....Yes ❑ No ❑

13. Serum Vial Collected (red) .....Yes ❑ No ❑ Hemolyzed ❑

14. Plasma Vial Collected (clear).....Yes ❑ No ❑ Hemolyzed ❑

15. Extra Serum Vials Collected (red) .....Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

16. Extra Plasma Vials Collected (clear) .....Yes ❑ No ❑ Hemolyzed ❑ # vials: ___

17. Initial Sample Collection Outcome Adequate (answer is YES to #12-16) ❑
Inadequate ❑

Overall Collection Outcome Initial draw was adequate, or was the best of the two ❑
Repeat draw was adequate, or was the best of the two ❑
Failed (neither draw can be sent to the lab) ❑

Collected by (staff ID): _____
Reviewed by (staff ID): _____

Overview

This form will be used to track the collection and shipping of fasting blood specimens collected at the eighteen month visit. It is expected that this form will be filled out for each participant at their initial attempt and, if one is necessary, their repeat attempt to collect a fasting blood specimen.

Administration Instructions

Fill out the worksheet first. After the initial (and repeat) collection is completed, transfer the data to the first page of the form.

Coding Instructions

Page	Field	Special Instructions
2	1	Record the collect date and collect time of the draw. For the date, use leading zeros as appropriate. For the time, use leading zeros as appropriate. Circle AM or PM. Remember that noon is 12 PM.
	2	Round answer, in hours, to the nearest whole number.
	3	Mark Yes if number of hours is at least 12. Otherwise, mark No.
	4-7	Mark Yes if the sample was collected. Mark No if the sample was not collected.
	8	Mark Adequate if answers are Yes to #3-7.
	10-17	Only go on to repeat sample if Q8 is coded as inadequate. Instructions for Q10-17 are the same as for Q1-8.
	Overall	Self-explanatory

If there was no repeat sample, or the initial sample was the best of the two, transfer the information from the top section of the worksheet to page 1 of the form. If the repeat sample was the best of the two, transfer the information from the bottom section of the worksheet to page 1 of the form.

Review Instructions

Make sure that if the sample collection outcome is "ready to ship to lab" or "ready to ship to storage" that you have the matching tube(s) in the freezer.

Check that the data were correctly transcribed from page 2 to page 1.

Additional Instructions

This form is used to generate the shipping logs for sending specimens to the lab or to storage. Specimens can not be shipped until this form is entered.

6 month – cluster visit 1
ID: _____
Date: ____ / ____ / _____

6 Month Visit Blood Pressure Form
Cluster Visit 1

	Yes	No
Has the participant's medication list changed since their last visit?……..	❑	❑

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements ..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Arm circumference (cm, round all fractions up) ..... _____ _____

Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse..... _____ _____

e. Pulse obliteration pressure (POP) ..... ____ ____ ____

\+ 6 0

f. Random zero peak inflation level (PIL), minimum 180 ..... ____ ____ ____

g. Blood pressure device number ..... ____ ____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

4. COMPUTE SUM

Sum of 2 SBPs and 2 DBPs (2c + 3c)..... __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Escape-level 1 BP ..... Sum of SBPs ≥ 319 ❑ 1

Sum of DBPs ≥ 199 ❑ 2

If box 1 or 2 is checked: complete form #52

Non-escape BP..... Sum of SBPs <319, Sum of DBPs <199 ❑ 7

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The 6 Month Visit Blood Pressure Forms (cluster visits 1-3) are filled out by clinic staff and are used to measure participant's blood pressure as a primary outcome measure and also to make sure it does not exceed safety limits.

If blood pressure values reach escape level 1, the BP Escape Form – 6, 18 Month Visit Clusters (#52) should be completed**.**

If item 1c=No, all subsequent questions are left blank. Before entering the form, contact the coordinating center for a decision on what follow up action should be taken.

If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Be sure to use the correct form for each cluster visit.

Page	Question		Special Administration Instructions
1	1		Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
		a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
		b.	At the first cluster visit, measure the participant's arm circumference. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). Record the rounded arm circumference. Based on the arm circumference obtained, mark an "X" on the corresponding line indicating proper <u>cuff size</u> for the measurement. Use this cuff size for cluster visits 2-4.
		c.	Indicate here whether or not the cuff fits properly. If the answer is Yes, go on. If the answer is No, contact the coordinating center for a decision on what follow up action should be taken.
1			**WAIT 5 MINUTES SEATED**
	1	d.	Obtain and record the <u>resting 30-second</u> pulse (radial artery) by counting the number of beats in 30 seconds.
		e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
		f.	Add 60 to the pulse obliteration pressure to obtain the <u>random zero peak inflation level</u> (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
		g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.

Page	Question		Special Administration Instructions
2	2	a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
		b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
		c.	Do Items 3a and 3b first. Then follow instructions for Item #3c.
			Wait 30 seconds
	3	a.	Repeat item #2a.
		b.	Repeat item #2b.
		c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4		Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100.
	5		Using the sum value from item #4, check the **first** applicable box . If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#52) should be filled out. Refer to MOP Chapter 23 for details and complete form #52.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

? Page 1 should be dated.

? Pages 1-2 should have correct ID# labels.

? Page 1:

-items 1a-b and 1d-g should be completed.

-check for correct addition in item 1f.

-item 1c should be coded as Yes, or if No, there should be a note explaining the follow up plan or other outcome for this participant.

? Page 2:

-items 2 and 3 should be completed.

-check for correct addition in items 2c, and 3c.

-item 4 should match the outcome selected in item 5

? All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

? If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2.

6 month – cluster visit 2
ID: _____
Date: ____ / ____ / _____

6 Month Visit Blood Pressure Form
Cluster Visit 2

Yes No

Has the participant's medication list changed since their last visit?…….. ❑ ❑

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements ..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Circle Cuff size from 6 month cluster visit 1

1 2 3 4

Cuff size used:..... Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____
+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number ..... ____ ____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

4. COMPUTE SUM

a. Sum of 2 SBPs and 2 DBPs (2c + 3c) __ __ __ / __ __ __

b. Sum of 2 SBPs and 2 DBPs from Cluster Visit 1 BP form (item #4) __ __ __ / __ __ __

c. Sum of 4 SBPs and 4 DBPs (4a + 4b) __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Escape-level 1 BP .....Sum of SBPs (4a) ≥ 319 ❑ 1

Sum of DBPs (4a) ≥ 199 ❑ 2

If box 1 or 2 is checked: complete form #52

Non-escape BP.....: Sum of SBPs (4a) <319, sum of DBPs (4a) <199 ❑ 7

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The 6 Month Visit Blood Pressure Forms (cluster visits 1-3) are filled out by clinic staff and are used to measure participant's blood pressure as a primary outcome measure and also to make sure it does not exceed safety limits.

If blood pressure values reach escape level 1 or 2, the BP Escape Form – 6, 18 Month Visit Clusters (#52) should be completed**.**

If item 1c=No, all subsequent questions are left blank. Before entering the form, contact the coordinating center for a decision on what follow up action should be taken.

If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Be sure to use the correct form for each cluster visit.

Page	Question	Special Administration Instructions
1	1	Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
	a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
	b.	Use the cuff size recorded at the first 6-month cluster visit.
	c.	Indicate here whether or not the cuff fits properly. If the answer is Yes, go on. If the answer is No, contact the coordinating center for a decision on what follow up action should be taken.
1		**WAIT 5 MINUTES SEATED**
	1 d.	Obtain and record the <u>resting 30-second</u> pulse (radial artery) by counting the number of beats in 30 seconds.
	e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
	f.	Add 60 to the pulse obliteration pressure to obtain the <u>random zero peak inflation level</u> (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
	g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.

Page	Question		Special Administration Instructions
2	2	a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
		b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
		c.	Do Items 3a and 3b first. Then follow instructions for Item #3c. **Wait 30 seconds**
	3	a.	Repeat item #2a.
		b.	Repeat item #2b.
		c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4		Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100. Enter the summed BPs from item 4c from the previous cluster visit form for item 4b. Then compute item 4c by adding 4a and 4b.
	5		Using the sum value from item #4, check the **first** applicable box . If the BP escape level is reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#52) should be filled out. Refer to MOP Chapter 23 for details and complete form #52.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

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? Pages 1-2 should have correct ID# labels.

? Page 1:

-items 1a-b and 1d-g should be completed.

-check for correct addition in item 1f.

-item 1c should be coded as Yes, or if No, there should be a note explaining the follow up plan or other outcome for this participant.

? Page 2:

-items 2 and 3 should be completed.

-check for correct addition in items 2c, 3c, and 4.

-item 4 should match the outcome selected in item 5

? All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

? If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2.

6 month – cluster visit 3
ID: _____
Date: ____ / ____ / _____

6 Month Visit Blood Pressure Form
Cluster Visit 3

	Yes	No
Has the participant's medication list changed since their last visit?……..	❑	❑

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements ..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Circle cuff size from 6 month cluster visit 1

1 2 3 4

Cuff size used:..... Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____

\+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number ..... ____ ____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

4. COMPUTE SUM

a. Sum of 2 SBPs and 2 DBPs (2c + 3c) __ __ __ / __ __ __

b. Sum of 4 SBPs and 4 DBPs from Cluster Visit 2 BP form (item #4c) __ __ __ / __ __ __

c. Sum of 6 SBPs and 6 DBPs (4a + 4b) __ __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Escape-level 1 BP .....Sum of SBPs (4a) ≥ 319 ❑ 1

Sum of DBPs (4a) ≥ 199 ❑ 2

If box 1 or 2 is checked: complete form #52

Escape-level 2 BP .....Cumulative sum of SBPs (4c) ≥ 837 ❑ 5

Cumulative sum of DBPs (4c) ≥ 537 ❑ 6

If box 5 or 6 is checked: complete form #52 & refer participant to their physician within the next two months. No escape BP's are taken for Level 2 escapes.

Non-escape BP: Cumulative sum of SBPs (4c) <837, cumulative sum of DBPs (4c) <537 ❑ 7

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The 6 Month Visit Blood Pressure Forms (cluster visits 1-3) are filled out by clinic staff and are used to measure participant's blood pressure as a primary outcome measure and also to make sure it does not exceed safety limits.

If blood pressure values reach escape level 1 or 2, the BP Escape Form – 6, 18 Month Visit Clusters (#52) should be completed**.**

If item 1c=No, all subsequent questions are left blank. Before entering the form, contact the coordinating center for a decision on what follow up action should be taken.

If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Be sure to use the correct form for each cluster visit.

Page	Question	Special Administration Instructions
1	1	Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
	a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
	b.	Use the cuff size recorded at the first 6-month cluster visit.
	c.	Indicate here whether or not the cuff fits properly. If the answer is Yes, go on. If the answer is No, contact the coordinating center for a decision on what follow up action should be taken.
1		**WAIT 5 MINUTES SEATED**
	1 d.	Obtain and record the <u>resting 30-second</u> pulse (radial artery) by counting the number of beats in 30 seconds.
	e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
	f.	Add 60 to the pulse obliteration pressure to obtain the <u>random zero peak inflation level</u> (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
	g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.

Page	Question		Special Administration Instructions
2	2	a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
		b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
		c.	Do Items 3a and 3b first. Then follow instructions for Item #3c. **Wait 30 seconds**
	3	a.	Repeat item #2a.
		b.	Repeat item #2b.
		c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4		Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100. Enter the summed BPs from item 4c from the previous cluster visit form for item 4b. Then compute item 4c by adding 4a and 4b.
	5		Using the sum value from item #4, check the **first** applicable box . If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#52) should be filled out. Refer to MOP Chapter 23 for details and complete form #52. Note that for a Level 2 escape no escape BP's need be taken, but form #52 should still be completed.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

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Review Instructions

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? Page 1:

-items 1a-b and 1d-g should be completed.

-check for correct addition in item 1f.

-item 1c should be coded as Yes, or if No, there should be a note explaining the follow up plan or other outcome for this participant.

? Page 2:

-items 2 and 3 should be completed.

-check for correct addition in items 2c, 3c, and 4.

-item 4 should match the outcome selected in item 5

? All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

? If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2.

6 month – cluster visit 4
ID: _____
Date: ____ / ____ / _____

6 Month Visit Blood Pressure Form
Cluster Visit 4

	Yes	No
Has the participant's medication list changed since their last visit?……..	❑	❑

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements ..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Circle cuff size from 6 month cluster visit 1

1 2 3 4

Cuff size used: ..... Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____

\+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number ..... ____ ____

PIL

6 month – cluster visit 4

ID: _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

4. COMPUTE SUM

a. Sum of 2 SBPs and 2 DBPs (2c + 3c) __ __ __ / __ __ __

b. Sum of 6 SBPs and 6 DBPs from Cluster Visit 3 BP form (item #4c) __ __ __ / __ __ __

c. Sum of 8 SBPs and 8 DBPs (4a + 4b) __ __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Escape-level 1 BP .....Sum of SBPs (4a) ≥ 319 ❑ 1

Sum of DBPs (4a) ≥ 199 ❑ 2

If box 1 or 2 is checked: complete form #52

Escape-level 2 BP .....Cumulative sum of SBPs (4c) ≥ 1116 ❑ 5

Cumulative sum of DBPs (4c) ≥ 716 ❑ 6

If box 5 or 6 is checked: complete form #52 & refer participant to their physician within the next two months. No escape BP's are taken for Level 2 escapes.

Non-escape BP: Cumulative sum of SBPs (4c) <1116, cumulative sum of DBPs (4c) <716 ❑ 7

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The 6 Month Visit Blood Pressure Forms (cluster visits 1-4) are filled out by clinic staff and are used to measure participant‘s blood pressure as a primary outcome measure and also to make sure it does not exceed safety limits.

If blood pressure values reach escape level 1 or 2, the BP Escape Form – 6, 18 Month Visit Clusters (#52) should be completed**.**

If item 1c=No, all subsequent questions are left blank. Before entering the form, contact the coordinating center for a decision on what follow up action should be taken.

If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Be sure to use the correct form for each cluster visit.

Page	Question	Special Administration Instructions
1	1	Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
	a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
	b.	Use the cuff size recorded at the first 6-month cluster visit.
	c.	Indicate here whether or not the cuff fits properly. If the answer is Yes, go on. If the answer is No, contact the coordinating center for a decision on what follow up action should be taken.
1		**WAIT 5 MINUTES SEATED**
	1 d.	Obtain and record the <u>resting 30-second</u> pulse (radial artery) by counting the number of beats in 30 seconds.
	e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
	f.	Add 60 to the pulse obliteration pressure to obtain the <u>random zero peak inflation level</u> (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
	g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.

Page	Question		Special Administration Instructions
2	2	a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
		b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
		c.	Do Items 3a and 3b first. Then follow instructions for Item #3c.
			Wait 30 seconds
	3	a.	Repeat item #2a.
		b.	Repeat item #2b.
		c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4		Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100. Enter the summed BPs from item 4c from the previous cluster visit form for item 4b. Then compute item 4c by adding 4a and 4b.
	5		Using the sum value from item #4, check the **first** applicable box . If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#52) should be filled out. Refer to MOP Chapter 23 for details and complete form #52. Note that for a Level 2 escape no escape BP's need be taken, but form #52 should still be completed.

Coding Instructions

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-item 1c should be coded as Yes, or if No, there should be a note explaining the follow up plan or other outcome for this participant.

? Page 2:

-items 2 and 3 should be completed.

-check for correct addition in items 2c, 3c, and 4.

-item 4 should match the outcome selected in item 5

? All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

? If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2.

18 month – cluster visit 1
ID: _____
Date: ____ / ____ / _____

18 Month Visit Blood Pressure Form
Cluster Visit 1

	Yes	No
Has the participant's medication list changed since their last visit?……..	❑	❑

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Arm circumference (cm, round all fractions up)..... _____ _____

Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____

\+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number ..... ____ ____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

4. COMPUTE SUM

Sum of 2 SBPs and 2 DBPs (2c + 3c)..... __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Escape-level 1 BP ..... Sum of SBPs ≥ 319 ❑ 1

Sum of DBPs ≥ 199 ❑ 2

If box 1 or 2 is checked: complete form #52

Non-escape BP ..... Sum of SBPs <319, Sum of DBPs <199 ❑ 7

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The 18 Month Visit Blood Pressure Forms (cluster visits 1-3) are filled out by clinic staff and are used to measure participant's blood pressure as a primary outcome measure and also to make sure it does not exceed safety limits.

If blood pressure values reach escape level 1, the BP Escape Form – 6, 18 Month Visits (#52) should be completed**.**

If item 1c=No, all subsequent questions are left blank. Before entering the form, contact the coordinating center for a decision on what follow up action should be taken.

If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Be sure to use the correct form for each cluster visit.

Page	Question		Special Administration Instructions
1	1		Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
		a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
		b.	At the first cluster visit, measure the participant's arm circumference. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). Record the rounded arm circumference. Based on the arm circumference obtained, mark an "X" on the corresponding line indicating proper <u>cuff size</u> for the measurement. Use this cuff size for cluster visits 2-4.
		c.	Indicate here whether or not the cuff fits properly. If the answer is Yes, go on. If the answer is No, contact the coordinating center for a decision on what follow up action should be taken.
1			**WAIT 5 MINUTES SEATED**
	1	d.	Obtain and record the <u>resting 30-second</u> pulse (radial artery) by counting the number of beats in 30 seconds.
		e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
		f.	Add 60 to the pulse obliteration pressure to obtain the <u>random zero peak inflation level</u> (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
		g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.

Page	Question		Special Administration Instructions
2	2	a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
		b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
		c.	Do Items 3a and 3b first. Then follow instructions for Item #3c. **Wait 30 seconds**
	3	a.	Repeat item #2a.
		b.	Repeat item #2b.
		c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4		Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100.
	5		Using the sum value from item #4, check the **first** applicable box . If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#52) should be filled out. Refer to MOP Chapter 23 for details and complete form #52.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

? Page 1 should be dated.

? Pages 1-2 should have correct ID# labels.

? Page 1:

-items 1a-b and 1d-g should be completed.

-check for correct addition in item 1f.

-item 1c should be coded as Yes, or if No, there should be a note explaining the follow up plan or other outcome for this participant.

? Page 2:

-items 2 and 3 should be completed.

-check for correct addition in items 2c and 3c.

-item 4 should match the outcome selected in item 5

? All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

? If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2.

18 month – cluster visit 2
ID: _____
Date: ____ / ____ / _____

18 Month Visit Blood Pressure Form
Cluster Visit 2

Yes No

Has the participant's medication list changed since their last visit?…….... ❑ ❑

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements ..... _____ _____ : _____ _____
(Noon is 12 PM)
AM ❑ 1
PM ❑ 2

b. Circle cuff size from 18 month cluster visit 1
1 2 3 4

Cuff size used:..... Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____
+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number ..... ____ ____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

4. COMPUTE SUM

a. Sum of 2 SBPs and 2 DBPs (2c + 3c) __ __ __ / __ __ __

b. Sum of 2 SBPs and 2 DBPs from Cluster Visit 1 BP form (item #4) __ __ __ / __ __ __

c. Sum of 4 SBPs and 4 DBPs (4a + 4b) __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Escape-level 1 BP ..... Sum of SBPs (4a) ≥ 319 ❑ 1

Sum of DBPs (4a) ≥ 199 ❑ 2

If box 1 or 2 is checked: complete form #52

Non-escape BP ..... Sum of SBPs (4a) <319, sum of DBPs (4a) <199 ❑ 7

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The 18 Month Visit Blood Pressure Forms (cluster visits 1-3) are filled out by clinic staff and are used to measure participant's blood pressure as a primary outcome measure and also to make sure it does not exceed safety limits.

If blood pressure values reach escape level 1 or 2, the BP Escape Form – 6, 18 Month Visits (#52) should be completed**.**

If item 1c=No, all subsequent questions are left blank. Before entering the form, contact the coordinating center for a decision on what follow up action should be taken.

If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Be sure to use the correct form for each cluster visit.

Page	Question		Special Administration Instructions
1	1		Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
		a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
		b.	Use the cuff size recorded at the first cluster visit.
		c.	Indicate here whether or not the cuff fits properly. If the answer is Yes, go on. If the answer is No, contact the coordinating center for a decision on what follow up action should be taken.
1			**WAIT 5 MINUTES SEATED**
	1	d.	Obtain and record the <u>resting 30-second</u> pulse (radial artery) by counting the number of beats in 30 seconds.
		e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
		f.	Add 60 to the pulse obliteration pressure to obtain the <u>random zero peak inflation level</u> (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
		g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.

Page	Question		Special Administration Instructions
2	2	a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
		b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
		c.	Do Items 3a and 3b first. Then follow instructions for Item #3c. **Wait 30 seconds**
	3	a.	Repeat item #2a.
		b.	Repeat item #2b.
		c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4		Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100. Enter the summed BPs from item 4c from the previous cluster visit form for item 4b. Then computer item 4c by adding 4a and 4b.
	5		Using the sum value from item #4, check the **first** applicable box . If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#52) should be filled out. Refer to MOP Chapter 23 for details and complete form #52.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

? Page 1 should be dated.

? Pages 1-2 should have correct ID# labels.

? Page 1:

-items 1a-b and 1d-g should be completed.

-check for correct addition in item 1f.

-item 1c should be coded as Yes, or if No, there should be a note explaining the follow up plan or other outcome for this participant.

? Page 2:

-items 2 and 3 should be completed.

-check for correct addition in items 2c, 3c, and 4.

-item 4 should match the outcome selected in item 5

? All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

? If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2.

18 month – cluster visit 3
ID: _____
Date: ____ / ____ / _____

18 Month Visit Blood Pressure Form
Cluster Visit 3

Yes No

Has the participant's medication list changed since their last visit?…….... ❑ ❑

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements ..... _____ _____ : _____ _____
(Noon is 12 PM)
AM ❑ 1
PM ❑ 2

b. Circle cuff size from 18 month cluster visit 1
1 2 3 4

Cuff size used:..... Small adult (<24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

c. Does cuff fit properly? ..... Yes ❑ 1
No ❑ 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse ..... _____ _____

e. Pulse obliteration pressure (POP)..... ____ ____ ____
+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

g. Blood pressure device number ..... ____ ____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

4. COMPUTE SUM

a. Sum of 2 SBPs and 2 DBPs (2c + 3c) __ __ __ / __ __ __

b. Sum of 4 SBPs and 4 DBPs from Cluster Visit 2 BP form (item #4c) __ __ __ / __ __ __

c. Sum of 6 SBPs and 6 DBPs (4a + 4b) __ __ __ / __ __ __

5. DETERMINE BLOOD PRESSURE OUTCOME **(check the <u>first</u> applicable box)**

Escape-level 1 BP .....Sum of SBPs (4a) ≥ 319 ❑ 1

Sum of DBPs (4a) ≥ 199 ❑ 2

If box 1 or 2 is checked: complete form #52

Escape-level 2 BP .....Cumulative sum of SBPs (4c) ≥ 837 ❑ 5

Cumulative sum of DBPs (4c) ≥ 537 ❑ 6

If box 5 or 6 is checked: complete form #52

Non-escape BP: Cumulative sum of SBPs (4c) <837, cumulative sum of DBPs (4c) <537 ❑ 7

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The 18 Month Visit Blood Pressure Forms (cluster visits 1-3) are filled out by clinic staff and are used to measure participant's blood pressure as a primary outcome measure and also to make sure it does not exceed safety limits.

If blood pressure values reach escape level 1 or 2, the BP Escape Form – 6, 18 Month Visits (#52) should be completed**.**

If item 1c=No, all subsequent questions are left blank. Before entering the form, contact the coordinating center for a decision on what follow up action should be taken.

If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Be sure to use the correct form for each cluster visit.

Page	Question		Special Administration Instructions
1	1		Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
		a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
		b.	Use the cuff size recorded at the first cluster visit.
		c.	Indicate here whether or not the cuff fits properly. If the answer is Yes, go on. If the answer is No, contact the coordinating center for a decision on what follow up action should be taken.
1			**WAIT 5 MINUTES SEATED**
	1	d.	Obtain and record the <u>resting 30-second</u> pulse (radial artery) by counting the number of beats in 30 seconds.
		e.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).
		f.	Add 60 to the pulse obliteration pressure to obtain the <u>random zero peak inflation level</u> (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
		g.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.

Page	Question		Special Administration Instructions
2	2	a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
		b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
		c.	Do Items 3a and 3b first. Then follow instructions for Item #3c. **Wait 30 seconds**
	3	a.	Repeat item #2a.
		b.	Repeat item #2b.
		c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4		Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100. Enter the summed BPs from item 4c from the previous cluster visit form for item 4b. Then computer item 4c by adding 4a and 4b.
	5		Using the sum value from item #4, check the **first** applicable box . If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#52) should be filled out. Refer to MOP Chapter 23 for details and complete form #52.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

? Page 1 should be dated.

? Pages 1-2 should have correct ID# labels.

? Page 1:

-items 1a-b and 1d-g should be completed.

-check for correct addition in item 1f.

-item 1c should be coded as Yes, or if No, there should be a note explaining the follow up plan or other outcome for this participant.

? Page 2:

-items 2 and 3 should be completed.

-check for correct addition in items 2c, 3c, and 4.

-item 4 should match the outcome selected in item 5

? All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

? If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2.

Non-Specific Visit
ID: _____
Date: ____ / ____ / _____

BP Escape ❑ 01
End of Study Measurement ❑ 02
Standard Manometer ❑ 03
Other (Call CC for code) ❑ __

General Blood Pressure Form

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements..... _____ _____ : _____ _____

(Noon is 12 PM)

AM ❑ 1
PM ❑ 2

b. Arm circumference (cm, round all fractions up)..... _____ _____

Small adult (< 24 cm) ❑ 1
Adult (24-32 cm) ❑ 2
Large adult (33-41 cm) ❑ 3
Thigh (42-52 cm) ❑ 4

WAIT 5 MINUTES SEATED

c. Resting 30-second pulse ..... _____ _____

d. Pulse obliteration pressure (POP)..... ____ ____ ____

\+ 6 0

e. Random zero peak inflation level (PIL), minimum 180..... ____ ____ ____

f. Blood pressure device number ..... ____ ____

PIL ID: _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

If using standard manometer, enter the BP reading in section 2c.

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

If using standard manometer, enter the BP reading in section 3c.

SBP / DBP

a. Uncorrected value ..... __ __ __ / __ __ __

b. Zero value ..... __ __

c. Corrected value (a-b) ..... __ __ __ / __ __ __

4. COMPUTE SUM

Sum of 2 SBPs and 2 DBPs (2c + 3c)..... __ __ __ / __ __ __

If these BP measurements were taken as a part of a BP escape evaluation, enter the sum computed in Question #4 onto Form #51, Question #5 (for 3, 12 month visits), or onto Form #52, Question #5 (for 6, 18 month visits).

Collected by (staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

General Blood Pressure Form and Coding Instructions

Overview

The General Blood Pressure Form is filled out by clinic staff and is used for collecting blood pressure measurements of PREMIER participants that are taken during non-visit situations, usually a follow-up BP escape measurement.

The General Blood Pressure Form must be filled out each time a BP is conducted in the clinic on a PREMIER participant that does not fall into any protocol-defined follow-up measurement period. ID # labels should be printed and placed on the form.

If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Use with form 51 & 52 for BP Escapes. The correct version will always be on the site workstation computer.

Place ID labels on pages 1 and 2. Check for accuracy.

Using a blue or black pen, check the appropriate box to designate why this form (#075) was administered: BP Escape, End of Study Measurement, Standard Manometer, or Other. If "Other", call the coordinating center for a code.

Fill out the visit date on page 1. Be sure to use a four digit year.

Page	Question	Special Administration Instructions
1	1	Before the actual measurements are obtained, items a-f must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.
	a.	Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.
	b.	Measure the participant's arm circumference. Round all fractions up to the next whole number (i.e. **32.1** should be coded as **33**). Record the rounded arm circumference. Based on the arm circumference obtained, mark an "X" on the corresponding line indicating proper cuff size for the measurement. Note: For a BP escape measurement, the cuff size should be the same as the size used for the original measurement. For end-of-study measurements, the cuff size should be the same for all measurements taken.
		WAIT 5 MINUTES SEATED
	c.	Obtain and record the resting 30-second pulse (radial artery) by counting the number of beats in 30 seconds.
	d.	Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).

Page	Question	Special Administration Instructions
1	e.	Add 60 to the pulse obliteration pressure to obtain the random zero peak inflation level (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.
	f.	Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.
2	2 a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use leading zeros if less than 100.
	b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest **even** number. Use a leading zero if less than 10.
	c.	Do Items 3a and 3b first. Then follow instructions for Item #3c. If using a standard manometer device, record the reading, and leave 2a & 2b blank.
		WAIT 30 SECONDS
	3 a.	Repeat item #2a.
	b.	Repeat item #2b.
	c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, **subtract** the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100. **If using a standard manometer device, record the reading, and leave 3a & 3b blank.**
	4	Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100. If these BP measurements were taken as a part of a BP escape evaluation, enter the sum computed in Question #4 onto Form #51, Question #5 (for 3, 12 month visits), or onto Form #52, Question #5 (for 6, 18 month visits).

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the "Collected by" , "Reviewed by" , and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Review Instructions

Check for correct addition in items 1e, 2c, 3c, and 4.

Check the following items:

? Page 1 should be dated.

? Pages 1-2 should have correct ID# labels.

? Page 1:

-items 1d-f should be completed;

? Page 2:

-items 2, 3, and 4 should be completed;

? All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

? If all of the above items look acceptable, enter your Staff ID in the "reviewed by" section at the bottom of page 2.

ID: _____

Date: ____ / ____ / _____

Intervention Suspension Form

Complete this form for all participants who suspend intervention participation, whether permanently or temporarily.

1. Is this suspension of intervention activities temporary or permanent?

   Temporary ❑ 1

   Permanent ❑ 2

2. Reason for intervention suspension (select one):

   Started on blood pressure medication ..... ❑ 31

   Physician's orders..... ❑ 32

   Illness..... ❑ 33

   Injury ..... ❑ 34

   Pregnancy ..... ❑ 35

   Death ..... ❑ 36

   Moved out of area..... ❑ 37

   Schedule/time conflict..... ❑ 38

   Transportation problems ..... ❑ 39

   Refused to continue..... ❑ 40

   Unable to tolerate intervention eating pattern ..... ❑ 41

   Other (contact the coordinating center for an appropriate code)..... ❑ ___

3. If this is a *temporary* suspension, what date will the participant next be contacted?……. ____ / ____ / _____

Description: _____

(Interventionist Signature)

(Intervention Director Signature)

(Date)

(Date)

(Principal Investigator Signature)

(Date)

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This form is used by intervention staff to document a participant who wishes to suspend their intervention participation, whether temporarily or permanently. This form refers to intervention participation *only* and does not absolve the site of responsibility for tacking the participant. If a participant permanently discontinues all aspects of the PREMIER study, then the Clinic Coordinator should complete Form #37 (Premature Termination Form) as well.

Coding Instructions

Date: Enter the date of the participant's **last** contact with the study.

Duration: Indicate whether the suspension is temporary in nature or permanent. Choose "permanent" only if you know *for certain* that no further intervention contact will be made. If you suspect for any reason that further intervention contact may be made, choose "temporary".

Reason: When selecting the reason for the suspension, be sure to review all of the choices before making a selection. If the situation does not fit any of the choices, give a detailed description of the situation on page 2 and fax the form to the Data Clerk at the Coordinating Center for a coding decision.

See the attached list of Termination Reason Codes for a detailed explanation of when to use each code. If there is a reason that is even close to the situation you are trying to code, use that reason instead of requesting a new code.

Do not code as "Other" without first consulting the Coordinating Center.

Description: Describe the reason for the termination. Include as much detail as needed.

Signatures: The interventionist, the Intervention Director and Principal Investigator must sign and date the form.

Review Instructions

Make sure the ID, date, and reason for termination have been completed.

Only one reason should be checked.

Review the notes and make sure the reason has been correctly coded.

Additional Instructions

Do not enter this form until all other intervention forms for the participant have been entered. If the participant is permanently suspended, you will not be able to enter any new intervention forms. Also be sure any edits to the participant's intervention data have been completed. Once the participant is suspended, many of the restricted edits may no longer be allowed.

Explanations of Suspension Reason Codes

Category	When to use this category
Started on BP meds	If participant reports going on BP medications. This could come up on a Medication Use Questionnaire, or may be mentioned by the participant during another contact. Note that starting on BP meds is not necessarily in and of itself a reason for suspending the intervention.
Physician's orders	If the participant's physician or the study clinician request that the participant stop participating in the intervention. If the participant is also put on BP medication, use that code instead.
Illness	Participant illness (code family illness as schedule/time conflict).
Injury	Participant injury. Do not code as a suspension reason unless participant stops all intervention-related activities due to the injury. Do not suspend the participant if they merely stop doing the physical activity portion of the intervention.
Pregnancy	Participant pregnancy. Do not code as a suspension reason unless participant stops all intervention-related activities due to the injury. Do not suspend the participant if they merely stop doing the physical activity portion of the intervention because of their pregnancy
Death	Participant death (code death in family as a schedule/time conflict)
Moved out of area	Participant has left the area permanently. Do not code if participant will be coming back later during the intervention period, or if the participant will be returning for follow up intervention sessions.
Schedule/time conflict	Participant is unable to make their intervention visits due to a scheduling problem or time conflict. This includes work schedule conflicts, inability to get day care, and vacations.
Transportation problems	Participant is unable to get to their intervention visits due to transportation problems.
Refusal	Participant refuses to complete any further intervention visits. Use only if none of the other reasons apply.
Unable to tolerate intervention eating pattern	Participant is unable to tolerate the intervention eating pattern.
Other	If none of these reasons apply, fax the form with a detailed description to the coordinating center. They will provide you with the appropriate code to use.

ID: _____

Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

CDC Lab Collection Form – Folate/Carotenoid/Vit. B12

Data from worksheet (best of initial sample or repeat)

Collect date ..... __ __ / __ __ / __ __ __ __

Collect time .....__ __ : __ __ AM or PM

Fasting time .....__ __ hours

Fasting time sufficient (12+ hours)..... Yes ❑ 1
No ❑ 2

Carotinoid Serum
Vial Collection Outcome .....Ready to ship to lab* ❑ 1
Failed ❑ 2

Folate/Vitamin B12 Serum
Vial Collection Outcome .....Ready to ship to lab* ❑ 1
Failed ❑ 2

Affix CDC Label .. ..

Collected by (staff ID): _____
Reviewed by (staff ID): _____
Entered by (staff ID): _____

*Includes adequate samples, and also inadequate samples where obtaining an adequate sample was not possible.

ID: _____

Visit: Pre-randomization ❑ 05
6 month ❑ 08
18 month ❑ 10

CDC Lab Collection Form – Baseline Folate/Carotenoid/Vit. B12 – Worksheet

Initial Sample

1. Collect date __ __ / __ __ / __ __ __ __ **Collect time** __ __ : __ __ AM or PM

2. Fasting time .....__ __ hours

3. Time Sufficient (12+ hours) .....Yes ❑ No ❑

4. Folate/Carotenoid/Vit.B12 Serum
Vial Collected (SST "tiger-top") .....Yes ❑ No ❑ Hemolyzed ❑

Repeat Sample

5. Collect date __ __ / __ __ / __ __ __ __ **Collect time** __ __ : __ __ AM or PM

6. Fasting time .....__ __ hours

7. Time Sufficient (12+ hours) .....Yes ❑ No ❑

8. Folate/Carotenoid/Vit.B12 Serum
Vial Collected (SST "tiger-top").....Yes ❑ No ❑ Hemolyzed ❑

Overall Collection Outcome

Initial draw was adequate, or was the best of the two ❑
Repeat draw was adequate, or was the best of the two ❑
Failed (neither draw can be sent to the lab) ❑

Collected by (staff ID): _____
Reviewed by (staff ID): _____

Overview

This form will be used to track the collection and shipping of fasting blood specimens collected during screening and 6 and 18 months. It is expected that this form will be filled out for each participant at their initial attempt and, if one is necessary, their repeat attempt to collect a fasting blood specimen.

Administration Instructions

Fill out the worksheet (Page 2) first. After the initial (and repeat) collection is completed, transfer the data to the first page of the form.

Coding Instructions

Page	Field	Special Instructions
2	1	Record the collect date and collect time of the draw. For the date, use leading zeros as appropriate. For the time, use leading zeros as appropriate. Circle AM or PM. Remember that noon is 12 PM.
	2	Round answer, in hours, to the nearest whole number.
	3	Mark Yes if number of hours is at least 12. Otherwise, mark No.
	4	Self-Explanatory. If "no" or "hemolyzed" proceed to Q5.
	5-8	Repeat the sample **only** if the initial sample is inadequate. Instructions for Q5-8 are the same as for Q1-4.
	Overall	Self-explanatory

If there was no repeat sample, or the initial sample was the best of the two, transfer the information from the top section of the worksheet to page 1 of the form. If the repeat sample was the best of the two, transfer the information from the bottom section of the worksheet to page 1 of the form.

Six labels have been provided for use with this blood draw. Affix one label to the cryovial for the folate analyses. Affix another to the Vitamin A cryovial. Affix a third label to the front of the form, over the box where it says: "Affix CDC Label". The "-05" designation is for the baseline specimen; "-08" is for the six month specimen, and the "-10" designation is for the 10 month specimen. **Be sure to affix the correct label to the form, as this is the only link between the participant's PREMIER ID number and their CDC ID number.**

Be certain to affix the label to the cryovial in a "stair-step" fashion. See Chapter 21 for further details on labels and lab processing.

Review Instructions

Check that the data were correctly transcribed from page 2 to page 1.

Additional Instructions

This form is used to generate the shipping logs for sending specimens to the lab or to storage. Specimens can not be shipped until this form is entered.

ID: _____

Visit: 3 month ❑ 07
6 month ❑ 08
12 month ❑ 09
18 month ❑ 10

Date: ____ / ____ / _____

Follow-Up Symptoms Questionnaire

Below is a list of problems or complaints people sometimes experience. For each item, if you did not have the problem **during the past month**, please check the box under "symptom did not occur".

If you did experience the problem **during the past month**, please check the box that best describes how bothersome it was for you. Use the key below:

Mild = symptom did not interfere with usual activities
Moderate = symptom interfered somewhat with usual activities
Severe = symptom was so bothersome that usual activities could not be performed.

Symptoms ***(during the last month)***	Symptom did not occur	Symptom occurred and was:		
		Mild	Moderate	Severe
1. Poor appetite	❑ 1	❑ 2	❑ 3	❑ 4
2. Diarrhea/loose stools	❑ 1	❑ 2	❑ 3	❑ 4
3. Constipation	❑ 1	❑ 2	❑ 3	❑ 4
4. Nausea or upset stomach	❑ 1	❑ 2	❑ 3	❑ 4
5. Bloating or excess gas	❑ 1	❑ 2	❑ 3	❑ 4
6. Wheezing or difficulty breathing	❑ 1	❑ 2	❑ 3	❑ 4
7. Heart palpitations	❑ 1	❑ 2	❑ 3	❑ 4
8. Leg/ankle swelling	❑ 1	❑ 2	❑ 3	❑ 4
9. Aches or pains in muscles or joints	❑ 1	❑ 2	❑ 3	❑ 4
10. Fatigue or low energy level	❑ 1	❑ 2	❑ 3	❑ 4
11. Excessive thirst	❑ 1	❑ 2	❑ 3	❑ 4
12. Lightheadedness when standing up	❑ 1	❑ 2	❑ 3	❑ 4
13. Headache	❑ 1	❑ 2	❑ 3	❑ 4
14. Difficulty sleeping	❑ 1	❑ 2	❑ 3	❑ 4

ID: _____

15. **Since this form was last completed** on ____/____/____, have you been told by a health care professional that you have had any of the following:

	Yes	No
a) Heart attack…….	❑ 1	❑ 2
b) Stroke……..	❑ 1	❑ 2
c) Transient Ischemic Attack (TIA or "mini-stroke")……	❑ 1	❑ 2
d) Heart Failure……...	❑ 1	❑ 2
e) Coronary angioplasty or bypass surgery…….	❑ 1	❑ 2
f) Angina pectoris……	❑ 1	❑ 2
g) Broken bone……	❑ 1	❑ 2
h) Cancer…….	❑ 1	❑ 2
i) Gallbladder disease…….	❑ 1	❑ 2
j) Hyperlipidemia or high cholesterol……	❑ 1	❑ 2
k) Diabetes……..	❑ 1	❑ 2
l) Torn ligament…….	❑ 1	❑ 2
m) Other serious injury to the bone or muscle……	❑ 1	❑ 2

16. **If yes to any item in Q15,** please explain:

_____

_____

_____

17. **In the last month,** have you had any other symptoms that have not been noted on this form? Yes ❑1 No ❑2

18. **If yes,** please explain: _____

_____

_____

_____

ID: _____

Office use only:

19. Is an Adverse Events form (#30) required (Items a-g, l or m in Q#15 marked "Yes", or clinician-determined response to Q#17)? ..... Yes ❑ 1 No ❑ 2

_____ _____

Clinician signature Date

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The purpose of this self-administered form is to identify individuals who have symptoms that could either interfere with their further participation in the study or be a result of some aspect of the intervention.

This form is administered at SV3, and again during intervention. Any positive responses should be brought to the attention of a study clinician, who initiates appropriate action in accordance with the protocol, and then signs the form.

After the form is completed, the interviewer should review the form for completeness with the participant.

Administration Instructions

Place ID labels on pages 1 through 3.

Using a blue or black pen, check the appropriate box to designated which visit this form (#78) was administered: 3, 6, 12, or 18 month. Only one box should be marked. For Baseline symptoms ascertainment, use Form #16.

Fill out the visit date on page 1. Be sure to use a four digit year.

Page	Question	Special Administration Instructions
1	1-14	Check to make sure only one response is marked for each symptom. If a symptom is left blank or more than one response is marked, review the symptom with the participant and mark one response.
	15	Use the "Symptom Date Report" to find the last date of a participant completed Symptoms Questionnaire. If Yes, go to Q16. "Health Care Professional" includes a physician (MD or DO), physician's assistant, or nurse practitioner.
	16	If Q15 = Yes, this question may not be left blank. Make sure the response is legible and review the illness with the study clinician.
	17	If Yes, go to Q18.
	18	If Q17 = Yes, this question may not be left blank. Make sure the response is legible and review the other symptoms with the study clinician.
	19	See coding instructions below.

Coding Instructions

If participant answered "Yes" to a-g, l or m on question 15, code question 19 as "Yes" and fill out an Adverse Events form (#30). The site clinician may also determine that an AE occurred based upon the participant's answer to Q#17. This determination is made on whether the clinician feels the answer to #17 could be recoded into one of the AE answers in Q #15. If the clinician determines that an Adverse Event has occurred, code question 19 as "Yes" and fill out an Adverse Events form (#30). Do NOT recode the participant's answer to Q #15. Otherwise, code question 19 as "No."

Review Instructions

Confirm that pages 1 through 3 have an ID label.

Make sure all items were completed (questions 16 and 18 can be blank if questions 15 and 17 are answered "No."

If participant answered "Yes" to questions 15 or 17, review the notes in questions 16 and 18 for completeness.

Additional Instructions

If an AE form was required, fax a copy of this form and the AE form to the Data Clerk at the coordinating center when completed.

ID: _____

Visit
3 month ❑ 07
6 month ❑ 08
12 month ❑ 09
18 month ❑ 10

Cluster: _____

Date: __ __ / __ __ / __ __ __ __

Follow-Up Medication Use Questionnaire

1. In the last month did you take any prescription medicines, over-the-counter medications, or nutritional supplements?	**Yes**	**No**
	❑	❑

2. **If yes** to question 1, please list the medications: (Use the back of the page if you need more space)

Name of Medication	Did you take it more than 4 times in the past month?	Date you last took a dose of the medication.	Reason for use:
1._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
2._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
3._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
4._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
5._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
6._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
7._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
8._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
9._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
10._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
11._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
12._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____
13._____	**Yes** ❑ **No** ❑	_____/_____/_____	_____

ID: _____

	Yes	No
3. Have you taken any medications for pain in the last month?	❑ 1	❑ 2

(see attached list of pain medications)

4. **If yes**, how many times did you take it? ..... **rarely**	❑ 2
most days	❑ 3
every day	❑ 4

Thank you for completing this form. Do not proceed any further.

ID: _____

Date: __ __ / __ __ / __ __ __ __

Medication Use Review: (to be completed by clinic staff after reviewing pages 1-2 and the medications brought in by the participant)

5. List all *prescription* medications used during the past month by the participant:

Name of Medication	Was it taken more than four times in the past month?	Date of the last medication dose.
1._____	**Yes** ❑ **No** ❑	_____/_____/_____
2._____	**Yes** ❑ **No** ❑	_____/_____/_____
3._____	**Yes** ❑ **No** ❑	_____/_____/_____
4._____	**Yes** ❑ **No** ❑	_____/_____/_____
5._____	**Yes** ❑ **No** ❑	_____/_____/_____
6._____	**Yes** ❑ **No** ❑	_____/_____/_____
7._____	**Yes** ❑ **No** ❑	_____/_____/_____

6. Is the participant taking any of the following medications?	Yes	Not Regularly	No
a. blood pressure medications (see list)……	❑ 1	❑ 2	❑ 3
b. weight loss medications that affect blood pressure (see list)……	❑ 1	❑ 2	❑ 3
c. weight loss medications that do not affect blood pressure (see list)….	❑ 1	❑ 2	❑ 3
d. oral steroids, oral breathing medications other than inhalers (see list)…….	❑ 1	❑ 2	❑ 3
e. insulin or oral hypoglycemics (see list)……..	❑ 1	❑ 2	❑ 3
f. lipid lowering medications (see list)……..	❑ 1	❑ 2	❑ 3
g. oral contraceptive pills (see list)……...……	❑ 1	❑ 2	❑ 3
h. hormone replacement therapy (see list)..……..	❑ 1	❑ 2	❑ 3

_____ _____

Clinician signature Date

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

The purpose of this self/interviewer-administered questionnaire is to identify individuals who are taking medications that may affect their blood pressure or otherwise might affect how their blood pressure data are analyzed in the study. This form is administered prior to any PREMIER blood pressure assessment.

If the participant reports taking ***any*** medications, a PREMIER clinician must review and sign the form. For cluster visits 2-4, if there have been no changes to the participant's medications, then a clinician does not need to sign the form.

Administration Instructions

Place ID label on page 1 and 2.

Using a blue or black pen, check the appropriate box to designate which visit this form (#79) was administered: 3, 6, 12 or 18 month.

Write in the appropriate cluster visit. Cluster visits occur at the six and 18 months visits, and are a sequence of four consecutive visits. If this is a three or 12 month visit, then write in 1.

Fill out the visit date on page 1. Be sure to use a four digit year.

The first two pages of this form should be completed by the participant and the third page should be completed by the interviewer. If this is a cluster 2, 3 or 4 visit, and the participant has not changed their medications, then the participant does not need to complete the form. However, the data questions (Q3, 4, and 6) must be completed by a PREMIER staff member, using the same data from the previously administered form. Note that the answers to Q6 may be different, depending upon the participant start dates, even if the participant reports no changes to their medications. Refer to the coding instructions on page 5 for complete details for coding Q6.

This form should always be completed at every visit where a study blood pressure is taken.

Page	Question	Special Administration Instructions (if any)
1	1	If Yes, fill out Q2. If No, skip to Q3.
	2	If Q1 = Yes, this question may not be left blank. Record any medications or nutritional supplements regularly taken by the participant in the space provided.
2	3	If Yes, fill out Q4.
	4	If Q3 = Yes, this question may not be left blank. Mark only one response with an "X".
3	**Page 3 to be completed by clinic staff only.**	
	5	~~Record all the prescription medications used by the participant. Refer to~~ page 1 and the medications brought in by the participant. Only list prescription medications that are taken in the past month.
	6	See Coding Instructions

Coding Instructions

- Using the list of medications in Q5, code each item under Q6.
- For Q6, code "Yes" if the participant has used the medication for five days or more during the preceding month.
- For Q6, code "Not Regularly" if the participant has used the medication for less than five days during the preceding month. Note the dates of use in Q5.
- If the participant has not used the medication during the last month, then check No.
- Use the attached lists of medications to identify medications in each category. These lists are extensive, but not exhaustive, so consult a clinician if in doubt about any medication.

Note that Q6d includes oral steroids taken for any reason, not just as an asthma medication, but does not include topical steroids.

If the participant reports taking ***any*** medications, a PREMIER clinician (MD, physician assistant, nurse practitioner) must review and sign the form. For cluster visits 2-4, if there have been no changes to the participant's medications, then a clinician does not need to sign the form.

Review Instructions

? Page 1 should be dated

? Page 1 - 3 should have correct ID# labels.

? For all participants with any medications listed, the clinician's signature and date should be filled in (at the bottom).

Additional Instructions

Only questions 3, 4, and 6 are entered.

If a participant starts taking BP medications after randomization, or any drug that affects their blood pressure, consult MOP chapter 24 for instructions.

Pain Medications List (Question 3)

Generic name	Brand name
Acetaminophen	Tylenol
Aspirin	Bayer, Bufferin, Ecotrin
Aspirin & Bicarbonate	Alka-Seltzer
Aspirin & Caffeine	Anacin
Diclofenac	Cataflam, Voltaren
Diflunisal	Dolobid
Etodolac	Lodine
Fenoprofen	Nalfon
Flurbiprofen	Ansaid
Ibuprofen	Advil, Motrin, Nuprin
Indomethacin	Indocin
Ketoprofen	Actron, Orudis, Oruvail
Ketorolac	Toradol
Mefanamic Acid	Ponstel
Nabumetone	Relafen
Naproxen	Aleve, Anaprox, Naprelan, Naprosyn
Oxaprazosin	Daypro
Piroxicam	Feldene
Salicylate	Trilisate
Salsalate	Disalcid, Salflex
Sulindac	Clinoril
Tolmetin	Tolectin
Tramadol	Ultram

Blood pressure medications (question 6, part a)

Generic name	Brand name
Acebutolol	Sectral
Amiloride	Midamor, Moduretic
Amlodipine	Norvasc
Atenolol	Tenormin
Benazepril	Lotensin, Lotrel
Bepridil	Vascor
Betaxolol	Kerlone
Bisoprolol	Zebeta, Ziac
Bumetanide	Bumex
Candesartan	Atacand
Captopril	Capoten, Capozide
Carteolol	Cartrol
Carvedilol	Coreg
Chlorthalidone	Hygroton
Clonidine	Catapres, Clonidine, Combipres
Diltiazem	Cardizem, Dilacor, Tiazac
Doxazosin mesylate	Cardura
Enalapril maleate	Vasoretic, Vasotec
Ethacrynic Acid	Edecrin
Filodipine	Plendil
Fosinopril sodium	Monopril
Furosemide	Lasix
Hydralazine	Apresoline, Apresazide
Hydrochlorothiazide	Esidrix, Hydrodiuril, Microzide
Indapamide	Lozol
Irbesartan	Avapro
Isradipine	Dynacirc
Labetolol	Normodyne, Trandate
Lisinopril	Prinivil, Prinzide, Zestoretic, Zestril
Losartan potassium	Cozaar, Hyzaar
Methyldopa	Aldoclor, Aldomet, Aldoril
Metoprolol	Lopressor, Toprol

(continued on next page)

Blood pressure medications (question 6, part a, continued)

Generic name	Brand name
Minoxidil	Loniten
Moexipril	Univasc
Nadolol	Corgard, Coroxide
Nicardipine	Cardene
Nifedipine	Adalat, Procardia
Nimodipine	Nimotop
Nisoldipine	Sular
Penbutolol	Levatol
Pindolol	Visken
Prazosin	Minipress, Minizide
Propranolol	Inderide, Inderol
Quinapril	Accupril
Ramipril	Altace
Sotalol	Betapace
Spironolactone	Aldactizide, Aldactone
Telmisartan	Micardis
Terazosin	Hytrin
Timolol	Timolide
Trandolapril	Mavik
Triamterene	Maxzide, Dyazide, Dyrenium
Valsartan	Diovan
Verapamil	Calan, Covera, Isoptin, Verelan

Weight-loss Drugs (Question 6, parts b & c)*

Generic name	Brand name
Benzphetamine	Didrex
D-Amphetamine	Dexadrine, Dextrostat
Dexfenfluramine	Redux
Diethylpropion	Tenuate, Tenuate Dospan, Tepanil
Fenfluramine	Pondimin
Mazindol	Mazanor, Sanorex
Methamphetamine	Desoxyn
Orlistat	Xenical
Phendimetrazine	Bontril, Prelu-2, Plegine, X-trozine
Phenmetrazine	Preludin
Phenylpropanolamine	Accutrim, Dexatrim
Phentermine	Adipex, Fastin, Ionamin, Obenix, Oby-Cap, Oby-Trim, Pro-Fast, Zantril
Sibutramine	Meridia

* All weight-loss medications affect blood pressure except for Xenical (Orlistat)

Oral steroids (Question 6, part d)

Generic name	Brand name
Betamethasone*	Celestone*
Dexamethasone	Decadron, Dexone, Hexadrol
Fludrocortisone	Florinef
Hydrocortisone	Cortef, Hydrocortone
Methylprednisolone*	Medrol*
Prednisolone	Delta-Cortef, Prelone
Prednisone	Deltasone, Orasone

Oral breathing medications other than inhalers (Question 6, part d)

Generic name	Brand name
Albuterol sulfate*	Proventil*, Ventolin*, Volmax*
Aminophylline	Amesec, Phyllocontin, Somophyllin
Dyphylline	Dilor, Lufyllin, Neothylline
Guaifenesin/theophylline	Elixophylline
Metaproterenol sulfate*	Alupent*, Metaprel*
Oxtriphylline	Choledyl
Terbutaline sulfate	Brethine
Theophyllin	Ami-Rax, Asbron, Azpan, Bronkolixir, Bronkotabs, Constant-T, Elixophyllin, Hydrophed, Labid, Marax, Quadrinal, Quibron, Respbid, Slo-Bid, Slo-Phyllin, Somophyllin, Tedral, T.E.P., Theo-24, Theochron, Theodrine, Theo-Dur, Theolair, Theophyl, T-Phyl, Uni-Dur, Uniphyl

Insulin/oral hypoglycemics (Question 6, part e)

Generic name	Brand name
Acetohexamide	Dymelor
Chlorpropamide	Diabinese
Dextrose	B-D Glucose, Glucose, Glutose, Insta-Glucose
Diazoxide	Proglycem
Glemipiride	Amaryl
Glipizide	Glucotrol
Glucagon	
Glyburide	Diabeta, Glynase, Micronase
Insulin	Actrapid, Humalog, Humulin, Ilentin, Iletin, Insulatard, Isophane, Lentard, Lente, Mixtard, Monotard, Novolin, Protaphane, Semilente, Semitard, Ultratard, Velosulin
Metformin	Glucophage
Tolazamide	Tolinase
Tolbutamide	Orinase

Lipid-lowering drugs (Question 6, item f)

Generic name	Brand name
Atorvastatin	Lipitor
Bizafibrate	Bezalip
Cholestyramine	Cholybar, Locholest, Prevalite, Questran
Clofibrate	Atromid-S
Colestipol	Colestid
Dextrothyroxine sodium	Choloxin
Fluvastatin	Lescol
Gemfibrozil	Lopid
Lovostatin	Mevacor
Nicotinic acid	Niacin, Niacinamide, Niacor, Nicobid, Nicotinamide, Slo-Niacin
Pravastatin	Pravachol
Probucol	Lorelco
Simvastatin	Zocor

Oral contraceptives (Question 6, item g)

Generic name	Brand name
Desogestel	Desogen, Mircette, Ortho-Cept
Ethynodiol	Demulen, Zovia, Ovulen
Levonorgestrel	Alesse, Leveln, Levora, Nordette, Tri-Levlen, Tri-Phasil
Medroxyprogesterone	Depo-Provera
Mestranol/norethynodrel	Enovid
Norethin A-ET	Loestrin, Norlestrin
Norethindrone	Brevicon, Enovid, Estrastep, Genora, Jenest, Micronor, Modicon, Necon, Nelova, Norinyl, Nor-Q-D, Ortho-Novum, Ovcon, Tri-Norinyl,
Norgestimate	Ortho-Cyclen, Ortho Tri-Cyclen
Norgestrel	Lo/Ovral, Ovral, Ovrette
Progesterone	Progestacert

Hormone replacement therapy (Question 6, part h)

Generic name	Brand name
chlorotrianesine	Tace
conjugated estrogens	Premarin, Premphase, Prempro
diethylstilbestrol	
esterified estrogens	Estratest, Estratab, Menest, Milprem, PMB
estradiol	Alora, Climara, Estrace, Estraderm, Fempatch, Vivelle, Depo, Deladumone, Delestrogen
estrone	Theelin
estropipate	Ogen, Ortho
ethinyl estradiol	Estinyl, Feminone
Quinestrol	Estrovis

Participant ID: _____

Date: __ __ / __ __ / __ __ __ __

Beliefs and Attitudes of PREMIER Participants

Below are some beliefs and attitudes about religion, families, racism, Black people, White people, and health. Please tell us how much you personally agree or disagree with these beliefs and attitudes by circling a number. There are no right or wrong answers, we simply want to know your views and your beliefs.

		I Totally Disagree Not True at All			Sort of Agree Sort of True			I Strongly Agree Absolutley True
1.	I believe in the Holy Ghost.	1	2	3	4	5	6	7
2.	I like gospel music.	1	2	3	4	5	6	7
3.	I believe in heaven and hell.	1	2	3	4	5	6	7
4.	The church is the heart of the Black community.	1	2	3	4	5	6	7
5.	I have seen people "get the spirit" or speak in tongues.	1	2	3	4	5	6	7
6.	I am currently a member of a Black church.	1	2	3	4	5	6	7
7.	When I was young, I was a member of a Black church	1	2	3	4	5	6	7
8.	Prayer can cure disease.	1	2	3	4	5	6	7
9.	What goes around comes around.	1	2	3	4	5	6	7
10.	I used to sing in the church choir.	1	2	3	4	5	6	7
11.	Most of the music I listen to is by Black artists.	1	2	3	4	5	6	7
12.	I like Black music more than White music.	1	2	3	4	5	6	7
13.	I listen to Black radio stations.	1	2	3	4	5	6	7

Beliefs and Attitudes of PREMIER Participants (con't)

		I Totally Disagree Not True at All			Sort of Agree Sort of True			I Strongly Agree Absolutley True
14.	I try to watch all the Black shows on TV.	1	2	3	4	5	6	7
15.	The person I admire the most is Black.	1	2	3	4	5	6	7
16.	I feel more comfort-able around Blacks than around Whites.	1	2	3	4	5	6	7
17.	When I pass a Black person (a stranger) on the street, I always say hello or nod at them.	1	2	3	4	5	6	7
18.	Most of my friends are Black.	1	2	3	4	5	6	7
19.	I read (or used to read) Essence or Ebony magazine.	1	2	3	4	5	6	7
20.	I don't trust most White people.	1	2	3	4	5	6	7
21.	IQ tests were set up purposefully to discriminate against Black people.	1	2	3	4	5	6	7
22.	Most Whites are afraid of Blacks.	1	2	3	4	5	6	7
23.	Deep in their hearts, most White people are racists.	1	2	3	4	5	6	7
24.	Whites don't understand Blacks.	1	2	3	4	5	6	7
25.	Most tests (like the SATs and test to get a job) are set up to make sure that Blacks don't get high scores on them.	1	2	3	4	5	6	7
26.	Some members of my family hate or distrust White people.	1	2	3	4	5	6	7

Beliefs and Attitudes of PREMIER Participants (con't)

		I Totally Disagree Not True at All			Sort of Agree Sort of True			I Strongly Agree Absolutley True
27.	When I was young, I shared a bed at night with my sister, brother, or some other relative.	1	2	3	4	5	6	7
28.	When I was young, my parent(s) sent me to stay with a relative (aunt, uncle, grandmother) for a few days or weeks, and then I went back home again.	1	2	3	4	5	6	7
29.	When I was young, my cousin, aunt, grandmother, or other relative lived with me and my family for awhile.	1	2	3	4	5	6	7
30.	When I was young, I took a bath with my sister, brother, or some other relative.	1	2	3	4	5	6	7
31.	Some people in my family use Epsom salt.	1	2	3	4	5	6	7
32.	Illnesses can be classified as natural types and unnatural types.	1	2	3	4	5	6	7
33.	Some old Black women/ladies know how to cure diseases.	1	2	3	4	5	6	7
34.	Some older Black women know a lot about pregnancy and childbirth.	1	2	3	4	5	6	7
35.	I was taught that you shouldn't take a bath and then go outside.	1	2	3	4	5	6	7

Beliefs and Attitudes of PREMIER Participants (con't)

		I Totally Disagree Not True at All			Sort of Agree Sort of True			I Strongly Agree Absolutley True
36.	I avoid splitting a pole.	1	2	3	4	5	6	7
37.	When the palm of your hand itches, you'll receive some money.	1	2	3	4	5	6	7
38.	There's some truth to many old superstitions.	1	2	3	4	5	6	7
39.	I eat black-eyed peas on New Year's Eve.	1	2	3	4	5	6	7
40.	I grew up in a mostly Black neighborhood.	1	2	3	4	5	6	7
41.	I went to (or go to) a mostly Black high school.	1	2	3	4	5	6	7
42.	I went to a mostly Black elementary school.	1	2	3	4	5	6	7
43.	I currently live in a mostly Black neighborhood.	1	2	3	4	5	6	7
44.	It's better to try to move your whole family ahead in this world than it is to be out for only yourself.	1	2	3	4	5	6	7
45.	Old people are wise.	1	2	3	4	5	6	7
46.	I often lend money or give other types of support to mem-bers of my family.	1	2	3	4	5	6	7
47.	A child should not be allowed to call a grown woman by her first name, "Alice." The child should be taught to call her "Miss Alice."	1	2	3	4	5	6	7

Completed by (Staff ID): _____

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Beliefs and Attitudes of PREMIER Participants Data Collection Form

Overview

This form will be completed once by all African-American participants in PREMIER. In general, the form should be completed:

For cohort 1: At their 12-month visit

For cohort 2: At their six-month visit

For cohort 3: At their three-month visit (or R/I if it hasn't yet taken place)

For cohort 4: At their R/I visit

If a participant misses the form, it should be completed at their next scheduled clinic visit.

Administration Instructions

Place an ID label at the top of Page 1.
Write in the date at the top of the form in the space provided. Use mm/dd/yyyy.
Using a blue or black pen, the participant completes the form as outlined below:

Question	**Special Administration Instructions**
All	The participant should read the statement next to the number (e.g. 1. "I believe in the Holy Ghost". The participant should then circle the number which best describes their agreement or disagreement with that statement. Circling a '1' means that the participant totally and completely disagrees with the statement. Circling a '7' means that the participant totally and completely agrees with the statement. Circling a '4' is the midpoint between these two extremes. It is up to the participant to determine what a '2', '3', '5' or '6' means. Participants should answer all questions. Upon review, if the staff determines that a question was missed, they may request that the participant answer the question *before he/she leaves the clinic for that visit*. You may not telephone a participant for a missed answer. It is admissible for a participant to refuse to answer a question.

After the form is completed it should be reviewed by a PREMIER staff member. This person should record their PREMIER Staff ID number in the "form reviewed by" section at the bottom of the page and send the form to data entry.

ID: _____

Date of BP Escape: ____ / ____ / _____

Blood Pressure Escape Form – 3 Month Visit

ESCAPE INFORMATION:

1. Escape Level ..... Level 1 ❑ 1

FOLLOW UP ACTIONS:

2. Obtain additional RZ BP within 1 week ..... Date obtained: __ __ / __ __ / __ __ __ __

3. Sum of 2 BP readings for the original visit: .....__ __ __ / __ __ __

4. Sum of additional 2 BP readings: .....__ __ __ / __ __ __

5. Cumulative sum of original and repeat BP readings (4+5): .....__ __ __ / __ __ __

6. Escape Outcome:..... ≤637/397 (no referral needed) ❑ 1

≥718/438 (refer to physician* within 1 week) ❑ 2

≥638/398 (refer to physician* within 1 month) ❑ 3

Date referred: __ __ / __ __ / __ __ __ __

Date referral confirmed: __ __ / __ __ / __ __ __ __

Notes: _____

_____

_____

*Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician.

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This form is used to track the process of following up on an escape-level blood pressure **during the 3 month visit.** Complete this form whenever the 3 Month Visit BP Form escape outcome is reached.

Start completing this form immediately after the escape-level BP is reached. You will need to have the BP form available as you complete this form.

Coding Instructions

Question	**Instructions**
Date of BP escape	Enter the date from the BP form.
1. Escape level	Level 1 is the only option at the 3 month visit.
2. Date of repeat	Enter the date the repeat measurement was obtained. Make sure this is within 1 week of the escape.
3. Previous BP	Enter the BP sum from the previous visit (the visit where the escape happened)
4. Repeat BP	Enter the sum of the two BP readings from the repeat reading.
5. Sum	Add items 4+5.
6. Outcome	Check the appropriate outcome, based upon the sum in Q#5.
Referral date	Enter the date the participant was referred. This is the date the participant was told to contact their physician for a follow-up appointment.
Confirmation date	During the following seven days, attempt to confirm with the participant that a follow-up appointment was made. If able to confirm, enter the date of confirmation. Write the date of the appointment in the "Notes" section. If unable to confirm after seven days, enter the date of the last attempt to confirm.

Notes: Indicate any issues, problems, or special circumstances. If referral could not be confirmed, be sure to indicate that in the notes.

Review Instructions

- Make sure ID label was attached and all items were completed.
- Make sure that the appropriate outcome is checked in Q#6.
- Check that referral happened within the allowed time window.
- Review the Notes section to be sure it adequately explains the follow-up. ("Referred" is not an adequate explanation.)

Additional Instructions

Once form has been reviewed and entered, fax a copy to the Data Clerk at the coordinating center). Be sure to use a shipping log (Form #316).

File the original form in the participant's chart.

ID: _____

Date of BP Escape: ____ / ____ / _____

Blood Pressure Escape Form – 12 Month Visit

1. Escape Level ..... Level 1 ❑ 1

Level 2 ❑ 2

FOLLOW UP ACTIONS:

2. Obtain additional RZ BP within 1 week ..... Date obtained: __ __ / __ __ / __ __ __ __

3. Sum of 2 BP readings for the original visit: ..... __ __ __ / __ __ __

4. Sum of additional 2 BP readings: ..... __ __ __ / __ __ __

5. Cumulative sum of original and repeat BP readings (4+5): ..... __ __ __ / __ __ __

6. Escape Outcome: ..... ≥718/438 (refer to physician* within 1 week) ❑ 2

≥638/398 (refer to physician* within 1 month) ❑ 3

≥558/358 (refer to physician* within 2 months) ❑ 6

≤557/357 (no referral needed) ❑ 4

Date referred: __ __ / __ __ / __ __ __ __

Date referral confirmed: __ __ / __ __ / __ __ __ __

Notes: _____

_____

_____

*Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician.

Reviewed by (staff ID): _____

Entered by (staff ID): _____

Overview

This form is used to track the process of following up on an escape-level blood pressure **during the 12 month visit.** Complete this form whenever the 12-Month Visit BP Form escape outcomes are reached.

Start completing this form immediately after the escape-level BP is reached. You will need to have the BP form available as you complete this form.

Coding Instructions

Question	**Instructions**
Date of BP escape	Enter the date from the BP form.
1. Escape level	Escapes are either level 1 (requiring more immediate follow-up) or level 2. The escape level is indicated on the BP form outcome.
2. Date of repeat	Enter the date the repeat measurement was obtained. If this is a Level 1 escape, the repeat measurement should occur within 1 week of the escape. If this is a Level 2 escape, the repeat measurement should occur within 1 month of the escape.
3. Previous BP	Enter the BP sum from the previous visit (the visit where the escape happened)
4. Repeat BP	Enter the sum of the two BP readings from the repeat reading.
5. Sum	Add items 4+5.
6. Outcome	Check the appropriate outcome, based upon the sum in Q#5. Note that while the outcomes are ordered from most severe to least severe, the codes are slightly out of order.
Referral date	Enter the date the participant was referred. This is the date the participant was told to contact their physician for a follow-up appointment.
Confirmation date	During the following seven days, attempt to confirm with the participant that a follow-up appointment was made. If able to confirm, enter the date of confirmation. Write the date of the appointment in the "Notes" section. If unable to confirm after seven days, enter the date of the last attempt to confirm.

Notes: Indicate any issues, problems, or special circumstances. If referral could not be confirmed, be sure to indicate that in the notes.

Review Instructions

- Make sure ID label was attached and all items were completed.
- Make sure that the appropriate outcome is checked in Q#6.
- Check that referral happened within the allowed time window.
- Review the Notes section to be sure it adequately explains the follow-up. ("Referred" is not an adequate explanation.)

Additional Instructions

Once form has been reviewed and entered, fax a copy to the Data Clerk at the coordinating center). Be sure to use a shipping log (Form #316).

File the original form in the participant's chart.

ID: _____

Date: ____ / ____ / _____

Participant Transfer Form

Complete this form for all participants who transfer from one PREMIER site to another.

---

1. To what site is the participant being transferred?

Baltimore ❑

Baton Rouge ❑

Durham ❑

Portland ❑

2. What date is the participant to be transferred? ____ / ____ / _____

Done

3. Transfer site notified and plans made for visit scheduling and records transfer: ❑

For office use only:

List of records transferred:

Date of data transfer:

Site validation of data transfer:

Event/CC_Edit #:

CC signature:_____ Date:_____

Overview

This form is completed *only* when PREMIER participants move from one site to another, *and* data collection will be done at the new site. The site completing this form should be sure to clear the transfer with the new site prior to completing this form, so that a smooth transition can be made for data collection. Before the transfer is complete, plans should be approved and set in place for future data collection and records transfer.

Coding Instructions

This form is not data entered.

ID:	Place a participant ID label on the form.
Date:	Enter the date the form is completed.
Site of Transfer:	Indicate the new site where the participant is being transferred.
Date of Transfer:	Indicate the date that the new site is expected to take responsibility for the participant's data.
Site Notification:	Indicate that the new site has been notified of the transfer, and that plans for follow-up visit scheduling and records transfer have been completed.

Once the form is complete, FAX it to the coordinating center, who will make the necessary data changes. Once the changes are complete, the CC will sign the form and fax it back to both sites involved with the transfer. The completed form should be filed in an unblinded portion of the participant's chart.

Review Instructions

Make sure ALL three questions have been answered and addressed.

Do not write in the shaded area of the form.

Additional Instructions

Fax this form to the CC when completed. The CC will make all necessary data changes and fax the completed form back to both sites.

This form is only completed when a participant is transferring to another PREMIER site. Other data collection arrangements for participants who move to areas not close to a PREMIER site should be made with the CC.

ID: _____

Participant Contact Information

The information requested on this form is very important to help us keep in contact with you during the course of the study. **Please complete each item, printing in block capital letters.** If there are parts that you cannot fill out, we will go over them with you later.

1. Name: _____
(first) (middle) (last)

2. Address: _____
(number) (street) (apt. number)

_____
(city) (state) (zip code)

3. Home phone number: (_____) _____ - _____

4. Name of employer: _____

Address: _____
(number) (street) (apt. number)

_____
(city) (state) (zip code)

Work phone number: (_____) _____ - _____
If necessary, may we call you at work? Yes _____ No _____
If necessary, may we mail information to you at work? Yes _____ No _____

5. Is there any other way to reach you?

Cell phone number: (_____) _____ - _____
Beeper number: (_____) _____ - _____
Fax number: (_____) _____ - _____
E-mail address: _____

6. What is the best time to call you? _____

Is this at HOME or at WORK (circle one)?

ID: _____

7. Who is your usual doctor or health care provider?*

Name: _____

Address: _____
(number) (street)

_____
(city) (state) (zip code)

Phone number: (_____) _____ - _____

If necessary, may we contact your doctor to make sure you have received appropriate follow up care? Yes _____ No _____

8. What is your Social Security number? _____ - _____ - _____ None ____

Since it will be very important for us to stay in touch with you throughout the study period, it would be a great help if you could provide us with the name of two relatives or friends who do not live with you and whom we could contact if we were unable to reach you directly:

9. Name: _____
(first) (middle) (last)

Address: _____
(number) (street) (apt. number)

_____
(city) (state) (zip code)

Daytime phone #: (_____) _____ - _____ Evening phone #: (_____) _____ - _____

Relationship to you: _____

10. Name: _____
(first) (middle) (last)

Address: _____
(number) (street) (apt. number)

_____
(city) (state) (zip code)

Daytime phone #: (_____) _____ - _____ Evening phone #: (_____) _____ - _____

Relationship to you: _____

Medications Allowed During PREMIER

Medical condition or symptom

Aches and pains	Tylenol Aspirin Ibuprofen (but not within 48 hours before BP measurement)
Indigestion	Amphogel Nephrox
Cold/flu/allergy	Tylenol, Extra Strength Tylenol Chlortrimeton Benadryl Hismanal Seldane Tavist Afrin, Otrivin or Ayr nasal spray Robitussin (NOT Robitussin DM) Claritin Beconase nasal spray
Constipation	Correctol Senokot
Infections	Antibiotics
Hormones	Estrogen and progesterone (but don't start these medications or change dose during the study)

Food Interview Instruction Sheet

You will be receiving 2 phone calls over the next three weeks so that we can ask you about the foods you eat. You will also receive another 2 calls in 6 months and again in 18 months.

During each call an interviewer from Penn State will call to ask you what foods you have eaten on the previous day. These calls are done on randomly selected days and are unannounced, so we are not able to tell you what specific day we will be calling, but the interview should only take about 20 minutes. We have also provided you with a poster that contains pictures of cups, bowls, circles, squares and rectangles. Keep this poster beside your phone. You may need it during the interviews to help you estimate the amounts of foods you eat.

Each food interview will have 3 parts:

- First, the interviewer will ask for the **time, type of meal, place**, and a **brief list of foods** that you ate throughout the day.

- Next, you will be asked for more detail about the **ingredients, preparation**, and **amounts** of each food.

- Then, the **interviewer will repeat** what you have reported to make sure everything is correct. You can add or change the information during the interview

You don't need to remember all of this. We just wanted to give you an idea what to expect.

We want to thank you for participating in this part of the project. The information you provide is confidential and is a very important part of the PREMIER Study.

SV3 6 Month 18 Month
ID: _____

Food Interview
Convenient Times Schedule
Eastern Time Zone

Please complete the following information:

Name: _____

Home phone: (_____) _____ - _____

Work phone: (_____) _____ - _____

Cellular phone: (_____) _____ - _____

In the table below, please identify each of the times that you will be available for a 20-minute interview. For the times when you are available, please write "home", "work", or "cell" in the box to indicate how we can reach you at that time.

Please check at least one time per day. We will try to call during those times.

	Mornings			Afternoons				Evenings		
DAY	**9-10**	**10-11**	**11-12**	**1-2**	**2-3**	**3-4**	**4-5**	**6-7**	**7-8**	**8-9**
Monday										
Tuesday										
Wednesday										
Thursday										
Friday										
Saturday										
Sunday										

Notes: _____

_____

_____

_____

_____

_____

SV3 6 Month 18 Month
ID: _____

Food Interview
Convenient Times Schedule
Central Time Zone

Please complete the following information:

Name: _____

Home phone: (_____) _____ - _____

Work phone: (_____) _____ - _____

Cellular phone: (_____) _____ - _____

In the table below, please identify each of the times that you will be available for a 20-minute interview. For the times when you are available, please write "home", "work", or "cell" in the box to indicate how we can reach you at that time.

Please check at least one time per day. We will try to call during those times.

	Mornings			Afternoons				Evenings		
DAY	**8-9**	**9-10**	**10-11**	**12-1**	**1-2**	**2-3**	**3-4**	**5-6**	**6-7**	**7-8**
Monday										
Tuesday										
Wednesday										
Thursday										
Friday										
Saturday										
Sunday										

Notes: _____

_____

_____

_____

_____

_____

SV3 6 Month 18 Month
ID: _____

Food Interview
Convenient Times Schedule
Pacific Time Zone

Please complete the following information:

Name: _____

Home phone: (_____) _____ - _____

Work phone: (_____) _____ - _____

Cellular phone: (_____) _____ - _____

In the table below, please identify each of the times that you will be available for a 20-minute interview. For the times when you are available, please write "home", "work", or "cell" in the box to indicate how we can reach you at that time.

Please check at least one time per day. We will try to call during those times.

	Mornings					Afternoons			Evenings	
DAY	**6-7**	**7-8**	**8-9**	**10-11**	**11-12**	**12-1**	**1-2**	**3-4**	**4-5**	**5-6**
Monday										
Tuesday										
Wednesday										
Thursday										
Friday										
Saturday										
Sunday										

Notes: _____

_____

_____

_____

_____

_____

Overview

This form is used to find out from participants when they will be available to do the diet recalls with the interview staff. There is a separate form for each time zone so that the times will match up to available slots for the interviewers. Be sure to select the correct form for your time zone.

Administration Instructions

Try to administer this form as close as possible to the time when the interviews will be done. If too much time elapses and the participant's schedule changes, you may need to administer the form again.

Ask participant to indicate the times they would be available to do a 20-minute phone interview. Encourage them to indicate at least one time slot in each day of the week.

Warn participants that if they indicate that they would like to be called at work or on their cellular phone, they need to be sure they have their poster with them, and that they can be interrupted for a 20-minute interview. Staff should try to encourage people to find times that they can take these calls at home.

If participant can only be reached by pager, please write the pager number and any other contact information in the Notes section at the bottom. They also need to stress with participants that it is really important that they call back as soon as possible.

If there are any particular dates when a participant is not available (for example, they are available on Mondays in general, but not on Monday the 27th), please add this information in the Notes section.

If the participant will be out of town during the entire calling period, try to get a number and times when the participant can be reached. Participants that can not be reached during the calling period can not be randomized.

For Portland participants, if they are unable to take calls during these time slots earlier in the day, the interviewers have a limited availability to call participants later. If necessary, offer participants a 6-7 PM PST time slot and indicate these dates/times in the Notes section.

Coding Instructions

Located above the ID label, please circle which visit the form covers, i.e. SV3, 6 month or 18 month.

Review Instructions

Make sure the participant has chosen at least one time slot per day, and that the form has been marked with "home", "work", or "cell" in the appropriate boxes. Check marks are not acceptable, even if participant has only listed their home phone number.

Other Instructions

Once form is complete, attach a cover sheet and fax to Diane Mitchell at (814) 865-9971. Sites may create their own cover sheets, or use the attached example cover sheet.

Convenient Times Schedules for the PREMIER study

To: Diane Mitchell Date: ___ / ___ / _____
Fax: (814) 865-9971
Phone: (814) 863-5955

From: _____
Site: _____
Phone: (_____) _____ - _____

Number of Convenient Times Schedules attached: _____

Notes:

SV1/SV2 Activity Fact Sheet

- PREMIER will last 18 months, from around _____ to _____.
- You will be asked to have your blood pressure checked regularly (a minimum of 10 times).
- You will be asked to have a fasting blood test and to collect a 24-hour urine specimen 3 times.
- You will be asked to change your eating and physical activity patterns.
- You will be asked to reduce sodium intake and to limit alcohol intake (if you drink).
- You will be contacted by phone 6 times to provide a detailed diet history.
- You may be asked to lose weight, if you are overweight according to the study recommendation.
- You may be asked to attend three sessions during the study to receive advice, **OR** you may be asked to attend weekly sessions of up to 2 hours for the initial 6 months and monthly sessions for the rest of the 12 months of the study.
- You may be asked to increase your consumption of fruits, vegetables, and dairy products.
- You may be asked to keep records of your diet and physical activities periodically.

SV3 Activity Fact Sheet

- PREMIER will last 18 months, from around _____ to _____. Please discuss with the staff if you have any planned extended out-of-town trips.

- You will be asked to have your blood pressure checked 10 times over 18 months. It will take you about 25 minutes each visit to check your blood pressure.

- You will be asked to give a fasting blood and to collect a 24-hour urine specimen 3 times. For the fasting blood sample, you need to come in to the center between 7 and 9 am after at least 12 hours fasting.

- You will be contacted by phone 6 times to provide a detailed diet history.

- You will be asked to change your eating and physical activity patterns.

- You may be asked to attend three sessions during the study to receive advice, **OR** you may be asked to attend weekly sessions of up to 2 hours for the initial 6 months and monthly sessions for the rest of the 12 months of the study.

- You may be asked to lose weight if you are overweight according to the study recommendation.

- You may be asked to reduce sodium intake to less than 2 grams (½ teaspoon) per day and to limit alcohol intake to less than two drinks a day. A drink is like a 12 oz. beer, 5 oz. wine, or a shot (1½ oz.) of liquor.

- You may be asked to eat at least 9 servings of fruits and vegetables a day (a serving is a medium piece of fruit or ½ cup of cooked vegetables or 1 cup of raw vegetables).

- You may be asked to eat at least 3 servings of dairy products a day (a serving is 8 oz. of milk or 1 cup of yogurt).

- You may be asked to keep records of your diet and physical activities frequently.

ID: _____

Food Record

Please record everything you eat and drink for:

Day of Week:	**Date:**
If you have questions call:	**At:**

Instructions:

1 Record each meal and snack right after you eat it. Note the time and indicate whether to food was a meal or a snack. Use as many pages as you need.

2 Write each food on a separate line and skip every other line.

3 Fully describe your foods and beverages. Identify brand names if known and list the main ingredients in home dishes, recipes, and mixed dishes.

4 Write down the amount of food and beverages you eat or drink. Measure your food using cups, spoons, a ruler, or the food label. For drinks use fluid ounces.

Sample Food Record

Time	Meal B = Brk L = Lunch D = Din S = Snack	Day: **__Saturday_____** Date: **_9_** / **_2_ _6_** / **_1_ _9_ _9_ _9_**	
		Food and Beverages	**Amount**
7:00 am	B	Orange Juice	6 oz
		Oatmeal, quick cooking made with water	1/3 cup
		Margarine, Mazola stick	1 tsp
		2% Milk	4 oz
		Brown Sugar	2 tsp
		Coffee, decaffeinated	2 cups
		Cream, half and half	2 tbsp
		Toast, whole wheat	1 slice
		Margarine, Mazola stick	1 tsp
12:00 N	L	Sandwich:	
		Bread, whole wheat	2 slices
		Turkey, white meat only	3 ounces
		Lettuce, Red Leaf	2 leaves
		Tomato, 3” diameter X ½ “ thick	2 slices
		Mustard, Dijon	1 tsp
		Mayonnaise, regular	2 tsp
		Apple, 3” diameter	1
		Taco Chips. Frito Lay, regular	12
		Cookies, chocolate chip, 3” diameter	3
		Milk, whole	8 oz
6:00 PM	D	Lasagna	
		Lasagna noodles	½ cup
		Tomato Meat sauce (12% hamburger; drained)	1/3 cup
		Cooked fresh spinach	1/3 cup
		Ricotta cheese, whole milk	¼ cup
		Egg, fresh	1/3 egg
		Sour Dough Bread, 3 X 4	2 slices
		Butter, melted	2 tsp
		Green Salad	1 cup
		Ranch Dressing, Good Seasoning	2 Tbsp
		Milk, 3.8%	1 cup
		Sliced canned peaches	½ cup
		Wine, Chablis	6 oz

Food Record Form

ID: ____________________

Please skip every other line. Do not record in the gray area.

Time	Meal B = Brk L = Lunch D = Din S = Snack	Day: ____________________ Date: __ __ / __ __ / __ __ __ __	
		Food and Beverages	**Amount**

Food Record Form

ID: ____________________

Please skip every other line. Do not record in the gray area.

Time	**Meal** B = Brk L = Lunch D = Din S = Snack	**Day:** ______________________________ Date: __ __ / __ __ / __ __ __ __ **Food and Beverages**	**Amount**

Coding Instructions

Review the food record with the participant to determine if there are any missing foods. Go back over the participant's activities for the day recorded to help him/her remember foods eaten. Add missing foods to the form with a red pen. When the participant successfully records what he/she eats for one day, mark the SV2 Food Record box "Eligible" on the SV3 Visit Form (Form #15).

Ineligible Participants

Participants are not eligible at the SV3 visit if they do not return their food record. Reasons records may not be returned are the participant:

- Did not record what they eat
- Refuses to record what they eat
- Is unable, due to physical or literacy limitations

However, all effort is made to support the participant to complete the record.

Food Records not Returned

For participants who do not return a food record at the SV3 visit seek out information why this occurred and ask them if they are willing to complete the record. Explain they are not able to participate without completing the record. Make every attempt to help them complete the record while at the clinical site.

If less than one day is recorded, randomization is delayed until the participant completes an acceptable food record. Ask the participant to complete the record in the next week and re-schedule the visit. If the participant does not return the one-day food record, he or she is not eligible for the study.

If the participant refuses or states they are unable to record what they eat they are ineligible.

If the nutritionist feels the participant is not able or capable to record what they eat regularly during the intervention the participant is ineligible.

Food Records Recorded and not Brought to the SV3 Visit

If the participant records what they eat, but does not bring the record to the visit, give the participant a stamped envelope to return. As soon as the food record is received, the nutritionist or Diet Tech reviews the food record and calls the participant by telephone as soon as it is received. If the record is not received, the participant is ineligible to continue.

Ill Participant

If the participant is sick during the record keeping time establish new dates the participant can keep the record and reschedule the SV3 visit.

Inadequate Food Information

If the participant does not record at least four foods, and attempt to write in the amounts, the participant is not eligible.

Weight Loss Medications That Affect Blood Pressure

AMPHETAMINE:

Adderall (& Aderall 20mg & 30mg)
Adiloss Ty-Med
Adipex Ty-Med
Am-Dex
Amphetamine Reducing Compound (& Reducing Compound Strong)
Amphetamine Sulfate
Amphetose
Amphocaps
Benzedrine
Biphetamine
Biphetamine-T
Bontril Tablets (& Bonatril Timed No. 1 & 2)
Cellumine
Centramina
Cydril
Daprisal
Delcobese
Desoxyn
Desoxyn Gradumet
Dexamin (FM)
Dex-Sed 10 (& Dex-Sed 15)
Dexytal No. 1 (& Dexytal No. 2)
Dietamine
Dintospina (FM)
Dobo
Dobo-Sed
Durophet
Durophet M
Dx-2.5
Epipropane
Eskatrol
Ferndex
Fetamin
Geriatric
Methampex
Obedrin-LA

Ampheatamines (con't)

Obetrol
Ortenal
Oxydess II
Phelantin
Reducing Tablet No. 1
Rid-Obese No. 1 (& Rid-Obese 2 & 3)
Spancap No.1
Stimdex
Vasocort

DEXFENFLURAMINE:

Adifax (FM)
Dipondal (FM
Glypolix (FM)
Isomeride (FM)
Redux

DIETHYLPROPION:

Anorex (FM)
Apisate (FM)
Atractil
Depletite
Diethylpropion
Diethylpropion Hydrochloide
Dietil
Dobesin
Linea
Menutil
Moderatan
Nobesine-75 Diffucaps
Prefamone
Prefamone Chronules
Regenon (& Regenon A FM)
Tenuate
Tenuate Dospan (& Tenuate Dospan FM)
Tenuate Retard
Tepanil (& Tepanil Ten-Tab)

FENFLURAMINE:

Adapomin (FM)
Dima-Fen (FM)
Fentrate (FM)
Fenured (FM)

FENFLURAMINE (con't)

Pesos (FM)
Ponderal (& Ponderal FM & P-caps)
Ponderax (& Ponderax FM & P-caps)
Ponderex (& Ponderex 40)
Pondimin (& Pondimin Extentab)
Ponflural (FM)

MAZINDOL:

Mazanor
Sanorex
Teronac (& Teronac FM)

PHENDIMETRAZINE:

Adipost
Adphen
Anorex
Antapentan (FM)
Bacarate
Bontril PDM (& Bontril Slow-Release)
Cam-Metrazine
Dital
Dyrexan-Od
Melfiat (& Melfiat Unicelle)
Obalan
Obeval
Phendiet-105
Phendimetrazine (& Phendimetrazine Tartrate)
Phenzine
Plegine
Prelu-2
Preludin
Slyn-LL
Sprx-1 (& Sprx 2, 3, & 105)
Statobex (& Statobex D & G)
Trimcaps
Trimtabs
Weh-less (& Wehless, Weh-less Timecells)
Weightrol

PHENMETRAZINE:

Preludin

PHENTERMINE:

Adipex 8 (& Adipex-P)
Duromine
Fastin
Ionamin
Minobese
Mirapront (FM)
Obenix
Obephen
Oby-Trim
Panbesy
Phentermine
Phentermine Hydrochloride
Phentermine Resin Complex
Phentrol (& Phentrol 2, 3, 4, 5, & 6)
T-Diet
Tora (Tora 30, I & II)
Unifast Unicelle
Wilpo

SIBUTAMINE:

Meridia

Overview

This form is used by clinical staff to assist them in identifying prescription weight loss medications which have blood pressure effects. The most common weight loss medications with BP effects are listed as an appendix to Forms 11 and 34. However, there may be rare instances where a PREMIER participant brings in a medication that is not listed on those two forms. Use this form to aid in identifying these medications. If you are still unsure about a weight loss medication, please contact the coordinating center for further instructions.

Intervention Alert Worksheet

Participant ID	Date	Report	Comments	Initials
		☐ Attendance ☐ Calorie ☐ Weight Loss		
		☐ Attendance ☐ Calorie ☐ Weight Loss		
		☐ Attendance ☐ Calorie ☐ Weight Loss		
		☐ Attendance ☐ Calorie ☐ Weight Loss		
		☐ Attendance ☐ Calorie ☐ Weight Loss		
		☐ Attendance ☐ Calorie ☐ Weight Loss		
		☐ Attendance ☐ Calorie ☐ Weight Loss		
		☐ Attendance ☐ Calorie ☐ Weight Loss		
		☐ Attendance ☐ Calorie ☐ Weight Loss		

Overview

The purpose of this form is to assist the intervention sites with documenting follow-up contacts with participants. Three different alert reports (weight, calorie and attendance) are distributed to the sites, with instructions to review them for possible safety issues with participants. Each participant should be listed on this sheet, and the action taken by the site outlined under the "comments" section. In some instances, no action needs to be taken; this should be documented as well.

This form is not data-entered, nor is it required. However, all sites are required to have a documentation plan in existence for use with the alert reports. Use of this form will satisfy all documentation requirements for the alert reports.

QUARTERLY CHECKLIST FOR MONITORING PREMIER BLOOD PRESSURE OBSERVERS

(To be kept on file at the Clinical Center)

Performing PREMIER Technician Certification Code #_____

Observer PREMIER Technician Certification Code #_____

Date Observed ___/___/___ (Month/Day/Year)

Instructions: Check if procedure step is carried out correctly.

Procedure			Comments
1.	____	Check equipment	_____
2.	____	Give participant explanation of procedures	_____
3.	____	Measure arm for correct cuff size	_____
4.	____	Palpate brachial artery	_____
5.	____	Mark brachial artery point	_____
6.	____	Check center of bladder and wrap cuff correctly	_____
7.	____	Wrap cuff center of bladder over brachial pulse	_____
8.	____	Leave subject for 5 min. rest, instruct on posture, smoking, talking	_____
9.	____	Take radial pulse	_____
10.	____	Determine pulse obliteration using standard manometer	_____
10a.	____	Calculate peak inflation level	_____
11.	____	Open bellows valve, wait for mercury to settle	_____
12.	____	Turn thumb wheel gently	_____
13.	____	Place stethoscope in ears	_____
14.	____	Palpate brachial artery, position bell of stethoscope on brachial artery	_____
15.	____	Inflate rapidly to peak inflation level (PIL)	_____
16.	____	Count full 5 seconds with pressure steady	_____
17.	____	Close bellows knob	_____
18.	____	Deflate cuff 2 mmHg per second	_____
19.	____	Deflate cuff 10 mmHg after last audible sound heard	_____
20.	____	Instruct participant to raise arm for 5 seconds	_____
21.	____	Record readings	_____
22.	____	Read zero value	_____
23.	____	Begin steps for next readings	_____

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

BLOOD PRESSURE WRITTEN EXAMINATION

1. Whenever the pulse is measured, it must be counted for ____ seconds.

2. Whenever the blood pressure is to be measured, the participant must first be in the _____ position for _____ minutes without _____.

3. a. To find the pulse obliteration pressure by use of a standard sphygmomanometer, first inflate the cuff while palpating the radial pulse until the pressure reaches _____mmHg, and then slowly inflate _____mmHg at a time until the radial pulse can no longer be felt.

   b. It is not permitted to use this inflation of the cuff for carrying out an actual PREMIER reading:

   True False

4. a. To find the peak inflation level to be used for Random-Zero (R-Z) readings, a number must be added to the correct pulse obliteration pressure.

   True False

   b. This number is _____.

5. The deflation rate of the cuff must be carefully controlled, at a rate of _____ mmHg per second.

6. The interval between readings must be at least _____ seconds.

7. Use of regular adult cuff when a larger one is required would (check which applies):

   ____ (1) give a falsely high blood pressure reading
   ____ (2) likely cause difficulty in securely wrapping the cuff
   ____ (3) be preventable by checking the PREMIER range markings before wrapping the cuff, and being properly equipped
   ____ (4) all of the above
   ____ (5) none of the above

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

8. The major cause of digit preference is dropping the mercury too quickly.

True False

9. One arm is used to measure the blood pressure. In PREMIER the preferred arm is: (circle one)

Right Left

10. All blood pressure technicians are to be blinded to group assignment, and participants are blinded to their study blood pressure data at the 3 and 12 month follow-up visits.

True False

11. The major advantage of the random-zero device is that it: Explain:

_____
_____
_____

Passed: Yes ☐
No ☐
Master Trainer Staff ID# _____
Entered by (Staff ID) _____

ANSWER KEY TO THE WRITTEN BLOOD PRESSURE EXAMINATION

(Answers to each question are underlined)

1. Whenever the pulse is measured, it must be counted for 30 seconds.

2. Whenever blood pressure is to be measured, the participant must first be in the seated position for 5 minutes without standing (or) moving about (or) crossing feet/legs.

3. a. To find the pulse obliteration pressure by use of either type of sphygmomanometer, first inflate the cuff while palpating the radial pulse until the pressure reaches 80 mmHg, and then slowly inflate 10 mmHg at a time until the radial pulse can no longer be felt.

   b. It is not permitted to use this inflation of the cuff for carrying out an actual PREMIER reading:

      True False

4. a. To find a peak inflation level to be used for Random-zero (R-Z) readings, a number must be added to the correct pulse obliteration pressure.

      True False

   b. This number is 60 mmHg.

5. The deflation rate of the cuff must be carefully controlled, at a rate of 2 mm Hg per second.

6. The interval between readings must be at least 30 seconds.

7. Use of the regular adult cuff when a larger one is required would (check which applies):

_____(1) give a falsely high blood pressure reading

_____(2) likely cause difficulty in securely wrapping the cuff

_____(3) be preventable by checking the PREMIER range marking before wrapping the cuff, and being properly equipped

__x___(4) all of the above

_____(5) none of the above

8. The major cause of digit preference is dropping the mercury too quickly.

True False

9. One arm is used to measure the blood pressure. In PREMIER the preferred arm is:

Right Left

10. All blood pressure technicians are to be blinded to participants' group assignment, and participants are blinded to their study blood pressure data at the 3 and 12 month follow-up visits. (Note: Participants will receive their average BP readings, but not their individual BP readings)

True False

11. The major advantage of the random-zero device is that it: Explain:

It reduces blood pressure observer bias by obscuring the actual blood pressure value and therefore, removes judgments about blood pressure levels for readings close to critical values such as a diastolic of 90 or 86 mmHg where critical decisions may be made.

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

Initial Certification ☐ 1
6 Month Re-Certification ☐ 2
Semi-Annual Master Trainer Cert. ☐ 3
Re-Certification requested by CC ☐ 4

Trainer ☐
Technician ☐

Set: 1 ☐ 2 ☐ 3 ☐

BLOOD PRESSURE (Y-TUBING) CERTIFICATION FORM

Blood Pressure Measurement
** Wait 5 minutes seated **

Resting 30-second pulse ___ ___/30 sec. Arm Circumference ___ ___/ cm.

Cuff Size 1) Small adult (<24 cm) _____ 2) Adult (24-32)_____
3) Large adult (>32-41cm)_____ 4) Thigh (>41 cm)_____

Pulse obliteration pressure (POP) ___ ___ ___ mmHg
+ 6 0

Peak inflation level (PIL) for RZM, minimum 180 ___ ___ ___ mmHg

1. First random zero blood pressure SBP/DBP
Uncorrected __ __ __/__ __ __ mmHg
Zero value _____

Corrected __ __ __/__ __ __ mmHg

** Wait 30 Seconds**

2. Second random zero blood pressure SBP/DBP
Uncorrected __ __ __/__ __ __ mmHg
Zero value _____

Corrected __ __ __/__ __ __ mmHg

SBP/DBP
Total of two measurements __ __ __/__ __ __ mmHg
Average of two measurements __ __ __/__ __ __ mmHg

Passed: Yes ☐ No ☐
Master Trainer Staff ID# _____
Entered by (Staff ID) _____

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

BLOOD PRESSURE OBSERVATION CHECKLIST

A. Equipment and Supplies

The technician should indicate that all equipment and supplies needed for blood pressure measurements are present. Check each item as identified:

____ (1) Random-Zero Sphygmomanometer
____ (2) Standard Sphygmomanometer
____ (3) Cuffs - full set of 4 ("small adult", "adult", or "regular", "large adult", and "thigh") with PREMIER range markings added.
____ (4) Inflation Bulb
____ (5) Bell Stethoscope
____ (6) Watch with second hand or stop watch
____ (7) BP Assessment Form

B. Arm Measurement

____ (1) Arm bare from elbow to shoulder
____ (2) Determination of correct cuff size using the PREMIER range markings or using the cm tape measure

C. Preparation for BP Reading

____ (1) Description of what participant should be told (no talking, feet flat on floor, legs uncrossed)
____ (2) Brachial artery palpated
____ (3) Midpoint of bladder within the cuff located
____ (4) Cuff applied with midpoint of bladder over brachial artery (don't extend beyond proper markings on cuff)
____ (5) Correct cuff size used
____ (6) Arm positioned with midpoint of cuff width at "heart level", lower edge 2-3 cm (1 inch) above crease
____ (7) Sphygmomanometer connected to cuff
____ (8) Sphygmomanometer scale (midpoint) is at sitting eye level
____ (9) Radial pulse located

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

D. Measurement of Pulse

____ (1) Five-minute period at rest (leave room to avoid talking)
____ (2) Radial artery palpated
____ (3) Counting with watch, full 30 seconds
____ (4) Recording of 30-second count
____ (5) Pulse obliteration pressure (POP) determined
____ (6) 60 mmHg added to POP to yield peak inflation level (PIL)

E. Measurement of Blood Pressure

____ (1) Brachial artery palpated, if cuff is to be reapplied
____ (2) Wheel of the RZ is spun downward several strokes (valve OPEN)
____ (3) Stethoscope in ears facing down and forward
____ (4) Bell over artery, without cuff or tubing contact
____ (5) Cuff inflated quickly, smoothly to 180 mmHg or to the peak inflation pressure, whichever is greater
____ (6) This pressure is maintained for 5 seconds
____ (7) Valve is turned to CLOSE
____ (8) Deflation at 2 mmHg/second to 10 mmHg below K5
____ (9) Cuff quickly and completely deflated
____ (10) Cuff disconnected
____ (11) Recording of SBP, DBP and "zero"
____ (12) Math not done until after third reading is completed

F. Between Readings

____ (1) Arm raised passively overhead for 5 seconds. Total 30 second rest
____ (2) Arm lowered and tubing reconnected

G. Second Blood Pressure Readings

____ (1) Conform with procedures as described in E above
____ (2) "Zero" values for all three readings subtracted using calculator

Passed: Yes ☐
No ☐
Master Trainer Staff ID# _____
Entered by (Staff ID) _____

BLOOD PRESSURE OBSERVATION CHECKLIST FORM ADMINISTERING INSTRUCTIONS

This form is required for BP observer certification, recertification and checks. It is to be completed by the BP certifier by observing the BP observer make a BP measurement. The measurement should be done on a non-study individual using a regular stethoscope. Do not complete this form for measurements made using the Y-stethoscope.

The certifier should not make any comments during the measurement.

The steps outlined should be done in the order indicated. Any departure from this sequence should be noted in the comments section of the forms.

STANDARD, RZ AND CUFFS
INSPECTION AND MAINTENANCE LOG
(to be completed every 6 months)

DATE	MANOMETER #	STAFF ID	SCREW CAPS	RECORD ZERO LEVELS (MIN & MAX)	MACHINE LEVEL?	BELLOWS VALVE (RZ)	GLASS COLUMN CLEAN?	MERCURY LEAKS?	CUFF(S)* FITTINGS & VALVES	**COMMENTS

*Check Cuff(s) with the machine. Techs should observe cuffs used in visits during use and repair/replace as needed.
**Minimum and Maximum zero level should be checked if readings >0 mmHg above posted.

QUARTERLY CLEANING, INSPECTION, AND COMPARISON LOG

DATE	MANOMETER #	STAFF ID	DID RZ AND STANDARD AGREE ON COMPARISON WITH Y CONNECTION?*	COMMENTS

*If not, explain discrepancy and repair plan under comments.

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

WEIGHT OBSERVATION CHECKLIST

Weight Certification (lbs)

____ (1) Scale zeroed correctly

____ (2) Participant in light, indoor clothing only, without shoes

____ (3) Participant standing in center of platform

____ (4) Measured to the nearest ¼ lb.

Passed: Yes ☐ No ☐

Master Trainer Staff ID# _____

WEIGHT OBSERVATION CHECKLIST FORM
ADMINISTERING INSTRUCTIONS

This form is required for weight technician certification, recertification and checks. It is to be completed by the weight trainer by observing the technician make a weight measurement.

The trainer should not make any comments during the measurement.

The steps outlined should be done in the order indicated. Any departure from this sequence should be noted in the comments section of the forms.

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

Initial Certification ☐ 1
12 Month Re-Cert. ☐ 2
Yearly Master Trainer Cert. ☐ 3
Re-Cert. requested by CC ☐ 4

Trainer ☐
Technician ☐

WEIGHT CERTIFICATION FORM

Person 1:

Weight (lb)

1) ___ ___ ___ . ___ ___
2) ___ ___ ___ . ___ ___

Average ___ ___ ___ . ___ ___

Repeat test if the two values are not within .5 lb of each other

Weight (lb)

3) ___ ___ ___ . ___ ___
4) ___ ___ ___ . ___ ___

Average ___ ___ ___ . ___ ___

Person 2:

Weight (lb)

1) ___ ___ ___ . ___ ___
2) ___ ___ ___ . ___ ___

Average ___ ___ ___ . ___ ___

Repeat test if the two values are not within .5 lb of each other

Weight (lb)

3) ___ ___ ___ . ___ ___
4) ___ ___ ___ . ___ ___

Average ___ ___ ___ . ___ ___

Passed: Yes ☐
No ☐
Master Trainer Staff ID# _____
Entered by (Staff ID) _____

Check one:
Kilograms ❑
Pounds ❑

WEIGHT SCALE (S): ACCURACY CHECK AND YEARLY CERTIFICATION LOG

(to be completed quarterly)

Date	Scale #	Tech Initials	Tech ID	Person Wt	Weight of mass added (20-30)	Person Wt + mass	Scale Reading*	Weight of mass added (40-50)	Person Wt + mass	Scale Reading*	Yearly Certification**	Comments

mass = amount of weight added to scale (either in Kgs or lbs)

* Please describe measures taken to correct discrepancies between Person Wt and mass added, under Comments.

** Place date in this column to indicate when yearly certification by the Bureau of Weights and Measures or equivalent body was completed. Documentation should be on file at the clinic.

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

HEIGHT OBSERVATION CHECKLIST

Height Certification (cms)

____(1) Shoes and headgear removed, heels together, feet flat on the floor

____(2) Participant looking straight ahead with his/her head in the Frankfort horizontal plane

____(3) Head of the person taking the measurement in the same horizontal plane as the participant

____(4) Height board brought down snugly (as opposed to tightly) on top of participant's head

____(5) Measured to the nearest .1 cm

Passed: Yes ☐ No ☐
Master Trainer Staff ID# _____

HEIGHT OBSERVATION CHECKLIST FORM
ADMINISTERING INSTRUCTIONS

This form is required for height technician certification, recertification and checks. It is to be completed by the height trainer by observing the height observer make a height measurement.

The trainer should not make any comments during the measurement.

The steps outlined should be done in the order indicated. Any departure from this sequence should be noted in the comments section of the forms.

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

Initial Certification ☐ 1
12 Month Re-Cert. ☐ 2
Yearly Master Trainer Cert. ☐ 3
Re-Cert. requested by CC ☐ 4

Trainer ☐
Technician ☐

HEIGHT CERTIFICATION FORM

Person 1:

Height (cm)

1) ___ ___ ___ . ___
2) ___ ___ ___ . ___

Average ___ ___ ___ . ___

Repeat test if the two values are not within 1 cm of each other

Height (cm)

3) ___ ___ ___ . ___
4) ___ ___ ___ . ___

Average ___ ___ ___ . ___

Person 2:

Height (cm)

1) ___ ___ ___ . ___
2) ___ ___ ___ . ___

Average ___ ___ ___ . ___

Repeat test if the two values are not within 1 cm of each other

Height (cm)

3) ___ ___ ___ . ___
4) ___ ___ ___ . ___

Average ___ ___ ___ . ___

Passed: Yes ☐ No ☐

Master Trainer Staff ID# _____

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

WAIST CIRCUMFERENCE OBSERVATION CHECKLIST

Waist circumference Certification (cm)

____(1) Landmark of 1 cm above the top of the navel was measured and marked

____(2) Tape remained horizontal during measurement

____(3) Technician gave instructions to participant regarding breathing and tightening of abdomen during measurement

____(4) Measurement was done at the end of normal expiration of air

____(5) Technician took two measurements

____(6) Technician removed tape between two measurements

Passed: Yes ☐ No ☐

Master Trainer Staff ID# _____

WAIST CIRCUMFERENCE OBSERVATION CHECKLIST FORM ADMINISTERING INSTRUCTIONS

This form is required for waist circumference technician certification, recertification and checks. It is to be completed by the waist circumference trainer by observing the waist circumference technician make a waist circumference measurement.

The trainer should not make any comments during the measurement.

The steps outlined should be done in the order indicated. Any departure from this sequence should be noted in the comments section of the forms.

Name (trainee) _____
Staff ID # _____
Date _____/_____/_____

Initial Certification ☐ 1
12 Month Re-Cert. ☐ 2
Yearly Master Trainer Cert. ☐ 3
Re-Cert. requested by CC ☐ 4

Trainer ☐
Technician ☐

WAIST CIRCUMFERENCE CERTIFICATION FORM

Person 1:

Waist Circumference (cm)
1) ___ ___ ___ . ___
2) ___ ___ ___ . ___

Average ___ ___ ___ . ___

Repeat test if the two values are not within two cm of each other.

Waist Circumference (cm)
3) ___ ___ ___ . ___
4) ___ ___ ___ . ___

Average ___ ___ ___ . ___

Person 2:

Waist Circumference (cm)
1) ___ ___ ___ . ___
2) ___ ___ ___ . ___

Average ___ ___ ___ . ___

Repeat test if the two values are not within two cm of each other.

Waist Circumference (cm)
3) ___ ___ ___ . ___
4) ___ ___ ___ . ___

Average ___ ___ ___ . ___

Passed: Yes ☐ No ☐
Master Trainer Staff ID# _____

Shipping Log

Ship to: Carrie Meeks
PREMIER Coordinating Center
Kaiser Permanente Center for Health Research
3800 N Interstate Avenue
Portland, OR 97227-1098

Phone: (503) 528 - 3978
FAX: (503) 528 - 3994

From: ❑ Baltimore ❑ Baton Rouge ❑ Durham ❑ Portland

Ship Date: __ __/__ __/__ __ Shipped by (Staff ID): _____

Total Pages Faxed: ____ (including 1 cover sheet)

or Via: Regular Mail ___ UPS/Fed. Ex. 2-day ___
UPS/Fed. Ex. Overnight ___ Hand-Delivery ___

Quantity Sent	Description	Coordinating Center Use # Received	Staff ID
_____	Certification Forms	_____	_____
_____	BP Escape Forms	_____	_____
_____	Adverse Event Forms	_____	_____
_____	Forms for validation	_____	_____
_____	Database corrections	_____	_____
_____	Other: _____	_____	_____
_____	Other: _____	_____	_____

Comments: _____
_____

Coordinating Center Use: Date Received: __ __/__ __/__ __ Received by (Staff ID):_____

Comments: _____
_____

Staff ID_____
Date_____
Test #_____

PREMIER VIDEOTAPE TEST SHEET

TEST #1		TEST #2	
1.	_____ / _____	1.	_____ / _____
2.	_____ / _____	2.	_____ / _____
3.	_____ / _____	3.	_____ / _____
4.	_____ / _____	4.	_____ / _____
5.	_____ / _____	5.	_____ / _____
6.	_____ / _____	6.	_____ / _____
7.	_____ / _____		
8.	_____ / _____		
9.	_____ / _____	9.	_____ / _____
10.	_____ / _____	10.	_____ / _____
11.	_____ / _____	11.	_____ / _____
12.	_____ / _____		

Passed: Yes ☐
No ☐
Master Trainer Staff ID# _____
Entered by (Staff ID) _____

STANDARD, RZ MANOMETER & CUFFS INSPECTION AND MAINTENANCE LOG

(to be completed Quarterly)

DATE	MANOMETER #	STAFF ID	CUFF(S)* FITTINGS & VALVES	RECORD MERCURY LEVEL	TUBINGS & FITTING	GLASS COL-UMN CLEAN?	MERCURY LEAKS?	COMMENTS

*Check Cuff(s) with the machine. Techs should observe cuffs used in visits during use and repair/replace as needed.

STANDARD MANOMETER QUARTERLY CLEANING AND INSPECTION LOG

DATE	MANOMETER #	STAFF	COMMENTS

STADIOMETER ACCURACY CHECK

Check Twice Annually:

Date	Initials	Tech ID	Rod length	Stadiometer reading	Recalibration required?	If yes, was recalibration successful?
					❑ yes ❑ no	
					❑ yes ❑ no	
					❑ yes ❑ no	
					❑ yes ❑ no	
					❑ yes ❑ no	
					❑ yes ❑ no	
					❑ yes ❑ no	
					❑ yes ❑ no	
					❑ yes ❑ no	
					❑ yes ❑ no	
					❑ yes ❑ no	
					❑ yes ❑ no	

If stadiometer cannot be successfully calibrated, do not use this device for participant height measurements.

Trainee (Staff ID): _____
Date: __ __ / __ __ / __ __ __ __

DATA ENTRY CERTIFICATION FORM

Centralized Training

___ Attended training session

___ Entered practice data

___ Passed written test

___ Completed entry of forms packet

- ___ Arranged forms in correct order
- ___ Entered all appropriate forms
- ___ Flagged problem forms appropriately
- ___ Filled out Staff ID on all forms that were entered
- ___ Resulting data was correct

___ Logged off computer

Trainer (staff ID): _____

Trainee (Staff ID): _____
Date: __ __ / __ __ / __ __ __ __

Data Entry Certification Form

Site-Based Training

___ Viewed training slide show

___ Read data entry users manual

___ Passed written test

___ Observed certified technician entering 10+ forms (3+ blood pressures)*

___ Observed by certified technician while entering 10+ forms (3+ blood pressures)*

___ Copied the forms entered by trainee and faxed to the Data Clerk at the CC

___ CC confirmed that forms were entered correctly

* If person is being trained for intervention data only, do 10+ forms with 3+ of each intervention form.

Trainer (staff ID): _____

Trainee (Staff ID): _____
Date: __ __ / __ __ / __ __ __ __

DATA MANAGEMENT CERTIFICATION FORM

Centralized Training

___ Attended training session

___ Completed training plan for form #4

___ Completed form review worksheet

___ Completed review of sample form #1

___ Completed review of sample form #12

___ Passed written test

___ Passed Data Management System hands on test

___ Logged off computer

Trainer (staff ID): _____

Trainee (Staff ID): _____
Date: __ __ / __ __ / __ __ __ __

Data Management Certification Form

Site-Based Training

___ Viewed training slide show

___ Read data management system users manual

___ Completed training plan for form #4

___ Completed form review worksheet

___ Completed review of sample form #1

___ Completed review of sample form #12

___ Spent one day shadowing the currently certified Data Manager

___ Passed written test

___ Passed Data Management System hands on test

Trainer (staff ID): _____

Trainee ID: _____
Date: __ __ / __ __ / __ __ __ __

Initial Certification ☐ 1
12 Month Re-Cert. ☐ 2
Yearly Master Trainer Cert. ☐ 3
Re-Cert. requested by CC ☐ 4

PHYSICAL ACTIVITY RECALL CERTIFICATION FORM

Evaluation Method:
- ☐ **Live Interview**
- ☐ **Audiotape certification**
- ☐ **Audiotape QC**

Participant Orientation to PAR	**Acceptable**	**Marginal**	**Unacceptable**
Provides thorough explanation before beginning the interview (previous 7 days, actual activities, explains sequence of recall, acknowledges but excludes "light" activity)	☐	☐	☐
Defines "moderate", "hard", and "very hard" activity according to protocol	☐	☐	☐
Defines "morning", "afternoon", and "evening" according to protocol	☐	☐	☐
Sleep/Nap Times			
Defines "sleep" according to protocol (time got into bed until time got out of bed)	☐	☐	☐
Reviews sleep habits in a clear, efficient manner ("Get into bed & out of bed at about same time each day", differentiate weekends/non-work days)	☐	☐	☐
Asks about naps or time spent lying down	☐	☐	☐

Interviewing Technique	**Acceptable**	**Marginal**	**Unacceptable**
Uses cues to aid the recall process ("What did you do that day?" "You said you had company that day?" use of holidays/local events)	☐	☐	☐
Queries activities by segment of the day (morning, afternoon, evening)	☐	☐	☐
Accurate determination of activity intensity using protocol guidelines	☐	☐	☐
Accurate determination of length of activity (At least 10 min in duration, queries for "breaks" in activity)	☐	☐	☐
Correct documentation of intermittent/ discontinuous activity (At least 10 min of single intensity in one segment of the day (or within 1.5 hr time span)	☐	☐	☐
Overall efficiency of probing technique	☐	☐	☐
Documentation			
Rounds sleep to nearest 15 min	☐	☐	☐
Records sleep on proper day	☐	☐	☐
Correct summation of sleep/nap time	☐	☐	☐
Correct labeling of days of the week	☐	☐	☐
Identifies weekends/non-work days	☐	☐	☐

General Comments

Action Items

PAR Certification Status:

Passed ❑ 1
Failed ❑ 2

Master Trainer ID_____

Trainee (Staff ID): _____
Date: __ __ / __ __ / __ __ __ __

Initial Certification ☐ 1
12 Month Re-Cert. ☐ 2
Yearly Master Trainer Cert. ☐ 3
Re-Cert. requested by CC ☐ 4

FITNESS TEST CERTIFICATION FORM

Trainee has successfully demonstrated the following skills or competencies for the fitness test (treadmill) protocol:

_____ Explanation of test objective

_____ Explanation of testing safety procedures

_____ Interpretation of RPE chart

_____ Pre-test calculations (age predicted MHR, 85% MHR)

_____ Test preparation procedures (heart rate monitor, BP cuff placement, resting BP and pulse)

_____ Selection of pace and incline appropriate for participant's age and gender

_____ Measurement of exercise blood pressure

_____ Measurement of exercise pulse

_____ Measurement of exercise intensity

_____ Appropriate and timely adjustment of treadmill pace and incline

_____ Accurate completion of Fitness Test Form

Outcome:
Passed ❑ 1
Failed ❑ 2

Trainer ID: _____

TREADMILL QC LOG

Month/Year	Treadmill raised to highest incline and vacuumed underneath	Tracking spring checked	Wax nozzle checked	Speed calibrated	Incline calibrated
	Date / initials	*Date / initials*	*Date / initials*	*Date / initials*	*Date / initials*

Treadmill QC Log

Overview

The Treadmill QC Form is used by clinic staff to record the maintenance checks on the treadmill machine and to track any problems that may occur.

QC Instructions

1. Raise each treadmill to the highest incline and vacuum underneath at least twice a month.
2. Raise each treadmill to the highest incline and check the tracking spring twice a month. The tracking spring keeps the belt appropriately aligned on the treadmill.
3. Raise each treadmill to the highest incline and check the wax nozzle once a month. The wax nozzle keeps the belt properly lubricated.
4. Keep a maintenance journal and record and date any problems that may occur.
5. Check the outlets and make sure each treadmill is securely plugged in before each usage.
6. Perform calibration procedures every three months or 50 hours.
7. Follow any additional maintenance procedures suggested in your treadmill's manual of operations.

Central Lab Freezer Log – Blood and Urine Samples

(Used to temporarily track locations of samples
in freezer. Do not enter form or send it with shipment)

Box number: _____

43	44	45	46	47	48	49
36	37	38	39	40	41	42
29	30	31	32	33	34	35
22	23	24	25	26	27	28
15	16	17	18	19	20	21
8	9	10	11	12	13	14
1	2	3	4	5	6	7

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					

Central Lab Freezer Log – Blood and Urine Samples

(Used to temporarily track locations of samples
in freezer. Do not enter form or send it with shipment)

Box number: _____

43	44	45	46	47	48	49
36	37	38	39	40	41	42
29	30	31	32	33	34	35
22	23	24	25	26	27	28
15	16	17	18	19	20	21
8	9	10	11	12	13	14
1	2	3	4	5	6	7

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					

Central Lab Freezer Log – Blood and Urine Samples

(Used to temporarily track locations of samples
in freezer. Do not enter form or send it with shipment)

Box number: _____

43	44	45	46	47	48	49
36	37	38	39	40	41	42
29	30	31	32	33	34	35
22	23	24	25	26	27	28
15	16	17	18	19	20	21
8	9	10	11	12	13	14
1	2	3	4	5	6	7

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
35					
36					
37					
38					
39					
40					
41					
42					
43					
44					
45					
46					
47					
48					
49					

Storage Lab Freezer Log – Urine Samples

(Used to temporarily track locations of samples
in freezer. Do not enter form or send it with shipment)

Box number: _____

43	44	45	46	47	48	49
36	37	38	39	40	41	42
29	30	31	32	33	34	35
22	23	24	25	26	27	28
15	16	17	18	19	20	21
8	9	10	11	12	13	14
1	2	3	4	5	6	7

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					

Storage Lab Freezer Log – Urine Samples

(Used to temporarily track locations of samples
in freezer. Do not enter form or send it with shipment)

43	44	45	46	47	48	49
36	37	38	39	40	41	42
29	30	31	32	33	34	35
22	23	24	25	26	27	28
15	16	17	18	19	20	21
8	9	10	11	12	13	14
1	2	3	4	5	6	7

Box number: _____

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					

Storage Lab Freezer Log – Urine Samples

(Used to temporarily track locations of samples
in freezer. Do not enter form or send it with shipment)

43	44	45	46	47	48	49
36	37	38	39	40	41	42
29	30	31	32	33	34	35
22	23	24	25	26	27	28
15	16	17	18	19	20	21
8	9	10	11	12	13	14
1	2	3	4	5	6	7

Box number: _____

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
35					
36					
37					
38					
39					
40					
41					
42					
43					
44					
45					
46					
47					
48					
49					

Storage Lab Freezer Log – Blood Samples

(Used to temporarily track locations of samples in freezer. Do not enter form or send it with shipment)

Box number: _____

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
1					(bottom left)
2					(bottom, second from left)
3					
4					
5					
6					
7					
8					
9					
10					
11					(row 2)
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					(row 3)
22					
23					
24					
25					

Storage Lab Freezer Log – Blood Samples

(Used to temporarily track locations of samples
in freezer. Do not enter form or send it with shipment)

Box number: _____

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
26					
27					
28					
29					
30					
31					(row 4)
32					
33					
34					
35					
36					
37					
38					
39					
40					
41					(row 5)
42					
43					
44					
45					
46					
47					
48					
49					
50					

Storage Lab Freezer Log – Blood Samples

(Used to temporarily track locations of samples
in freezer. Do not enter form or send it with shipment)

Box number: _____

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
51					(row 6)
52					
53					
54					
55					
56					
57					
58					
59					
60					
61					(row 7)
62					
63					
64					
65					
66					
67					
68					
69					
70					
71					(row 8)
72					
73					
74					
75					

Storage Lab Freezer Log – Blood Samples

(Used to temporarily track locations of samples in freezer. Do not enter form or send it with shipment)

Box number: _____

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
76					
77					
78					
79					
80					
81					(row 9)
82					
83					
84					
85					
86					
87					
88					
89					
90					(row 10)
91					
92					
93					
94					
95					
96					
97					
98					
99					
100					(top right corner)

Storage Lab Freezer Log – Blood Samples

(Used to temporarily track locations of samples
in freezer. Do not enter form or send it with shipment)

Box number: _____

Slot #	Participant ID	Visit	Collect Date	Sample Type	Comment
1					(bottom left)
2					(bottom, second from left)
3					
4					
5					
6					
7					
8					
9					
10					
11					(row 2)
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					(row 3)
22					
23					
24					
25					

Date: _____
Staff Name: _____
Staff ID: _____

Training and Certification Checklist for Intervention-related Screening Forms and Activities

1. ❑ Read the following materials:

PREMIER Manual of Procedures

- ❑ Chapter 6, Prescreening visit (PSV)
- ❑ Chapter 7, Screening Visit 1 (SV1)
- ❑ Chapter 8, Screening Visit 2 (SV2)
- ❑ Chapter 9, Screening Visit 3 (SV3)
- ❑ Chapter 19, 24-Hour Recalls

PREMIER Forms and Instructions

- ❑ Prescreen Eligibility Form (Form #01)
- ❑ Diet and Physical Activity Change Checklist (Form #08)
- ❑ SV1 Visit Form (Form #3)
- ❑ SV1/SV2 Activity Fact Sheet (Form #106)
- ❑ SV2 Visit Form (Form #10)
- ❑ Food Record and Instruction (Form #200)
- ❑ SV3 Visit Form (Form #15)
- ❑ SV3 Activity Fact Sheet (Form #107)
- ❑ Screening Motivational Session Notes (Form #41)
- ❑ Diet and Physical Activity Change Questionnaire (Form #40)
- ❑ 24-Hour Diet Recall Instruction Sheet (Form #104)
- ❑ Diet Recall Convenient Time Schedule (Form #105)

2. ❑ Complete the motivational assessment training session.

3. ❑ Be observed and evaluated by the Intervention Screening trainer on administering and reviewing the following forms:

- ❑ Screening Motivational Session Notes (Form #41)
- ❑ Diet and Physical Activity Change Questionnaire (Form #40)

Passed: Yes _____
No _____

Trainer Staff ID# _____

Instructions for completing the checklist of Training/Certification for Intervention-related Screening

The checklist of Training/Certification for Intervention-related Screenings (Form # 331) is used to ensure that a trainee has acquired the skills and information to properly conduct screening activities related to PREMIER interventions.

All staff who will conduct the intervention-related screening activities are trained and (re) certified annually. The lead trainer ensures that the trainee has read the materials listed, demonstrated appropriate skills and/or completed designated tests before certification is granted. After completing the training, complete the form as follows:

1. In the upper right box, record the name of the trainee. Record the trainee's PREMIER ID number. Record the date certification is complete.

2. Check the box when the trainee completes each activity satisfactorily.

3. In bottom right box, mark yes or no depending on the outcome of the training/ certification process.

4. Record the lead trainer's PREMIER ID number.

5. Store the form with other training/certification forms for your site for audit purposes. Mail a copy of the form to the Coordinating Center for each newly trained/recertified staff member.

Proposal for a PREMIER Paper

Submit to PC Chair (David Harsha, FAX: 225-763-3045)
and to CC (Linda Tellis, FAX: 503-335-2428)

TO BE COMPLETED BY THE PROPOSER:

Date Submitted: _____ Clinical Center: _____

Proposer's Name*: _____ Phone: _____

Proposed Paper Title: _____

_____

Short title (3-10 words): _____

Research question:

Primary variables to be used in the analysis:

Do you plan to make a presentation at a scientific meeting based on these results?

Y ____ N ____

If yes, when is the abstract due? _____

Other authors who you know will be working on the analysis?

_____

Analysis/Data Release Plans

Note: *This information for CC planning purposes only. You may request analyses or data releases later even if not noted on this form.*

At this time are you planning to have any analyses performed at the coordinating center? ❑ Yes ❑ No

Do you plan to request a data release? ❑ Yes ❑ No

**If approved, the proposer will serve as convener of the writing committee. The committee will select the chair after it has convened.*

Instructions for PREMIER Form 400

Use Form 400 to propose a new PREMIER paper. This form must include:

- The proposer's name and clinical center,
- The title of the proposal (long and short versions),
- A brief description of the research question and the primary variables to be used in the analysis.

Proposers also note whether a presentation at a scientific meeting is planned and, if applicable, the abstract due date, the names of other interested authors who will be working on the analysis, and any known plans for analyses or custom data releases to be preformed by the Coordinating Center. These analysis plans may change as an approved paper develops.

Submit Form 400 by FAX or ELECTRONICALLY to the Publications Committee chair (David Harsha) and to the Coordinating Center data clerk (Carrie Meeks). The Coordinating Center will then circulate Form 400 to the publications committee (or post on the web), along with a ballot contained on Form 401. Balloting will be conducted electronically at the PREMIER web site or, if necessary, by FAX. The deadline for responses to proposed new papers is 14 days. Non-response is considered approval.

To access electronic balloting, Publications Committee members log onto the PREMIER web site, select 'Publication Committee', then select 'Vote on Paper Proposal', at the bottom of the papers description, select 'Go to Voting page for Paper Proposal', enter their vote, and select 'submit vote'. This posts the vote for the CC to retrieve. Contact the CC if unable to access ballot on the web once notified of new proposal. The CC will either correct the web problem or FAX ballot.

Steps for conveners when scheduling first manuscript conference calls:

If your writing group includes someone from the project office:

1. Arrange a date for the call with your group
2. E-mail the date and time for the call to Eva
3. Eva will forward to her secretary, who will schedule the call.

If no one from the project office is in your writing group:

The CC will assist with scheduling and cover the cost of the first writing group call only:

1. Arrange a date for the call with your group
2. E-mail the date and time for the call to Linda Tellis at the CC

The CC will schedule this first call for the writing group. After that it is up to the chair to schedule the calls.

PC Review Form for a PREMIER Publication Proposal

Return completed form to the CC Project Data Clerk
(Linda Tellis, FAX: 503-335-2428)

Attached is Form 400 (Proposal for a PREMIER Paper) for a new PREMIER publication project. Please complete the items below and FAX your response as soon as possible (or enter on PREMIER web site if available). Include the names of other potential authors from your site. *Nonresponse will be considered approval after the approval deadline below.*

Approval deadline: _____

Project Title: _____

Reviewer's name: _____ Reviewer's Site: _____

_____ Approve _____ Disapprove _____ Need to discuss further

Comments (include any stipulations that might allow you to approve a project you feel needs more discussion, or disapproval as well as suggestions for improvement):

_____

_____

_____

_____

_____

_____

Other interested authors from your site:

_____

_____

Instructions for PREMIER Form 401

The PREMIER Coordinating Center uses Form 401 (PC Review form) to help facilitate timely PC approval of PREMIER paper proposals, which are submitted on Form 400 (Proposal for a PREMIER paper).

When the Coordinating Center receives a Form 400, the CC posts the information on the PREMIER internal web site and electronically notifies the Publications committee of the new proposed paper and the deadline for voting. A back-up to the web site will be to FAX Form 401 along with the Form 400 and any attachments, to the members of the PC. The approval deadline is 14 days after the form is posted or distributed.

PC members are responsible for notifying potential authors at their sites and informing the CC on Form 401. PC members who are not PREMIER PIs also notify their PI. The members of the PC cast their ballot electronically from the PREMIER web site or return Form 401 by FAX to the CC project data clerk within 14 days. Nonresponse is considered to be approval of the project.

To access electronic balloting, PC members need to log onto the PREMIER internal web site, select 'Publication Committee', then select 'Vote on Paper Proposal', at the bottom of the papers description, select 'Vote on Paper', enter their vote, and select 'submit vote'. This posts the vote for the CC to retrieve.

If no negative votes or concerns are raised, the project is considered approved. The CC contacts the PC chair and the convener with the results.

If negative votes or concerns have been raised, the PC chair notifies the CC and the convener once the project is approved or disapproved.

PREMIER Ancillary Study Request Form

Submit to D&A Chair (Laura Svetkey FAX: 919-419-5841)
to PC Chair (David Harsha FAX: 225-763-3045)
and to CC (Linda Tellis FAX: 503-335-2428)

TO BE COMPLETED BY INVESTIGATOR

Date Submitted:_____

Investigator's Name:_____

Clinical Center:_____

Project Title:_____

_____

Brief Description of Project (attached, 3 to 4 pages):

Please provide the following information:

1. Reason for doing study and questions to be asked.
2. Procedures to be employed and which patients will qualify.
3. Potential risks and procedures to be used to minimize these risks.
4. How much time will be required by each subject.
5. How will the study affect participant flow.
6. Will study require resources from the current grant?___Yes ___No
   If so, what are the resources?

Note: the following information is for CC planning purposes only. Analyses or data releases may be requested later even if not noted on this form.

At this time, are you planning to have any analyses performed at the CC? ___Yes ___No

Do you plan to request a data release? ___Yes ___No

NOTE: If a proposal is subsequently submitted to your IRB, you must send a copy of the IRB letter of approval to the CC.

TO BE COMPLETED BY CC:

Deadline for receiving comments:_____ (2 weeks)

Return form to CC (Tellis) FAX: 503-335-2428

TO BE COMPLETED BY D&A MEMBERS: Reviewer's Name: _____

_____ Approve _____ Disapprove _____ Need more information

Comments:_____

_____

Other interested collaborators from your site:

Instructions for PREMIER Form 402

The PREMIER Coordinating Center uses Form 402 (Ancillary Study Request Form) to help facilitate timely Design and Analysis Committee (D&A) approval of proposed PREMIER ancillary studies.

When the Coordinating Center receives a Form 402, the CC posts the information on the PREMIER web site and electronically notifies the D&A committee of the new proposed ancillary study and the deadline for voting. A back-up to the web site will be to FAX Form 402, along with any attachments, to the members of the D&A Committee. The approval deadline is 14 days after the form is posted or distributed.

D&A Committee members are responsible for notifying potential collaborators at their sites and informing the CC using Form 402. D&A Committee members who are not PREMIER PIs also notify their PI. The members of the D&A Committee cast their ballot electronically from the PREMIER web site or return Form 402, by FAX to the CC project data clerk within 14 days, or their nonresponse is considered to be approval of the ancillary.

To access electronic balloting, D&A members need to log onto the PREMIER web site, select 'Publication Committee', then select 'Vote on Ancillary/Paper Proposal', at the bottom of the papers description, select 'Go to Voting page for Ancillary/Paper Proposal', enter their vote, and select 'submit vote'. This posts the vote for the CC to retrieve. Contact the CC if unable to access ballot on the web once notified of new proposal. The CC will either correct the web problem or FAX ballot.

If no negative votes or concerns are raised, the project is considered approved by the D&A Committee. The CC contacts the D&A chair and the convener with the results.

If negative votes or concerns have been raised, the D&A chair notifies the CC and the convener once the project is approved or disapproved.

Once approved by the D&A, ancillary studies are reviewed by the Steering Committee.

PREMIER Data Analysis Request Form

Submit to CC (Gayle Meltesen, FAX: 503-528-3994)

Paper #:_____(required if approved paper)
Short title: _____
Request Date: _____
Requester: _____ Staff ID: _____
Continuation of another request: Y___N___ Previous Req. #: _____

Is this request for an abstract submission? Y___N___
If yes, what is the abstract due date? _____

Summary of Request: (include objective, outcome measures, and statistical methods)

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Population (Define by checkboxes and notes below):

Select Cohort ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ All
Include prematurely terminated participants? ❑ Yes ❑ No
Include participants suspended from intervention? ❑ Yes ❑ No
Phase of Intervention (if applicable) ❑ 1 ❑ 2 ❑ 3
Include Treatment Groups ❑ A ❑ B ❑ C

_____
_____
_____
_____
_____

Please use the Coordinating Center Analysis Guide to complete the following.

Datasets needed: (list across top row of table)
Variables needed: (list under each data set)

New variables/calculations: _____
_____
_____
_____
_____
_____
_____
_____
_____

Tables, figures, and graph mock-ups must be created before the work begins on this request. Have you included these with your request? _____ yes
_____ no

Instructions for the Data Analysis Request Form

The step by step instructions are given below for filling out a data analysis request form. This form has to be filled out before any analysis will take place. Following these instructions are two sample requests that have been filled to help you in this process.

Paper #:	If this is an analysis request for an approved paper, then the paper number is **required**. If this is an exploratory analysis, then a number will be assigned upon submission of this form to the CC.
Request Date:	Self-explanatory
Requester:	Self-explanatory
Staff ID:	Fill in your staff ID. These are the same IDs that have been assigned previously. See your clinic coordinator if you do not know your staff ID number.
Continuation:	Circle Y if you are requesting additional analyses from an analysis request that has already gone through the request system. Circle N if this is an original request.
Previous Req. #:	Answer this only if you answered yes to continuation. Write in the number that was assigned to the previous analyses. Leave blank if this is an original request.
Abstract	Circle Y if this is for an abstract submission and if so, write abstract due date. If this is not an abstract submission, circle N.
Summary of Req:	Write a summary of the data analysis request in this section. This should include the objective, the outcome measures and statistical methods. Attach any additional information if more space is needed.
Population:	Define the population by checking the appropriate boxes and by writing in other population parameters needed for this request.
Datasets Needed:	Using the analysis guide, list the datasets needed for this analysis request. List the dataset names across the top row of the blank table.
Variables Needed:	Using the analysis guide, list the variables under the appropriate dataset that you need in your analysis**.**
New Variables:	Describe any new variables or calculations that you need to have for this request. List the variables needed to create these variables.
Tables, Figures:	In order for us to begin this request, we need to have a clear picture of your vision of the endpoint. We need copies of any tables, figures and/or graphs that you want created for this request. Check yes, if they are attached.

SUBMIT COMPLETED FORM TO GAYLE MELTESEN AT THE CC (FAX: 503-528-3994)

PREMIER Data Release Request Form

Submit to CC (Gayle Meltesen, FAX: 503-528-3994)

This form is to be used to request release of data for conducting your own analysis.

Paper #: _____

Short title: _____

Request Date: _____

Requester: _____ Staff ID: _____

Approved by SC (date):_____

Summary of Request:

_____
_____
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_____

Population: _____
_____
_____
_____

Please use the Coordinating Center Analysis Guide to complete the following.

Datasets needed: (list across top row of table)
Variables needed: (list under each dataset)

Format:
_____DBF
_____ASCII

To ensure that people are receiving the correct data for their request, these data should not be used by or given to anyone other than the requester.

Instructions for the Data Release Form

The step by step instructions are given below for filling out a data release form.

Paper #:	**Required**
Request Date:	Self-explanatory
Requester:	Self-explanatory
Staff ID:	Fill in your staff ID. These are the same IDs that have been assigned previously. See your clinic coordinator if you do not know your staff ID number.
Summary of Req:	Write a brief summary of the research questions you are trying to answer. This will help us assess your data needs.
Population:	Write in the population from this request. (e.g., participants entering randomization)
Datasets Needed:	Using the analysis guide, list the datasets needed for this analysis request. List the dataset names across the top row of the blank table.
Variables Needed:	Using the analysis guide, list the variables under the appropriate dataset that you need in your analysis.
Format:	Choose a DBF or ASCII file format.

PREMIER Abstract Review Form

Submit directly to PC members
(Harsha, Stevens, Appel, Elmer, Svetkey Obarzanek, Vollmer, copy to Tellis @ CC)

TO BE COMPLETED BY THE AUTHOR:

Writing Group Sign-off: _____ Numbers Verified: _____

Date Submitted: _____ Manuscript #_____

Title of Abstract: _____

_____

Authors: _____

Date of abstract deadline: _____
(form must be submitted at least 5 working days prior to the abstract deadline)

Deadline for receiving comments: _____ (3 working days)

TO BE COMPLETED BY PC MEMBERS (or designated alternates, if unavailable) and returned to the PC Chair and CC.

Reviewer's Name:_____ Reviewer's Site:_____

Rating: _____ Approval

_____ Approval with suggestions for revision (do not wish to re-review)

_____ Approval only after appropriate revision (request re-review)

_____ Disapproval

Comments for Author:

Instructions for PREMIER Form #405

The PREMIER Coordinating Center uses Form 405, Abstract Review Form, to help support rapid review of PREMIER abstracts prior to submission for publication.

After obtaining sign-off from writing group members and at least 5 working days prior to the intended date of submission, requesters submit the abstract and a Form 405 directly to Publications Committee members and to the Project Office. The abstract is concurrently submitted to the Coordinating Center for numbers review.

Requesters complete the top part of Form 405: indicate writing group sign-off by initialing the form in the appropriate field, state date submitted, and manuscript number, title of abstract, list all authors, and note deadline for receiving comments.

Committee members complete the bottom section of the form showing whether or not the abstract is approved, note any comments for the author, and return the completed form directly to the Publications Committee chair (Harsha: FAX 225-763-3045) and a copy to the Coordinating Center project data clerk (Meeks: FAX 503-528-3994) within three working days of receiving the Form 405. Abstracts may not be submitted for publication until (1) numbers are verified by the CC, and (2) the requester is informed by the chair that the abstract was approved.

PREMIER Manuscript Review Form

Submit to PC Chair (David Harsha, FAX: 225-763-3045)
and to CC Data Clerk (Linda Tellis FAX: 503-335-2428)

TO BE COMPLETED BY THE LEAD AUTHOR:

Writing Group sign off: _____ Numbers Verified: _____

Date Submitted to PC: _____ Manuscript number _____

Title of Manuscript: _____

_____

Authors: _____

Deadline for receiving comments:_____ (30 days)

Return form to PC Chair and CC

TO BE COMPLETED BY PC MEMBERS:

Reviewer's Name:_____ Reviewer's Site: _____

Rating: _____ Approval

_____ Approval with suggestions for revision (do not wish to re-review)

_____ Approval only after appropriate revision (request re-review)

_____ Disapproval

Comments for Author:

Instructions for PREMIER Form 406

The PREMIER Coordinating Center uses Form 406, Manuscript Review Form, to help facilitate timely review of PREMIER manuscripts prior to submission for publication.

After obtaining sign-off from writing group members, lead authors submit the manuscript to the Coordinating Center data manager for numbers review at least one week prior to submission to the Publications Committee for approval.

Once numbers are verified, the lead author sends a copy of the corrected manuscript to the Publications Committee chair and to the Coordinating Center project data clerk along with a Form #406, Manuscript Review Form. Lead authors complete the top part of the form: indicate writing group sign-off and numbers review completion by initiating the form in the appropriate fields, state date submitted, title of manuscript and manuscript number, and list all authors.

The Coordinating Center will add the deadline for receiving comments to the form, and distribute a copy of the form and manuscript to each Publications Committee member. and two copies to the NHLBI Project Scientist. The NHLBI Project Scientist submits the manuscript for NHLBI internal review, which can require up to six weeks. All manuscripts must be received by NHLBI. NHLBI approval is required only if there is an NHLBI author. Although PC approval and Project Office approval may be requested simultaneously, the PC chair may require a second PC review if the Project Office recommends substantive revisions.

Committee members complete the bottom section of the form showing whether or not the manuscript is approved, note any comments for the author, and return the completed form to the Coordinating Center project data clerk.