

**in**  
**Weight Loss Maintenance MOP**  
**Table of Contents**

Number	Description	Version /Date
<b>1</b>	<b>Introduction and Definitions</b>	<b>1.2 12/12/03</b>
1.1	Using the Manual of Operations	
<b>2</b>	<b>Organizational Structure and Contact Information</b>	<b>1.0 7/3/03</b>
2.1	Organizational Chart	
2.2	Steering Committee	
2.3	Sub Committees	
2.4	Coordinating Center	
2.5	Data and Safety Monitoring Board (DSMB)	
2.6	Project Office	
2.7	Clinical Sites	
2.8	Laboratories	
2.9	Recruitment, Administrative, and Data Management Websites	
<b>3</b>	<b>Trial Administration</b>	<b>1.7 9/18/07</b>
3.1	Trial Policies	
3.1.1	Protocol	
3.1.2	Protocol and Procedure Exceptions	
3.1.3	Institutional Review Board (IRB)	
3.1.4	Provision of Medical Care to Participants	
3.1.5	Disclosure of Study Results	
3.1.6	Publicity	
3.1.7	Access to Stored Laboratory Specimens	
3.1.8	Archiving of Source Documents and Biological Specimens	
3.2	Publications and Ancillary Studies	
3.2.1	Initiation of a Writing Project	
3.2.2	To Propose a Paper	
3.2.3	Assigning Priorities	
3.2.4	Forming a Writing Group	
3.2.5	Submission of Analysis Requests	
3.2.6	Approval of Abstracts	
3.2.7	Approval of Manuscripts	
3.2.8	Acceptance of Abstracts and Manuscripts	
3.2.9	Authorship	
3.2.10	Ancillary Studies	
3.2.11	Paper Monitoring	
3.2.12	Release of Data for Public Access	
3.3	Outcomes and Adjudication	
3.4	Unblinding	
<b>4</b>	<b>Requirements for Clinical Sites</b>	<b>1.3 4/7/05</b>
4.1	IRB	
4.1.1	Principles of Informed Consent	
4.1.2	Process of Obtaining Informed Consent	

4.1.3	Summary of Site-Specific Consent Procedures		
4.1.4	Assurance of Informed Consent		
4.1.5	Confidentiality		
4.1.6	Data Integrity		
4.1.7	Risks		
4.1.8	Benefits		
4.2	Internet Access for Study Staff		
4.3	Equipment Calibrations and QC		
4.3.1	Scale		
4.3.2	Stadiometers		
4.3.3	Ambulatory Blood Pressure Monitor (ABPM)		
4.3.4	Accelerometer		
4.4	Staff Training and Certification		
4.4.1	Clinic Staff		
4.4.2	Phase I Weight Loss Staff		
<b>5</b>	<b>Eligibility and Recruitment</b>	<b>1.2</b>	<b>12/26/03</b>
5.1	Recruitment Targets		
5.2	Randomization into Phase II		
<b>6</b>	<b>Clinic Visits</b>	<b>1.5</b>	<b>11/21/05</b>
6.1	Pre-Visit Communications		
6.2	Offsite Data Collection		
6.3	Participant Closeout		
6.4	Pre-Screening Visit (PSV)		
6.5	Screening Visits		
6.6	Motivational Assessment		
6.7	Phase I Registration		
6.8	Baseline Visits		
6.9	Randomization Visit		
6.10	6-Month Visit		
6.11	12-Month Visit		
6.12	18-Month Visit		
6.13	24-Month Visit		
6.14	30-Month Visit		
<b>7</b>	<b>Measurements</b>	<b>1.10</b>	<b>9/13/06</b>
7.1	Visit and Measurement Priorities		
7.2	Height		
7.3	Weight		
7.4	Blood Pressure		
7.5	Accelerometry		
7.5.1	Data Collection Standards		
7.5.2	Equipment		
7.5.3	Installation		
7.5.4	Creating a User Profile/Initializing the RT3		
7.5.5	Starting Data Collection		
7.5.6	Download Activity Data		
7.5.7	Troubleshooting		
7.5.8	Contact Information		

- 7.5.9 Accelerometer Activity Form (Form #121)
- 7.5.10 RT3 Manual
- 7.5.11 Review of RT3 CSV file
- 7.6 Laboratory Tests
- 7.7 FFQ Shipping

<b>8</b>	<b>Participant Safety and Adverse Events</b>	<b>1.5</b>	<b>2/12/07</b>
8.1	Safety Measures		
8.2	Serious Adverse Events		
<b>9</b>	<b>Phase 1 Weight Loss Program</b>		
9.1	Program Structure	<b>1.0</b>	<b>8/29/03</b>
	9.1.1 Program Goals		
	9.1.2 Program Format		
	9.1.3 Program Materials		
9.2	Program Implementation		
	9.2.1 Cultural Adaptation of the Intervention	<b>1.0</b>	<b>9/12/03</b>
	9.2.2 Calories Recommendations for Weight Loss	<b>1.0</b>	<b>8/29/03</b>
	9.2.3 Incorporating the DASH Diet	<b>1.0</b>	<b>9/12/03</b>
	9.2.4 Physical Activity Goals	<b>1.0</b>	<b>8/29/03</b>
	9.2.5 Guidelines For How to Facilitate Group Sessions	<b>1.0</b>	<b>9/12/03</b>
	9.2.6 Guidelines For Taste-It, Do-It, and Check-In Session Components	<b>1.0</b>	<b>8/29/03</b>
	9.2.7 Phase I Intervention Data Collection	<b>1.0</b>	<b>9/12/03</b>
9.3	Program Quality Assurance	<b>1.0</b>	<b>9/12/03</b>
	9.3.1 Quality Control		
	9.3.2 Triage System and Local Case Management		
	9.3.3 Participant Safety Issues		
9.4	Leader's Guides Session Outlines		
	LG Group Session TOC		
	G1	<b>1.0</b>	<b>7/30/03</b>
	G2	<b>1.1</b>	<b>12/30/03</b>
	G3	<b>1.0</b>	<b>7/30/03</b>
	G4	<b>1.0</b>	<b>7/30/03</b>
	G5	<b>1.1</b>	<b>12/30/03</b>
	G6	<b>1.0</b>	<b>7/30/03</b>
	G7	<b>1.0</b>	<b>7/30/03</b>
	G8	<b>1.0</b>	<b>7/30/03</b>
	G9	<b>1.0</b>	<b>7/30/03</b>
	G10	<b>1.0</b>	<b>7/30/03</b>
	G11	<b>1.0</b>	<b>7/30/03</b>
	G12	<b>1.0</b>	<b>7/30/03</b>
	G13	<b>1.0</b>	<b>7/30/03</b>
	G14	<b>1.0</b>	<b>7/30/03</b>
	G15	<b>1.0</b>	<b>7/30/03</b>
	G16	<b>1.0</b>	<b>7/30/03</b>
	G17	<b>1.0</b>	<b>7/30/03</b>
	G18	<b>1.0</b>	<b>7/30/03</b>
	G19	<b>1.0</b>	<b>7/30/03</b>
	G20	<b>1.0</b>	<b>7/30/03</b>

9.5	Leader's Guides Check-ins		
	• Check in Purpose	1.0	8/20/03
	• Question and Answer	1.0	7/31/03
	• Partnering Up For Action Planning and the Next Check-In	1.0	7/31/03
	• Ball Toss	1.0	7/31/03
	• Group Food Record/Self-Monitoring Check-In	1.0	7/31/03
	• Group Feedback Progress Check	1.0	7/31/03
	• MI Scale	1.0	7/31/03
	• Musical Chairs	1.0	7/31/03
	• Names In Bag	1.0	7/31/03
	• Partner Check-In	1.0	7/31/03
	• Participant Led Progress Check	1.0	7/31/03
	• Questions Concerns Challenges	1.0	7/31/03
	• Questions on Participant's Chairs	1.0	7/31/03
9.6	Leader's Guides Do Its!		
	• Purpose	1.0	8/20/03
	• Visit to a Fitness Center	1.0	7/31/03
	• Fitness Destination	1.0	7/31/03
	• Group Aerobic Class	1.0	7/31/03
	• Group Walk	1.0	7/31/03
	• Interval Training	1.0	7/31/03
	• Race Walking	1.0	7/31/03
	• Strength Training With Resistance Bands	1.0	7/31/03
	• Stretching	1.0	7/31/03
	• Exercise Videos	1.0	7/31/03
9.7	Leader's Guides Taste Its!		
	• Breakfast	1.0	7/31/03
	• Dash Diet	1.0	8/15/03
	• Healthy Alternative Desserts	1.0	7/31/03
	• Dinners	1.0	7/31/03
	• Dining Out/Fast Food	1.0	7/31/03
	• Lunch	1.0	7/31/03
	• Party Foods	1.0	7/31/03
	• Quick Meals	1.0	7/31/03
	• Taste-It Purpose	1.0	8/20/03

## **10 Phase II Intervention**

### **10.1 Phase II – PC Intervention**

10.1.1	Structure (Format and Materials)	1.2	8/11/05
10.1.2	Implementation (Contacts and Data Collection)	1.1	8/12/04
10.1.3	Quality Assurance	1.2	10/3/05
10.1.4	Leader's Guides: Randomization Visit	1.0	1/15/04
10.1.5	Leader's Guide: Telephone Contact	1.0	1/15/04
10.1.6	Leader's Guide: Face-to-Face Visit	1.1	1/21/04
10.1.7	Topics for Discussion Vignettes	1.0	1/15/04

•	Body Image	1.0	1/15/04
•	Keeping Your Calorie Intake Within Your Maintenance Goal	1.0	1/15/04
•	Changing Your Negative Thoughts	1.0	1/15/04
•	Energy Needs Revisited	1.0	1/15/04
•	Maintaining Family Commitment	1.0	1/15/04
•	Problem Solving	1.0	1/15/04
•	Relapse Prevention	1.0	1/15/04
•	Situational Triggers Related to Relapse	1.0	1/15/04
•	Social Support For Physical Activity Maintenance	1.0	1/15/04
•	Stay Motivated With Exercise	1.0	1/15/04
•	Deep Breathing For Stress Management	1.0	1/15/04
•	Time Management	1.0	1/15/04
10.1.8	Group Session Leader's Guide	1.0	2/2/05
10.1.9	PC Holiday Group Session Leader's Guide	1.0	8/11/05
<b>10.2</b>	<b>Phase II – Interactive Technology</b>		
10.2.1	Structure	1.0	1/30/04
10.2.2	Implementation of IT Intervention	1.2	8/11/05
10.2.3	Quality Assurance (Training, Case management, etc.)	1.0	1/30/04
10.2.4	IT Participant User's Guide	1.0	1/29/04
10.2.5	IT Randomization Leader's Guide	1.0	1/30/04
10.2.6	IT Re Orientation Leader's Guide	1.1	5/11/05
10.2.6a	IT Re Orientation Handout	1.0	5/11/05
<b>10.3</b>	<b>Phase II – Self Directed</b>		
10.3.0	Structure	1.0	2/2/05
10.3.1	Randomization Leader's Guide	1.0	1/2/04
10.3.2	12- and 30-month Follow-up Leader's Guide	1.0	1/6/05
<b>10.4</b>	<b>Phase II –Lifestyle Guidelines</b>	1.2	12/26/03
10.4.1	Phase II Lifestyle Guidelines		
10.4.2	Phase III Lifestyle Guidelines		
<b>10.5</b>	<b>Phase III –PC- Active</b>		
10.5.1	PC Active Transition Visit Leader's Guide	1.2	9/26/06
10.5.2	PC Active Structure	1.2	8/23/06
10.5.3	PC Active Implementation	1.1	11/24/06
10.5.4	PC Active QA	1.0	7/14/06
10.5.5	PC Active Booster #1 Leader's Guide	1.0	7/27/06
10.5.6	PC Active Booster #2 Leader's Guide	1.0	7/27/06
10.5.7	PC Active Booster #3 Leader's Guide	1.0	7/27/06
10.5.8	PC Active Booster #4 Leader's Guide	1.0	7/27/06
<b>10.6</b>	<b>Phase III –IT – Active</b>		
10.6.1	IT Active Transition Visit Leader's Guide		
10.6.2	IT Active Implementation	1.2	8/23/06
10.6.3	IT Active Structure	1.1	8/23/06
10.6.4	IT Active QA	1.1	7/13/06
10.6.5	IT Active Booster #1 Leader's Guide	1.0	7/27/06
10.6.6	IT Active Booster #2 Leader's Guide	1.0	7/27/06
10.6.7	IT Active Booster #3 Leader's Guide	1.0	7/27/06
10.6.8	IT Active Booster #4 Leader's Guide	1.0	7/27/06

<b>10.7</b>	<b>Phase III SD and Control Groups</b>		
10.7.1	Phase III Controls and Self-Directed Retention Visit Leader's Guide	<b>1.1</b>	<b>7/26/06</b>
<b>11</b>	<b>Communication &amp; Internet Websites</b>	<b>1.2</b>	<b>12/26/03</b>
11.1	Website for Recruitment Information		
11.2	Secure Websites: Study Administration, Randomization and Data Entry		
11.3	Secure Website: IT Intervention		
11.4	Secure Website: File Transfer System		
<b>12</b>	<b>Data Management</b>	<b>1.3</b>	<b>3/26/04</b>
12.1	Randomization into Phase II		
12.2	Data Entry Using the WLM Secure Website		
12.3	Procedure for WLM Study Participants to Submit Study ID to the Webtest Website for Internet Eligibility Requirements		
12.4	Procedure for Repeat Accelerometer		
12.5	WLM Accelerometer File Transfer Procedure		
12.6	Data Flow From Clinical Screening Forms to Phase I Intervention Forms		
12.7	Data Query Reports		
12.8	Participant Closeout		
12.9	Editing Data		
12.10	Missing or Overdue Forms		
12.11	Quality Control Methods		
12.12	Data Validation and Quality Assurance		
12.13	DEMA Instruction Sheet for New Staff Certification and Training		
<b>13</b>	<b>Forms</b>		
	Bundle 1: F106, F108, F205, F500		
	Bundle 2: F109-113, F121		
	Bundle 3: F104, F106, F116, F117, F204, F209		
	Bundle 4: F106, F108, F205, F500, F506, F400		
	Eligibility PAL (E-PAL)	<b>1.4</b>	<b>10/3/03</b>
	VPA PAL	<b>1.0</b>	<b>9/25/03</b>
13.1	Confidentiality of Data	<b>1.0</b>	<b>10/27/03</b>
13.2	Form Completion	<b>1.0</b>	<b>10/27/03</b>
13.3	Forms List		
	<b>Screening</b>		
	Form 100: Participant Contact Form	<b>1.0</b>	<b>5/20/03</b>
	Form 101A: PSV Form Participant ID Registration (interviewer administered)	<b>1.1</b>	<b>6/6/03</b>
	Form 101B: PSV Form Participant ID Registration (self administered)	<b>1.1</b>	<b>6/6/03</b>
	Form 102: Eligibility Questionnaire	<b>1.4</b>	<b>10/3/03</b>
	Form 103: Medication Tracking Form	<b>1.2</b>	<b>8/6/04</b>
	Form 104: Summary Medication Use Form	<b>1.7</b>	<b>12/13/05</b>
	Form 105: BMI Eligibility Form	<b>1.1</b>	<b>6/6/03</b>
	Form 106: Weight Form	<b>1.4</b>	<b>12/2/03</b>
	Form 107: Eligibility Follow-up Questionnaire	<b>1.1</b>	<b>10/29/03</b>
	Form 108: Rose Questionnaire—Angina	<b>1.2</b>	<b>2/24/06</b>
	Form 109: SF-36 Questionnaire	<b>1.0</b>	<b>6/2/03</b>
	Form 110: Social Support and Eating Habits Questionnaire	<b>1.0</b>	<b>6/2/03</b>

Form 111: Social Support and Exercise Questionnaire	1.0	6/2/03
Form 112: Perceived Stress Questionnaire	1.0	6/3/03
Form 113: Patient Health Questionnaire (PHQ-8)	1.2	3/29/05
Form 114: Depression Alert Form	1.1	6/2/03
Form 116: Accelerometry Form	1.1	6/4/03
Form 117: Lab Collection Form—Fasting Blood	1.3	7/16/03
Form 118: Motivational Assessment Interview	1.0	6/6/03
Form 119: Phase 1 Eligibility Review Form	1.4	1/29/04
Form 120: Physician Approval Form	1.3	2/24/06
Form 121: Physical Activity Form	1.3	12/12/03
Form 121B: Follow-Up Physical Activity Form	1.3	12/21/06
Form 122: Beliefs and Attitudes of WLM Participants	1.1	6/12/03
Form 122: Cover Letter		
Form 123: Perceptions of Participation in Clinical Research	1.2	6/30/03
Form 124: Weight Loss History Questionnaire	1.2	7/14/03
Form 125: Patient History Questionnaire	1.0	6/6/03
Form 126: Initial Phase I Group Assignment	1.1	6/25/03
Form 127: Internet Accessibility Form-Screening	1.0	1/30/04

#### **Phase 1 and at Baseline**

Form 200: Phase 1 Attendance/Weight Form	1.1	8/15/03
Form 201: Food and Fitness Diary Instructions	1.2	7/31/03
Form 202: Phase 1 Missed Group Session Form	1.2	8/15/03
Form 203: Baseline Eligibility Questionnaire	1.0	11/03/03
Form 204: Blood Pressure Form (Visit 1)	1.5	11/3/06
Form 205: Short Physical Activity Form	1.4	12/21/06
Form 206: Change of Group Assignment	1.0	8/15/03
Form 207: Change of Main Interventionist	1.0	8/15/03
Form 208: Phase II Eligibility Review Form	1.0	10/31/03
Form 209: Blood Pressure Form (Visit 2)	1.6	11/3/06
Form 210: Weight Management Strategies Questionnaire	1.2	12/21/06
Form 211: Berlin Sleep Questionnaire	1.4	2/19/07
Form 212: Phase III Eligibility Weight Form	1.1	4/27/06

#### **Intervention & Clinic Forms: Phase II: 300 & 400 series**

Form 300: PC Contact Data Form	1.5	10/6/06
Form 301: Local IT Case Management	1.2	10/05/06
Form 302: SD Follow-up Visit Form	1.3	12/21/06
Form 303: IT Intervention Orientation Assessment Form	1.0	1/30/04
Form 304: Phase II Extra Contacts	1.2	5/10/06
Form 305: IT Reorientation Visit	1.3	11/9/06
Form 306: Phase III Booster Group Attendance and Weight Form	1.1	10/20/06
Form 400: 6, 18 and 24 Month Visit Form	1.1	7/21/04
Form 401: 12 and 30 Month Visit Forms	1.0	12/15/04
Form 402: 30 Month & Phase III Eligibility Visit Form	1.1	4/27/06

#### **Adverse Event and Ad Hoc Forms**

Form 500 Medical Events Screening Form	1.7	4/24/06
Form 502: Study Suspension Form	1.6	6/9/06

Form 503: Participant Transfer Form	1.0	5/23/03
Form 504: Recruitment Activity Form (For Recruitment Committee use)	1.0	7/14/03
Form 505: Protocol Exception Form	1.1	4/15/04
Form 506: Hormone and Weight Loss Form	1.0	7/8/04

**Staff & Equipment Certification Forms:**

Form 600: Weight Certification Form	1.0	5/23/03
Form 601: Weight Observation Checklist	1.0	5/23/03
Form 602: Weight Scale(s) Accuracy Check and Yearly Certification Log	1.1	6/11/03
Form 603: Height Certification Form	1.0	5/23/03
Form 604: Height Observation Checklist	1.0	5/23/03
Form 605: Stadiometer Accuracy Check	1.0	5/20/03
Form 606: ABP Monitor Blood Pressure Certification Form	1.1	6/11/03
Form 607: Blood Pressure (ABPM) Observation Checklist	1.1	6/23/03
Form 608: Blood Pressure Written Examination (ABPM)	1.1	6/11/03
Form 608ak: Blood Pressure Test Answer Key <i>(sent to clinic coordinators only)</i>	1.1	6/13/03
Form 609: Space Lab Device and Cuffs Inspection and Maintenance Log	1.0	5/20/03
Form 610: Accelerometry Certification Form	1.2	6/20/03
Form 611: RT3 Written Test Question Set	1.3	4/25/06
Form 611ak: WLM RT3 Certification Test Answer Sheet <i>(sent to clinic coordinators only)</i>	1.1	4/10/04
Form 612: Data Entry and Data Management Certification Form	1.1	6/19/03
Form 613: Data Entry and Data Management Written Test	1.0	5/27/03
Form 613ak: Data Entry and Data Management Test answer key <i>(sent to clinic coordinators only)</i>	1.1	6/18/03

**Data Analysis & Publication Forms:**

Form 700: Proposal for a WLM Paper	1.1	1/9/05
Form 701: PASC Review Form for a WLM Publication Proposal	1.1	1/9/05
Form 702: WLM Manuscript Review Form (Ballot)	1.1	1/9/05
Form 703: WLM Ancillary Study Request Form	1.1	1/9/05
Form 704: WLM Abstract Review Form	1.1	1/9/05
Form 705: WLM Analysis Request Form	1.1	1/9/05
Form 706: WLM Data Release Request Form	1.1	1/9/05

**Other Forms**

5 Day Food Record		
Website Access/Staff ID Request Form	1.2	5/6/05

<b>14</b>	<b>Trial Monitoring</b>	<b>1.0</b>	<b>7/3/03</b>
14.1	Monitoring Program		
14.2	Trial Monitoring Reports		
14.3	Site Visit Monitoring Procedures		



# Weight Loss Maintenance MOP

## Summary of edits between Version 1.0 and Version 1.1

- Adds contact information for coordinating center

## Summary of edits between Version 1.1 and Version 1.2

- Updated contact information for coordinating center

## 1 Introduction and Definitions

The WLM Trial, “Maintenance,” is a multi-center, randomized, controlled trial to determine the effects on maintenance of weight loss of two innovative behavioral interventions, each designed to provide frequent contacts, compared to a usual care control group. Overweight and obese individuals who are taking medication for hypertension and/or dyslipidemia will enter a 5-month weight loss program. Eight hundred individuals who lose at least 9 lbs will then be randomized into one of three groups: a Personal Contact (PC) Intervention that provides monthly personal contacts with a trained interventionist, primarily via telephone; an Interactive Technology (IT) Intervention that provides frequent contacts through a state-of-the-art interactive web-based program supplemented by other communication technologies; or a Self-Directed/Usual Care (SD/UC) group. The primary outcome will be weight change from the end of the initial weight loss program to the end of the 30-month weight maintenance intervention period. The study is funded by the NHLBI and will involve 4 clinical sites (Duke University Medical Center, Johns Hopkins Medical Center, the Pennington Biomedical Research Center, and the Kaiser Permanente Center for Health Research). The study is coordinated by Kaiser Permanente Center for Health Research, Portland, Oregon.

### 1.1 Using the Manual of Operations

The WLM Trial Manual of Operations (MOP) contains information about all the practical aspects of conducting the study. An electronic version is available on the WLM secure website. Additional scientific information is contained in the study protocol. If you have problems or questions that are not addressed in the MOP, contact the Coordinating Center – [Mike.Allison@kpchr.org](mailto:Mike.Allison@kpchr.org) or [Fran.Heinith@kpchr.org](mailto:Fran.Heinith@kpchr.org)

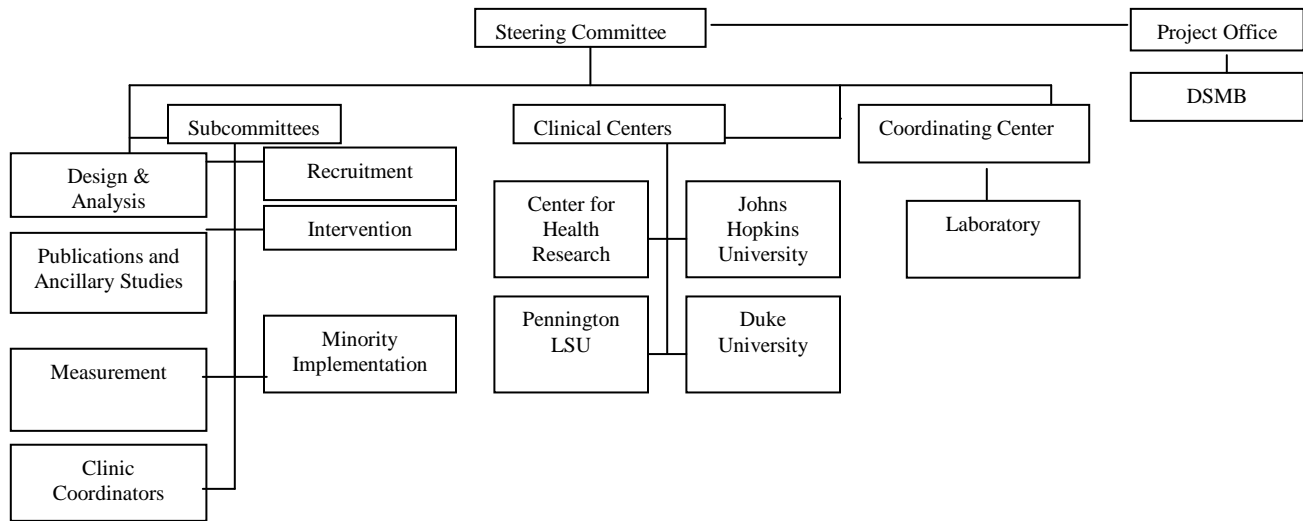
The MOP is a working document that translates the protocol into working procedures. Its goal is to describe the procedures with sufficient clarity to ensure that all clinical centers use the same examination procedures, participant management, intervention schedules, definitions, and, as far as possible, the same equipment.

The Coordinating Center is responsible for revisions of the MOP and for monitoring adherence to procedures. Substantive changes require approval of the Steering Committee or a WLM subcommittee. Changes to the MOP and relevant forms are made as soon as practical and, unless otherwise noted, become effective when the clinical sites are notified of the change. Once accepted, the policies in the protocol and the procedures described in the MOP must be followed by each clinical center.

# Weight Loss Maintenance MOP

## 2. Organizational Structure and Contact Information

### 2.1 Organizational Chart



The Steering Committee is the primary decision-making body for the trial. Standing subcommittees include: Design and Analysis, Recruitment, Measurement, Minority Implementation, Intervention, Clinic Coordinators, and Publications and Ancillary Studies. An independent Data and Safety Monitoring Board (DSMB) also serves the study. The functions of these committees and the DSMB are summarized below.

### 2.2 Steering Committee

**Membership:** Principal investigators (PIs) from each of the four clinical centers and from the Coordinating Center each have one vote, as does the NHLBI project officer. Committee chairs (if other than PIs) and co-investigators attend and participate in discussions but do not have voting privileges.

**Functions and Responsibilities:** Ensure clear delineation of roles and responsibilities among participating institutions; review and approve all policies, protocols, and trial-wide procedures; monitor performance of WLM overall and of each clinical center, including recruitment, adherence, data collection, quality control, and data analysis; consider and approve any ancillary studies and access to study data. The Steering Committee meets face-to-face approximately twice a year, with conference calls or additional meetings as needed and with regular sharing of information. Meetings are open to all study personnel.

### 2.3 Sub Committees

#### *Clinic Coordinators*

**Membership:** Clinic coordinators from each clinical site, a representative from the Minority Implementation Committee, and the data manager from the Coordinating Center.

**Functions and Responsibilities:** Serve as primary liaison on issues of data management, quality assurance, and training and certification procedures; also serve as forum for sharing experience and problem solving among clinic coordinators. In order to maximize communications, one member of this committee serves on each of the other committees.

### ***Design and Analysis Committee***

**Membership:** Key trial personnel appointed by Steering Committee with each center and the Project Office having a representative; includes a mix of disciplines and skills needed to conduct the trial. Also includes a member of the Minority Implementation Committee.

**Functions and Responsibilities:** Recommend to the Steering Committee the basic design components of the trial and recommend changes in and additions to the protocol.

### ***Measurement Committee***

**Membership:** Key trial personnel including representatives from each clinical center, the Coordinating Center, and the Project Office. Also includes a member of the Minority Implementation Committee

**Functions and Responsibilities:** Recommend to the Steering Committee measures, processes, and procedures for assuring quality control of the trial, including training, certification, quality control measures and procedures, and other activities directed at ensuring that data are valid and reliable.

### ***General Intervention (Umbrella) Committee***

**Membership:** Selected trial investigators with additional expertise in intervention delivery and technology interventions.

**Functions and Responsibilities:** Oversee the work of all other intervention subcommittees; recommend to the Steering Committee changes and additions to the protocol pertaining to the interventions.

### ***Phase I Weight Loss Committee***

**Membership:** Selected investigators and staff from each site, including a member of the Minority Implementation Committee.

**Functions and Responsibilities:** Work with the Coordinating Center to develop the Phase I weight loss program.

### ***PC Committee***

**Membership:** Selected investigators and staff from each site, including a member of the Minority Implementation Committee.

**Functions and Responsibilities:** Work with the Coordinating Center to develop the PC intervention program.

### ***IT Committee***

**Membership:** Selected investigators and staff from each site, including a member of the Minority Implementation Committee.

**Functions and Responsibilities:** Work with the Coordinating Center to develop the IT intervention program.

### ***Interventionists Committee***

**Membership:** Interventionists from all sites. Also includes a member of the Minority Implementation Committee

**Functions and Responsibilities:** Facilitate case management across sites. Recommend to the Intervention Umbrella Committee processes for assuring quality intervention delivery.

### ***Recruitment Committee***

**Membership:** Recruitment coordinators from each clinical site, selected PIs appointed by the Steering Committee, and a Coordinating Center representative.

**Functions and Responsibilities:** Facilitate the successful recruitment of study participants, monitor and report on progress to the Steering Committee, and recommend actions to be taken to improve recruitment.

### ***Publications and Ancillary Studies Committee***

**Membership:** Representatives from each clinical site, the Coordinating Center, and the Project Office appointed by the Steering Committee.

**Functions and Responsibilities:** Develop and recommend to the Steering Committee policies on publications and presentations and oversee the implementation of these policies. This committee also recommends policies for the conduct of ancillary studies, reviews all ancillary study proposals, and makes recommendations to the Steering Committee regarding ancillary study proposals.

### ***Minority Implementation Committee***

**Membership:** This committee includes a PI, clinic coordinator, recruitment coordinator, and other investigators and staff members with a special interest or experience in minority health research. The concerns of this working group cut across all aspects of the trial, with a focus on adapting the recruitment and intervention materials to be culturally appropriate for African Americans.

**Functions and Responsibilities:** Review materials, protocols, and procedures for cultural appropriateness to African Americans and make recommendations to the Steering Committee for maximizing full participation of African Americans in the trial.

## **2.4 Coordinating Center**

The Coordinating Center, under the direction of the Steering Committee, develops final versions of the study protocol, Manual of Operations, data collection forms, and intervention materials. The Coordinating Center maintains current versions of the protocol, MOP, and data collection forms, and makes documents easily available to all trial staff and investigators using the secure staff Web site.

In addition, the CC is responsible for the following:

- Centralized staff training and certification
- Trial communications
- Access to project documents
- Project websites
- Data Management System.
- Trial monitoring and quality control, including trial monitoring reports, end-user reports, conducting site visits, and weight quality control
- Data analysis, including producing the analysis guide and a trial-wide data release upon the completion of all data collection and cleaning

## **2.5 Data and Safety Monitoring Board (DSMB)**

**Membership:** Research scientists not otherwise connected with the study are appointed by NHLBI. Their expertise includes the disciplines and skills needed to initially review the protocol, and then to monitor trial progress, quality of data, and safety of the participants.

**Functions and Responsibilities:** The DSMB reviews the protocol prior to implementation and makes recommendations to improve it, and considers whether or not the risks associated with implementation of the protocol are reasonable and are minimized appropriately. Following adoption of the protocol, the DSMB serves in an advisory capacity to the NHLBI in order to monitor, review, and assess study progress. The DSMB has access to unblinded outcome data during the trial, and, in order that participants are not exposed to unreasonable or unnecessary research risks, recommends early termination of one or more arms of the trial if the data suggest significant adverse risk to participants, if the questions posed by the trial appear to have been answered and there are no ethical or other reasons to continue the trial, or if continuation of the trial is futile. The DSMB also reviews the timeliness of recruitment and the timeliness and quality of the data, based on data monitoring reports and other materials submitted by the Coordinating Center.

The DSMB meets at least annually throughout the trial. Meetings are attended by representatives from the Coordinating Center, the Steering Committee (including the chair, vice-chair, and chair of the intervention committee), and the NHLBI, in addition to DSMB members. Only the DSMB members may vote. None of the clinical center investigators are exposed to blinded study data until final outcome data has been collected, or until the DSMB recommends that unblinding should occur.

The "*Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Sponsored Multi-Center Clinical Trials*", published in the NIH Guide for Grants and Contracts on June 11, 1999, requires all multi-site clinical trials with a DSMB to forward summary reports of Adverse Events to each IRB associated with the trial. Each summary report includes:

- a statement that a DSMB review of data and outcomes across all centers took place, and the date of the review
- a summary of the DSMB review of the cumulative adverse events reports from all participating sites
- without specific disclosure by treatment arm, unless safety considerations require such disclosure, or a statement indicating that no adverse events were reported from the participating sites
- the DSMB's conclusion with respect to progress or need for modification of the protocol.

These summary reports are in addition to all other adverse event reporting procedures required by the NHLBI, the trial protocol, each organization, and each local IRB, and are distributed to each Principal Investigator by the Coordinating Center within 30 days after each DSMB meeting. Principal Investigators are required to forward Summary Reports of Adverse Events to their local IRBs. Adverse events are defined in section 10 of the WLM protocol, Safety Monitoring.

## **2.6 Project Office**

This trial is sponsored by the National Heart, Lung, and Blood Institute (NHLBI), a division of the National Institutes of Health. A project officer assigned by NHLBI is a voting member of the Steering Committee. The project officer is responsible for assembling the DSMB and sets the agenda for DSMB meetings. Scientists from the Project Office serve on most trial committees.

## **2.7 Clinical Sites**

There are four clinical centers: Johns Hopkins University in Baltimore, MD, Pennington Biomedical Research Center in Baton Rouge, LA, Duke University Medical Center in Durham, NC, and a clinical center also located at the Kaiser Permanente Center for Health Research in Portland, OR.

## **2.8 Laboratories**

A laboratory yet to be determined will be the central laboratory for analyses and the repository for WLM storage specimens. This lab will provide all supplies for collection of biological specimens for the trial, and will process and store them according to study protocol. The Lab will also notify clinical sites of all alert laboratory values. See section 7.6 for details.

## **2.9 Recruitment, Administrative, and Data Management Websites**

The WLM Trial maintains trial websites 365 days a year. Access is controlled by password and all data transfer is encrypted. The security systems in place are similar to those used for banking transactions. This service is available to study staff and is accessed using standard browser software (e.g. Internet Explorer). See sections 11 & 12 for details.

# Weight Loss Maintenance MOP

## Summary of edits between Version 1.0 and Version 1.1

- Added that ancillary studies must be approved by the DSMB as well as the SC and PASC.
- Added instructions to complete Form 503 if a protocol exception is requested.

## Summary of edits between Version 1.1 and Version 1.2

- Revised actions of project office in presenting ancillary studies to the DSMB
- Added Figure 2, showing process for ancillary studies

## Summary of edits between Version 1.2 and Version 1.3

- Revised publications procedures

## Summary of edits between Version 1.3 and Version 1.4

- Revised publications procedures to add procedure for dividing papers, which differ for ancillaries and non-ancillaries.

## Summary of edits between Version 1.4 and Version 1.5

- Revised publications procedures to describe new process for submitting manuscripts for NHLBI review
- Revised section 3.2.10 to update co-authorship policies

## Summary of edits between Version 1.5 and Version 1.6

- Revised publications procedures to describe new process for submitting abstracts for NHLBI review

## Summary of edits between Version 1.6 and Version 1.7

- Revised publications procedures to shorten timeline for review of manuscripts for both NHLBI and the PASC to 3 weeks.

### **3. Trial Administration**

#### **3.1 Trial Policies**

This section contains trial policies that have been approved by the steering committee.

##### **3.1.1 Protocol**

The trial Protocol presents the scientific background, design, and governing policies of the study. Any member of the Steering Committee may propose protocol changes. Proposed modifications must be approved by the Steering Committee, the Data and Safety Monitoring Board, and appropriate offices at the NHLBI in the order listed. The Steering Committee and the Data and Safety Monitoring Board vote on changes at regularly scheduled meetings and conference calls. A majority vote of approval is required for each committee before forwarding to the next level. Protocol changes affecting participant eligibility must be submitted by each clinical center to its Institutional Review Board (IRB) according to local IRB guidelines. Changes must be approved by the IRB before being instituted at any site.

##### **3.1.2 Protocol and Procedure Exceptions**

It is the policy of the Weight Loss Maintenance Trial Steering Committee not to allow exceptions to the procedures laid out in the study Protocol and Manual of Procedures. Investigators wishing exceptions should petition the Steering Committee to amend the Protocol and/or MOP to formally allow the exception.

Unusual circumstances may arise where this procedure is not practical. In these instances the PI or designee can petition the principal investigator of the Coordinating Center, or his designee, to grant the exception. This is done by completion and entry for Form 503 (Protocol Exception Form). This decision can further be appealed to the full Steering Committee. The Coordinating Center will maintain and regularly post a list of allowed and disallowed exceptions, as well as a list of clarifications to the Protocol and MOP.

##### **3.1.3 Institutional Review Board (IRB)**

The Coordinating Center and each clinical center must obtain permission from its local IRB to conduct the study before beginning recruitment. As noted above all Protocol changes must also be submitted for IRB review and approval according to local IRB guidelines. Documentation of local IRB approval from each WLM center should be sent to the Coordinating Center, along with approvals of subsequent changes. Periodically, the Coordinating Center will provide each PI with trial-wide information on adverse events for their IRB.

##### **3.1.4 Provision of Medical Care to Participants**

Medical problems will occasionally be identified among participants. The responsibility of clinical centers in following up such problems will vary from site to site according to generally accepted medical guidelines, individual IRB requirements, and the resources available to provide referral and follow-up services. In no instances, however, should resources essential to the proper implementation of the protocol be utilized to provide medical care services.

##### **3.1.5 Disclosure of Study Results**

Participants are told their baseline weight, height, and BMI, and also receive results of clinical laboratory tests when they are available from the central laboratory. Participants also receive a summary of all their clinical measurements and information about the overall findings of the trial at the conclusion of intervention. Participants are informed of blood pressure levels when measured (baseline, 12 and 30 months) and are alerted if their blood pressure goes above a predetermined escape level at any of these visits.

WLM Investigators may not share outcome data either within or outside of their own departments at their own institutions without permission from the Steering Committee. In general, WLM results may

not be presented until after the main outcomes paper is in press. Exceptions (e.g., data based from Phase I) must be approved by the SC.

### **3.1.6 Publicity**

Unpublished results derived from WLM data may not be discussed or released without authorization of the Steering Committee. The Publications and Ancillary Studies Committee will recommend to the SC general guidelines for the content and timing of news releases and interviews for presentations and publications. WLM investigators may discuss design and recruitment issues with the media, but should inform the Steering Committee of any WLM related information scheduled for release in the national media.

### **3.1.7 Access to Stored Laboratory Specimens**

WLM will store a variety of frozen blood and buffy coat samples from WLM participants. Proposals to use these samples should be submitted to the WLM Steering Committee in writing. These proposals should include the type of study/test proposed, the amount of each sample required to conduct it, the rationale for the test, the study questions and hypotheses to be addressed, the plans for publication of the data, the approximate cost of the proposed test(s), and the source of funds to conduct them. Study investigators not involved in the initial proposal may request to be included in the working group conducting the additional studies.

The discussion of whether to permit use of the stored samples should include attention to possible alternative uses of limited materials. The Steering Committee will attempt to plan for optimal uses of the stored samples rather than simply to grant requests for their use on the basis of which were submitted first. Use of stored specimens requires that an ancillary studies request be submitted and approved by the PASC.

Any analysis of biological specimens must be approved by each center's IRB.

### **3.1.8 Archiving of Source Documents and Biological Specimens**

All source documents and biological specimens obtained during the conduct of WLM should be stored until the year 2009 or until the PASC formally dissolves, whichever is later. Before any source documents or biological specimens are discarded, approval must be sought from the Steering Committee. Before disbanding, the Steering Committee will determine the future storage or disposal of source documents and stored biological specimens.

## **3.2 Publications and Ancillary Studies**

These policies cover papers, abstracts, posters, and oral presentations that involve data collected as a part of the Weight Loss Maintenance Trial. These policies will remain in force until the Publications and Ancillary Studies Committee (PASC) is formally dissolved. The PASC consists of each principal investigator or designee and an NHLBI Project Scientist. Other WLM investigators and coordinating center staff may also participate.

### **3.2.1 Initiation of a Writing Project**

Initiation of a writing project can begin in one of two ways:

- A member of the WLM project may complete a Proposal for a WLM Paper (Form #700)
- The SC or PASC may also initiate and approve a paper

The SC or PASC may appoint a writing group to work on a specific publication.



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**Figure 1. Outline of WLM Process for Producing a Paper**

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**Approval**

WLM Investigator proposes paper  
PASC members review proposal, inform potential authors at their site, and vote  
CC notifies convener and PASC chair of outcome  
CC assigns statistician

↓

**Writing Group Formation / Exploratory Analyses**

Convener works with assigned statistician to prepare for first call  
Writing group convened, writing group identifies chair; Writing group chair informs CC of group membership/chair  
Writing group chair works with assigned statistician on exploratory analyses  
Writing group chair and assigned statistician generate formal analysis requests

↓

**Analysis Requests**

Requests sent to CC Lead Analyst; Analyst is assigned to each request  
Analyses completed and reviewed; Results or data release sent to writing group chair

↓

**First Draft**

Writing group reconvened  
Chair prepares outline of manuscript and distributes writing assignments  
First draft completed and circulated for review

↓

**Subsequent Drafts**

In consultation with assigned statistician, additional analyses may be specified  
Requests sent to CC Lead Analyst; Analyst is assigned to each request  
Analyses completed and reviewed; Results or data release sent to writing group chair  
Manuscript draft recirculated to writing group.

↓

**Review**

Annotated manuscript submitted to Lead Analyst at CC for numbers verification  
*Note: Annotate using data requests specific to the paper; do not use results other than from data requests specific to the manuscript to annotate*  
Manuscript submitted to PASC for approval  
Manuscript submitted to NHLBI for approval  
Final revisions made

↓

**Submitted to Journal**

Manuscript submitted for publication; author supplies CC with copy of submitted manuscript  
Author notifies PASC Chair and CC of acceptance or rejection of manuscript

↓

**Paper Published**

Author supplies CC with citation and an electronic copy of the published manuscript

Note: The writing group chair is responsible for updating the CC on the progress of a paper through each of its milestones.

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### **3.2.2 To Propose a Paper**

A member of the WLM project completes Form #700 (Proposal for a WLM Paper), which specifies the research question(s) and the primary variables to be used in the analysis. The individual who completes this form is termed the “convener.” The convener adds known interested authors from his/her own site and submits the form to the CC and PASC chair by paper or electronically via the website. This form is available on the WLM website.

The CC makes the proposal available to the PASC members for approval via the WLM administrative web site. Paper ballots may still be used in certain situations. As soon as a proposal is posted on the web site, PASC members are notified that a new proposal is ready for online voting. After reviewing information from Form #700 on the WLM administrative web site, PASC members can then cast their vote. If a paper ballot is used, the CC circulates the Form #700 along with Form #701 (PASC Review Form for a WLM publications proposal) to the PASC members for approval. Each PASC member is responsible for circulating new paper proposals to investigators at his/her site and indicating on the ballot all interested co-authors.

PASC members review the proposal, and vote online or sign and return the completed Form #701 to the CC within 14 days. Non-response is considered to be approval. PASC members who are unavailable can delegate responsibility for their vote.

Once the voting deadline is reached, the CC informs the convener and the PASC Chair whether or not the proposed paper has been approved. If not approved, the PASC Chair discusses questions or concerns raised by reviewers on the website or on Form #701 with the convener. The convener responds to the PASC Chair with a revised request or with a written response to the concerns, and sends a copy to the CC. The PASC Chair decides if the response satisfies the concerns, or may defer approval until the PASC can discuss the issues. The PASC Chair notifies the CC and PASC members whether or not proposed projects requiring discussion are approved.

The CC maintains and distributes a list of approved papers. Each approved paper is assigned a number and a short title that should be used on all correspondence related to the paper. See Figure 1 for an outline of the paper approval process.

### **3.2.3 Assigning Priorities**

The PASC, in conjunction with the SC, assigns a priority number from 1 to 3 to each paper indicating the importance of the proposed manuscript, with 1 being most important. The CC uses these priority scores to help prioritize the work it does in meeting analysis requests.

### **3.2.4 Forming a Writing Group**

PASC members inform potential authors at their site of the formation of the writing group when the proposal is submitted. The CC also assigns a senior level statistician from the CC, one of the clinical sites, or the PO, to assist in the development and writing of each paper. This person will typically also be a co-author on the paper.

After approval, the convener sets up the first conference call or meeting of the writing group. At this first call/meeting, if a chair has not already been appointed, the writing group selects a chairperson from among its members. The chairperson serves as the first author on the paper, and is responsible for reporting progress on the paper to the CC at regular intervals.

The writing group chair notifies the CC that the group has convened and a chair has been selected, and also confirms the membership of the writing group. After formation, changes in the writing group (withdrawals or additions of members) are directed to the committee chair, who then notifies the CC. The current composition of each group is updated and posted on the WLM administrative website by the CC. Membership can be changed only by the writing group chair.

### **3.2.5 Dividing a Paper – (Non-ancillaries)**

For papers that are not ancillaries, a new Form 700 must be submitted for each new title.

### **3.2.6 Submission of Analysis Requests**

All requests to the CC for statistical analysis come directly from the writing group chair or the lead statistician on the project. The lead statistician reviews all requests for appropriateness before analysis is begun. Requests receive some level of appropriate statistical review prior to being assigned to a CC analyst. Exceptions may be made for simple requests such as descriptive tables not requiring analysis. All requests are made using the Data Analysis Request Form ( #705).

To facilitate manuscript preparation for ancillary studies, the CC works with the lead author to develop an analysis file for use with each approved paper. The Data Release Request Form (#706) is used to document the necessary information.

Copies of the analysis file are given to the lead statistician and to other members of the writing group who request a copy so that they can conduct their own preliminary analyses. The CC also uses this file to fill data requests. The CC informs the investigators if the data in the analysis file have not been fully cleaned. All analyses made using preliminary data require subsequent verification before a

manuscript can be approved for publication. *If this verification is not conducted by the CC, a statement to this effect must be included in the METHODS section of the paper.*

Once requests are submitted, the lead analyst at the CC assigns one or more staff analysts to work on the request. The CC also sends a memo summarizing the request to the lead author to insure that it has correctly interpreted the request. The CC will not begin work on a data request until it receives confirmation from the requestor that the CC has correctly interpreted the request.

Each request is assigned a data request number that is used in subsequent communications. The CC often works on multiple requests and uses the assigned number to avoid confusion. Some requests, due to their complexity, may be divided into several separate requests internally at the CC. When this occurs, each of these “requests” is treated according to the procedures outlined above.

The data request numbers should be left on all tables and figures until the final manuscript submission. This number is also used to reference any numbers used in the text (i.e., in parentheses, following the text). This annotation allows the CC to efficiently return to the original output to verify the numbers in a table, figure, or text discussion as part of the manuscript verification process. Failure to use this data request number may add substantially to the verification time. If this number is missing, the CC is unable to verify the manuscript and will return it to the author for the information to be added.

### **3.2.7 Approval of Abstracts**

Abstracts of WLM results intended for presentation at scientific meetings are sent directly by the lead author to members of the PASC, and to the Project Office by email to [CAPDOCS@nhlbi.nih.gov](mailto:CAPDOCS@nhlbi.nih.gov), along with a completed Form #704 (WLM Abstract Review Form), for approval prior to submission. When submitting to CAPDOCS, include the meeting name and abstract deadline in the e-mail request for review. A copy is also sent to the lead analyst at the CC for numbers verification. The sites and the CC must receive these abstracts at least five working days prior to the intended date of submission. Members of the PASC and the Project Office must respond (using Form #704) within three working days of receipt of an abstract. Designated alternates may respond on behalf of PASC members or Project Office representatives who are unavailable. Non-response within 3 days is considered approval. The CC must verify all numbers on the abstract prior to approving the abstract request.

Responses are sent directly to the PASC Chair and the CC and indicate approval or disapproval, and any suggested/required edits. The PASC Chair notifies the author and the CC when an abstract is approved. Abstracts may not be submitted for publication until the PASC chair informs the requester that the abstract was approved.

### **3.2.8 Approval of Manuscripts**

Prior to submission of manuscripts for approval, a copy of the annotated manuscript is submitted to the CC for verification of all numbers and figures, including those in the text, by the analyst staff. Once the numbers and figures have been verified and any needed corrections have been made, the manuscript can be submitted for approval. *Manuscripts not verified by the CC must explicitly state this in the METHODS section.*

An electronic copy of the manuscript and a completed Manuscript Review Form (#702) should be sent to the Coordinating Center, which in turn forwards a copy directly to NHLBI by email to [CAPDOCS@nhlbi.nih.gov](mailto:CAPDOCS@nhlbi.nih.gov) and to each member of the PASC for review. The request should include the journal name. All manuscripts must be received by NHLBI. NHLBI internal review can take up to three weeks. Although PASC approval and Project Office approval may be requested simultaneously, the PASC chair may require a second PASC review if the Project Office recommends substantive revisions.

The members of the PASC respond in writing or by e-mail to the PASC chair with any comments for the lead author (using Form #702, WLM Manuscript Review Form). Votes are due within 3 weeks of receipt of the manuscript. The PASC chair relays comments to the chairperson of the writing group and to the coordinating center. Designated alternates can respond on behalf of PASC members who are unavailable. In this case, non-response is considered a *non-approval*. Manuscript approvals require 4 “yes” votes, including one from the project office.

The PASC resolves conflicts over the acceptability of manuscripts. If a consensus cannot be reached, then a majority vote of the committee resolves the issue. Authors can appeal any such decision to the Steering Committee. The PASC may withdraw, by majority vote, any manuscript after it has been submitted and before it is published.

### 3.2.9 Acceptance of Abstracts and Manuscripts

The main author sends a copy of the submitted abstract and submitted manuscript to the CC, and, if further revisions were made to the manuscript, a copy of the final version. It is the responsibility of the first author of any manuscript, abstract, or presentation to notify the PASC Chair and the CC of the acceptance or rejection of the paper, abstract, or presentation. After publication, the main author sends a copy and the appropriate citation for any published abstract to the CC and a reprint and the citation for any published manuscript. The CC stores copies of all scientific manuscripts both for ancillary and for full study papers and abstracts. It is the responsibility of individual PIs to distribute copies of abstracts and manuscripts to other investigators at their sites. The CC distributes regular reports of publications and presentations. Investigators are encouraged to share copies of slides and handouts. Hard or electronic copies of data slides and handouts to be presented at national meetings should also be circulated to the PASC Chair and the CC for distribution to other WLM investigators. The coordinating center maintains copies of all the slides it receives, and makes them available to other investigators upon request.

### 3.2.10 Co-Authorship

Co-authorship on a paper will be determined by the first author. All persons designated as authors must qualify for authorship based on NEJM guidelines. That is, each author must have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to (a) conception and design of the study and/or interventions, or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author.

The WLM Steering Committee recognizes that a trial of this size, complexity and duration involves creative contributions from a broad range of individuals who contribute to the development and execution of the overall study design, phase I intervention procedures, phase II intervention procedures, data collection procedures, quality control procedures, data analyses strategies, and interpretation of the results. No one person can be aware of the total effort required to design and manage the trial, and contributions early on in the process are no less valuable than contributions at the end of the process. Consequently, the SC recommends an **inclusive approach to determining authorship**. All individuals who can reasonably be considered to meet authorship criteria indicated above should be encouraged to join a paper and contribute to its production. Contributions to manuscript production may involve a variety of activities, but should at least meet NEJM criteria and involve review and approval of the final document. If a lead author feels that a co-author is not contributing at this level, the first step should be conversation between lead author and co-author to clarify expectations. If a lead author feels that a co-author should be removed from the list of authors for any reason, such a proposal would be considered sufficiently serious to warrant PASC review, which will make the final determination. In general, each site PI and the CC PI should encourage co-investigators to propose and join papers, and to meet authorship responsibilities.

### **Authorship order**

For key trial outcome papers, priority for authorship order will be given to those who have contributed most to the design and implementation of the trial, while insuring balance across centers. For secondary papers, greater weight will be given to authors' contributions to the writing and creative development of the particular paper. When contributions have been equal, priority should be given to those who led in the design and implementation of the component of the trial that is the focus of the paper and to more junior investigators.

Early in the development of a paper, writing groups should discuss and clarify intended roles, responsibilities, and a proposed order of authorship. If roles and contributions of individual authors differ from what was agreed on, the lead author will make appropriate changes in the order or list of authors. If the writing group cannot resolve conflicts regarding the order of authorship, the PASC will adjudicate and may assign the order.

### **3.2.11 Ancillary Studies**

All studies of participants enrolled in the WLM project that are not part of the main protocol, including proposals to analyze stored specimens, must be approved by the PASC prior to enrolling participants and collecting data. In order to obtain approval, the investigator wishing to do an ancillary study must complete and submit the Ancillary Study Request Form #703 to the CC for circulation to the PASC. PIs are responsible for ensuring IRB approval for ancillary studies at their site. If a proposal is subsequently submitted for IRB approval, copy of the final approval letter from your IRB must be sent to the CC, which maintains a centralized file of all such approvals for archival purposes. The PASC reviews the proposal within two weeks to ensure that the ancillary study will not interfere with recruitment, intervention or data collection for the main study. The PASC may make suggestions for modification to assure that the ancillary study meets the non-interference criterion. The PASC may refuse to approve ancillary projects that appear to interfere with conduct of the main trial.

All ancillary studies approved by PASC must then be approved by the Steering Committee and the DSMB. The CC maintains a listing of approved ancillary studies and periodically provides a copy to the DSMB. Once the ancillary study has been approved, oversight of publications resulting from it is the responsibility of the PASC.

Papers resulting from ancillary studies do not go through the regular manuscript approval process. The following statement, or its equivalent, should be inserted in the Methods section of a paper resulting from an ancillary study:

“This was a study ancillary to the WLM study and, as such, was designed, conducted, and analyzed by the co-authors only.”

Papers resulting from ancillary studies should acknowledge the WLM research group and participants by including the following statement, or its equivalent, in the acknowledgement section. Acknowledgement of specific individuals, groups, or committees may also be appropriate. The local PI will adjudicate disagreements over authorship.

“The authors are extraordinarily appreciative of the WLM participants and of the entire WLM Research Group, which included investigators and staff from the Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute, Bethesda, MD; the Kaiser Permanente Center for Health Research, Portland, OR; Duke University Medical Center, Durham, NC; Pennington Biomedical Research Center, Louisiana State University, Baton Rouge, LA; and The Johns Hopkins Medical Institutions, Baltimore, MD.”

As with other trial publications and presentations, it is the responsibility of the first author of any manuscript, abstract, or presentation resulting from an ancillary study to notify the PASC Chair and the CC of the acceptance or rejection of the paper, abstract, or presentation. Either prior to or concurrent with journal submission, authors of such papers also submit a copy to NHLBI for their

files. After publication, the main author also sends a copy and the appropriate citation for any published abstract to the CC and NLHBI, and a reprint and the citation for any published manuscript. It is the responsibility of individual PIs to distribute copies of abstracts and manuscripts to other investigators at their sites. The CC distributes regular reports of publications and presentations.

No abstracts from WLM ancillary studies that include post-randomization data may be submitted until the main outcomes abstract has been presented. Papers for WLM ancillary studies may not be submitted until the main outcome paper for WLM has been accepted for publication. Exceptions to this rule (e.g., papers based on Phase I data) must be approved by the SC.

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**Figure 2. Outline of WLM Process for Reviewing and Implementing Ancillary Studies**

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**Developing Ancillary Study Proposals**

1. A WLM Investigator (or group of investigators) develops a plan for an ancillary study
2. If the study is to be conducted at more than one clinical center, investigators at other clinical center(s) are brought into the planning process
3. A detailed study plan is written including a description and justification of the research objective, data collection methods, and data analysis plan. Particular attention is focused on the data collection methods, participant burden, and human subjects issues
4. Provide power calculations or an explanation for why power calculations are not provided
5. In most cases, the CC will not be responsible for collecting or analyzing the data collected for ancillary studies

**Review and Approval**

1. Convener submits ancillary study form (#703) to the CC
2. CC posts ancillary study form on the web site and notifies members of the Publications and Ancillary Studies Committee (PASC) to review and vote on the proposed study within two weeks
3. Convener submits study proposal to local IRB (can be done before submission to CC)
4. PASC members review proposal to assure that the study meets the non-interference criteria
5. PASC chair notifies convener and SC of the outcome
6. Ancillary study proposal is reviewed and voted on at the next SC meeting. Comments and concerns (if any) are sent to the convener
7. If approved by the SC, the project officer arranges for the executive secretary to send the ancillary study proposal to the DSMB for review
8. The DSMB reviews the ancillary study with particular attention paid to how it might affect the main trial and how it might affect participant burden
9. If the DSMB recommends approval, the ancillary study may be implemented

**Papers from Ancillary Studies**

1. The PASC is responsible for the oversight of publications resulting from an ancillary study
  2. The methods sections for papers based on ancillary studies should include the following text:  
"This was a study ancillary to the WLM study and , as such, was designed, conducted, and analyzed by the co-authors only."
  3. Ancillary study papers should acknowledge the WLM research group and participants. The clinical center PI is responsible for disagreements over authorship
  4. After publication, the lead author should send a copy of the paper to the CC and NHLBI
- 

**3.2.12 Dividing a Paper (Ancillaries)**

Upon approval, ancillary studies are assigned a single paper number. Ancillary study authors may make the decision about how many papers they wish to publish, but should send the citation for each published paper to the CC. The CC will then assign a paper number to each additional paper for the purpose of tracking trial output.

**3.2.13 Paper Monitoring**

The CC notifies the requestor of the projected number of hours and timeline for completion of all data requests. The CC also supplies regular reports to WLM investigators as to the status of requests, and progress of individual papers. It is recognized that timelines may change from initial estimates due to unanticipated difficulties or competition from requests with higher priorities.

### **3.2.14 Release of Data for Public Access**

At the end of the trial, the CC supplies each PI and the PO with a clean copy of the study data along with appropriate documentation in electronic form. The Project Office is responsible for making the dataset available to the general public under the terms of the Freedom of Information Act.

### **3.3 Outcomes and Adjudications**

In the event that Protocol rules relating to censoring and outcome determination do not clearly apply in a specific case, an Adjudication Committee reviews blinded individual participant data and makes a final resolution. This committee is comprised of study investigators and includes at least two clinicians and one statistician. The coordinating center tracks the activities of the Adjudication Committee and the outcome of its deliberations, and regularly reports back to the Steering Committee and DSMB.

Examples of issues that are likely to come to the Adjudication Committee include (but are not limited to) the following:

- Outcome measurements that are obtained outside the recommended time windows.
- Intermittent use of medication for hypertension, dyslipidemia, or weight loss.

### **3.4 Unblinding**

There is no blinding during Phase I. Therefore, participants are told the results of clinically relevant entry and Phase I measurements. After randomization, WLM study participants know their intervention assignments, as do clinical center staff that are involved in delivering the interventions. However, all clinical center staff involved in follow-up data collection are kept blinded to participants' treatment assignments, and all intervention staff are kept blinded to participants' official study measurements. Participants receive a complete set of weight measurements, along with a summary of their other clinical measurements (blood pressure, accelerometry, and laboratory measurements) at the conclusion of intervention (at 30 months post randomization).

This information is conveyed by an interventionist or other unblinded staff.

# Weight Loss Maintenance MOP

## 4. Requirements for Clinical Sites

### Summary of edits between Version 1.0 and Version 1.1

- Formatting correction
- Added that clinical measurement certification forms for height, weight, BP, and accelerometry are data entered

### Summary of edits between Version 1.1 and Version 1.2

- Clarified relationship between Netscape Navigator browser and the WLM website.

### Summary of edits between Version 1.2 and Version 1.3

- Accelerometry annual recertification for initialization, downloads, and file transfers is not required. Annual recertification for this measure covers any new problem areas identified.



## **4.1 IRB**

To participate in the WLM Trial, participants must provide written informed consent using procedures reviewed and approved by each clinical center's local IRB. This consent should cover screening visits, Phase I events, randomization, Phase II intervention, and follow-up. At a minimum, an initial consent is obtained prior to commencing the first screening visit to cover screening and Phase I activities, and a separate consent is obtained prior to randomization to cover randomization and Phase II activities and measurements.

Information leading to informed consent must be provided in a language that is understandable to the participant. Even when extensive printed information is provided, the investigator or interviewer must verify that the participant understands what he/she has read and heard. The participant must be given the opportunity to ask questions, and the interviewer should ask questions to determine the participant's level of understanding.

### **4.1.1 Principles of Informed Consent**

Consent forms must include language that is HIPAA compliant, as determined by the HIPAA privacy officer at each site. In addition, the following information must be provided to each participant when seeking informed consent:

1. State that the study involves research; explain the purpose of the research, state the expected duration of the individual's participation, describe the procedures, and identify any experimental procedures.
2. Describe any reasonably foreseeable risks or discomforts to the participants.
3. Describe any benefits to the participants (or to others) that may reasonably be expected from the research.
4. Describe how confidentiality and anonymity of records are maintained
5. Explain whether any compensation or medical intervention is available if injury occurs and, if so, what it consists of. State where further information may be obtained.
6. Explain whom to contact for answers to questions about the research and the participant's rights, and whom to contact in the event of a research-related injury to the participant.
7. State that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant may otherwise be entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant may otherwise be entitled.
8. Describe circumstances under which the individual's participation may be terminated by the investigator without regard to the individual's consent.

### **4.1.2 Process of Obtaining Informed Consent**

The circumstances under which consent is obtained in clinical trials can have a profound influence on the participant's interpretation of information communicated during the consent discussion and on the freedom of participants to make their own decision. Follow the guidelines listed below when obtaining informed consent:

1. Participants need adequate time to evaluate the pros and cons of participation. Allow the participant to take the consent form home to review if necessary.
2. Encourage participants to discuss the study with anyone they wish, particularly family and friends who might be affected (e.g., persons who might be needed to provide transportation).
3. Individuals must have the capacity to give their own consent to be eligible for participation. If a participant is incapable of understanding what is expected of him or her as a participant in the study, it is not permissible to obtain informed consent from a guardian. The study requires daily responsibilities that cannot be easily assumed by other persons.
4. Obtain consent in a private setting so that participants can freely ask questions without embarrassment. If group consent is conducted, participants must have the opportunity to ask questions privately.

5. To avoid pressuring the participant, only one person associated with the study should be present when the participant reviews the consent form. Additional staff may be present for other purposes, such as training, if participant permission is obtained.
6. Give the participant a copy of the consent form after it is signed and witnessed.
7. Encourage participants to keep the consent form because it contains useful information about the study that they can review if they wish.
8. When the person or organization responsible for obtaining the participant's consent is also involved in that participant's regular medical care, the participant must be told in no uncertain terms that they will be treated with the same degree of interest and concern regardless of whether or not they participate in the study. It is preferable that someone other than the participant's health care provider be the person responsible for obtaining the informed consent.

#### **4.1.3 Summary of Site-Specific Consent Procedures**

##### ***Baltimore***

Consent for volunteers at the Johns Hopkins ProHealth clinical site is obtained twice. The first consent covers all screening and Phase I activities and is obtained at the first screening visit. The second consent is obtained at the randomization visit and covers all participant activities that occur following randomization.

##### ***Baton Rouge***

Consent for volunteers at the Pennington Biomedical Research Center clinical site is obtained three times. The first consent, obtained at the first screening visit, is a pre-screening consent which covers all routine screening activities that are performed on all participants receiving evaluations for any study at the Pennington Center. The second consent, obtained at the second screening visit, covers study specific screening activities and participant activities that will occur following entry into Phase I of the study. The third consent will be obtained at the randomization visit and covers all participant activities that occur following randomization into Phase II.

##### ***Portland***

Consent for volunteers at the Portland clinical site is obtained twice. The first consent covers all screening and Phase I activities and is obtained at the first screening visit. The second consent is obtained at the randomization visit and covers all participant activities that occur following randomization.

##### ***Durham***

Consent for volunteers at the Duke clinical site is obtained twice. The first consent covers all screening and Phase I activities, and is obtained at the first screening visit. The second consent is obtained at the randomization visit and covers all participant activities that occur following randomization.

#### **4.1.4 Assurance of Informed Consent**

A blank copy of all consent documents in use at each site as well as copies of each site's yearly IRB assurances forms are sent to the CC annually. During site visits, the CC verifies properly signed consent documents on a random subset of participants.

#### **4.1.5 Confidentiality**

All participant information, including the fact that an individual is participating in the study, is considered confidential. This confidentiality is assured in WLM through several mechanisms:

- Each participant is assigned an anonymous study ID, which is then used on all study forms. Only where absolutely necessary to assure data integrity is a participant's name also included on study forms.
- All study forms, biological specimens, and paper records that contain participant information (e.g., address lists, phone lists) are kept in secured, locked areas when not in

use. In addition, when in use, such materials are kept away from public scrutiny. Materials and specimens that need to be discarded are destroyed.

- Access to all participant data and information, including laboratory specimens, is restricted to authorized personnel. This restricted access is assured in several ways. Access to the study data on websites is password protected. Staff members receive individualized account numbers and passwords that allow them access only to those elements of the data management system to which they are authorized. At the Coordinating Center, access to computerized data is restricted in two ways. First, only authorized personnel are granted access to the data, and, second, this access is further restricted by password protection. Coordinating Center personnel are annually required to sign a confidentiality statement affirming that they agree to abide by the Center for Health Research's policies on research confidentiality and ethics.

When the study database is made available to clinical centers, to the Project Office, and, ultimately, to the public, it will not include actual identities and contact information for participants. Such information is retained under lock and key at the individual clinical centers for use in the event that future follow-up of the study participants is necessary. Following the final data release, all identifiers are stripped from databases retained at the Coordinating Center. Participants are not identified by name in any reports or publications, nor are data presented in such a way that the identity of individual participants can be inferred.

#### **4.1.6 Data Integrity**

The master databases maintained at the Coordinating Center are backed up daily and archived off-line on a daily, weekly, monthly, and yearly basis. Sites will be instructed on proper archiving procedures for the accelerometry and FFQ data.

#### **4.1.7 Risks**

The WLM eligibility criteria are designed to exclude those individuals at undue medical risk or for whom the WLM interventions would be inappropriate. Wherever feasible, we have followed national guidelines in determining these criteria. We have also followed national guidelines in setting our blood pressure escape monitoring criteria, and all participants meeting escape thresholds are referred to a physician for further evaluation.

As a result of these safeguards, the WLM study should not pose any major health risk to participants. The most likely physical health risks associated with participation are gastrointestinal upset (e.g., bloating), increased frequency and bulk of stools (resulting from the high fiber content associated with adherence to some of the study dietary recommendations), minor discomfort from the venipunctures, and possible increase in minor injuries (muscle strains, sprains, etc) associated with the adoption of a physical activity regimen. These effects are either transient or readily reversible when intervention procedures are stopped. Participants are monitored for reactions to study procedures and these procedures can be terminated if necessary.

Additional risks and inconveniences to study participants may include: accidental breach of confidentiality; the inconvenience of having to come to clinic or counseling sessions on a frequent basis; and the inconvenience of receiving data collection interviews via the telephone within specified time windows.

The WLM protocol also provides for regular monitoring of participants for other adverse health outcomes, and all adverse outcomes are routinely reported to the trial's Data and Safety Monitoring Board, which may propose termination or modification of the study if it determines that participants in any of the intervention groups are being placed at undue risk through their participation in WLM.

#### **4.1.8 Benefits**

The benefits associated with participation in the study include: counseling for positive health related behavior change, regular weight and blood pressure monitoring, cash reimbursement (amounts vary

by center and may not be provided at all centers), and free laboratory tests that have a small possibility for early diagnosis of an illness. Participants also have the satisfaction of participating in a clinical trial with potentially major public health implications.

Based on the results of earlier behavioral research, we anticipate that a majority of participants randomized to the active interventions will experience health improvements such as a reduction in blood pressure or reduction of serum lipid values while participating in WLM. Moreover, we anticipate that participants will lose a significant amount of weight. We also anticipate an increase in regular physical activity and a resulting improvement in fitness measures in Phase I.

## **4.2 Internet Access for Study Staff**

A brief outline of what is required to connect to the Internet is provided here. For more detailed information, please talk the computer services administrator at your site. Connections to the Internet generally requires:

1. A modem or network connection: If your computer is not connected to a network then access to the Internet is achieved through the telephone line. This will require a modem, which can be purchased from a computer supplier. The computer supplier will also be able to advise you about other steps towards getting an internet connection. If your computer is part of a network then talk to the System Administrator to find out if the network is connected to the Internet and if so how to get access.

It is advised that the connection to the Internet be via cable, dsl or T1 line. Telephone modem connections can be slow and you may not experience optimal performance of the website.

2. An Internet Service Provider (ISP): An ISP is a company that provides a connection to the Internet for its subscribers. If you do not have Internet access via a network you will need to set up an account with an ISP to gain access to the Internet. Setting up an Internet account is very easy and similar to getting a phone account. When the account is set up the ISP will send you instructions on how to connect to the Internet (go on-line) and any software that you may need.

3. A web browser: Once you have connected to the Internet, either through your network or through an ISP with your modem, you are ready to use the internet. To do this you will need a program called a web browser (browser). A browser is a piece of software that can be loaded onto your computer. You will require a recent version of Internet Explorer (version 5 or newer) as WLM data entry forms and websites are designed to be viewed best with Internet Explorer. The WLM data system will NOT support Netscape Navigator.

## **4.3 Equipment Calibration and QC**

### **4.3.1 Scale**

Scales are certified at the start of the trial by the local Bureau of Weights and Measures or an equivalent body. Re-certification must be completed annually thereafter and posted in the appropriate column of the Scale QC Form (#602), along with any documents provided by the inspector. Form #602 is also used to record scale accuracy. The scale is tested quarterly at two levels to ensure accuracy in the range of weights measured during the trial. The lower range is checked using 20-30 lb weights. The upper range is checked using 40-50 lb weights.

1. The technician is weighed on the scale first and this weight recorded.
2. The lower weight is then placed on the scale and this weight recorded.
3. The technician then gets on the scale with the lower weight and this weight recorded.
4. The sum of the value obtained in step 1 and the value obtained in step 2 should equal the weight measured in step 3.
5. Next, the higher weight is placed on the scale by itself and this weight is recorded.
6. The technician now gets on the scale with the higher weight; this combined weight is recorded.

7. The sum of the value obtained in step one and the value obtained in step 5 should equal the weight measured in step 6.

These records are requested periodically and checked during site visits. Scales which fail to meet standards within 1 lb. at any weight level should not be used for collection of study data and should be immediately reconditioned and re-certified by the Bureau of Weights and Measures or an equivalent body. All scales used must be uniquely identifiable, either by serial number or by a study-specific number printed in indelible ink.

#### **4.3.2 Stadiometers**

Height is measured using a stadiometer. Perform Stadiometer QC twice each year while in use to verify accuracy as follows. The stadiometer height board is mounted at a 90° angle to a calibrated vertical height bar. Prior to the beginning of screening for the first cohort, use a level to check that the floor is level and that the wall on which the height bar is mounted is straight. Check that the vertical height bar is mounted at a 90° angle to the floor.

This information is recorded on the Stadiometer Equipment Certification Form (#605). If the stadiometer cannot be successfully calibrated, it may not be used for participant height measurements.

1. Place a 600 mm (60 cm) height rod against stadiometer and lower the height gauge to the top of the rod.
2. If the counter does not record the correct length of the rod:
  - loosen by undoing the two metal retaining screws and pull away from the main fiber cog of the carriage;
  - turn until the counter records the true length of the metal rod;
  - press against the backplate so that the teeth of the counter cog and the carriage cog engage;
  - tighten the retainer screws;
  - move headboard up and down the backboard a number of times;
  - re-check calibration
3. When accurate, record recalibration on Form #605

#### ***Fixed Stadiometers:***

Monitor these devices for obvious signs that they have been moved. If the device appears to have moved from its original position, confirm accuracy of measurements from floor level. Remount if inaccurate.

#### **4.3.3 Ambulatory Blood Pressure Monitor (ABPM)**

See section 7.4, "Equipment Required"

#### **4.3.4 Accelerometer**

See section 7.5.2, "Equipment"

### **4.4 Staff Training and Certification**

#### **4.4.1 Clinic Staff**

Certification of a master trainer is done annually at a central location. At that time, the study wide trainers review the appropriate techniques for measuring and recording height, weight, blood pressure, and accelerometry.

#### ***Height and Weight Certification***

Technicians are certified for height once at the beginning of the trial only. Technicians are certified annually for weight. For these measures, all technicians take duplicate measurements on two

individuals. The technician takes the first measurement of the height or weight on the individual, then repeats the process for the second measurement of height or weight on the same individual. The average of the duplicate measurements on a given individual must be within 1.0 lb weight and 1 cm height of the master trainer's measurement. Both measurements on a given individual must be within 1.0 lb/1cm of each other. Individuals at the sites may be trained as appropriate by the master trainers. For each person trained, the following forms are completed by the master trainer and copies are sent to the Coordinating Center:

1. Weight Certification Form (#600)
2. Weight Observation Checklist Form (#601)
3. Height Certification Form (# 603)
4. Height Observation Checklist Form (#604)

Forms #600 and #603 are data entered.

### ***Blood Pressure Certification***

#### **Overview of Blood Pressure Training and Certification**

All persons obtaining WLM blood pressure measurements are required to undergo training and certification in ABP measurement technique by the study-wide trainer. Each clinical site designates at least one site-specific trainer. Each site will also designate an unlimited number of technicians.

#### **Training and Certification**

The study-wide trainer trains and certifies the site-specific trainers, who in turn train the technicians at their sites. The Coordinating Center, on receipt of all necessary documentation of successful training, certifies all technicians. At least one trainer from each site is annually recertified by the study-wide trainer. These trainers then recertify the technicians and (if necessary) the other trainer at their sites. All BP staff, including trainers and technicians, are recertified annually. Certification is verified by the Coordinating Center.

*Initial certification* for blood pressure requires taking 3 sets of measurements on 3 different individuals. *Recertification* requires taking 3 sets of measurements on only two individuals.

#### **Introduction**

In order to standardize the previously described methods of blood pressure measurement and to ensure that a high level of performance is attained, a two-stage training program has been developed. Before the actual initiation of standardized measurements, a program of training and certification must be provided so that all staff responsible for recording blood pressure readings will be certified as having met a stipulated level of performance. BP master trainers are recertified centrally at an annual training session.

The Coordinating Center receives documentation of each technician's training performance from the trainers in the clinical centers (including the successful completion of the written test (Form #608) and the Blood Pressure Certification (Form #606). Following successful completion of training, enter the certification forms into the Data Entry system. Recertification reports can be generated from the datasystem at any time to identify who needs to be re-certified and when.

The first step of blood pressure certification is the completion of the Blood Pressure Written Examination (Form #608) after lectures have been presented. This is a short examination consisting of questions that test the blood pressure technician's knowledge and understanding of the measurement technique detailed in the training course. Technicians must score 100% on this Exam. Scoring of this exam is completed by the master trainer.

The second step is the successful completion of the Blood Pressure Certification Form (Form #606). For initial training, the trainer verifies the correct procedure for blood pressure measurement by observing the technician in three complete and uninterrupted exercises of the full procedure on three different individuals. This is done on only two different individuals in all subsequent trainings. When carried out without procedural errors, this form is completed, signed, and included with the certification packet for the technician. Errors of procedure are reviewed, discussed, and corrected until one completed determination is accomplished without error.

#### Observation of BP Measurement Procedures and Techniques

All BP technicians are checked to ensure that they are following procedures correctly and utilizing proper measurement techniques. This is necessary for both initial certification and re-certification. The trainer uses the BP Observation Checklist (Form #607) to grade the technician while he or she follows the entire BP protocol.

### **Summary of Requirements for Blood Pressure Certification and Recertification**

#### Certification

1. Attend training session, or receive training from a certified WLM blood pressure trainer.
2. Read Blood Pressure Assessment (section 7.4 of the MOP).
3. Successfully complete blood pressure measurement technique and procedure. Record and enter results on WLM Blood Pressure Observation Checklist Form (#607).
4. Successfully complete three readings on three different people, with BP Trainer (two different people for all trainings except initial training)
5. Successfully complete the Blood Pressure Written Exam (Form #608) (100% correct).
6. Data enter Form #606

#### Recertification

1. Required annually for all staff collecting BP data.
2. Successfully complete blood pressure measurement technique and procedure. Record and submit results on Blood Pressure Observation Checklist Form (Form #607).
3. Record and submit results on Blood Pressure Certification form.
4. Successfully complete the Blood Pressure Written Exam (Form #608) on blood pressure measurement (100% correct).
5. Data enter Form #606.

#### Study Forms Required for Certification Procedures

Four study forms are required for certification

1. Blood Pressure Written Examination (Form #608) and its key (Form #608ak).
2. Blood Pressure Observation Checklist Form (Form #607).
3. Blood Pressure Certification Form (Form #606).

#### ***Accelerometry:***

Master trainers are certified in the use of accelerometry at annual trial wide training meetings. Local staffs are trained by the site master trainer and certified annually. If a staff member has completed fewer than two RT3 initializations and or downloads in the past three months they must be recertified before resuming completion of this task. Training includes creating a user profile, initialization of the RT3, explaining the purpose of the device to participants, starting the RT3, downloading data, assessing data quality, and transferring data to the secure website. Certification includes return demonstration of these tasks and a written test with sample participant data that will assess the staff members' ability to assess RT3 data assuring that it meets the criteria. Staff perform certification skills at least once, and more times if needed to demonstrate competency. Because the coordinating center evaluates data management performance of accelerometry technicians on an ongoing basis, annual recertification for accelerometry initialization, downloads, and file transfers is

not required. Annual recertification for this measure covers any new problem areas identified. Form #610 (Accelerometry Certification) is data entered.

#### **4.4.2 Phase I Weight Loss Staff**

Although *certification* is not required for interventionists, training for Phase I weight loss visits occurs prior to the beginning of Phase I group visits. See section 9 for more information.



# Weight Loss Maintenance MOP

## 5. Eligibility and Recruitment

### Summary of Edits between Version 1.0 and Version 1.1

- Removes Inclusion/Exclusion criteria Tables for Phase I and Phase II. These tables are posted in the current protocol.
- Adds that randomization data must be collected no later than 2 weeks post G20. Refer to section 7 for windows for collecting weight data.

### Summary of Edits between Version 1.0 and Version 1.1

- Implements new randomization windows.

## 5.1 Recruitment Targets

### Setting Recruitment Targets

The WLM study will recruit a population that is 40% African American and 50% female. Recruitment of minorities and women is formally monitored quarterly and reports forwarded to NHLBI. Minorities other than African Americans are also eligible to participate, although no targets are set for these categories. Further, we have specifically designed the study to have good power to detect effects on the primary study endpoints for race and gender subgroups.

### Monitoring Recruitment Targets

The coordinating center monitors recruitment activities and facilitates recruitment efforts by providing regular recruitment reports, organizing meetings and conference calls, and distributing meeting/call minutes for the recruitment committee. In addition to these regular trial monitoring reports, the coordinating center develops additional reports (either on a regular or ad hoc basis) as requested by the recruitment committee or by the Data and Safety Monitoring Board.

## 5.2 Randomization into Phase II

### Timing

Randomization into Phase II occurs following the completion of Phase I (initial weight-loss program). Randomization data may be collected between 17 and 25 weeks post G1, but no later than three weeks post G20. See section 7 for windows for collecting weight data. Participants must not be randomized prior to the end of their Phase I group. The target for completing randomization is therefore three weeks following the last group session. To exceed this window a Protocol Exception Form (Form #503) must be completed and entered by the site, and then approved by the SC.

### Eligibility

Participants who have lost at least 4 kg during Phase I and who meet the additional Phase II inclusion/exclusion criteria (see protocol) are eligible for randomization into Phase II.

### Procedures

Prior to randomization, staff review the study requirements with the participant, answer questions, administer the randomization consent, and collect any remaining baseline data. Randomization assignments are generated on-site via the study website using software developed by the Coordinating Center. These assignments are stratified by clinic, race (African-American vs. non African-American), and weight loss during Phase I. Allocation assignments are also blocked within these categories to provide a balance in treatment assignments over time. As part of the randomization process, the computer program verifies eligibility and the completeness of entry and baseline data. Individuals lacking proper documentation of eligibility or key data elements are not randomized.

Participants learn their treatment assignment from a staff member who is not involved in clinical follow-up data collection.

**Blinding**

WLM study participants know their intervention assignments, as do clinical center staff that are involved in delivering the interventions. However, all clinical center staff involved in follow-up data collection are kept blinded to participants' treatment assignments, and all intervention staff are kept blinded to participants' official study measurements.

# innWeight Loss Maintenance MOP

## 6. Clinic Visits

### Summary of edits between Version 1.0 and Version 1.1

- Weight windows changed (see Randomization)
- Randomization visit separated from other baseline visits and clinic visits renumbered
- Form numbers updated
- Adds procedure for dropouts during screening
- Eligibility form to G1 must be  $\leq 105$  days
- Adds procedure for obtaining participant ID number from WLM website
- Form #500 was renamed Medical Events Screening Form
- Added Form 209 BP Form (visit 2) to Visit Checklist/Procedures in sections 6.9, 6.11, & 6.14

### Summary of edits between Version 1.1 and Version 1.2

- Clarified that participants who are rescreened *after* being declared ineligible must have a new ID number assigned.
- Baseline data collection was modified to “de-link” collection of medication data and weight data.
- Baseline visit windows were modified.

### Summary of edits between Version 1.2 and Version 1.3

- All visit checklists updated
- Form numbers and names updated
- In Phase I Registration clarified that the Coordination Center *data systems* validates the participant is eligible for Phase I

### Summary of edits between Version 1.3 and Version 1.4

- Updated all checklists to remove Form103 and Form104 from 6, 18, and 24-month follow-ups.

### Summary of edits between Version 1.4 and Version 1.5

- Updated target follow-up rate at the 12-month visit to 97%

### Summary of edits between Version 1.5 and Version 1.6

- Updated 12m visit windows
- Added 30m Phase III randomization and visit elements
- Added final data collection visit plan

## **6.1 Pre-Visit Communications**

### ***Visit Windows***

Windows of time appropriate to the collection of study data specific to each data collection frame are discussed in the following section. Collection of data within specified visit windows is expected. However, data may be collected outside of windows as approved by the SC or Adjudication Committee.

### ***Missed and Make-Up Visits***

Participants occasionally miss scheduled study visits. If this occurs, a study staff member contacts the participant and reschedules a visit where appropriate, or makes an intervention contact that replaces the missed visit. A participant who fails to appear for a rescheduled visit, or develops a pattern of missing appointments, is considered problematic for adherence. Case management is a regular part of adherence monitoring and problem-solving at each site.

### ***Adherence***

Target levels for follow-up are 95% for 6- and 30-month visits, 97% at 12 months, and 90% for 18- and 24-month visits. Adherence to study procedures, intervention sessions, and data collection schedules is crucial for the success of the trial. Sites evaluate potential participants' ability and willingness to fully participate in the study. These include consideration of eligibility criteria, psychosocial questionnaire information, case review, staff/investigator perceptions, and other sources of information bearing on the reliability of a potential participant. The principal investigator may exclude a volunteer at his/her discretion.

Participants are monitored continuously for attendance at study visits. During Phase II, regular case conferencing of participants occurs at each clinical site with attention given to the design of strategies for improving adherence to study requirements.

After randomization at the end of Phase I, efforts by study staff focus on techniques for maintaining interest and enthusiasm for the program and encouraging participation in both the intervention and in clinical data collections.

Throughout the WLM study, committees involved with implementation of procedures will convene on a regular basis via conference calls, and occasionally in face-to-face meetings to discuss, among other issues, progress of the program and review data on adherence and related matters. These groups identify problems and formulate procedures to correct them. To assist this process, the CC provides monthly visit completion data as part of trial monitoring reports.

## 6.2 Offsite Data Collection

### Visit Preparation

- Arrange private setting for data collection
- Check that a table and chairs are available
- Check for uncarpeted area to place scale for weight measurement
- Obtain participant charts
- Prepare accelerometers
- Prepare lab kit for offsite sample collection
- Prepare portable scales

### Visit Checklist/Procedures

___	Weight	Section 7	Form 105, 106
___	Rose Angina Questionnaire	Section 13	Form 108
___	Medical events screening form	Section 13	Form 500

### *If needed:*

___	Consent		Local
___	Blood pressure	Section 7	Form 204
___	Complete medication forms	Section 13	Forms 103, 104
___	Draw blood and store for lab tests	Section 7	Form 117
___	Accelerometer application, instructions, and return	Sections 7, 13	Forms 116, 121
___	Other forms as needed for visit	Section 13	See specific visit

### Equipment Required

If blood samples are collected, they must be transported in a closed container with at least 2 latches, such as a tackle box or toolbox. Blood samples in vacutainers must be put into 2 plastic zip lock bags and transported inside the closed container.

<i>Number</i>	<i>Item(s)</i>
1	UC-300 portable scale

### *if needed*

1	ABPM
1	Set lab supplies
1	Accelerometer
1	Kit for offsite blood draw (visit specific)
1	Table
1	Chair
1	Sheet of hard plastic or wood to place under portable scale

Lab supplies for fasting blood draw:

*Transport container with at least 2 latches*

- Ice packs to cool samples
- A biohazard sign must be placed on the outside of the container.

*In addition to supplies for the blood draw listed in Section 7, the container must include:*

- Plastic zip lock bags
- A spill kit including 10% bleach solution
- Plastic-backed “diapers” or barrier material to place under participant’s arm during blood draw
- Biohazard bags for all potentially infectious materials
- Sharps containers for needle disposal

## 6.3 Participant Closeout

### Screening Dropouts

If a screening participant becomes ineligible, their relevant screening form should indicate they have become ineligible. If the last form administered did not have the eligibility question, then fill out a Study Suspension Form #502.

### Phase I Dropouts

If a Phase I participant indicates that they are unwilling to continue in the WLM study, a Study Suspension Form (#502) should be completed. This form captures the date of suspension, and the primary reason the participant refused to continue. Once a Form 502 is received at the Coordinating Center, no further data are expected to be received on that participant.

### Phase II

*Early Termination after Randomization:* If a participant becomes pregnant during the study, she is excluded immediately from further participation in all study activities. Participants reaching the blood pressure escape thresholds are referred to their personal physician for evaluation and possible drug treatment. If possible, before blood pressure medications are started, the clinical center should endeavor to obtain a final blood pressure measurement on all participants who meet one of the BP escape criteria.

Where possible, randomized individuals who are unable to complete the study for any reason should have a final official study weight measurement, all other end of intervention measurements that sites are able to obtain, and receive a closeout briefing. This briefing should occur as soon after the terminating event as the participant's condition permits. However, it need not be done as a face-to-face meeting; the information may be sent by mail.

Any participant who has an early permanent termination during the Phase II portion of this study should have a Study Suspension Form (Form #502) completed for them.

*End of study:* At the conclusion of participation in the clinical trial, individual participants receive a summary of their clinical measurements.

The structure and content of close-out activities is left largely up to the individual sites, but in all cases includes personalized feedback, a summary of clinical measurements (weight, blood pressure, clinically relevant laboratory tests), and counseling on heart disease prevention by qualified personnel (e.g., dietitian, nurse, health educator).

### End of Trial

At the conclusion of the full trial, study participants are informed about the overall findings of the trial. This may occur in the context of an individual interview, group meeting, or mailing.

## Screening and Data Collection Visits

### 6.4 Pre-Screening Visit (PSV)

#### Visit Windows

- If there is a reason to believe that eligibility status has changed, participants may repeat the PSV if they were ineligible the first time it was administered. The participant must be assigned a new ID number in this circumstance.
- If 4 months (120 days) or more elapse between the PSV and G1, some PSV questions must be repeated (Form #107)
- If 3.5 months (105 days) or more elapse between Eligibility Form #102 and G1, then participant must repeat the entire screening process using a new participant ID.

Screening Visit Windows	
PSV to G1	≤ 4 months (120 days)
Eligibility Form #102 to G1	≤ 3.5 months (105 days)

#### Visit Preparation and Obtaining Participant ID#

- Obtain participant's name and DOB
- Obtain a participant ID number by logging on to the WLM website at <https://www.kpchr.org/wlmmanage/>
- Go to Data Entry/management/participant management/add participant
- Enter first name, last name, DOB, cohort number, site
- Click on <Add participant/Get participant ID>
- Use the 6-digit ID number on all forms and relevant paperwork relating to participant
- Sites can type the participant ID for all forms (except PSV) straight on to the participant ID area for .pdf version of forms on the website. All screening forms except PSV also have an additional area on the top of the form to type in a 10-digit acrostic. The acrostic is not required and is left up to individual sites to use if needed. Participant ID is required on all forms.

#### Visit Checklist/Procedures

___	Consent for PSV (if required by local IRB)		Local procedure
___	Greet participant(s)		
___	Describe study and answer questions		
___	Obtain participant contact information	Section 13	Form #100
___	Obtain prescreen eligibility information	Section 13	Form #101A or B

#### Equipment Required

Locally determined

#### Form Completion Checklist

<i>Number</i>	<i>Form Name</i>
Form 100	Participant Contact Form
Form 101A or B	PSV Form (data entry not required for ineligibles)
Form 107	Eligibility Follow-Up Questionnaire (if PSV ≥ 4 months)

## 6.5 Screening Visits

Screening Visit Windows	
All screening measurements to G1	≤ 3.5 months (105 days)
Second weight to G1	≤ 2 weeks, preferably at G1
Form #122, Beliefs and Attitudes Questionnaire	Completed and data entered by G4

### Screening Schedule and Visit Windows

Each site determines how many visits to schedule in order to obtain the measurements required during screening. At a minimum, however, at least two visits are required since weight must be measured twice during screening (BMI Form #105, Weight Form #106). Weight (Form #105 and #106) and medication forms (#103 and #104) should be completed at the same time.

Screening schedules may differ from site to site. The shortest possible screening interval is 6 days (to include 4 days of accelerometry and 5 days of food records.) Accelerometry must be measured for 94 hours from the start of recording to the end of recording and, at a minimum, must capture at least 10 hours/day of activity on 4 days, one of which must be a weekend day. Consecutive days of accelerometry measurement are preferred. Where possible, collecting a full 7 days of activity with both weekend days is preferred. Five days of food records are required within an 8-day window. Form #122, the Beliefs and Attitudes Questionnaire, must be completed and data entered by G4.

If more than 4 months elapse between the PSV and G1, the PSV eligibility requirements must be repeated by filling out Form #107. The window for all other data collection and G1 is 3.5 months (105 days).

### Visit Preparation

- Obtain participant charts
- Prepare accelerometers

### Visit Checklist/Procedures

___	Consent	Local procedure	
___	Weight	Section 7	Form 106
___	Height	Section 7	Form 105
___	Calculate BMI		Form 105
___	Draw and store blood for lab tests	Section 7	Form 117
___	Complete Rose Angina Questionnaire	Section 13	Form 108
___	Complete Medication Forms	Section 13	Forms 103, 104
___	Complete FFQ	Section 13	Block 98
___	Accelerometer application, instructions, and return	Sections 7, 13	Form 116
___	Physical Activity	Sections 7, 13	Form 121
___	Complete other questionnaires	Section 13	Forms 109-114
___	Complete and collect 5-day Food Record		Local form
___	Complete Motivational Assessment	Section 6	Form 118
___	Complete Phase I Elig Checklist	Section 13	Form 119
___	Beliefs and Attitudes Quest.	Section 13	Form 122
___	Perception of Participation in Research	Section 13	Form 123
___	Weight Loss History Quest	Section 13	Form 124
___	Patient History Quest	Section 13	Form 125
___	Physician Approval Form	Section 13	Form 120
___	Eligibility Form		Form 102
___	Initial Phase I Group Assignment Form		Form 126



## Equipment Required

<i>Number</i>	<i>Item(s)</i>
1	Digital scale
1	Stadiometer
1	Set lab supplies
1	Accelerometer

## Form Completion Checklist

<i>Number</i>	<i>Form Name</i>
Form 102:	Eligibility Form ( <b>Screening</b> )
Form 103:	Medication Tracking Form ( <b>Screening</b> , Baseline, 12, 30 months)
Form 104:	Summary Medication Use Form ( <b>Screening</b> , Baseline, 12, 30 months)
Form 105:	BMI Form ( <b>Screening</b> )
Form 106:	Weight Form ( <b>Screening</b> , Baseline, 6, 12, 18, 24, 30 months)
Form 107:	Eligibility Follow-Up Questionnaire ( <b>Screening</b> , if exceeded 4 month window)
Form 108:	Rose Angina Questionnaire ( <b>Screening</b> , Baseline, 6, 12, 18, 24, 30 months)
Form 109:	SF-36 Questionnaire (Screening, Baseline, 12, 30 months)
Form 110:	Social Support and Eating Habits ( <b>Screening</b> , Baseline, 12, 30 months)
Form 111:	Social Support and Exercise ( <b>Screening</b> , Baseline, 12, 30 months)
Form 112:	Perceived Stress Questionnaire ( <b>Screening</b> , Baseline, 12, 30 months)
Form 113:	PHQ-8 ( <b>Screening</b> , Baseline, 12, 30 months)
Form 114:	Depression Alert Form ( <b>Screening</b> , Baseline, 12, 30 months) (If needed)
Block 98:	FFQ ( <b>Screening</b> , Baseline, 12, 30 months) (Sent to site)
Form 116:	Accelerometry ( <b>Screening</b> , Baseline, 12, 30 months)
Form 117:	Lab Collection Form ( <b>Screening</b> , Baseline, 12, 30 months)
Form 118:	Motivational Assessment Interview ( <b>Screening</b> )
Local Form:	5-day Food Record ( <b>Screening</b> ) (Sent to sites)
Form 119:	Phase I Eligibility Review ( <b>Screening</b> )
Form 120:	Physician Approval Form (If needed, <b>Screening</b> , Baseline, 6, 12, 18, 24, 30 months) (If needed)
Form 121:	Physical Activity Form ( <b>Screening</b> , Baseline, 12, 30 months)
Form 122:	Beliefs and Attitudes of WLM participants ( <b>Screening</b> )
Form 123:	Perception of Participation in Clinical Research ( <b>Screening</b> )
Form 124:	Weight Loss History Questionnaire ( <b>Screening</b> )
Form 125:	Patient History Questionnaire ( <b>Screening</b> )
Form 126:	Initial Phase I Group Assignment Form ( <b>Screening</b> )
Form 502:	Study Suspension Form ( <b>Screening</b> , Phase I, Phase II, If needed)
Form 503:	Participant Transfer Form (If needed)

## Additional Information

- Schedule participant accelerometer removal and return of the device 4-7 days (at least 94 hours) following initiation of accelerometer measurement, or arrange for participant to return the device by mail.
- Upload accelerometer data to CC.
- Send e-mail to participant instructing them to go to the WLM participant web access website and enter their participant ID#. E-mail should include their participant ID# and the website URL for confirming internet access:  
<http://www.wlmtrial.org/Anonymous/WLMWebTest.aspx>
- To obtain a list of participants who have fulfilled the web usage eligibility requirements, check report “Recruitment – Confirm Web Access” on WLM website:  
[www.kpchr.org/wlmmanage](http://www.kpchr.org/wlmmanage)  
Select <Data entry/management>  
Select <Reports>  
Select <Recruitment – confirm web access>
- Store lab samples.

## 6.6 Motivational Assessment

### Motivational Assessment Questionnaire Interview Form 118

#### Overview

Potential research participants may be ambivalent about participating in behavioral clinical trials. When people are ambivalent, participation becomes challenging and interest may wane. Over time, that ambivalence may lead to lack of interest, guilt, disappointment, and/or apathy, and cause them to consider dropping out of the study. Therefore, participants need the opportunity to identify and resolve some of their ambivalence before they agree to participate in a study.

In addition, a participant who exudes enthusiasm with no questions about participation may be unrealistic. This also needs to be explored.

#### Purpose and Goals

Form 118: Motivational Assessment Interview is a tool to facilitate a collaborative and evocative discussion about trial participation with the participant. The discussion focuses on:

1. Their interest, reasons and commitment to participating in WLM
2. Identifying ambivalence about participating
3. Identifying unrealistic expectations
4. Helping participants determine whether or not to participate.

#### Background

Motivational interviewing (MI) is an effective approach to overcoming the ambivalence that interferes with making decisions. Miller and Rollnick began publishing their theories and beliefs in the early 1990's. They have developed specific strategies that can help people make decisions and strengthen their commitment to habit change. Some of their strategies are used in the administration of Form 118.

#### Materials and Reading

##### Books

- *Motivational Interviewing, Preparing People to Change Addictive Behavior*, William R. Miller & Stephen Rollnick, The Guilford Press, 1991
- *Health Behavior Change, A Guide for Practitioners*, Stephen Rollnick, Pip Mason, Chris Butler, Churchill Livingstone, 1999
- *Motivational Interviewing, Preparing People for Change, Second Edition*, William R. Miller, Stephen Rollnick, The Guilford Press, 2002

##### Video (optional)

Health Behavior Change, A Selection of Strategies, An Aid for Trainers

Media Resources Centre

UWCM, Cardiff CF14 4XN, Wales, UK

Tel: 029 2074 3305

FAX: 029 2074 2120

Email: [med-res@cardiff.ac.uk](mailto:med-res@cardiff.ac.uk)

<http://www.uwcm.ac.uk/med-res> or

<http://www.jeffallison.co.uk>

##### Website

<http://motivationalinterview.org>

##### Training Tasks

1. Read/review the above books and website. Specifically,
2. View the video and answer the following questions:
  - What was different about the two scenarios?
  - Describe the relationship between the patient and counselor in Scenario 1 and 2.
  - What was different about the patient response in Scenario 1 and 2?
3. Review the sample interview script
4. Do a practice interview with another WLM staff member acting as a participant

## **Form 118 Interview**

### **Interview Flow**

Set the agenda:

- Introduce self
- State why you are meeting
- Identify a time line
- Ask permission to continue

Conduct the Interview

Summarize

Ask final question

### **Interview Objectives**

#### **Staff Person Objectives**

1. Establish rapport with the participant
2. Set an agenda
3. Assess how important it is for the participant to participate in WLM
4. Assess how confident they are that they can meet the study goals regarding retention and habit changes
5. Reduce participant's resistance
6. Exchange information
7. Use reflective listening statements, and open-ended questions
8. Show and be empathetic.
9. Summarizes for clarity

#### **Potential Participant's Objectives**

1. Comfortable and open talking with the staff person about their reasons for wanting to participate in the study
2. Allowed to talk without frequent interruptions
3. Not resistant

## **Form 118: Motivational Assessment Interview Script**

### *Directions*

1. The questions do not need to be asked in order and not all questions may need to be used since the participant may give responses to questions when answering another question.
2. There are more questions than needed and some questions are the same, but worded differently. The questions are there to support the discussion with the participant. Do not use them as a verbatim script.
3. Give the participant time to respond to the questions and reflect back as a statement (not a question) what they said.
4. Use open-ended questions or statements sparingly.
5. Use reflections more often than open ended questions.
6. Use no closed ended questions. (Ex. How many servings of fruits and vegetables do you eat each day?)
7. Suggest not giving the participant your professional credentials to reduce potential participant discomfort. For example if participant knows you are a nutritionist they may be uncomfortable talking about what they eat.

### *Set the Agenda*

*Hi, my name is \_\_\_\_\_ (name). I am one of the WLM staff here at \_\_\_\_\_ (site name).*

*I would like to take about 15 minutes to talk about some of your thoughts about why you might be interested in participating in WLM and also discuss some of the concerns that you might have.*

*Is that OK with you?*

*What would you like to add to this discussion or what questions do you have?*

### **Interview**

1. Explore participant's rationale for participating in the Weight Loss Maintenance Study.
  - *Tell me some of the reasons why you are interested in participating in WLM.*
  - *What might be some reasons that you shouldn't participate in the study?*
  
2. Explore participant's interest and ability to eat fewer calories, less fat and more fruits, vegetable and dairy foods.
  - *Tell me about some of your experiences trying to eat fewer calories?*
  - *If you participate in the group sessions you will be asked to eat a lot of fruits, vegetables and dairy foods. What is your interest and ability in doing this?*
  - *How likely is it for you to be able to do this?*
  - *What might make it hard?*
  - *As you look back at your experience, particularly as a younger child, eating fruits and vegetables, what are some those experiences? What are your favorite fruits and vegetables? Least favorite? Which fruits and vegetables will you even consider eating?*
  
3. Explore participant's willingness and ability to eat a healthy diet and lose 9 pounds.
  - *The study goal is for each person to lose at least 9 pounds. What has been your experiencing losing weight?*
  - *How confident are you that you will reach the 9-pound goal?*
  - *What will be some of your challenges?*
  
4. Explore participant's interest in not using weight loss medications for the duration of the trial.
  - *For the study investigators to adequately answer the question about what it takes to help people maintain weight loss, they need each participant to not use any weight loss medications. What have been your experiences using weight loss medications in the past?*
  - *If used drugs ...how comfortable are you to not use drugs over the next 3 years?*
  - *How likely is it that you would not use them? Very likely? Not so likely?*
  - *If not used drugs – go no further*
  
5. Explore participant's commitment to the study time demands. (Review study time commitments).
  - *Clinical trials can take a lot of your time (clinic visits, group sessions, keeping food records, exercising, cooking differently). What do you think about this?*
  - *What might make it hard to meet all the study commitments? (Home demands, work schedule, other commitments, caring for other family members, etc).*
  - *What are some of your concerns?*
  - *Because the study is three years we realize that other commitments may arise that you don't expect now that might make it hard to participate. What are your thoughts about this the effect on your participation in the study if such a demand on your time occurs during the 36-months?*
  
6. Explore participant's interest and ability in keeping food records 5 days per week for 3 years.
  - *From previous research we know that keeping records of what you eat and the physical activity you do is one of the leading indicators of weight loss. In other words, the more records you keep the more weight you lose. Tell me about your interest and confidence in being able to keep food records during the course of the study.*
  - *What might you not like about keeping food records?*
  - *What will make it hard? What might interfere?*
  - *How likely are you to be able to do this?*
  - *What did you think if the food recording that we asked you to keep a few weeks ago? If you had to keep these indefinitely, what might your reaction be?*

7. Explore participant's feelings and concerns about weight loss.
  - *Tell me about your experiences trying to lose weight in the past?*
  - *What has worked?*
  - *What has made it hard?*
  - *What do you find the most challenging about losing weight?*
  - *What concerns or fears do you have about losing weight?*
  - *You won't be able to participate in the second phase of the study unless you lose at least 9 pounds, how likely do you think it will be for you to do this?*
  
8. Explore participant's commitment to doing regular physical activity
  - *We know from past experience that those that are the most successful losing weight and maintaining the weight loss are people who do regular physical activity. They exercise almost daily. We will be emphasizing and asking you to do physical activity in the group sessions then continue to emphasize it when you begin the second phase. Tell me about your thoughts around physical activity.*
  - *What is your interest in making physical activity part of your daily routine?*
  - *How confident are you that will be able to do this?*
  - *What has been your past experience incorporating physical activity into your "life"?*
  - *What do you think might interfere?*
  - *What influence might your family have?*
  
9. Explore participant's commitment to attending 20 weekly group sessions and being randomized into one of three treatment groups
  - *As you know the study has two phases. Phase 1 is 20 weekly group sessions. The second phase is another 30 months. Tell me about the likelihood that you will be able to attend all 20-group sessions.*
  - *What might interfere?*
  - *What might make it hard?*
  
10. Explore participant's comfort level and willingness to accept randomization assignment no matter which arm.
  - *At the end of the 20 group sessions and after losing at least 9 pounds, you will be asked to join the study and will be randomly assigned to one of three groups. What might be your reaction if you are not assigned to your favorite group?*
  - *If you are assigned to your least favorite group, how might that effect your participation?*
  
11. Explore participant's support system.
  - *Making habit changes is challenging and can be difficult. Tell me about your family or friends. What role will they play in your effort to do more physical activity, eat healthier and lose weight?*
  - *When you have tried to lose weight in the past, what has been their involvement?*
  - *What made it hard?*
  - *What were some of the challenges that they posed or how did they interfere?*
  - *How did they help?*
  - *What is their interest now?*
  
12. Explore participant's confidence accessing the web and using the Internet.
  - *Earlier in the screening visits we asked you to access our website. What did you think?*
  - *How did it go?*
  - *What were some of the challenges?*
  - *If you were asked to go to our website daily, what would be your response? How hard would this be?*
  
13. Explore participants overall commitment to the study.

- *We have just spent \_\_\_\_\_ (minutes) talking about the study, if I was going to ask you to join the study in the next few minutes, what might be your answer?*
- *How do you rate your enthusiasm to participate, if 0 was you had no interest at all to 10 being totally interested? Where would you put yourself on this scale?*
- *Why did you pick a \_\_\_\_ instead of a \_\_\_\_\_ (use a lower number)?*
- *What would have to happen to make you select a number further up on the scale?*
- *How confident are you that you will participate in the study over the next 3 years?*

#### *Summarize*

So let me see if I can summarize our conversation.

*On one side you are feeling ... (reflect emotions).*

*On the other side you are .....*

So where does that leave you?

Reflect back.

#### *Next Steps*

Thank you so much for taking the time to talk with me today. I have really enjoyed visiting with you and thank you for your effort and time attending the screening visits.

*After today's visit the staff will review the information that you have given us, determine your eligibility and then we will get back to you about your participation in the study. One of the staff will call you.*

*Is that OK with you? What questions do you have?*

## **6.7 Phase I Registration**

A participant is considered registered for Phase I when the site has entered a valid and complete Phase I Eligibility Checklist Form #119 and passed all the eligibility criteria set by the data system. Upon submission of this form, the Coordinating Center data systems validates that the participant is eligible for Phase I, and notifies the site that the participant is eligible. If a participant fails an eligibility check, the site is also notified, and the site must rectify any eligibility errors in the participant's data as soon as possible. If the site is not able to validate the data, the participant may be assigned to another Phase I group, and subsequent attempts to establish eligibility may be made. If eligibility is never adequately established, the CC may declare the participant ineligible for Phase II.

Under no circumstances may a participant begin a Phase I group if they have not passed all of their eligibility checks. If a site allows a participant to begin a Phase I group prior to establishing their eligibility, it will be considered a protocol violation. Protocol violations will be tracked and reported to the Steering Committee.

## 6.8 Baseline Visits

Baseline Visit Windows	
All data except weight	Beginning of week 17 post G1 to randomization but no later than three weeks post G20
First baseline weight	On or after G19 and at least 1 week before second baseline weight
Second baseline weight	At least one week after first baseline weight, up to and including the randomization visit. No later than three weeks after G20.
*If outside allowed range, collect data, enter forms, and adjudication committee will determine if/how to use. It should <b>not</b> be assumed that protocol exceptions will be granted for instances where randomization eligibility is concerned.	

### Baseline Schedule and Visit Windows

The data collection window for baseline data goes from week 17 of Phase I up to the time of randomization, which must occur no later than three weeks post G20. G20 must occur not later than 25 weeks after G1. Each site determines how many visits to schedule in order to obtain the required baseline measurements. At a minimum, however, at least two visits are required since weight and blood pressure must each be measured twice during screening, and baseline weights must occur at least one week apart. Blood pressure and medication data should be collected on the same day.

### Visit Preparation

- Obtain participant charts
- Prepare ABPM devices
- Prepare accelerometers

### Visit Checklist/Procedures

___	Consent	Local procedure	
___	Weight	Section 7	Form 106
___	Rose Angina Questionnaire	Section 13	Form 108
___	Complete Medication Forms	Section 13	Forms 103, 104
___	Complete FFQ	Section 13	Block 98
___	Accelerometer application, instructions, and return	Sections 7, 13	Form 116
___	Physical Activity	Sections 7, 13	Form 121B
___	Blood pressure	Section 7	Form 204, 209
___	Draw and store blood for lab tests	Section 7	Form 117
___	Medical Events Screening Form	Section 13	Form 500
___	Complete other questionnaires	Section 13	Forms 109-114
___	Baseline Eligibility		Form 203
___	Phase II Eligibility Review		Form 208

### Equipment Required

Number	Item(s)
1	Scale
1	ABPM
1	Set lab supplies
1	Accelerometer

## Form Completion Checklist

<i>Number</i>	<i>Form Name</i>
Form 103:	Medication Tracking Form (Screening, <b>Baseline</b> , 12, 30 months)
Form 104:	Summary Medication Use Form (Screening, <b>Baseline</b> , 12, 30 months)
Form 106:	Weight (Screening, <b>Baseline</b> , 6, 12, 18, 24, 30 months)
Form 108:	Rose Angina Questionnaire (Screening, <b>Baseline</b> , 6, 12, 18, 24, 30 months)
Form 109:	SF-36 Questionnaire (Screening, <b>Baseline</b> , 12, 30 months)
Form 110:	Social Support and Eating Habits ((Screening, <b>Baseline</b> , 12, 30 months)
Form 111:	Social Support and Exercise (Screening, <b>Baseline</b> , 12, 30 months)
Form 112:	Perceived Stress Questionnaire (Screening, <b>Baseline</b> , 12, 30 months)
Form 113:	PHQ-8 (Screening, <b>Baseline</b> , 12, 30 months)
Form 114:	Depression Alert Form (Screening, <b>Baseline</b> , 12, 30 months) (If needed)
Block 98:	FFQ (Screening, <b>Baseline</b> , 12, 30 months)
Form 116:	Accelerometry (Screening, <b>Baseline</b> , 12, 30 months)
Form 121B:	Physical Activity Form (Screening, <b>Baseline</b> , 12, 30 months)
Form 117:	Lab Collection Form (Screening, <b>Baseline</b> , 12, 30 months)
Form 120:	Physician Approval Form (if needed)
Form 203:	Baseline Eligibility Questionnaire ( <b>Baseline</b> )
Form 204:	Blood Pressure (Visit 1)( <b>Baseline V1</b> , 12 month V1, 30 month V1)
Form 205:	Short Physical Activity Form (G10 - Phase I)
Form 208:	Phase II Eligibility ( <b>Baseline</b> )
Form 209:	Blood Pressure (Visit 2) ( <b>Baseline V2</b> , 12 month V2, 30 month V2)
Form 500:	Medical Events Screening Form ( <b>Baseline</b> , 6, 12, 18, 24, 30 months)
Form 502:	Study Suspension Form (If needed)
Form 503:	Participant Transfer Form (If needed)

## Additional Information

- Schedule participant accelerometer removal and return of the device 4-7 days following initiation of accelerometer measurement
- Upload accelerometer data to CC
- Store lab samples



## 6.9 Randomization Visit

Randomization Visit Windows	
Randomization visit	Following completion of Phase I, no later than three weeks after G20.
<i>*If outside allowed range, collect data, enter forms, and adjudication committee will determine if/how to use. Randomization will <b>not</b> be allowed until clearance has been given by the adjudication committee.</i>	

### Randomization Schedule and Visit Windows

Any baseline data collection may happen at the Randomization visit except for the first baseline weight, which must occur at least one week prior to the second baseline weight.

Randomization must occur no later than three weeks after G20. Baseline measurements may be obtained at the randomization visit except for the first baseline weight, BP, and medication forms (#103 and #104), which must be obtained at least one week prior to the second baseline weight.

### Visit Preparation

- Obtain participant charts
- Prepare ABPM devices
- If needed, prepare accelerometers

### Visit Checklist/Procedures

___	Consent (if not already obtained)	Local procedure	
___	Weight	Section 7	Form 106
___	Blood pressure (Visit 1)	Section 7	Form 204
___	Blood pressure (Visit 2)	Section 7	Form 209
___	Complete Medication Forms	Section 13	Forms 103, 104

And, if not already obtained:

___	Rose Angina Questionnaire	Section 13	Form 108
___	Complete FFQ	Section 13	Block 98
___	Accelerometer application, instructions, and return	Sections 7, 13	Forms 116
___	Physical Activity	Sections 7, 13	Form 121B
___	Draw and store blood for lab tests	Section 7	Form 117
___	Medical Events Screening Form	Section 13	Form 500
___	Complete other questionnaires	Section 13	Forms 109-114
___	Baseline Eligibility		Form 203
___	Phase II Eligibility Review		Form 208

### Equipment Required

<i>Number</i>	<i>Item(s)</i>
1	Scale
1	ABPM
1	Set lab supplies (if needed)
1	Accelerometer (if needed)

## Form Completion Checklist

<i>Number</i>	<i>Form Name</i>
Form 103:	Medication Tracking Form (Screening, <b>Baseline</b> , 12, 30 month)
Form 104:	Summary Medication Use Form (Screening, <b>Baseline</b> , 12, 30 months)
Form 106:	Weight (Screening, <b>Baseline</b> , 6, 12, 18, 24, 30 months)
Form 107:	Eligibility Follow-Up Questionnaire (if needed)
Form 108:	Rose Angina Questionnaire (Screening, <b>Baseline</b> , 6, 12, 18, 24, 30 months)
Form 109:	SF-36 Questionnaire (Screening, <b>Baseline</b> , 12, 30 months)
Form 110:	Social Support and Eating Habits ((Screening, <b>Baseline</b> , 12, 30 months)
Form 111:	Social Support and Exercise (Screening, <b>Baseline</b> , 12, 30 months)
Form 112:	Perceived Stress Questionnaire (Screening, <b>Baseline</b> , 12, 30 months)
Form 113:	PHQ-8 (Screening, <b>Baseline</b> , 12, 30 months)
Form 114:	Depression Alert Form (Screening, <b>Baseline</b> , 12, 30 months)
Block 98:	FFQ (Screening, <b>Baseline</b> , 12, 30 months)
Form 116:	Accelerometry (Screening, <b>Baseline</b> , 12, 30 months)
Form 121B:	Physical Activity Form (Screening, <b>Baseline</b> , 12, 30 months)
Form 117:	Lab Collection Form
Form 203:	Baseline Eligibility Questionnaire ( <b>Baseline</b> )
Form 204:	Blood Pressure (Visit 1) ( <b>Baseline V1</b> , 12 month V1, 30 month V1)
Form 205:	Short Physical Activity Form ( <b>Phase I G10</b> , 6, 18, 24 months)
Form 208:	Phase II Eligibility ( <b>Baseline</b> )
Form 209:	Blood Pressure (Visit 2) ( <b>Baseline V2</b> , 12 month V2, 30 month V2)
Form 500:	Medical Events Screening Form ( <b>Baseline</b> , 6, 12, 18, 24, 30 months)
Form 502:	Study Suspension Form (If needed)
Form 503:	Participant Transfer Form (If needed)

## Additional Information

- Schedule participant accelerometer removal and return of the device 4-7 days following initiation of accelerometer measurement
- Upload accelerometer data to CC

## 6.10 6-Month Visit

6-Month Visit Measurement Targets and Allowable Windows	
<i>Target</i>	<i>6 months from Randomization date ± 3 weeks</i>
Earliest 6-month Data Collection	5 months from Randomization date*
Latest 6-month Data Collection	8 months from Randomization date*
*If outside allowed range, collect data, enter forms, and adjudication committee will determine if/how to use.	

### Six-month Schedule and Visit Windows

The six-month data is expected to be completed at a single clinic visit. The target window for this visit is plus or minus 3 weeks from the six-month anniversary date. The allowable window extends from 1 month before to 2 months after the six-month anniversary date.

### Visit Preparation

- Obtain participant charts

### Visit Checklist/Procedures

___	Measure weight	Section 7	Form 106
___	Complete Rose Angina	Section 13	Form 108
___	Complete Medical Events Screening Form	Section 13	Form 500
___	Complete Short Physical Activity Form		Form 205

### Equipment Required

<i>Number</i>	<i>Item(s)</i>
1	Scale

### Form Completion Checklist

<i>Number</i>	<i>Form Name</i>
Form 106:	Weight (Screening, Baseline, 6, 12, 18, 24, 30 months)
Form 108:	Rose Angina Questionnaire (Screening, Baseline, 6, 12, 18, 24, 30 months)
Form 205:	Short Physical Activity Form (Phase I G10, 6, 18, 24 months)
Form 500:	Medical Events Screening Form (Baseline, 6, 12, 18, 24, 30 months)

## 6.11 12-Month Visit

12-Month Visit Measurement Targets and Windows	
Target	12 months from Randomization date $\pm$ 3 weeks
Earliest 12-month Data Collection	10 months from Randomization date*
Latest 12-month Data Collection	17 months from Randomization date*
*If outside allowed range, collect data, enter forms, and adjudication committee will determine if/how to use.	

### 12-month Schedule and Visit Windows

The 12-month data is expected to be completed in two clinic visits. The target window for these measures is plus or minus 3 weeks from the 12-month anniversary date. The allowable window extends from 2 months before to 5 months after the 12-month anniversary date. Each site determines how many visits to schedule in order to obtain the required measurements. At a minimum, however, at least two visits are required since weight and blood pressure must each be measured on two separate days. Weight and blood pressure measurements should be taken on the same day, and the medication forms (#103 and #104) should also be completed at this time.

### Visit Preparation

- Obtain participant charts
- Prepare ABPM devices
- Prepare accelerometers

### Visit Checklist/Procedures

___	Weight	Section 7	Form 106
___	Rose Angina Questionnaire	Section 13	Form 108
___	Complete Medication Forms	Section 13	Forms 103, 104
___	Complete FFQ	Section 13	Block 98
___	Accelerometer application, instructions, and return	Sections 7, 13	Forms 116
___	Physical Activity	Sections 7, 13	Form 121B
___	Blood pressure (Visit 1)	Section 7	Form 204
___	Blood pressure (Visit 2)	Section 7	Form 209
___	Draw and store blood for lab tests	Section 7	Form 117
___	Medical Events Screening Form	Section 13	Form 500
___	Complete other questionnaires	Section 13	Forms 109-114

### Equipment Required

Number	Item(s)
1	Scale
1	ABPM
1	Set lab supplies
1	Accelerometer

## Form Completion Checklist

<i>Number</i>	<i>Form Name</i>
Form 103:	Medication Tracking Form (Screening, Baseline, <b>12</b> , 30 months)
Form 104:	Summary Medication Use Form (Screening, Baseline, <b>12</b> , 30 months)
Form 106:	Weight (Screening, Baseline, 6, <b>12</b> , 18, 24, 30 months)
Form 107:	Eligibility Follow-Up Questionnaire (if needed)
Form 108:	Rose Angina Questionnaire (Screening, Baseline, 6, <b>12</b> , 18, 24, 30 months)
Form 109:	SF-36 Questionnaire (Screening, Baseline, <b>12</b> , 30 months)
Form 110:	Social Support and Eating Habits ((Screening, Baseline, <b>12</b> , 30 months)
Form 111:	Social Support and Exercise (Screening, Baseline, <b>12</b> , 30 months)
Form 112:	Perceived Stress Questionnaire (Screening, Baseline, <b>12</b> , 30 months)
Form 113:	PHQ-8 (Screening, Baseline, <b>12</b> , 30 months)
Form 114:	Depression Alert Form (Screening, Baseline, <b>12</b> , 30 months)
Block 98:	FFQ (Screening, Baseline, 12, 30 months)
Form 116:	Accelerometry (Screening, Baseline, <b>12</b> , 30 months)
Form 121B:	Physical Activity Form (Screening, Baseline, <b>12</b> , 30 months)
Form 117:	Lab Collection Form
Form 500:	Medical Events Screening Form (Baseline, 6, <b>12</b> , 18, 24, 30 months)

## Additional Information

- Schedule participant accelerometer removal and return of the device 4-7 days following initiation of accelerometer measurement
- Upload accelerometer data to CC

## 6.12 18-Month Visit

18-Month Visit Measurement Targets and Windows	
<i>Target</i>	<i>18 months from Randomization date ± 3 weeks</i>
Earliest 18-month Data Collection	17 months from Randomization date*
Latest 18-month Data Collection	20 months from Randomization date*
*If outside allowed range, collect data, enter forms, and adjudication committee will determine if/how to use.	

### 18-month Schedule and Visit Windows

The 18-month data is expected to be completed at a single clinic visit. The target window for this visit is plus or minus 3 weeks from the 18-month anniversary date. The allowable window extends from 1 month before to 2 months after the 18-month anniversary date.

### Visit Preparation

- Obtain participant charts

### Visit Checklist/Procedures

___	Measure weight	Section 7	Form 106
___	Complete Rose Angina	Section 13	Form 108
___	Complete Medical Events Screening Form	Section 13	Form 500
___	Complete Short Physical Activity Form		Form 205

### Equipment Required

<i>Number</i>	<i>Item(s)</i>
1	Scale

### Form Completion Checklist

<i>Number</i>	<i>Form Name</i>
Form 106:	Weight (Screening, Baseline, 6, 12, <b>18</b> , 24, 30 months)
Form 108:	Rose Angina Questionnaire (Screening, Baseline, 6, 12, <b>18</b> , 24, 30 months)
Form 500:	Medical Events Screening Form (Baseline, 6, 12, <b>18</b> , 24, 30 months)
Form 205:	Short Physical Activity Form (Phase I G10, 6, <b>18</b> , 24 months)

## 6.13 24-Month Visit

24-Month Visit Measurement Targets and Windows	
<i>Target</i>	<i>24months from Randomization date <math>\pm</math> 3 weeks</i>
Earliest 24-month Data Collection	23 months from Randomization date*
Latest 24-month Data Collection	26 months from Randomization date*
<i>*If outside allowed range, collect data, enter forms, and adjudication committee will determine if/how to use.</i>	

### 24-month Schedule and Visit Windows

The 24-month data is expected to be completed at a single clinic visit. The target window for this visit is plus or minus 3 weeks from the 24-month anniversary date. The allowable window extends from 1 month before to 2 months after the 24-month anniversary date.

### Visit Preparation

- Obtain participant charts

### Visit Checklist/Procedures

___	Measure weight	Section 7	Form 106
___	Complete Rose Angina	Section 13	Form 108
___	Complete Medical Events Screening Form	Section 13	Form 500

### Equipment Required

<i>Number</i>	<i>Item(s)</i>
1	Scale

### Form Completion Checklist

<i>Number</i>	<i>Form Name</i>
Form 106:	Weight (Screening, Baseline, 6, 12, 18, <b>24</b> , 30 months)
Form 108:	Rose Angina Questionnaire (Screening, Baseline, 6, 12, 18, <b>24</b> , 30 months)
Form 500:	Medical Events Screening Form (Baseline, 6, 12, 18, <b>24</b> , 30 months)
Form 205:	Short Physical Activity From (Phase I G10, 6, 18, <b>24</b> months)

## 6.14 30-Month Visit and Phase III Randomization

30-Month Visit Measurement Targets and Windows	
<i>Target</i>	<i>30 months from Randomization date <math>\pm</math> 3 weeks</i>
Earliest 30-month Data Collection	28 months from Randomization date*
Latest 30-month Data Collection	33 months from Randomization date or end of June, 2007, whichever is earlier*
<i>*If outside allowed range, collect data, enter forms, and adjudication committee will determine if/how to use.</i>	

### 30-month Visit and Phase III Randomization Schedule and Visit Windows

The 30-month visit both closes out Phase II and begins the process of randomizing eligible participants to Phase III. Phase III procedures will be discontinued if the trial receives notification that funding for this phase is denied. The 30-month data is expected to be completed in two clinic visits. The target window for these measures are plus or minus 3 weeks from the 30-month anniversary date. The allowable window extends from 2 months before to 3 months after the 30-month anniversary date. Each site determines how many visits to schedule in order to obtain the required measurements. At a minimum, however, at least two visits are required since weight and blood pressure must each be measured on two separate days. Weight and blood pressure measurements should be taken on the same day, and the medication forms (#103 and #104) should also be completed at this time.

All 30-month data must be collected prior to randomization into Phase III. Phase II ends at the time a participant is randomized into Phase III and the Randomization program is run. If the participant does not show for a 30-month visit then Phase II ends at the end of the Phase II 30-month allowable window. Following the completion of 30-month data collection, an unblinded staff person obtains consent and randomizes the participant into Phase III. Please see diagram for scenarios of 30-month visit, Phase III consent, randomization, and transition visits. After a participant is randomized, no more 30-month data can be collected.

To randomize a participant a 30-month Form 106: Weight and Form 402: 30-Month and Phase III Eligibility Visit Form must be entered. An unblinded staff person will then need to go to the Phase III eligibility and randomization screens to check the participant's eligibility and randomize the participant. For each randomized participant a clinic schedule report will be run. Additional reports may be run depending on the participants randomization assignment.

For Phase III secondary aims, all participants will be randomized, regardless of whether or not they consent to re-enroll. Those participants who do not provide informed consent at the 30-month visit will be contacted at the 66m final visit and asked if they would be willing to consent to final data collection. In this case, consent for final data collection will be obtained prior to obtaining the 66m measurements.

A transition visit to enhance retention (for those randomized to usual care), to orient the participant to Phase III intervention (for those randomized to an active treatment arm), or to orient the participant to a control treatment group (PC-Control or IT-Control) is then held. The transition visit ideally occurs at the time of randomization, but must occur within one month of randomization.

Participants who are not eligible or who refuse to sign consent for Phase III are closed out at this visit. Staff should thank the participant for their contribution to the study. Staff may give participants individual-level feedback regarding their study measurements. *IF ASKED*, remind participants that lab specimens are banked for future research and may not ever be analyzed, that results would not likely be clinically useful when analyzed at a future time, but may help us understand predictors and responses to weight loss maintenance efforts in this population. NOTE: If desired, PC case managers may contact PC participants to thank participants and say goodbye.



### Phase III Randomization criteria

- Currently enrolled in WLM Phase II
- At least one 30-month Weight - Weight Form 106
- Not Pregnant or breastfeeding - Weight Form 106
- Signed consent for Phase III - Phase III Eligibility Form
- Weight must be within 2 weeks of randomization (Either from Form 106 or a Phase III Eligibility Follow-up Questionnaire)

### Visit Preparation

- Obtain participant charts
- Prepare ABPM devices
- Prepare accelerometers

### Visit Checklist/Procedures

___	Weight	Section 7	Form 106
___	Rose Angina Questionnaire	Section 13	Form 108
___	Complete Medication Forms	Section 13	Forms 103, 104
___	Complete FFQ	Section 13	Block 98
___	Accelerometer application, instructions, and return	Sections 7, 13	Forms 116
___	Physical Activity	Sections 7, 13	Form 121B
___	Blood pressure (Visit 1)	Section 7	Form 204
___	Blood pressure (Visit 2)	Section 7	Form 209
___	Draw and store blood for lab tests	Section 7	Form 117
___	Medical Events Screening Form	Section 13	Form 500
___	Complete other questionnaires	Section 13	Forms 109-114
___	Complete Phase III forms	Section 13	Forms 210, 211, 212, 402

### Equipment Required

<i>Number</i>	<i>Item(s)</i>
1	Scale
1	ABPM
1	Set lab supplies
1	Accelerometer

### Form Completion Checklist

#### Phase II closeout

<i>Number</i>	<i>Form Name</i>
Form 103:	Medication Tracking Form (Screening, Baseline, 12, <b>30</b> months)
Form 104:	Summary Medication Use Form (Screening, Baseline, 12, <b>30</b> months)
Form 106:	Weight (Screening, Baseline, 6, 12, 18, 24, <b>30</b> months)
Form 107:	Eligibility Follow-Up Questionnaire (if needed)
Form 108:	Rose Angina Questionnaire (Screening, Baseline, 6, 12, 18, 24, <b>30</b> months)
Form 109:	SF-36 Questionnaire (Screening, Baseline, 12, <b>30</b> months)
Form 110:	Social Support and Eating Habits ((Screening, Baseline, 12, <b>30</b> months)
Form 111:	Social Support and Exercise (Screening, Baseline, 12, <b>30</b> months)
Form 112:	Perceived Stress Questionnaire (Screening, Baseline, 12, <b>30</b> months)
Form 113:	PHQ-8 (Screening, Baseline, 12, <b>30</b> months)
Form 114:	Depression Alert Form (Screening, Baseline, 12, <b>30</b> months)
Form 115:	FFQ (Screening, Baseline, 12, <b>30</b> months)
Form 116:	Accelerometry (Screening, Baseline, 12, <b>30</b> months)
Form 121B:	Physical Activity Form (Screening, Baseline, 12, <b>30</b> months)
Form 117:	Lab Collection Form
Form 500:	Medical Events Screening Form (Baseline, 6, 12, 18, 24, <b>30</b> months)

#### Phase III

<i>Number</i>	<i>Form Name</i>
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Form 210	Weight Management Strategies
Form 211	Berlin Sleep Questionnaire
Form 212	Phase III Eligibility Follow-up Form
Form 402	30-Month and Phase III Eligibility Visit Form Phase III consent forms

#### Additional Information

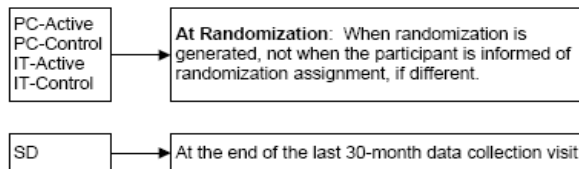
- Schedule participant accelerometer removal and return of the device 4-7 days following initiation of accelerometer measurement
- Upload accelerometer data to CC
- Obtain Phase III consent
- Randomize participant
- Hold transition visit immediately or schedule within one month

## WLM End of Phase II -Start of Phase III Process Revised-Wednesday, April 12, 2006

Phase III Randomization criteria:

- Currently enrolled in WLM Phase II
- At least on 30-month Weight-Weight Form 106
- Not Pregnant or breastfeeding-Weight Form 106
- Signed consent for Phase III-Phase III Eligibility Form
- Weight must be within 2 weeks of randomization (Either from Form 106 or a Phase III Eligibility Follow-Up Questionnaire)

### Phase III Begins:

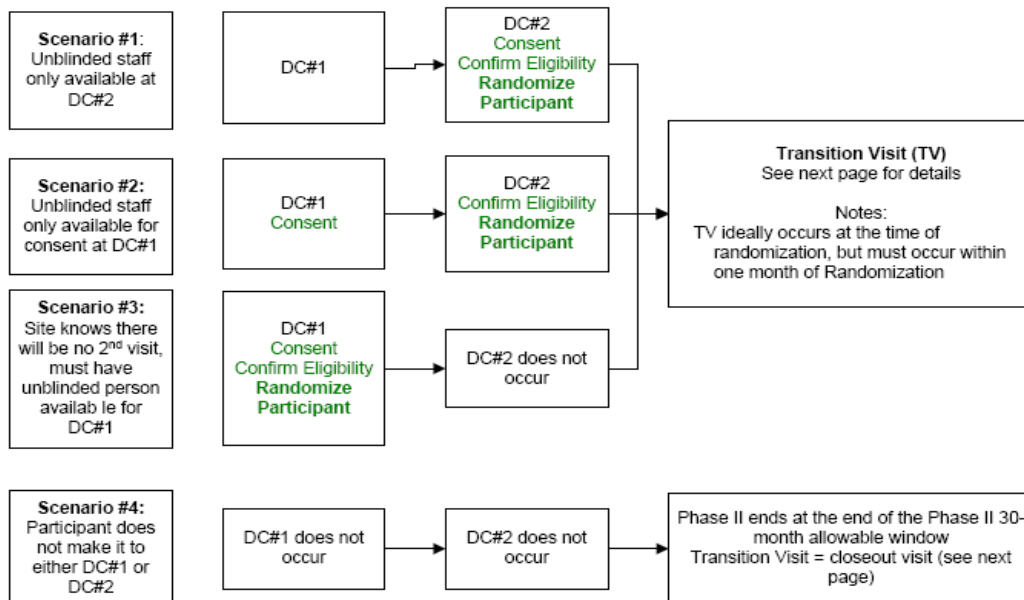


Consent, Confirm Eligibility, Randomize Participant = Unblinded Staff

Data collection = blinded staff

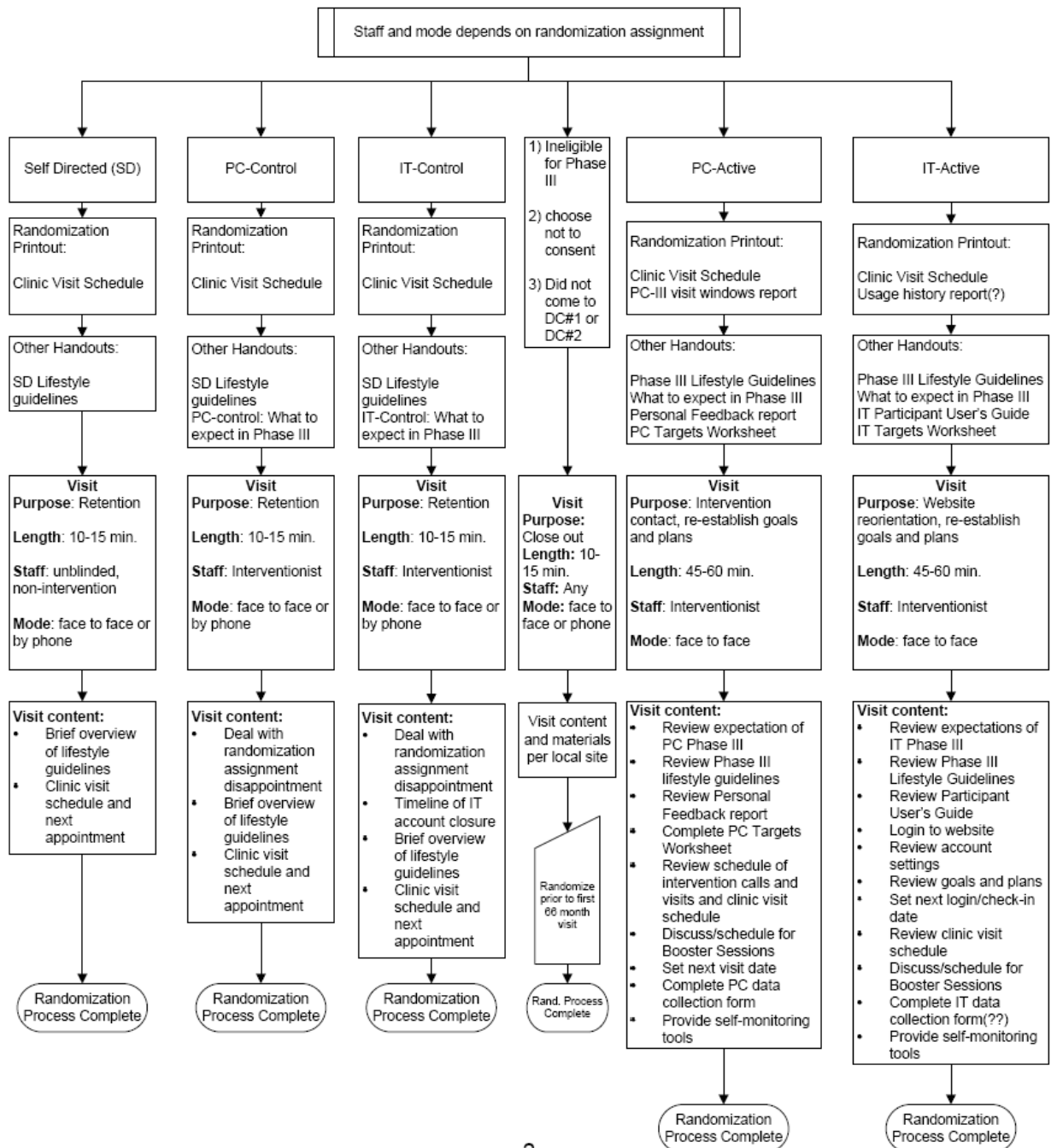
DC#1 = Phase II 30-month Data Collection Visit #1

DC#2 = Phase II 30-month Data Collection Visit #2



# Transition Visit Flow

Revised  
4/12/06



## 6.15 Final WLM Data Collection Visit

### Content and Schedule

Who: All participants who were randomized to Phase III

What: Phase III participants in all groups are invited to a single large event at which final data is collected. Phase II results may be presented at this event. No other data collection will be done. At sites' option, final data may instead be collected at individual visits.

### Window

The final data collection is expected to be completed at a single visit. The target window for this visit is 1 year +/- 6 months from the 30m visit. While the goal is to see as many people as possible prior to the holidays, participants may be scheduled after the holidays if necessary. Data collection must be completed by 2/29/08.

### Preparation

Prior to the event, sites have sent a locally-composed letter informing participants that the trial will end. Coordinators arrange to invite participants to a final meeting where results of the study will be presented and a final weight collected. Both clinic and intervention staff may attend this event. Certified staff collect final data.

### Procedures

#### *Final outcome collection*

Data collection for this visit includes only weight and the weight management strategies questionnaire. For group visits, participants are invited to arrive before the presentation for data collection.

#### *Presentation may include*

1. Phase II main results
2. Value to the community
3. Thanks for participating

#### *Other*

The self-administered form may be mailed ahead of time and brought to clinic staff at this group meeting or at the individual visit. Refreshments may be provided. At the presentation, Interventionists greet participants while waiting for data collection and the presentation.

### Equipment Required

<i>Number</i>	<i>Item(s)</i>
1	Digital scale

### Visit forms

<i>Number</i>	<i>Form Name</i>
Form 106	Weight
Form 210	Weight Management Strategies
Form 403	Closeout Visit Form

### Follow-up

This event is the final participant activity.

# Weight Loss Maintenance MOP

## 7 Measurements

### Summary of edits between Version 1.0 and Version 1.1:

#### Section 7.3

- Clarifies timing for second entry weight when participants have missed up to the first two intervention group meetings. This weight must be taken before any intervention takes place, must occur prior to G3, and can occur no later than 2 weeks after G1

### Summary of edits between Version 1.1 and Version 1.2:

- Clarifies the latest date that a second entry weight may be taken in order for a participant to take part in Phase I
- Clarifies new visit windows for randomization
- “De-links” weight and medication data collection

### Summary of edits between Version 1.2 and Version 1.3:

- Blood Pressure arm circumference measurement change: At baseline, 12, and 30 months, arm circumference is measured only at the first of the set of two visits. Use that same cuff size for all measures in that set.

### Summary of edits between Version 1.3 and Version 1.4:

### Summary of edits between Version 1.4 and Version 1.5:

#### Section 7.3

- Correction to timing of first baseline weight: removed incorrect reference to week 22.

#### Section 7.5.3

- Link to accelerometer software upgrade and instructions
- RT3 procedures updated to add instructions for review of CSV files

#### Section 7.4

- ABP monitor may be initialized several days to a week before beginning measurements on a participant
- APB ID number may be 999 or any other unique 3-digit number decided on by the clinic
- Deleted “WLM APBM Initialization/Downloading Form #204. This form is not in use and form number is assigned to a different form.
- Ask participants if they have engaged in vigorous activity, ingested food or caffeine, or smoked within the ½ hour prior to beginning APB Monitoring.
- Bladder placement inside the cuff for both right and left arm measurements clarified
- When downloading the ABP monitor, sites may enter 999990000 or a any other unique 9-digit clinic number
- Added contact information for ABPM manufacturer, Space Labs Medical, Inc.

### Summary of edits between Version 1.5 and Version 1.6:

#### Section 7.3

- Correction to definition of baseline weight

#### Section 7.7 added

- FFQ shipping procedure
- Lab tracking procedure

### Summary of edits between Version 1.6 and Version 1.7:

#### Section 7.7

- FFQ shipping procedure – added need for cover letter including site of origin and name of CC contact, specifying SAS transport file for nutrient and food group estimates data to FFQ shipping procedure
- Added procedure for shipping lab samples to NHLBI repository, BBI Biotech.

### **Summary of edits between Version 1.7 and Version 1.8:**

#### *Section 7.5.11*

- Revised RT3 procedures

#### *Section 7.5.12*

- Added Swing test procedure for RT3 QC

### **Summary of edits between Version 1.8 and Version 1.9:**

#### *Section 7.6*

- Changed name and contact person at NHLBI storage lab from Misti Dowell at BBI to Christine Demasco at SeraCare. Note that SeraCare bought BBI.
- 

### **Summary of edits between Version 1.9 and Version 1.10:**

#### *Section 7.6*

- Added Debbie Atkinson to contact person at CHR for lab supplies
- Eliminated 10-minute wait for blood draw
- Added lab instructions for participants using antidiabetic medications
- Changed vacutainer tube sizes for lavender and tiger top tubes
- Updated addresses and contact information for Stayhealthy RT3 tech support and corporate headquarters

### **Summary of edits between Version 1.10 and Version 1.11:**

#### *Section 7.5*

- Added instructions for software upgrades to accelerometry section

#### *Section 7.6*

- Updated e-mail addresses for contacts at SeraCare BioServices

## 7.1 Visit and Measurement Priorities

### *Visit priorities*

- Home (or worksite) visits are an option (see Section 6, Offsite Data Collection Visits).
- Staff may be sent out of town to complete visits in a remote location.

### *Participant transfers between sites*

When participants transfer between sites, the following procedures should be observed:

- 1) Coordinator at the site of origin notifies the CC and the coordinator at the receiving site
- 2) Coordinator at the site of origin makes sure that any necessary HIPAA agreement is established between the sites involved, and that any other HIPAA requirements are met
- 3) Site of origin provides copies of records to receiving site using procedures approved by the sending site's IRB.
- 4) CC adjusts the data system to allow entry of forms at the new site, or makes arrangements for data entry of future forms.

### *Measurement priorities*

1. *Weight*- weight is the highest priority measurement and should be done before the other procedures.
2. Medication Questionnaire
3. SAE Screening Form (#500) and, if necessary, SAE Form (#501)
4. Blood Pressure
5. Psychosocial Questionnaires
6. Accelerometry
7. FFQ
8. Labs

## 7.2 Height

Height measurement to the nearest 0.1 cm is taken by a certified WLM clinical staff member using a stadiometer. Height is measured in metric units with the participant standing on a firm, level surface that is at a right angle to the vertical board of the stadiometer.

Instruct the participant to remove shoes and headgear (hats and unusually large hairpieces) and to stand erect with feet flat on the floor and both heels together, touching the base of the vertical board. The participant stands erect with back, shoulder blades, and buttocks in contact with the vertical height board. If the participant cannot be positioned so that all of the above are in contact with the board, position so that the participant is standing erect with buttocks in contact with the board. The participant's weight is evenly distributed on both feet, and arms remain relaxed at the sides with palms facing inward. The participant stands facing straight ahead with her head in the horizontal (Frankfort) plane. The eyes of the examiner should be at the same level as the height indicator bar to obtain the most accurate measurement (Figure 1, Frankfort Horizontal Plane).

Ask the participant to inhale deeply and maintain a fully erect position without altering the load on the heels. Bring the height board down snugly, but not tightly, on the top of the participant's head. Record the height to the nearest 0.1centimeter on the BMI Form (#105).



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**Figure 1. Frankfort Horizontal Plane for Measuring Body Height**

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TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point.

FRANKFORT PLANE: Orbitale tragon line horizontal.

### 7.3 Weight

The first of the two entry weight measurements taken during screening is used with the height measurement to compute body mass index (BMI) to exclude candidates whose body mass index is in excess of 45 kg/m<sup>2</sup> or under 25 kg/m<sup>2</sup>.

The second entry weight is preferably measured at G1. At the earliest, it must be measured at least one day following the first screening weight, but no more than 2 weeks prior to G1. For participants who miss up to the first two group sessions, this weight measure must occur a) prior to the participant attending *any* group session, b) prior to G3, and c) may be no later than 2 weeks after G1. This weight serves as the starting point against which the Phase I weight loss eligibility criterion is assessed.

The first of the two baseline weights must be measured on or after G19. The second baseline weight is taken at least one week (7 days) following the first baseline weight, and no later than on the date of the randomization visit.

Both the first baseline weight and the second baseline weight must be at least 4 kg less than the second entry weight in order for the participant to be eligible for Phase II. The second of the two baseline weights defines the baseline weight for analysis of post randomization weight loss maintenance.

<b>Data Collection for Eligibility and Baseline Weights</b>			
<b>Definition</b>	<b>Period</b>	<b>Timing</b>	<b>Purpose</b>
First entry weight (a single weight measurement)	Screening	Anytime between PSV and 1 day prior to second screening weight. No more than 3.5 months (105 days) prior to G1.	Used with height to compute Phase I eligibility BMI. BMI must be between 25-45 kg/ m <sup>2</sup> . <i>Minimum and maximum weights, in pounds, corresponding to these limits, can be found in Form #105</i>
Second entry weight	Screening	<i>Must occur before any intervention takes place.</i> <u>Earliest:</u> At least one day following first screening weight, no more than 2 weeks prior to G1 <u>Preferred:</u> At G1 <u>Latest:</u> Prior to the participant attending <i>any</i> group session. No later than 2 weeks after G1. Must occur prior to G3.	Use this as the weight against which Phase I weight loss is assessed.
First baseline weight	End of Phase I	On or after G19 and at least 1 week before second baseline weight.	Use in conjunction with second entry weight to determine if weight loss criterion is met. Must be at least 4kg less than the second entry weight to be eligible for Phase II.
Second baseline weight	End of Phase I	At least one week after first baseline weight, up to and including the randomization visit, and no later than three weeks after G20.	Use in conjunction with second entry weight to determine if weight loss criterion is met. This weight must <i>also</i> be at least 4kg less than the second entry weight to be eligible for Phase II.  <b>The second baseline weight is the baseline weight for analysis of weight change following randomization.</b>

Ask the participant to stand in the center of the scale platform, since standing off-center may affect the weight measurement. It is suggested that marks be made on the platform to insure the proper position of the participant's feet. The participant should stand with arms relaxed at the sides, head erect, and eyes looking straight ahead.

Make sure the scale reads "0" before the subject stands on the measurement platform. When the digital readout stabilizes, record the observed weight to the nearest 0.10 or 0.25 lbs, depending on the resolution of the scale.

With the exception of the first entry weight, all weight measurements consist of two independent weight assessments. Have the participant get off of the scale and then repeat the above procedure. Record both weights and, if they differ by more than 1.0 lbs, take a third measurement. The computer will determine the official weight measurement after data entry. In the meantime, staff should report the approximate weight, to the nearest whole pound, to the participant.

## **7.4 Blood Pressure**

Because of the EPA ban on mercury, the WLM steering committee made the decision to use the ABPM method rather than standard or random-zero sphygmomanometer, to obtain blood pressure measurements in WLM.

However, rather than obtaining ambulatory measurements, the ABPM instrument is used as an automated method for obtaining seated, in-clinic measurements.

### ***Equipment Required***

#### ***ABPM software***

Install ABP software on an IBM PC or compatible computer.

#### ***ABP monitor***

The Space Labs Medical Model 90207 Ambulatory Blood Pressure (ABP) Monitor is a small, lightweight battery-powered unit designed to take blood pressure and heart rate measurements. The monitor has the following features:

- 4-digit LCD display
- Battery powered
- Serial communications port
- Power on/off switch
- Blood pressure cuff

#### ***Monitor cable***

The monitor cable is attached to a serial port on PC. The other end of the cable attaches to the monitor arrow to arrow.

#### ***Cuffs***

*Tru-Cuff* are reusable, single hose, and can be self applied.

Cuff sizes are as follows:

- Small < 23 cm
- Adult 24 - < 31cm
- Large adult 32 - < 42 cm
- XL adult  $\geq$ 43 cm

The arm circumference is measured to determine correct cuff size. Round all fractions up to the next whole number (i.e. 32.1 should be coded as 33). The rounded arm circumference is recorded on the Blood Pressure Form (#204). Arm circumference should be done at every visit to determine correct cuff size. At baseline, 12, and 30 months, measure arm circumference only once, at the first of the two visits in the set. The same cuff size is used for each visit in the set.

### ***Programming/"Initializing" the ABP Monitor***

Prior to daily BP measurements, the monitor must be initialized (this can be several days to a week before) as follows:

1. Insert fresh batteries into the monitor {new batteries should be inserted after 40 readings}.
2. Log into your computer and bring up windows. Double click on the ABP Report Management System icon.
3. Turn on monitor.
4. Be sure the ABPM cable is attached to the appropriate port on the computer and to the monitor (arrow towards arrow).
5. From the menu bar click on "Communications". From the "Communications", choose "Init monitor" (Initialize Monitor).
6. To set the default settings choose "Setup" from the menu bar. Choose "monitor" from the pull down menu. From the settings menu choose "New" to change the settings as to WLM protocol (See Table 1). To accept default settings click on save, then OK.

7. Since you will be initializing the monitor for multiply readings, enter the monitor number in the name field, and 999 or a unique number that the clinic decides on in the "ID number" field.
8. Click on "Start Init" to initialize the monitor. Disconnect monitor from cable, turn it off, and place monitor in its padded carrying case. *Be sure to turn the monitor off between participants.*

Table 1 Monitor Initialization Default Settings Initialization Name: Weight Loss Maintenance Trial (WLM)				
<input checked="" type="checkbox"/> Show results of readings <input type="checkbox"/> Clinic Verifications Setup <input type="checkbox"/> Display Cuff Pressure Show clock time in: 0 12 hour 0 24 hour				
Period	Starting Hour	Ending Hour	Cycle Time	Tone (Y/N)
1	0	6	30	N
2	6	0	30	Y

***Preparation for Blood Pressure Measurement***

The setting at which BP readings are taken must be a separate, quiet room where no other activity is taking place and where temperature fluctuations are minimal. It is recommended that the room temperature be 65-75° F. Clinic scheduling procedures should also establish consistent appointment times to minimize, insofar as possible, the impact of daily BP variations.

Participants should be asked if they have engaged in vigorous exercise, ingested food or caffeine, or smoked within a half hour of BP measurements. If a half hour has not elapsed since such activities have occurred, the BP measurements must be delayed until a half hour has passed. Instruct participants to turn off pagers and cell phones till the readings are completed.

***Measurement Procedures***

In WLM, BP will be measured three times during each designated visit. It will take approximately 10 minutes to take the three readings, including an initial five-minute rest period. Once the participant has had the procedures explained and the equipment has been checked, BP measurement begins. The following steps must be followed precisely.

The right arm should always be used for the measurements. Make sure that the rubber bladder of the cuff is placed correctly in the cloth covering for right arm placement. If the participant indicates that there is a medical reason for not having BP measured on his or her right arm (such as surgery, or if the right arm is missing), reverse chairs, reverse the position of the bladder in the cloth covering for placement on the left arm and proceed with taking measurements on the left arm. Write a note on the BP form indicating that the left arm has been used. If the participant seems particularly apprehensive about the procedure, delay wrapping the cuff until after the five-minute wait. Otherwise, check for correct cuff size by using the WLM markings on the cuff. Measure the arm circumference using the following procedure. Have participant stand erect holding the forearm horizontal at a 90° angle. Arm length is measured using a measuring tape in metric units, measuring from the acromion or bony extremity of the shoulder girdle to the olecranon or tip of elbow. The midpoint is marked on the dorsal surface of the arm. Have participant relax his/her arm. With the participant's arm relaxed at their side, measure the arm circumference at the midpoint.

Seat the participant with the right arm on the table. The bend at the elbow (antecubital fossa) should be at heart level. Legs should be uncrossed and feet comfortably flat on the floor. If necessary, place a book, footstool, or other flat object beneath the participant's feet so that they do not dangle.

Palpate the brachial artery (just medial to and above the antecubital fossa) and mark this location for placement of the center of the bladder. Place the cuff on the right arm in the proper position. If the cuff occludes the brachial artery, as might happen with a very large but short arm, indicate on Form #204 that you were unable to obtain a valid reading and note the reason.

**Allow a five-minute wait before taking the BP.** Conversation should be limited during his period. However, a brief explanation of the procedure can be repeated at this time, if necessary.

#### *Measurement #1*

Turn monitor on. Connect tubing of cuff to ABPM. Record the time of the measurement on BP Form #204. Initiate BP reading #1 by pressing the blue start/stop button on the top of the monitor and hold the button down until count down starts. The monitor display will show a numerical countdown sequence and begin to inflate. After the monitor has deflated and the reading is completed, check the systolic, diastolic and pulse rate values on the monitor display. Record these values on Form #204 as they appear.

#### *Measurement # 2*

After waiting 30 seconds with participants arm remaining at heart level, repeat as in measurement #1.

#### *Measurement # 3*

After waiting 30 seconds with participants arm remaining at heart level, repeat as in measurement #1.

When finished recording the three BP measurements use a calculator to get the sum of the 2nd and 3rd systolic and diastolic readings. Proceed to then get average of the total systolic and diastolic.

#### *Missing BP Information*

If for any reason the technician is unable, or has forgotten, to complete any portion of this protocol and the participant has left this area, draw two horizontal lines through the relevant spaces on the data collection form. This is the correct way to indicate the missing information. If an entire reading is missed or is technically invalid and the participant is still in the clinic, a replacement reading should be obtained. The ABPM can also be downloaded to verify a reading. **UNDER NO OTHER CIRCUMSTANCES, HOWEVER, MAY A REPLACEMENT READING BE OBTAINED SIMPLY BECAUSE THE RESULTS SEEM UNUSUAL.** Always wait at least 30 seconds between readings.

#### *Down-Loading the Monitor*

At the end of the day or designated times the monitor should be down-loaded using the following protocol:

1. Access the ABP Report Management Systems in windows. Connect the monitor via the cable (arrow to arrow), turn monitor on, click on the "Communications" and choose "Read Monitor" from the pull down menu. The system will ask for a unique 9-digit number. Enter 999990000 or a unique 9-digit clinic number. When "Select A Group" message appears, select WLM from the scan groups. Click OK.
2. The screen will display 9999.
3. To review data for BP readings click on "Review" from the menu bar and choose "Raw Data Tables" from the pull down menu. Look at the time the reading was done in the clinic and record reading off of the report if needed.
4. Complete the center section of WLM ABPM Initialize/Downloading checklist (Form #204).
5. Print Out the readings and place in local logbook.
6. To initialize the monitor for the next group of readings, repeat steps in "Programming / Initializing" the ABP Monitor.

#### *Blood Pressure Measurement Quality Control*

The primary method for monitoring the performance of trained technicians in the measurement of blood pressures during the course of a clinical trial is the completion of an annual recertification set of procedures.

In addition, WLM has adopted and instituted a comprehensive program to insure the collection of high quality blood pressure measurements. Factors contributing to this include:

1. Recruitment of the most qualified personnel.
2. Standardized training and certification.
3. Retraining of technicians having difficulties with standardized measurements.
4. Frequent staff meetings to provide feedback.
5. Editing and analysis of data by the Coordinating Center.
6. Equipment maintenance program

### ***Maintenance of ABP Monitor***

Each clinical center is responsible for the proper operation and maintenance of its ABP equipment. The clinical coordinator assumes responsibility for proper maintenance and all staff are instructed to report promptly any real or suspected equipment problems to that person. All checks and inspections are documented and recorded by date in a permanent log maintained separately for each unit. Problems and solutions are also recorded. All maintenance logs (Form #609) should be stored in a permanent binder.

If you have a technical problem, or if the equipment needs repair, contact:

Space Labs Medical, Inc.  
22011 SE 51<sup>st</sup> Street  
Issaquah, Washington 98029  
425-657-7200

### ***Periodic Maintenance***

Periodic maintenance consists of replacement of the batteries used in the monitor, the main battery and the backup battery. The AA alkaline batteries are the main battery and must be replaced before each use. The Lithium battery is the backup battery and should be replaced as needed. The computer will prompt you when the lithium battery is getting low. Check the Space Labs Operation Manual for proper placement of batteries. Centers should keep extra lithium batteries on hand.

### ***Checking Accuracy***

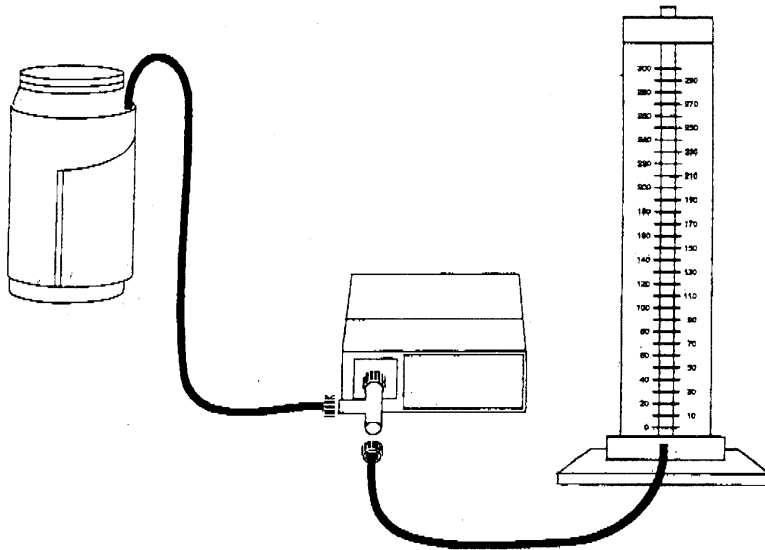
Accuracy of the monitor pressure readings should be checked annually. Recalibration is necessary only if the unit is not within the accuracy limits.

### Required Equipment

1. A full-size mercury sphygmomanometer or aneroid gauge.  
**! Ensure the mercury sphygmomanometer or aneroid gauge is calibrated and indicates "0" with no pressure.**
2. T-tube (P/N 016-0040-00)
3. A pressure cuff and a rigid cylinder sized to fit the pressure cuff.

### Accuracy Procedure

1. Disconnect the cuff hose from the monitor. Connect the T-tube splitter to the monitor Luer-Loc connector and the sphygmomanometer.
2. Wrap the pressure cuff around the rigid cylinder, and fasten the cuff. Connect the cuff hose to the remaining connection on the T-tube splitter. The text setup should appear as shown below.
3. Press **START/STOP** on the monitor; the monitor should read approximately 165. Compare the readings on the monitor and the manometer as the pressure bleeds down. The monitor reading should be within three millimeters of the manometer reading or 2% of the reading, whichever is greater ( $\pm$  the accuracy of the manometer).  
**! If the monitor pressure values fall outside of the allowed tolerance, call your local Customer Service Representative or Space Labs Medical for servicing.**
4. At the end of the procedure, the monitor displays an event code indicating that no dynamic blood pressure measurements were obtained.
5. Disconnect the T-tube splitter from the monitor. Disconnect the air hose and sphygmomanometer.



**Event Codes**

The monitor will display an event code whenever an event prevents the unit from successfully completing a blood pressure measurement. The two numerical digits of the event code indicate the reason the measurement was aborted. The table below lists event codes that are displayed on the monitor, as well as event codes that appear on the Event Code Report.

<b>Monitor</b>	<b>Report</b>	<b>Condition</b>	<b>Corrective Action</b>
EC00			
	EC10	Excess movement artifact. Frequent EC10 messages may indicate an air leak.	Ask participant not to move during measurement
	EC20	A) A very large number of movement artifacts B) Heart rate arrhythmia	Ask participant not to move during measurement
	EC30	A) Movement artifact at mean arterial pressure B) Heart rate arrhythmia	Ask participant not to move during measurement
	EC40	A) Movement artifact at asystole B) Heart rate arrhythmia	Ask participant not to move during measurement
	EC50	A) Movement artifact at diastole B) Heart rate arrhythmia	Ask participant not to move during measurement
	EC60	A) Movement artifact B) Heart rate arrhythmia	Ask participant not to move during measurement
	EC70	Systole was found to be above the highest cuff pressure. However, this result appears to be an error caused by motion artifact. Therefore, the cuff will not be inflated to a higher pressure on the next measurement attempt.	Re-initialize monitor
	EC80	A) Movement artifact B) Heart rate arrhythmia	Ask participant not to move during measurement
	EC90	A) Movement artifact B) Heart rate arrhythmia	Ask participant not to move during measurement
EC01			
	EC11	Did not pump above the mean arterial level	Repeat reading with different monitor
	EC21	Did not pump above systolic pressure	Repeat reading with different monitor
	EC91	Systole appears higher than the selected maximum cuff pressure limit	Repeat reading with different monitor
EC02			
	EC12	Did not reach initial cuff pressure. The cuff may have been improperly applied or there may be an air leak.	Wrap the cuff correctly and measure again
	EC22	Overpressure	Confirm that airflow connecting the cuff and unit isn't being restricted



<b>Monitor</b>	<b>Report</b>	<b>Condition</b>	<b>Corrective Action</b>
	EC32	Overpressure	Confirm that airflow connecting the cuff and unit isn't being restricted
	EC42	No cuff attached	Attach cuff and measure again
	EC52	Kinked hose	Straighten hose and measure again
	EC62	Cuff applied too loosely	Wrap cuff correctly and measure again
	EC82	Kinked hose	
EC03			
	EC03	Patient canceled reading by pressing STOP key. No retry attempt is made following an EC03 code.	NA
	EC13	The Office Check Mode has been reinstated. No retry attempt is made following and EC13 code.	NA
EC04			
	EC04	Blood pressure measurement not completed in the maximum time allowed. Occasional EC04 messages may result from excessive patient movement. Frequent EC04 messages would indicate an improperly applied cuff or a monitor malfunction which requires service.	
	ECn4	(where n = 1 to 9) Indicates that one or more of the blood pressure results have been corrupted and subsequently recovered. Frequent occurrence of this message would indicate a malfunction which requires service.	
	EC05	The individual blood pressure result has been corrupted and cannot be recovered.	Repeat reading
EC15		Equipment malfunction. Return to Space Labs Medical for service.	
EC25		Unit felled to initialize. Please initialize.	
EC35		90207 At least one of the blood pressures or time readings obtained before the event code is erroneous. Interpret all readings with caution. 90217 The monitor needs to be reinitialized.	

<b>Monitor</b>	<b>Report</b>	<b>Condition</b>	<b>Corrective Action</b>
EC05			
EC05 & EC45	EC45	Invalid bleed size. The monitor automatically has changed the bleed size to 8 mmHg.	Repeat reading
EC05 & EC55	EC55	An unexpected loss of power possibly caused by a) removal of the batteries during a blood pressure measurement, b) hardware overpressure, or c) a hardware time-out. Frequent EC55 messages would indicate a malfunction which requires service.	
EC05 & EC65	EC65	90207 Equipment malfunction. Return to Space Labs Medical for service. 90217 Extremely large artifact.	
EC05 & EC75	EC75	Equipment malfunction. Return to Space Labs Medical for service.	
EC05 & EC85	EC85	Equipment malfunction. Return to Space Labs Medical for service.	
EC05 & EC95	EC95	Cuff pressure baseline out of bounds. The monitor should correct the baseline automatically within 10 minutes; or it can be set by initialization of the monitor. If initialization does not correct the condition the monitor must be returned to Space Labs Medical for calibration.	
EC07			
	EC78	Clogged luer filter	Return to Spacelabs
EC08			
	EC18	Too few data entries to accurately determine blood pressure. The message may indicate that the cuff is not being worn by the patient (taken off but left connected to the monitor). The message may also indicate that motion artifacts cause the majority of the incomplete data.	NA
	EC28	Diastole above 200 mmHg	
	EC38	Pulse pressure less than 16 mmHg	
	EC48	A) Movement artifact at mean arterial pressure B) Heart rate arrhythmia	Ask participant not to move during measurement
	EC58	A) Movement artifact at diastole B) Heart rate arrhythmia	Ask participant not to move during measurement
	EC68	Division by zero	Repeat reading with another monitor

<b>Monitor</b>	<b>Report</b>	<b>Condition</b>	<b>Corrective Action</b>
EC09			
	EC19	Contradictory instructions sent to hardware (e.g., "pump on and valve open")	Return to Spacelabs
	EC29	Diastolic pressure value cannot be obtained from the data available	Repeat reading with another monitor
	EC39	90207 Systolic pressure cannot be obtained from the data available 90217 Algorithm could not process input data quickly enough resulting in an input queue overflow.	Attempt another reading with a different monitor
	EC49	90207 Man arterial pressure cannot be obtained from the data available. 90219 This monitor must be initialized.	
	EC59	Heart rate value cannot be obtained from the data available.	Repeat reading with another monitor
	EC69	Heart rate value cannot be obtained from the data available.	Repeat reading with another monitor
	EC79	Bleed steps were too small. This may be caused by a partially obstructed air hose. All blood pressure attempts following this message are inhibited. Attempts can be enabled by turning the power switch off then on.	Repeat reading with another monitor
	EC99	Unexpected or contradictory data (such as a negative cuff pressure).	Repeat reading with another monitor
LLL			
	EC16	Low battery detected prior to start of measurement.	Replace batteries
	EC26	Low battery detected after measurement started. Usually caused by the pump drawing enough current to lower the battery voltage.	Replace batteries
Lbb		The report does not print an event code for this condition, which is a low backup battery. Contact Space Labs Medical for replacement of the battery.	

## **7.5 Accelerometry**

### **7.5.1 Data collection standards**

1. Minimum data collection must include at least one weekend day and four days of activity data. (94 hours or 5640 minutes). Participants not meeting this standard of data collection must be asked to repeat the measurement.
2. Activity data will be collected in Mode 3 (3 Axis / 1 Minute Log)
3. Every effort should be made to structure visits so that data can be collected on two weekend days. It is believed this will help decrease the variability of the weekend day data.
4. Whenever possible a full seven days of data should be collected.
5. The RT3 battery will last about 1 month. The battery should be replaced at least every third week to prevent a participant from getting a low battery signal.

### **7.5.2 Equipment**

1. StayHealthy Research Kit
  - 1.1. CD with Software and Manual
  - 1.2. RT3 Docking station
  - 1.3. Interface Cable
  - 1.4. RT3 Installation Instructions
  - 1.5. AAA alkaline batteries, 2 for docking station, 1 for each RT3 unit
2. PC with internet access (Internet required for data transfer to coordinating center)
  - 2.1. PC requirements
    - 2.1.1. Minimum
      - 2.1.1.1. Pentium 133 MHz or faster
      - 2.1.1.2. 32MB RAM
      - 2.1.1.3. Windows 95/98/NT Windows 2000
      - 2.1.1.4. 10MB free hard disk space
      - 2.1.1.5. CD-ROM Drive
      - 2.1.1.6. 256 Color video card and monitor
      - 2.1.1.7. Mouse
      - 2.1.1.8. Keyboard
      - 2.1.1.9. One available serial communications (COM) (RS-232) port
      - 2.1.1.10.
    - 2.1.2. Optimum
      - 2.1.2.1. Pentium MHz 233
      - 2.1.2.2. 64MB RAM
      - 2.1.2.3. Windows 95/98/NT Windows 2000
      - 2.1.2.4. 10MB free hard disk space
      - 2.1.2.5. CD-ROM Drive
      - 2.1.2.6. 256 color video card and monitor
      - 2.1.2.7. Mouse
      - 2.1.2.8. Keyboard
      - 2.1.2.9. One available serial communications (COM) (RS-232) port

### **7.5.3 Installation**

1. Insert the software CD in the DC driver. The software will run automatically and prompt you through the installation. If it fails to install follow the instructions on the handout "RT3 Installation Instructions."
2. After loading the software, with the computer connected to the Internet, click on the link below to install the upgrade software. The upgrade will improve the downloading and initialization process.  
<http://bc1.stayhealthy.com/download/cvtcomm%20v1.1.8.exe>

3. Insert telephone type connector into the port on the back of docking station labeled PC. Connect the larger end of the cable in the free RS-232 port on the computer.
4. Install two AAA alkaline batteries into the docking station through the bottom panel.
5. After installation of the RT3 Assistant set the defaults on the mode and other options.
  - 5.1. Open the RT3 Assistant
  - 5.2. Open “File” then Preferences.
  - 5.3. Set Preferences
    - 5.3.1. Default Data Collection Mode to “Mode 3 ( 3 Axis 1 Minute )
    - 5.3.2. Other options set at:
      - 5.3.2.1. Automatically connect, on
      - 5.3.2.2. Auto save after download, on
      - 5.3.2.3. Prompt for annotations, on
      - 5.3.2.4. Clear RT3 after download set on or off at the discretion of the site

#### **7.5.4 Creating a User Profile / Initializing the RT3**

1. To create a user profile
  - 1.1. Dock the RT3 in the RT3 dock with the buttons facing towards the front
  - 1.2. Launch the RT3 Assist software by double clicking the RT3 Assist icon on your Windows desktop. If the software is unable to establish communication with the RT3, remove and dock the RT3 again. If communication is still unable to be established, make sure you have the correct COM port selected in the Preferences dialog.
  - 1.3. Select New Profile from the User Profile menu at the top of the window. Enter or change the User Information into the fields. The only optional information is the Name field. Enter the participant’s study ID in the Name field.
  - 1.4. Select Data Collection **Mode 3 (3 Axis, 1 Minute)** from the drop down box.
  - 1.5. Click the Write Profile button to copy the User Profile to the RT3. If an error occurs, a message box appears. The most likely cause of the error is invalid information in one or more of the User Profile fields. If the User Profile update is successful a message appears in the status bar. Writing the User Profile automatically sets the RT3 real-time clock.

Your RT3 is now initialized and is ready to start recording activity.

#### **7.5.5 Starting Data Collection**

1. Remove the RT3 from the RT3 Dock.
2. Press the large (START) button when the participant begins wearing the RT3. Pressing the START allows the RT3 to begin recording data. The RT3 will emit a short beep to indicate it has started data collection. The colons on the RT3 display will begin flashing to indicate the RT3 is recording. Once the RT3 has been started, the user cannot stop it. The RT3 will continue recording activity until it runs out memory, or it is docked and cleared using the RT3 Assist software.
3. Instruct the participant to:
  - 3.1. Wear the device on their left hip waistband. It may be worn under clothing if needed but should not be clipped to their pocket as this will give false readings
  - 3.2. Wear it all day but remove it when going to bed.
  - 3.3. The RT3 must be worn for at least four days including one weekend day and at least 10 hours per day.
  - 3.4. Prevent the device from getting wet, do not wear it while swimming and take care when near sinks or bathrooms.
  - 3.5. The device has a fresh battery that should last more than a month but if the display reads LOW BATT (see below) and the participant is not scheduled to return to the clinic with 24 hours they should call the clinic to arrange for a replacement RT3.



- 3.6. Inform the participant that they will be completing a questionnaire about their activity during week they have worn the RT3. They may make notes about their exercise activities while wearing the RT3 to help them complete the form at their next visit.

### 7.5.6 Download Activity Data

To download activity data to your PC:

1. Dock your RT3.
  - 1.1. With RT3 label facing you and the RT3 label on the docking station facing you insert it into the dock. (Inserting the RT3 backwards in the dock can damage the dock by breaking the metal prongs that insert into the bottom of the RT3.)
2. Launch the Assist software by double clicking on the desktop icon.
3. Select RT3 Functions | Retrieve Data
4. RT3 Assist will transfer the Activity Data. When the process completes, RT3 Assist will ask if you would like to clear the RT3 Activity memory. Stayhealthy recommends not clearing the RT3 memory until you have confirmed the integrity of the data. When the download process completes, the Activity Data will be graphically presented on the chart.
5. Add Annotations using the File | Add Annotations command

Note: If the Prompt for Annotations option is enabled, the Add Annotations dialog is automatically displayed. Record special information related to the participant's data, i.e., minimum data not collected, refused to recollect, Participant reported swimming 120 minutes during the last week, etc.

6. Review the activity graph, verifying the following criteria:
  - 6.1. At least four days (94 hours) of data are present (minimum 5640 minutes)
  - 6.2. At least one weekend day. The day of week can be determined by using the start date on Form #116 to identify the day data collection started. Data from this date/day are displayed in the right most column of the graph. One 24-hour period is 1440 minutes. Usually each day is easy to identify by the cluster of activity separated by the period of no activity recorded while the participant is sleeping and RT3 is not worn.
  - 6.3. Minimum recording time can be assessed by reading the RT3 display screen if 94 or more hours have been recorded it will read "3 03:22:00 or greater. The first number on the left shows the recording mode, the next shows the number of days recorded, the next shows the number of hours and the two digits on the right side show minutes recorded (see below).



- 6.4. Data quality control
  - 6.4.1. Assess data quality by reviewing the activity graph.
    - 6.4.1.1. The graph should show a mix of the X (blue), Y (light green), and Z (dark green) axis data.
    - 6.4.1.2. If one or more of the axis (Z, X or Y) displays data either much higher than the others or flat on the activity axis the RT3 unit must be sent for repair.
  - 6.5. If the data does not meet study criteria or pass data quality control review the participant must wear an RT3 again.
7. Save the activity data to a file using the File Save command.
  - 7.1. The annotation function should be set open
8. Save file using the two-digit site code, the two-digit visit code, and the six-digit participant ID as the file name. Separate the site, visit and ppt id with underscores, i.e., 02\_02\_000023.
9. After verifying that the file is saved clear the memory:

- 9.1. Select RT3 Functions menu at the top of the window.
  - 9.2. Select Clear Memory from the dropdown box
  - 9.3. Select clear
  - 9.4. Click “yes” to clear
10. Return the RT3 to storage or follow the directions in 7.4.3 to set-up for a new participant.

### **7.5.7 Troubleshooting**

The users manual is available on the RT3 software CD. It includes complete instructions for set-up, problem solving, and contact information.

#### ***Troubleshooting tips***

##### ***Low Battery***

The low battery alert occurs when the RT3 battery reaches a low voltage condition. The LCD will display “LOW BATT” until you press either the START or STOP button. This action will acknowledge the low battery condition and allow the display of regular mode information. The low battery alert will reappear (with acknowledgement option) every hour until the battery in the RT3 is replaced with a new one. The appearance and acknowledgement of low battery alert does not interfere with data collection. However, Data can be lost if the low battery is not replaced within 24 hours.

##### ***“RT3 not responding”***

This dialog box will appear when the docking station has “gone to sleep”, its batteries are dead, the RT3 is not seated in the station, or the program has “timed out” the search for the RT3.

1. The computer, docking station, RT3 connection can be tested by Pinging the system
  - 1.1. Select RT3 Functions menu at the top of the StayHealthy RT3 Assist window
  - 1.2. Select Diagnostics
  - 1.3. Select Ping
  - 1.4. The Results window will show if the device responded or not a second Ping may be needed to assess the RT3 if the docking station was “asleep.”
2. Inserting the RT3 into the dock station so it is slightly rotated to the right and bring it to a vertical position as it is lowered into the dock can help assure a connection between the device and the dock. You may hear the prongs in the docking station spring into place as it is lowered into the dock.
3. Timing out can be minimized by installing an upgrade to the software provided in the Research Kit

### **7.5.8 Contact information**

For RT3 Assist Technical Support from Stayhealthy Inc.,

Tel: (626) 256-6152 FAX: 626-357-7534

or email [RT3support@stayhealthy.com](mailto:RT3support@stayhealthy.com)

Tech support shipping address:

Reference

690 East Bridge Street

Elkader, IA 52043

Tel: 563-245-1042, extension 106

Notify Ron Green by e-mail when you send units for repair or testing:

[rg@referencellc.com](mailto:rg@referencellc.com)

Website <http://www.stayhealthy.com>

Corporate Headquarters

Stayhealthy, Inc.

300 Elfwood Drive

Monrovia, CA 91016

### 7.5.9 Accelerometer Activity From (Form #121)

1. On completion of data collection by the RT3 accelerometry ask the participant to complete Form #121.
  - 1.1. First the participant should review the list and check the box next to each item they did in the past 7 days.
  - 1.2. After reviewing both pages of activities the participant then estimates the amount of time spent in each checked activity during the last 7 days.

If additional activities are recalled while estimating the time spent, those activities should be checked and time spent estimated.

### 7.5.10 RT3 Manual

Sites should obtain a copy of the RT# Manual from the CC.

### 7.5.11 Review of RT3 CSV file

#### Purpose:

Assure adequate RT3 data collection by enabling staff to more closely review RT3 data in cases where a participant's display graph does not clearly meet or not meet minimum data requirements.

#### Policy:

1. Staff will review CSV files of participants that have not clearly met or missed the minimum data collection and are considering asking to repeat RT3 measurement. RT3 wear time must be at least four ten-hour days including at least one weekend day.

#### Definitions:

1. **CSV file** – The file format used by the RT3 assistant software to store data downloaded from the StayHealthy accelerometer (RT3).
2. **AutoFilter** – A data filter option in Excel that allows data to be selected or excluded from view.
3. **RT3 wear time** – The length of time the RT3 was worn by the participant on any day during the measurement period. Calculated from the start and end time for each day reviewed, minus any gaps greater than 15 minutes.

#### Equipment:

1. CSV file of participant with questionable RT3 data collection.
2. PC with Windows Explorer and Excel software.
3. RT3\_qc Excel spread sheet.

#### Procedures:

Responsibility	Action
----------------	--------



Responsibility	Action
----------------	--------

RT3 download reviewer

1. Open participant's CSV file
  - a. Open Windows explorer.
  - b. Find and open the saved CSV file, note the date the RT3 was started.
  - c. Open the RT3\_qc spread sheet, enter the date the RT3 was started in cell B2.
2. Set AutoFilter
  - a. In the CSV file to be reviewed select columns A through K row 20 of the CSV file.
  - b. On the menu bar click on "Data"
  - c. From the dropdown list, click on filter then AutoFilter.
4. Select date to be reviewed.
  - a. Click on cell B:20 (Date)
  - b. Select the date to be reviewed from the drop down list.
  - c. Select start and end times
    - i. The start time is shown in the cell just below C:20, if the cells following that time are continuous. If not continuous, scan the column to find the first time that is followed by 5 or more minutes of continuous activity, use this as the start time.
    - ii. The end time is the last cell with continuous data. Use the process above but working up, if needed to find the end time.
  - d. Copy the start time from the appropriate cell of the CSV file being reviewed and paste into row 3 of the RT3 qc sheet and the column matching the date selected in b above. Repeat for the end time.
  - e. Select the observation numbers for the date being reviewed by selecting the numbers in column A starting with the end time continuing through to the start time. Paste this copied data into day observation count column (row 10 columns b, d, f, h, l, n, or p). Repeat for all dates needing review.
  - f. Identify any gaps greater than 15 minutes and calculate total gap time.
    - i. In the RT3 qc sheet, click on the AutoFilter drop down list of the Day Minute Count column.
    - ii. If a number 15 or greater is not shown, no gaps equal to 15 minutes or greater are present in that day's data.
    - iii. If 15 or greater is shown in the AutoFilter dropdown box at least one gap the size of each number shown is present. Set a custom AutoFilter to "equal to or greater than" and "15". This will show each cell with 15 or more minutes of missing activity time. Copy the cells from the day minute count column and paste into cell 7/09/47 under "gap time calculator, minutes from >= 15 filter. (use paste special and values to transfer this information)."
    - iv. Convert the count of minutes to time by

Responsibility	Action
Clinic staff conducting the visit	<ol style="list-style-type: none"> <li>5. Review the QC findings with the ppt.</li> <li>6. If needed, arrange to recollect RT3 data.</li> <li>7. Assure that appointments are made according to local procedures for RT3 pick-up and return.</li> </ol>

### 7.5.12 RT3 Swing Test Procedure

#### Policy:

1. Each RT3 will be swing tested before starting visits requiring this measure and quarterly while the units are in use.
2. RT3 devices identified by the coordinating center as out of range will be sent to StayHealthy for service and removed from use if out of range operation is confirmed by StayHealthy engineers.

#### Equipment

- Swing test device
- Stop watch
- RT3 dock,
- RT3 dock/PC cable
- PC with RT3 Assistant software and patch loaded
- RT3 units to test
- 10-20 Kg weight

1. Place the RT3 monitor in the dock, download and clear any data in the RT3 monitor.
2. Under “File” go to “Preferences and change the default collection mode to “Mode 1” and units to “Metric.”
3. Create a new user profile using the following information:
  - Name: RT3 monitor number from the back of the device
  - Height: 177cm (the computer will automatically change the value to 178cm)
  - Weight: 70kg (the computer will automatically change the value to 69.9kg)
  - Age: 35
  - Gender: Male
4. Position the base of the swing tester with the label (RT3 Swing tester #X, Top) up and facing the user, on the edge of a desk or table so that the swing arm moves freely in both directions (thru a 180 degree arc). Place a 10 to 20 Kg weight on the label. Insert the RT3, without the belt clip, in the slot at the end of the swing tester arm. Secure it with the Velcro strap so the long axis of the RT3 is parallel to the swing arm, the start button is accessible, and the RT3 is firmly held in the slot.
5. Allow the swing arm to rest perpendicular to the base and table/desk surface. Start the RT3 and allow it warm-up for at least 2 minutes before beginning the swing test. Use a stopwatch to time the 2-minute interval.
6. Once the 2-minute mark has passed,
  - a. Raise the swing arm so that it is next to the base of the tester unit by holding the RT3/swing arm horizontal (parallel to the desk).
  - b. Press the start button until it beeps and then release the RT3/swing arm allowing it to swing freely for at least 30 seconds.
  - c. Repeat steps a to c once.
7. On completion of the second 30-second swing test download the swing test data. Use your site ID #, the monitor number, and the date of the swing test for the file name and save the information. ie., 09\_01\_09132004
8. WinZip the swing test files, name the file with your site ID#, and the date of the swing test, and QAfile; ie., 09\_09132004\_QAfile.

9. Transfer files to the coordinating center using your local procedure to transfer the test files to the coordinating center.
10. Email Carrie Meeks and Gayle Meltesen when the test files are transferred.
11. Review coordinating center report and send out of range units to:

Ron Green  
 Reference LLC  
 690 East Bridge Street  
 Elkader, IA 52043,  
 (563) 245-1042  
 rg@referencellc.com

12. Stayhealthy will replace detective units. (The current charge is \$125.00) Full service is \$50.00 basic service is \$35.00.

## 7.6 Laboratory Tests

### *Materials and Supplies*

- Blood collection tubes
- Labels and vials for specimen aliquots
- Shipping and storage boxes for specimens
- Blood collection kits for screening, baseline, 12, and 30 months
- Shipping containers and supplies
- Pre-addressed Federal Express airbills, airbill pouches, dry ice labels, and instructions
- Disposable transfer pipettes

### *Ordering supplies*

1. Allow **3 weeks** for the order process, from order request to delivery.
2. Complete the lab re-order form as follows:
  - a. Facility name
  - b. Shipping address
  - c. Contact name, phone, and e-mail
  - d. Quantity of each item needed in the highlighted “QTY TO ORDER” column.
3. E-mail or FAX a readable copy of the form to Fran Heinith, Judy Donald, and Mike Walter at:
  - fran.heinith@kpchr.org
  - cc: Judy Donald at judy.l.donald@kpchr.org
  - cc: Mike Walter at [michael.walter@kp.org](mailto:michael.walter@kp.org)
  - cc: Debbie Atkinson at Debbie.j.Atkinson@kp.org
4. The coordinating center reviews and approves the request, signs, dates, and sends (e-mail or fax) to Debbie Atkinson and Mike Walter for order placement. All orders will ship to the address listed on the order form, and will be billed to the coordinating center.
5. Mike Walter or Debbie Atkinson will have the supplier override the ship to address and send the supplies to the facility requesting replenishment
6. Supplies contact persons:
 

Mike Walter	Debbie Atkinson
Tel. 503-571-5709	Tel. 503-652-5711
FAX: 503-571-5769	FAX: 503-571-5166

### STAT orders:

In an emergency, a STAT order may be placed directly by calling Mike Walter or Debbie Atkinson at the above telephone numbers.

### *Supplies required at clinical sites*

- Standard clinical centrifuge (a refrigerated centrifuge is preferred, but a non-refrigerated centrifuge is acceptable).
- Ultra-low temperature freezer (-70C or colder, i.e., ultra low REVCO or equivalent). All blood specimens must be stored at -70C.
- Dry ice for shipping.
- Federal Express pick-up service, UPS drop-off service
- Racks for tubes
- Phlebotomy supplies
- Indelible markers for labels
- Biological waste bags

#### Description of Visit Kits used for Blood Draws

A single kit of blood collection supplies will be used for all visits (screening, baseline, 12 months, and 30 months). Labels will be completed at the site until further notice.

#### Supplies:

3 x 10 mL or 4 x 8.5 ml SST Vacutainer tubes (red/gray top) - for lipids and glucose  
 1 x 13 mL plastic pooling vial (red cap)  
 7 x 2 mL plastic freezing vials (red cap)

2 x 10 mL or 3 x 7 mL EDTA Vacutainer tubes (purple top)  
 4 x 2 mL plastic freezing vials (clear cap)  
 1 x 13 mL plastic pooling vial (purple cap)

Buffy Coat (screening only):

1 or 2 x 2 mL plastic freezing vial (purple cap)

#### Preparing the Tube and Vial Labels

1. Blank labels are provided for all tubes and vials.
2. At each visit, for all labels: Record the subject's unique 6-digit identification code. Record the draw date of the visit. Indicate plasma or serum. Indicate visit type (screening, baseline, 12-month, or 30-month).

*Note:* If a label becomes unusable during processing, affix an extra label

*Note:* It is imperative that all tubes are labeled correctly and completely, and that the writing be legible.

Subjects must have fasted 8 - 14 hours prior to blood collection, with only water allowed. Fasting is required for baseline samples. If the subject has not been fasting, the baseline blood draw must be rescheduled. At follow-up visits, if the participant is not fasting, the sample may be drawn. In this case, note on the form whether fasting time is sufficient **Blood tests must be drawn before 11:00 am.**

#### Participant Instructions for diabetics who use antidiabetic medications

1. Do not eat or drink anything but water for at least eight hours prior to the visit
2. Do not exercise vigorously for at least eight hours prior to the visit (vigorous exercise includes such activities as running or cycling)
3. Do not take your diabetes medications the morning of the visit. Bring them with you to take after the fasting portion of your visit (with the snack). Other prescription medications may be taken.

#### *Collection of Blood Samples*

### *Safety Note*

It is recommended, as good laboratory practice that all blood specimens, used needles, etc., are treated as though they were infectious for HIV and hepatitis B virus. All used needles and lancets should be placed in puncture-resistant containers; then, along with used gauze, Vacutainers, pipettes, vials, Hemocue cuvettes, plastic-backed “diapers”, etc., they should be autoclaved prior to final disposal. Use of disposable gloves when collecting and processing blood is also required.

Due to the sensitivity involved in specific testing, standardization of specimen collection is imperative. A tourniquet may be used for no longer than two minutes. Deviation from this standardized sample collection protocol will cause significant variability in assay results.

- ❑ Clean with an alcohol pad, then draw blood from the crook of the arm, generally from the antecubital vein. Fully fill all tubes.
- ❑ Draw the three 10-mL or four 8.5 – mL (red/gray top) SST serum tubes before the two 10-mL or Three 7 mL (purple top) EDTA plasma tubes. Non-additive tubes are drawn before additive tubes to avoid additive contamination of the non-additive tube. Cross-contamination between different additive tubes can also occur, making test results erroneous.
- ❑ Thoroughly mix all tubes immediately after collection by gently inverting the tubes at least five times. Do not shake.
- ❑ Remove the needle and apply pressure to the venipuncture site. Cover with an adhesive strip when the blood has stopped flowing.
- ❑ Make sure that each Vacutainer is clearly labeled with the subject’s ID number, using the site printed labels.

### *Offsite blood draws*

Refer to procedures outlined in Chapter 6.2, Offsite Data Collection Visits, for additional information regarding transporting specimens from offsite locations.

### *Specimen Processing- General*

- For all samples, allocate 1.5 ml per cryovial. Use fewer cryovials if your sample is short and you would not have enough to fill the total number of vials to 1.5 ml each.
- Hemolyzed specimens are not acceptable.
- Keep all participant samples (plasma, serum, and buffy coat) together in a freezer box.
- Do not use a centrifuge break, as this may affect the EDTA sample.

### *Process and Store Serum Specimens*

- ❑ Allow the SST tubes (red/gray top) to clot for 30-60 minutes at room temperature in an upright position. Verify that the specimen is fully clotted.
- ❑ Centrifuge the clotted tubes for 15 minutes at 1,500 x g. After centrifugation, check the SST tubes for a complete gel barrier between the serum and the cells. Re-centrifuge if the barrier is incomplete or if red cells are seen above the barrier.
- ❑ Pour the serum from the SST tubes into the 13 mL pooling vial. Cap the pooling vial and gently invert several times to obtain a homogeneous specimen.
- ❑ Using a transfer pipette, transfer 1.5 mL of serum from the 13 mL pooling vial into 7 x 2 mL freezing vials with red caps, labeled “Serum”. A minimum of 1.5 mL is required for analysis.
- ❑ Fasten the appropriately colored caps tightly and immediately place the vials in freezer racks at -70°C. As the samples are put into the box or rack in the freezer, you can use the Freezer Log Form (TBD) to help keep track of specimen locations. Use the log to note the box or rack slot number, participant ID, visit, collection date, sample type (e.g., plasma, serum) and any comments about the particular sample. These forms are for internal use only. They will not be entered.
- ❑ Fill out the worksheet for the Central Lab Collection Form- Fasting Blood (Form #117)

- ❑ If a repeat draw is necessary, repeat the steps above.
- ❑ After any repeat draws for this participant are complete, use the worksheet to complete Form #117

#### *Process and Store EDTA Plasma*

- ❑ Invert 2 x 10ml or 3 x 7 mL (purple top) EDTA tube several times to obtain a homogeneous specimen.
- ❑ Centrifuge the (purple top) EDTA tube without delay at room temperature. Centrifuge at >1,500 x g for 15 minutes to remove blood cells. No red cells should be present in the plasma or along the sides of the tubes.
- ❑ Pipette the plasma from the EDTA tubes into a 12 ml pooling vial. Cap pooling vial (purple) and gently invert several times to obtain homogenous specimen.
- ❑ Using transfer pipettes, transfer 1.5 mL of the plasma from the pooling vial into each of 4 x 2 mL freezing vials (clear cap), labeled “Plasma.” A minimum of 1.5 mL is required for analysis.
- ❑ Fasten the appropriately colored caps tightly and immediately place the vials in freezer racks at -70°C. As the samples are put into the box or rack in the freezer, you can use the Freezer Log Form (TBD) to help keep track of specimen locations. Use the log to note the box or rack slot number, participant ID, visit, collection date, sample type (e.g., plasma, serum) and any comments about the particular sample. These forms are for internal use only. They will not be entered.
- ❑ **At the baseline visit only:** Save the EDTA tubes that contain the cell pellet for the buffy coat. The buffy coat is the whitish layer of cells overlaying the packed red cells remaining in the EDTA tube after the plasma is removed. Collect the buffy coats from the EDTA tubes and transfer into two 2 mL freezing vials with purple caps labeled for “Buffy Coat.”  
**For buffy coat only:** If for any reason an acceptable buffy coat is not collected at the baseline blood draw, notify the CC to make arrangements to replace the buffy coat specimen at the next blood draw.
- ❑ Fasten the appropriately colored caps tightly and immediately place the vials in freezer racks at -70°C. As the samples are put into the box or rack in the freezer, you can use the Freezer Log Form (TBD) to help keep track of specimen locations. Use the log to note the box or rack slot number, participant ID, visit, collection date, sample type (e.g., plasma, serum) and any comments about the particular sample. These forms are for internal use only. They will not be entered.
- ❑ Fill out the worksheet for the Central Lab Collection Form- Fasting Blood (Form #117).
- ❑ If a repeat draw is necessary, repeat the steps above.
- ❑ After any repeat draws for this participant are complete, use the worksheet to complete Form #117.

#### *Complete Collection Forms*

Once specimen processing has been completed, transfer the data from the worksheets for the Central Lab Collection Forms (#117) to the first page of each form. Send the forms to the data entry technician to be entered.

#### *Preparing the Storage/Shipping Specimens*

Specimens will be stored at the sites until a lab is selected to perform analyses or samples are shipped to the storage lab. A -70C freezer must be available for storing samples after collection and processing. The baseline shipment is sent out after randomization, and the follow-up shipments are sent at the end of the 12- month and 30-month periods.

The following procedures are for the WLM site clinics to process samples using the Lab Tracking Database in accordance with the Coordinating Center and the Lab storage facility requirements.

The Lab Tracking is located on the WLM Manage site. To process samples staff must have access to the website. If staff do not have access their supervisor must fill out and submit the Website Access/Staff ID Request Form located in Chapter 13 on the web site.

Purpose:

- Create and View Specimen Box Map
- Create and View Specimen Shipping Log

Box Map

- Map will be placed in the shipping box with the sample boxes

Shipping Log

- Log is sent with the shipping box to be completed by the lab

Tracking system is in 3 sections:

1. Create New Box Map

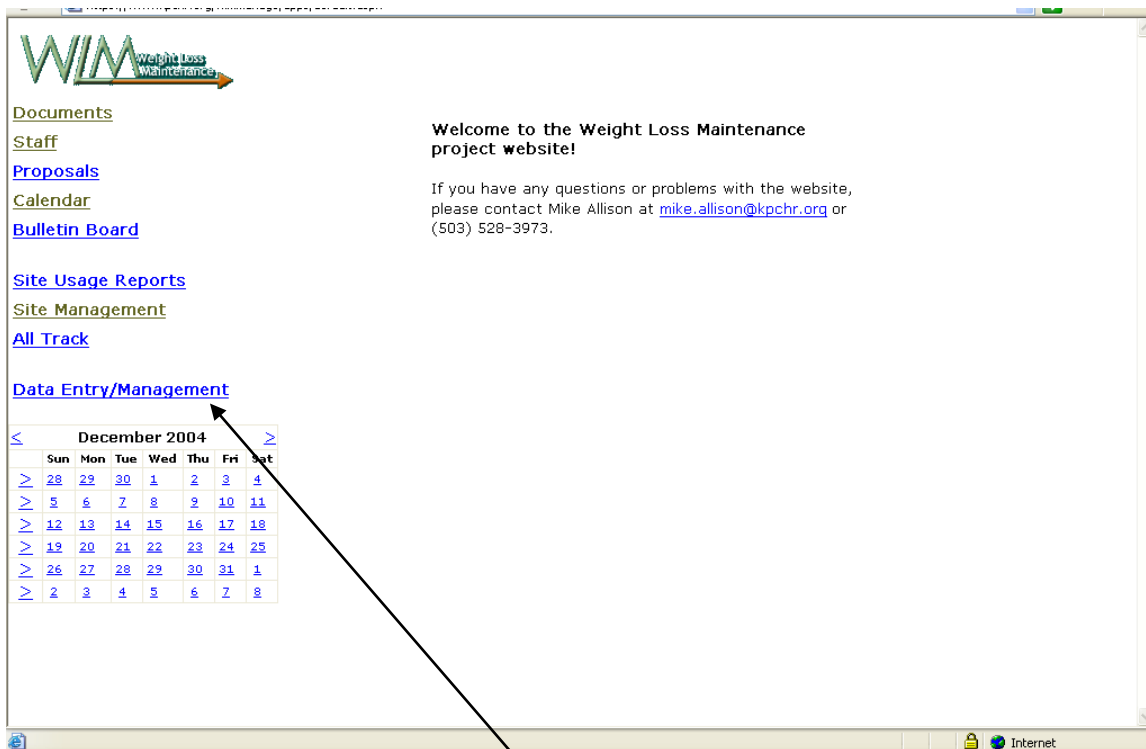
Click the “Create New” button and a box map will be create. The numbering for the boxes is sequential for the project and not the site. There will only be one box number 1. You can create numerous box maps at once or work on one box at a time. If the map needs to be edited do so on the shipping log.

2. Create / Edit Shipping Log

Enter the box number and hit the “Create/Edit” button. This creates a log that corresponds with the map. The only type of edits allowed on the log is the Ship Condition of the vials.

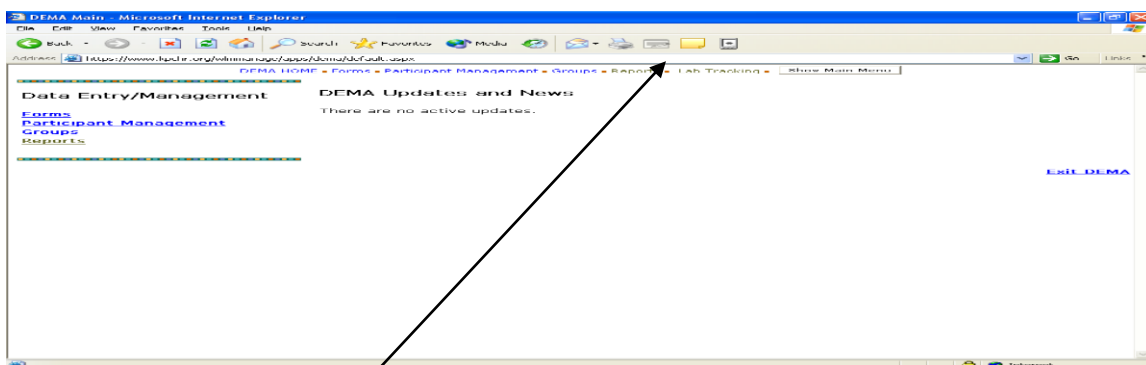
3. View Final Box Map

Enter the box number and hit the “View” button. This creates the final box map including changes made on the shipping log.



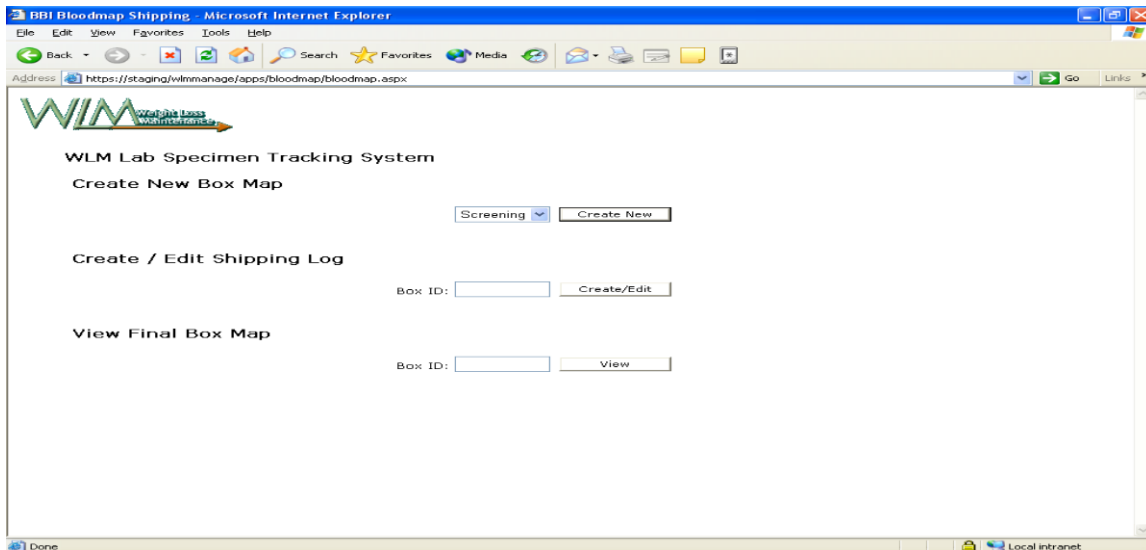
The Lab Tracking System is located on the WLM Manage site:  
<https://www.kpchr.org/wlmmanage/system/login.aspx>

At the home page click on Data Entry/Management

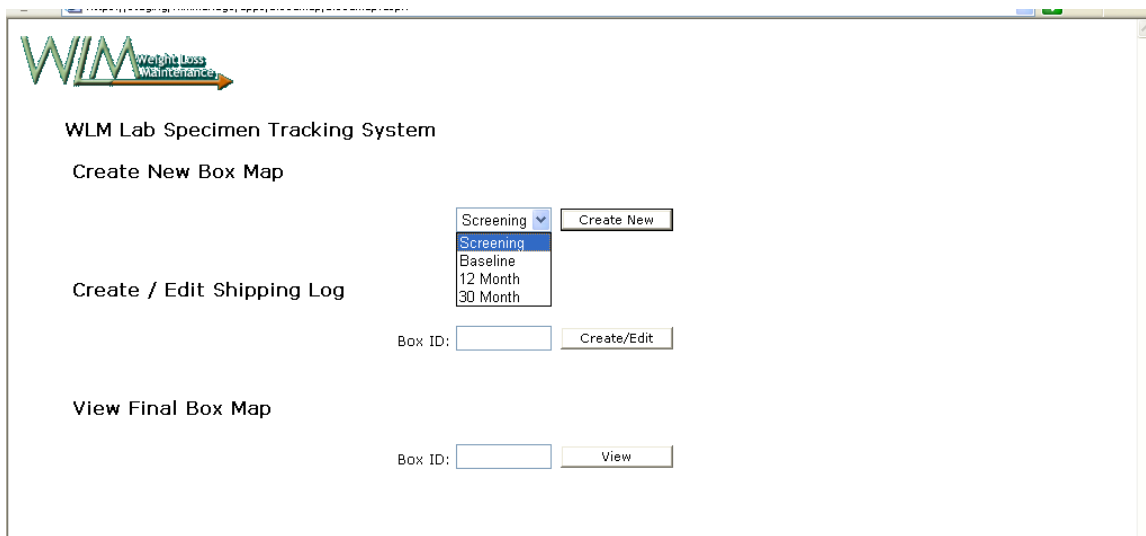


Click on the Lab Tracking

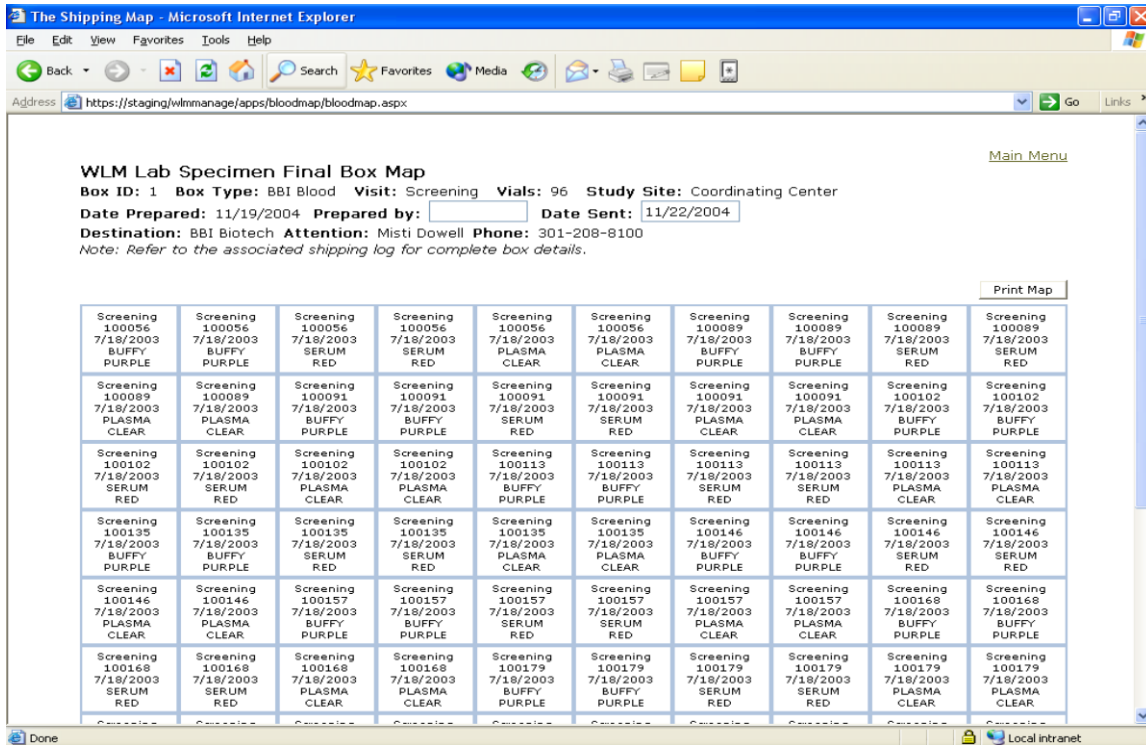




This is the Main Page for the Lab Tracking System



Click on the Create New button to create the next sequential box map or choose the next box from the site visit in the drop down menu



The Date Prepared will automatically be the date map was created.  
 In the "Prepared by" box enter the name or code of the person creating the map.  
 Enter the date sent  
 Print the map

Numerous box maps can be created at the same time or one at a time.

Use this map to compare with the box to insure the vials are in order and are in shipping condition

Note the box number

Click on Main Menu to return to the Main page

WLM Lab Specimen Tracking System

Create New Box Map

Screening

Create / Edit Shipping Log

Box ID:

View Final Box Map

Box ID:

Enter the box number to create the corresponding shipping log  
Click the “Create/Edit” button

WLM Lab Specimen Shipping Log [Main Menu](#)

Box ID: 1 Box Type: BBI BLOOD Visit: Screening Vials: 96 Study Site: Coordinating Center  
Date Prepared: 11/19/2004 Prepared by:  Date Sent: 11/22/2004  
Destination: BBI Biotech Attention: Misti Dowell Phone: 301-208-8100

	Slot ID	Specimen ID	Participant ID	Collect Date	Sample Type	Vial Color	Ship Condition	Code	Specimen Note
<a href="#">Edit</a>	1	100056031	100056	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	2	100056032	100056	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	3	100056051	100056	7/18/2003	SERUM	RED	GOOD		
<a href="#">Edit</a>	4	100056052	100056	7/18/2003	SERUM	RED	GOOD		
<a href="#">Edit</a>	5	100056041	100056	7/18/2003	PLASMA	CLEAR	GOOD		
<a href="#">Edit</a>	6	100056042	100056	7/18/2003	PLASMA	CLEAR	GOOD		
<a href="#">Edit</a>	7	100089031	100089	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	8	100089032	100089	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	9	100089051	100089	7/18/2003	SERUM	RED	GOOD		
<a href="#">Edit</a>	10	100089052	100089	7/18/2003	SERUM	RED	GOOD		
<a href="#">Edit</a>	11	100089041	100089	7/18/2003	PLASMA	CLEAR	GOOD		
<a href="#">Edit</a>	12	100089042	100089	7/18/2003	PLASMA	CLEAR	GOOD		
<a href="#">Edit</a>	13	100091031	100091	7/18/2003	BUFFY	PURPLE	GOOD		

This is the log sent to the lab. The condition of the received samples will be recorded on this form. Edits are made to the log, which will revise the box map.

Confirm box number  
Enter the Prepared by information

[Main Menu](#)

**WLM Lab Specimen Shipping Log**  
**Box ID: 1 Box Type: BBI BLOOD Visit: Screening Vials: 96 Study Site: Coordinating Center**  
**Date Prepared: 11/19/2004 Prepared by: [ ] Date Sent: 11/22/2004**  
**Destination: BBI Biotech Attention: Misti Dowell Phone: 301-208-8100**

[View Printable Version](#)

	Slot ID	Specimen ID	Participant ID	Collect Date	Sample Type	Vial Color	Ship Condition	Code	Specimen Note
<a href="#">Update</a> <a href="#">Cancel</a>	1	100056031	100056	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	2	100056032	100056	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	3	100056051	100056	7/18/2003	SERUM	RED	DAMAGED (USABLE)		
<a href="#">Edit</a>	4	100056052	100056	7/18/2003	SERUM	RED	BROKEN (NOT USABLE)		
<a href="#">Edit</a>	5	100056041	100056	7/18/2003	PLASMA	CLEAR	LOST / MISSING		
<a href="#">Edit</a>	6	100056042	100056	7/18/2003	PLASMA	CLEAR	NO VIAL - DATA ENTRY ERROR		
<a href="#">Edit</a>	7	100089031	100089	7/18/2003	BUFFY	PURPLE	INADEQUATE SAMPLE		
<a href="#">Edit</a>	8	100089032	100089	7/18/2003	BUFFY	PURPLE	HEMOLYZED		
<a href="#">Edit</a>	9	100089051	100089	7/18/2003	SERUM	RED	LIPEMIC		
<a href="#">Edit</a>	10	100089052	100089	7/18/2003	SERUM	RED	THAWED		
<a href="#">Edit</a>	11	100089041	100089	7/18/2003	PLASMA	CLEAR	MISSING LABEL		
<a href="#">Edit</a>	12	100089042	100089	7/18/2003	PLASMA	CLEAR	GOOD		
<a href="#">Edit</a>	13	100091031	100091	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	14	100091032	100091	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	15	100091051	100091	7/18/2003	SERUM	RED	GOOD		
<a href="#">Edit</a>	16	100091052	100091	7/18/2003	SERUM	RED	GOOD		
<a href="#">Edit</a>	17	100091041	100091	7/18/2003	PLASMA	CLEAR	GOOD		

To edit the condition of the vials click on edit. The dropdown box has a list of condition options. Click on the option best describing the condition of the vial, then click on Update

[Main Menu](#)

**WLM Lab Specimen Shipping Log**  
**Box ID: 1 Box Type: BBI BLOOD Visit: Screening Vials: 96 Study Site: Coordinating Center**  
**Date Prepared: 11/19/2004 Prepared by: [ ] Date Sent: 11/22/2004**  
**Destination: BBI Biotech Attention: Misti Dowell Phone: 301-208-8100**

[View Printable Version](#)

	Slot ID	Specimen ID	Participant ID	Collect Date	Sample Type	Vial Color	Ship Condition	Code	Specimen Note
<a href="#">Edit</a>	1	100056031	100056	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	2	100056032	100056	7/18/2003	BUFFY	PURPLE	DAMAGED (USABLE)		
<a href="#">Edit</a>	3	100056051	100056	7/18/2003	SERUM	RED	BROKEN (NOT USABLE)		
<a href="#">Edit</a>	4	100056052	100056	7/18/2003	SERUM	RED	LOST / MISSING		
<a href="#">Edit</a>	5	100056041	100056	7/18/2003	PLASMA	CLEAR	NO VIAL - DATA ENTRY ERROR		
<a href="#">Edit</a>	6	100056042	100056	7/18/2003	PLASMA	CLEAR	INADEQUATE SAMPLE		
<a href="#">Edit</a>	7	100089031	100089	7/18/2003	BUFFY	PURPLE	HEMOLYZED		
<a href="#">Edit</a>	8	100089032	100089	7/18/2003	BUFFY	PURPLE	LIPEMIC		
<a href="#">Edit</a>	9	100089051	100089	7/18/2003	SERUM	RED	THAWED		
<a href="#">Edit</a>	10	100089052	100089	7/18/2003	SERUM	RED	MISSING LABEL		


Click on View Printable Version to see final version.

[Main Menu](#)

**WLM Lab Specimen Shipping Log**  
**Box ID:** 1 **Box Type:** BBI **Visit:** Screening **Vials:** 89 **Study Site:** Coordinating Center  
**Date Prepared:** 11/19/2004 **Prepared by:** 12 **Date Sent:** 11/22/2004  
**Destination:** BBI Biotech **Attention:** Misti Dowell **Phone:** 301-208-8100

Slot ID	Specimen ID	Participant ID	Collect Date	Sample Type	Vial Color	Ship Condition	Code	Specimen Note
1	100056031	100056	7/18/2003	BUFFY	PURPLE	GOOD		
2	100056032	100056	7/18/2003	BUFFY	PURPLE	DAMAGED (USABLE)		
3	100056051	100056	7/18/2003	SERUM	RED	BROKEN (NOT USABLE)		
4	100056052	100056	7/18/2003	SERUM	RED	LOST / MISSING		
5	100056041	100056	7/18/2003	PLASMA	CLEAR	NO VIAL - DATA ENTRY ERROR		
6	100056042	100056	7/18/2003	PLASMA	CLEAR	INADEQUATE SAMPLE		
7	100089031	100089	7/18/2003	BUFFY	PURPLE	HEMOLYZED		
8	100089032	100089	7/18/2003	BUFFY	PURPLE	LIPEMIC		
9	100089051	100089	7/18/2003	SERUM	RED	THAWED		
10	100089052	100089	7/18/2003	SERUM	RED	MISSING LABEL		
11	100089041	100089	7/18/2003	PLASMA	CLEAR	GOOD		
12	100089042	100089	7/18/2003	PLASMA	CLEAR	GOOD		
13	100091031	100091	7/18/2003	BUFFY	PURPLE	GOOD		
14	100091032	100091	7/18/2003	BUFFY	PURPLE	GOOD		
15	100091051	100091	7/18/2003	SERUM	RED	GOOD		
16	100091052	100091	7/18/2003	SERUM	RED	GOOD		

Print



**WLM Lab Specimen Tracking System**

Create New Box Map

Screening

Create / Edit Shipping Log

Box ID:

View Final Box Map

Box ID:

If edits were made to the log you will need a new map. Enter the box number in the View Final Box Map box and click View.

[Main Menu](#)

**WLM Lab Specimen Final Box Map**  
**Box ID:** 1 **Box Type:** BBI Blood **Visit:** Screening **Vials:** 89 **Study Site:** Coordinating Center  
**Date Prepared:** 11/19/2004 **Prepared by:** 12 **Date Sent:** 11/22/2004  
**Destination:** BBI Biotech **Attention:** Misti Dowell **Phone:** 301-208-8100  
*Note: Refer to the associated shipping log for complete box details.*

[Print Map](#)

Screening 100056 7/18/2003 BUFFY PURPLE	Screening 100056 7/18/2003 BUFFY PURPLE						Screening 100089 7/18/2003 BUFFY PURPLE		
Screening 100089 7/18/2003 PLASMA CLEAR	Screening 100089 7/18/2003 PLASMA CLEAR	Screening 100091 7/18/2003 BUFFY PURPLE	Screening 100091 7/18/2003 BUFFY PURPLE	Screening 100091 7/18/2003 SERUM RED	Screening 100091 7/18/2003 SERUM RED	Screening 100091 7/18/2003 PLASMA CLEAR	Screening 100091 7/18/2003 PLASMA CLEAR	Screening 100102 7/18/2003 BUFFY PURPLE	Screening 100102 7/18/2003 BUFFY PURPLE
Screening 100102 7/18/2003 SERUM RED	Screening 100102 7/18/2003 SERUM RED	Screening 100102 7/18/2003 PLASMA CLEAR	Screening 100102 7/18/2003 PLASMA CLEAR	Screening 100113 7/18/2003 BUFFY PURPLE	Screening 100113 7/18/2003 BUFFY PURPLE	Screening 100113 7/18/2003 SERUM RED	Screening 100113 7/18/2003 SERUM RED	Screening 100113 7/18/2003 PLASMA CLEAR	Screening 100113 7/18/2003 PLASMA CLEAR
Screening 100135 7/18/2003 BUFFY PURPLE	Screening 100135 7/18/2003 BUFFY PURPLE	Screening 100135 7/18/2003 SERUM RED	Screening 100135 7/18/2003 SERUM RED	Screening 100135 7/18/2003 PLASMA CLEAR	Screening 100135 7/18/2003 PLASMA CLEAR	Screening 100146 7/18/2003 BUFFY PURPLE	Screening 100146 7/18/2003 BUFFY PURPLE	Screening 100146 7/18/2003 SERUM RED	Screening 100146 7/18/2003 SERUM RED
Screening 100146 7/18/2003 PLASMA CLEAR	Screening 100146 7/18/2003 PLASMA CLEAR	Screening 100157 7/18/2003 BUFFY PURPLE	Screening 100157 7/18/2003 BUFFY PURPLE	Screening 100157 7/18/2003 SERUM RED	Screening 100157 7/18/2003 SERUM RED	Screening 100157 7/18/2003 PLASMA CLEAR	Screening 100157 7/18/2003 PLASMA CLEAR	Screening 100168 7/18/2003 BUFFY PURPLE	Screening 100168 7/18/2003 BUFFY PURPLE
Screening 100168 7/18/2003 SERUM RED	Screening 100168 7/18/2003 SERUM RED	Screening 100168 7/18/2003 PLASMA CLEAR	Screening 100168 7/18/2003 PLASMA CLEAR	Screening 100179 7/18/2003 BUFFY PURPLE	Screening 100179 7/18/2003 BUFFY PURPLE	Screening 100179 7/18/2003 SERUM RED	Screening 100179 7/18/2003 SERUM RED	Screening 100179 7/18/2003 PLASMA CLEAR	Screening 100179 7/18/2003 PLASMA CLEAR

Confirm box #.  
 Fill in the Prepared by box.  
 Confirm edits.

Address <https://staging/wlmmanage/apps/bloodmap/bloodmap.aspx> [Go](#) [Links](#)

**WLM Lab Specimen Tracking System**

**Create New Box Map**

Screening

**Create / Edit Shipping Log**

Box ID:

**View Final Box Map**

Box ID:

If the Map needs to be edited again, go back to the Main Menu, enter the box # in the Edit Shipping Log box and click on the Create/Edit button.

Address <https://staging/wlmmanage/apps/bloodmap/shippinglog.aspx> Go Links

[Main Menu](#)

### WLM Lab Specimen Shipping Log

**Box ID:** 1 **Box Type:** BBI BLOOD **Visit:** Screening **Vials:** 96 **Study Site:** Coordinating Center  
**Date Prepared:** 11/19/2004 **Prepared by:** 12 **Date Sent:** 11/22/2004  
**Destination:** BBI Biotech **Attention:** Misti Dowell **Phone:** 301-208-8100

[View Printable Version](#)

	Slot ID	Specimen ID	Participant ID	Collect Date	Sample Type	Vial Color	Ship Condition	Code	Specimen Note
<a href="#">Edit</a>	1	100056031	100056	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	2	100056032	100056	7/18/2003	BUFFY	PURPLE	DAMAGED (USABLE)		
<a href="#">Edit</a>	3	100056051	100056	7/18/2003	SERUM	RED	BROKEN (NOT USABLE)		
<a href="#">Edit</a>	4	100056052	100056	7/18/2003	SERUM	RED	GOOD		
<a href="#">Edit</a>	5	100056041	100056	7/18/2003	PLASMA	CLEAR	GOOD		
<a href="#">Edit</a>	6	100056042	100056	7/18/2003	PLASMA	CLEAR	INADEQUATE SAMPLE		
<a href="#">Edit</a>	7	100089031	100089	7/18/2003	BUFFY	PURPLE	HEMOLYZED		
<a href="#">Edit</a>	8	100089032	100089	7/18/2003	BUFFY	PURPLE	LIPEMIC		
<a href="#">Edit</a>	9	100089051	100089	7/18/2003	SERUM	RED	THAWED		
<a href="#">Edit</a>	10	100089052	100089	7/18/2003	SERUM	RED	MISSING LABEL		
<a href="#">Edit</a>	11	100089041	100089	7/18/2003	PLASMA	CLEAR	GOOD		
<a href="#">Edit</a>	12	100089042	100089	7/18/2003	PLASMA	CLEAR	GOOD		
<a href="#">Edit</a>	13	100091031	100091	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	14	100091032	100091	7/18/2003	BUFFY	PURPLE	GOOD		
<a href="#">Edit</a>	15	100091051	100091	7/18/2003	SERUM	RED	GOOD		

Make needed changes.  
 Print final log.






Address <https://staging/wlmmanage/apps/bloodmap/bloodmap.aspx> Go Links

[Main Menu](#)

### WLM Lab Specimen Final Box Map

**Box ID:** 1 **Box Type:** BBI Blood **Visit:** Screening **Vials:** 91 **Study Site:** Coordinating Center  
**Date Prepared:** 11/19/2004 **Prepared by:** 12 **Date Sent:** 11/22/2004  
**Destination:** BBI Biotech **Attention:** Misti Dowell **Phone:** 301-208-8100  
*Note: Refer to the associated shipping log for complete box details.*

[Print Map](#)

Screening 7/18/2003 BUFFY PURPLE	Screening 100056 7/18/2003 BUFFY PURPLE		Screening 100056 7/18/2003 SERUM RED	Screening 100056 7/18/2003 PLASMA CLEAR			Screening 100089 7/18/2003 BUFFY PURPLE		
Screening 100089 7/18/2003 PLASMA CLEAR	Screening 100089 7/18/2003 PLASMA CLEAR	Screening 100091 7/18/2003 BUFFY PURPLE	Screening 100091 7/18/2003 BUFFY PURPLE	Screening 100091 7/18/2003 SERUM RED	Screening 100091 7/18/2003 SERUM RED	Screening 100091 7/18/2003 PLASMA CLEAR	Screening 100091 7/18/2003 PLASMA CLEAR	Screening 100102 7/18/2003 BUFFY PURPLE	Screening 100102 7/18/2003 BUFFY PURPLE
Screening 100102 7/18/2003 SERUM RED	Screening 100102 7/18/2003 SERUM RED	Screening 100102 7/18/2003 PLASMA CLEAR	Screening 100102 7/18/2003 PLASMA CLEAR	Screening 100113 7/18/2003 BUFFY PURPLE	Screening 100113 7/18/2003 BUFFY PURPLE	Screening 100113 7/18/2003 SERUM RED	Screening 100113 7/18/2003 SERUM RED	Screening 100113 7/18/2003 PLASMA CLEAR	Screening 100113 7/18/2003 PLASMA CLEAR
Screening 100135 7/18/2003 BUFFY PURPLE	Screening 100135 7/18/2003 BUFFY PURPLE	Screening 100135 7/18/2003 SERUM RED	Screening 100135 7/18/2003 SERUM RED	Screening 100135 7/18/2003 PLASMA CLEAR	Screening 100135 7/18/2003 PLASMA CLEAR	Screening 100146 7/18/2003 BUFFY PURPLE	Screening 100146 7/18/2003 BUFFY PURPLE	Screening 100146 7/18/2003 SERUM RED	Screening 100146 7/18/2003 SERUM RED
Screening 100146 7/18/2003 PLASMA CLEAR	Screening 100146 7/18/2003 PLASMA CLEAR	Screening 100157 7/18/2003 BUFFY PURPLE	Screening 100157 7/18/2003 BUFFY PURPLE	Screening 100157 7/18/2003 SERUM RED	Screening 100157 7/18/2003 SERUM RED	Screening 100157 7/18/2003 PLASMA CLEAR	Screening 100157 7/18/2003 PLASMA CLEAR	Screening 100168 7/18/2003 BUFFY PURPLE	Screening 100168 7/18/2003 BUFFY PURPLE

Print final map.

## Shipping of Frozen Samples to Repository

### Repository Contact Information

NHLBI Repository  
ATTN: Christine Demasco  
SeraCare BioServices  
217 Perry Parkway  
Gaithersburg, MD 20877  
Tel: (301) 208-8100 x196  
Fax: (301) 208-8829  
Email: [cdemasco@seracare.com](mailto:cdemasco@seracare.com)  
Alternate contact info:

- Common e-mail for NHLBI repository projects: [nhlbi@seracare.com](mailto:nhlbi@seracare.com)
- Misti Dowell: [Mdowell@seracare.com](mailto:Mdowell@seracare.com)

### Schedule: Shipments may be made Monday through Wednesday Only

#### Using the Saf-T-Pak STP 310

1. Remove the “empty” packaging flap from the front of the box. Box is pre-labeled.
  - a. Once Empty Packaging Flap is removed the box should contain the following labels. If any of the labels are missing please contact us for replacements
    - i. To Label (To Christine Demasco)
    - ii. From Label (From your site)
    - iii. 24 Hour Emergency Contact Label
    - iv. Responsible Person Label
    - v. Class 9 Diamond Label
    - vi. UN3373 Diamond Diagnostic Specimens Label
    - vii. Dry Ice Un 1845 Label with space to add weight
    - viii. Air Eligible Label
2. Place Dry Ice around the small inner brown box (between brown box and Styrofoam container).
3. Place Rubber band (at least ¼” thick) around Freezer Box.
4. Place White Absorbent Strip around box.
5. Place Box in Clear Biohazard bag and seal according to instructions on the bag.
6. Place bag in White Biohazard bag and seal according to the instructions on the bag.
7. Place bag in the inner brown box (the shipping container can hold 3-2” Freezer boxes or 2-3” Freezer Boxes) and tape the inner brown box shut.
8. Add additional dry ice to bring total amount to the same level as the top of the brown inner box. Note that the total amount of dry ice will be ~16lbs or 9 Kgs
9. Place the styrofoam lid onto the container (do not tape the styrofoam lid), place the “empty” packaging flap on top of the Styrofoam, and then seal the cardboard box.
10. Complete FedEx Airbill with your shipping address and the amount of Dry Ice placed in box:
  - a. Section 2 - The Internal Billing Reference Section must have the following information “138, Diagnostic Specimens UN 3373”
  - b. Section 4a - Check the “FedEx Priority Overnight” box
  - c. Section 5 - Check the “other” box
  - d. Section 6 - Check the box that says, “Yes Shipper’s Declaration not required”. Check the “Dry Ice box” and write “1” in the first blank line and the “kg” of dry ice used on the second line; i.e., 1 x 9 kg
  - e. Section 7 - Check Recipient. The account number is 2541-8815-8
11. Fill in the Dry Ice Label on box with the amount of dry ice used.



12. Please fax a copy of the airbill to BBI Biotech at (301) 208-8829 to the Attention of Christine Demasco.
13. Send an e-mail to Chem-Tel (our 24-hour contact) at [bbibiotech@chemtelinc.com](mailto:bbibiotech@chemtelinc.com). Please cc BBI Biotech at [nhlbi@bbii.com](mailto:nhlbi@bbii.com). Include the following information in your e-mail.
  - a. Subject Line of E-mail should read: Project # 138, FedEx, “insert tracking number”, “insert date of shipment”:
  - b. Shipper’s Name:
  - c. Shipper’s Address:
  - d. Shipper’s Phone:
  - e. Shipment Date:
  - f. Courier: FedEx
  - g. Tracking Number (no spaces):
  - h. Package Weight and Unit of Measure (i.e. 20 kg):
  - i. Total Volume: (total amount of volume per sample - approximate volume is allowed. EXAMPLE: if each vial is 1 ½ ml and you ship 400 samples, total volume = 600 ml.)
  - j. Sample Identifier/Number of vials (Approximate number for Frozen vials is allowed).
  - k. Shipment Temperature: Dry Ice, UN1845, \_\_\_ kg (insert weight of Dry Ice) – Enter the amount of dry ice in the box. No need to measure it’s temperature.
  - l. Dangerous Goods Classification: Diagnostic Specimens UN3373, Dry Ice
  - m. Manifest Information (indicate if electronic manifest is being provided via e-mail or with the shipment. A paper copy must be included in the shipment).
  - n. Recipient: Christine Demasco
  - o. Recipient Address: 217 Perry Parkway, Gaithersburg, MD, 20877
  - p. Recipient Phone: (301) 208-8100 x196

Faxes may only be sent to Chem-Tel in an emergency situation when the e-mail system is not functioning at (813) 248-0582.

If you should have any questions regarding these instructions please contact BBI Biotech using the contact information above.

### ***Reporting of Results***

**TBD**

## 7.7 FFQ Shipping

Sites ship FFQ forms directly to Block Dietary Data Systems at the address listed below. Each shipment will contain a list inventorying the contents of the shipment. Block prefers to receive larger batches whenever possible.

### *Preparing FFQ's for shipping*

The coordinating center recommends making a copy of each FFQ shipped to Block, but does not require sites to make copies.

### *Packing Boxes for Shipping*

1. Make a list of all FFQ's shipped to Block.
2. Group the list by visit. Include the participant's ID number
3. Place the list in the box with the forms.
4. Sites keep a copy of the list.
5. Include a cover letter stating the total number of forms, which site they are coming from, and a statement that the forms and data files should be sent to Carrie Meeks at the CC. The datafile with nutrient and food group estimates should be a SAS transport dataset.

### *Shipping Forms*

1. Send all shipments to Block by some type of "tracked" mail.
2. Send an e-mail to Block (copy in the CC: carrie.s.meeks@kpchr.org) announcing that a package has been sent.
3. Each site needs to obtain proof that Block received the package and it's contents, either by a reply to the announcement e-mail or something from the mailing company. This reply should be stored with the copy of the packing list outlined in section 7.7.

Ship the questionnaires to the following address:

Attention: Torin Block  
Block Dietary Data Systems  
15 Shattuck Square  
Suite 288  
Berkeley, CA 94704  
TEL: 510-704-8514  
FAX: 510-704-8996  
e-mail: tblock@nutritionquest.com

## Weight Loss Maintenance MOP

### **8 Participant Safety and Adverse Events**

#### **Summary of edits between Version 1.0 and Version 1.1:**

- Clarifies the rules for VPALs
- Adds that sites should fax the SAE form to the CC
- Makes BP escape level 1 more conservative and expands required action to involve site clinician
- Adds a more conservative BP escape level 3 for diabetics

#### **Summary of edits between Version 1.1 and Version 1.2:**

- Expands required action of involve site clinician for BP escape level 1: participant is evaluated within 48 hours

#### **Summary of edits between Version 1.2 and Version 1.3:**

- Updates SAE procedures to expand list of expected events
- Revises SAE adjudication procedure
- Expands required action for high BP escapes and for Rose Angina escape levels: Sites must send out physical activity physician approval letters.
- Adds table showing details of the PA alert process

#### **Summary of edits between Version 1.3 and Version 1.4:**

- Adds additional procedures for Phase III, including review of SAEs prior to phase III randomization and letter for unhealthy weight management strategies

#### **Summary of edits between Version 1.4 and Version 1.5:**

- Adds procedure for Berlin Sleep Questionnaire referral and sample referral letter

#### **Summary of edits between Version 1.5 and Version 1.6:**

- Corrects procedure for Berlin Sleep Questionnaire referral

## 8.1 Safety Measures

This chapter describes measures to ensure the safety of participants in the WLM Trial. In general, participants are carefully screened to insure that participation in the study does not put them at undue risk. The study's eligibility criteria serve to exclude those in whom more aggressive therapy is indicated or in whom the dietary and physical activity components of the WLM interventions might pose some risk. For example, individuals with a CVD event in the past year and those with medication-treated diabetes are excluded.

Additionally, surveillance for serious adverse events and relevant clinical events occurs by questionnaire at regularly scheduled intervals. This chapter describes safety monitoring and management of serious adverse events.

### **Provider Approval Letters (PALs)**

Provider approval is documented using one of three Provider Approval Letters (PALs), and is required or requested, depending on the circumstances, as described in detail below and summarized in Table 1.

#### *Eligibility PAL (E-PAL)*

The E-PAL notifies the participant's health care provider that a condition exists that requires that the provider:

1. attest that the participant has had a non-positive stress test or equivalent (i.e., negative cardiac catheterization) in the past 12 months,
2. attest that the participant does not have active CAD that would preclude participation in the study, and
3. give approval for the participant to take part in WLM.

The E-PAL is required during screening if the participant has had a CVD event more than 12 months prior (a more recent CVD event is exclusionary), unmedicated diabetes mellitus (medicated diabetes is exclusionary) or a positive Rose angina questionnaire. The E-PAL is also required during the baseline evaluation (i.e., at the end of Phase I) if the participant has a positive Rose angina questionnaire. In the case of a positive Rose angina questionnaire, all three requirements are again needed in order for the participant to be eligible for Phase I or II.

Evidence of a negative and adequate stress test is not required for participants who are currently engaging in vigorous physical activity but would otherwise need an E-PAL (unless they have a positive Rose Questionnaire). However they must still get physician permission to participate (and an HbA1C for unmedicated diabetics).

If, for any reason, a clinician indicates that the participant cannot take part in WLM, they are excluded, regardless of responses to other items.

#### *Vigorous Physical Activity PAL (VPA-PAL)*

The VPA-PAL is used to notify the participant's health care provider that study personnel have become aware that the participant is engaging in vigorous physical activity (VPA), and that the American College of Sports Medicine (ACSM) would recommend a non-positive stress test for patients similar to WLM participants prior to engaging in VPA. The VPA-PAL is not an eligibility requirement for entry into Phase I or Phase II; it is primarily for the purpose of providing safety advice to participants and documenting that this advice has been provided. (See physical activity section below.)

*Physical Activity After Escape PAL (PA-PAL)*

Participants who have a positive Rose Angina questionnaire or who reach certain high escape level BPs are advised to discontinue exercise until cleared by their personal health care provider. The PA-PAL notifies the participant’s health care provider that a safety escape for possible angina or elevated blood pressure has been reached. It notifies the provider of the alert and requests participants obtain their providers advice on whether to take part in exercise.

**Safety procedures in participants with elevated blood pressure or possible angina**

In response to a DSMB recommendation, the Steering Committee has developed a “Physical Activity Procedure” for ensuring that participants who exceed a safety threshold stop physical activity pending evaluation and clearance by their personal physician.

**Guidelines triggering Physical Activity Alert process**

There are three scenarios that could occur at the Baseline, 12-month and 30-month clinic visit, that would trigger the Physical Activity Alert process:

1. Average blood pressure at a single clinic visit in excess of 180 mmHg systolic or 110 mmHg diastolic (this is equivalent to the current BP Alert Level 1 – see tab 7 in your packet).
2. The average BP at visit 1 **and** the average BP at visit 2 (at any data collection point - Baseline, 12-month or 30-month follow-up) **both** exceed 160 mmHg systolic or 100 mmHg diastolic. (that is, if both blood pressures reach our Alert Level 2 threshold – see Tab 7).
3. A positive Rose Angina Screening per the Rose Angina Questionnaire.

**Physical Activity Alert**

Process STEP/Responsibility      Action:

1. Elevated BP or positive Rose Questionnaire Detected at Data Collection Visit by Blinded Staff	For all participants: a) Notifies participant that s/he should stop exercising until s/he gets clearance from personal MD, and that future exercise should be in accordance with MD’s instructions. b) Documents in chart that participant was advised to stop exercising and consult with his/her doctor. c) Notifies study coordinator of elevated BP or positive Rose Questionnaire. Comment: steps 1a+b can be performed by a study coordinator or other unblinded individual
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<p><b>2. Study Coordinator or other unblinded individual</b></p>	<p>ACTION depends on group assignment</p> <p><u>For PC participants</u></p> <p>a) Sends letter to participant’s MD (or alternatively sends MD letter to participant to give to MD) notifying MD of the elevated blood pressure reading and/or positive Rose angina.</p> <p>b) Notifies PC interventionist that participant should be counseled not to exercise until clearance obtained from MD and that any future advice concerning exercise should be in accordance with MDs instructions.</p> <p>c) Fills out a Form 120 Physician Approval Form, Questions 2.1 and 2.2 (Date alert identified; date patient/MD notified).</p> <p><u>For IT participants</u></p> <p>a) Sends letter to participant’s MD (or alternatively sends MD letter to participant to give to MD) notifying MD of the elevated blood pressure reading and/or positive Rose angina.</p> <p>b) Sends an email message, which advises the participant not to exercise until clearance obtained from MD and that any future exercise should be in accordance with MDs instructions, which may differ from general instructions on the web site. Alternatively, the IT case manager can send the email. Request a read receipt from the participant.</p> <p>c) Fills out a Form 120 Physician Approval Form, Questions 2.1 and 2.2 (Date alert identified; date patient/MD notified).</p> <p><u>For SD participants</u></p> <p>a) Sends letter to participant’s MD (or alternatively sends MD letter to participant to give to MD) notifying MD of the elevated blood pressure reading and/or positive Rose angina questionnaire.</p> <p>b) Fills out a Form 120 Physician Approval Form, Questions 2.1 and 2.2 (Date alert identified; date patient/MD notified).</p>
<p><b>3. PC interventionist</b></p>	<p>During monthly contacts, PC Interventionist does not provide physical activity recommendations until s/he hears from the patient that MD has okayed it, and in this case merely encourages and assists participant to follow MDs exercise advice.</p>

*Failure to Return a PAL*

- Failure to return an E-PAL that is required during screening will result in ineligibility for WLM.
- Failure to return an E-PAL that is required during baseline will result in ineligibility for randomization into Phase II.
- Failure to return a VPA-PAL will not affect eligibility or continued participation in the WLM interventions.
- Failure to return a PA-PAL results in our continued advice to the participant not to exercise until clearance to do so by their personal health care provider.

**Physical Activity**

### *Vigorous Physical Activity*

Participants will enter WLM with a range of physical activity patterns. In WLM, participants are expected to conduct moderate physical activity on a regular basis. Because all participants have at least two CVD risk factors (overweight/obesity PLUS hypertension and/or dyslipidemia), any individual who initiates vigorous physical activity at any time during the study receives the VPA-PAL to bring to his/her health care provider for review and approval. However, as noted above, failure to return a completed VPA-PAL or to receive clinician approval for VPA is not exclusionary. In this circumstance, the participant will be reminded periodically of our recommendation to follow ACSM guidelines or until the provider sends back documentation approving physical activity.

### *Assessment of Vigorous Physical Activity*

Vigorous physical activity is identified using a question on the Physical Activity (PA) Form (#121) and the Short Physical Activity (SPA) Form (#205) that asks if the participant is currently engaged in VPA. If a VPA-PAL is indicated, the participant is referred to a designated staff member for distributing the VPA-PAL form and instructions for its completion. The identification of a designated staff member is left to the discretion of each clinical site, but could be part of the intervention, measurement, or clinical staff.

### *Monitoring Vigorous Physical Activity*

**Screening** - Participants who enter WLM currently engaging in regular vigorous physical activity are allowed to continue VPA throughout the trial. No VPA-PAL is needed.

**Phases I and II** - During Phase I, participants are asked to complete the SPA Form at 10 weeks. During Phase II, participants are asked to complete the PA Form #121 (at randomization, 12-months and 30-months) or SPA Form #205 (at 6, 18, and 24 months) at regular data collection visits. If a participant indicates that they have initiated or are continuing vigorous physical activity, they are given a VPA-PAL to take to their clinician for completion. If a VPA-PAL has already been given to a participant and was fully completed, returned and given VPA clearance by the participant's clinician to a WLM clinical center, no additional VPA-PAL will be required for the remainder of the study. If their clinician refuses to give VPA clearance to a participant, or does not return the VPA-PAL, and the participant indicates at subsequent visits that they are still engaging in VPA, then another VPA-PAL is sent to the clinician. At any time, a site clinician may request an additional VPA-PAL if responses to a previous VPA-PAL were incomplete or inconclusive.

**At any time during the trial, clearance for VPA becomes null and void if the participant indicates that they have had a CVD event.**

### *Tracking physician approval for vigorous physical activity*

The CC tracks responses to the PA and SPA forms, whether a VPA-PAL was given to a participant, and whether the VPA-PAL was returned to the clinical site. If a participant reports doing VPA, s/he is referred to a designated staff person who first checks whether the participant has been 'cleared' for vigorous physical activity. (In order to be cleared for vigorous activity, a participant must have already been engaged in vigorous activity prior to screening for WLM or they must have a completed VPA-PAL on file documenting their clinician's approval.) If the participant has not been cleared for vigorous activity, the designated staff gives the participant a VPA-PAL to take to his/her provider for completion. Once the VPA-PAL has been returned and, upon review by a WLM study clinician, found to be complete and satisfactory, the participant may be cleared for vigorous physical activity. If the VPA-PAL has not been returned by the next data collection visit (every 6-months), or the provider refuses to

give permission for VPA, a note is made of this locally and the participant is reminded to take the VPA-PAL to their clinician if the participant continues to report VPA.

### **Diabetes Mellitus**

Special consideration is given to participants with diabetes mellitus since there is the added risk of hypoglycemia in medication-treated diabetics with exercise and weight loss. In order to minimize the risk of hypoglycemia, self-reported diabetics who are currently being treated with any medications aimed at reducing blood sugar levels will be excluded from participation in WLM. In addition, diabetics who are likely to start medications during Phase I, as determined by an HbA1C level >8.0%, are excluded from participation in WLM. For the remaining participants with well-controlled, non-medication treated diabetes, personal clinician approval, including attestation of a negative stress test within the last 12 months and the absence of active CAD, is required prior to participation in Phase I (Eligibility PAL).

If a participant (either newly diagnosed or with existing disease) begins to take hypoglycemic medications for the control of diabetes prior to the start of Phase II, they are excluded from participating in Phase II. However participants who develop unmedicated diabetes during Phase I do not require a normal HbA1C in order to be eligible for Phase II. Under these scenarios, there is minimal risk of hypoglycemia since, during Phase I, only non-medication treated diabetics are allowed to participate, and during Phase II, the period of intense weight loss (Phase I) will have passed.

### **Positive Rose Angina Questionnaire**

A positive Rose angina questionnaire during screening or baseline assessment requires an Eligibility PAL to be completed and returned to the clinical site. In addition, if a positive Rose Angina questionnaire is obtained during Phase II, participants are advised to cease physical activity until their provider confirms the absence of active CAD. The decision to resume physical activity by the participant is left to the participant and the provider. If the participant subsequently reports engaging in VPA, then a VPA-PAL is sent to the participant's provider.

### **Blood Pressure**

Many WLM participants are on antihypertensive medication. During the course of the study, blood pressure may become excessively high or excessively low (i.e., with weight loss). The WLM investigators do not assume responsibility for clinical care of the participants' hypertension, and participants are reminded to seek this care with their primary care provider. For safety monitoring and secondary outcome analysis, blood pressure is measured at baseline, 12 and 30 months. Participants with elevated BP are referred to their primary care provider based on the following algorithm:

#### ***HIGH BP ESCAPES:***

Escape Level #1: The mean blood pressure recorded at any single visit is SBP  $\geq$  180 mm Hg or DBP  $\geq$  110 mm Hg.

*Action* Participant is referred to his/her health care provider for further evaluation **within one week.**

Notify site clinician as soon as possible.

Site clinician calls participant within 48 hours of data collection to:

- a) assess whether the participant has any symptoms that might suggest progressive target organ dysfunction or that might otherwise require emergency medical care (if so, the ppt is advised to seek it);



- b) reinforce the need to seek f/u with the ppt's health care provider for further evaluation within one week; and
- c) advise the ppt to stop exercising until he/she sees the provider and BP is under better control.

Escape Level #2: The mean blood pressure recorded at any single visit is SBP  $\geq$  160 mm Hg or DBP  $\geq$  100 mm Hg.

*Action* Participant is referred to his/her health care provider for further evaluation **within one month.**

Escape Level #3 (for *non-diabetic* participants):

The mean of four blood pressures recorded during a data collection point (i.e., baseline, 12 or 30 months) is SBP  $\geq$  140 or DBP  $\geq$  90 mm Hg

*Action* Participant is referred to his/her health care provider for further evaluation **within two months.**

Escape Level #3 (for *diabetic* participants):

The mean of four blood pressures recorded during a data collection point (i.e., baseline, 12 or 30 months) is SBP  $\geq$  130 or DBP  $\geq$  80 mm Hg

*Action* Participant is referred to his/her health care provider for further evaluation **within two months.**

### ***LOW BP ESCAPE***

Low BP Escape (hypotension): The mean blood pressure recorded at any single visit is SBP  $<$  100 mm Hg and the participant is taking blood pressure lowering medications.

*Action* Participant is referred to his/her health care provider for further evaluation **within two months.**

The clinical sites identify participants with escape BP's at the time the measurements are made (or shortly thereafter), and are responsible for making the appropriate referral. In addition, the CC notifies the sites of participants with escape BP and track that the appropriate referral was made. It is not necessary to document the consequence of that referral.

### **Cardiovascular Disease**

Persons with cardiovascular disease (myocardial infarction, stroke, angioplasty, bypass surgery, congestive heart failure, or peripheral vascular surgery) that is new or occurring within 12 months of screening are excluded from WLM. If any of the conditions defining CVD occur during Phase I, the participant is excluded from randomization into Phase II. If a CVD event occurs during Phase II, participants are advised to stop physical activity. Resumption or initiation of physical activity is at the discretion of the participant's health care provider.

Persons with a history of a CVD event over 12 months prior to screening are required to have their health care provider return an Eligibility PAL prior to beginning Phase I of WLM.

### **Musculoskeletal Injury**

Participants are informed of the potential risks, such as musculoskeletal discomfort, when new types of physical activities are started. Risk of injury is minimized by instruction on proper exercise technique. As a component of Phase I, participants are taught techniques for stretching, warm-up, and cool-down.

In the case of illness or injury during Phase I, interventionists advise the participants on adapting their physical activity program. For example, individuals who have been in automobile accidents may need to alter their physical activity patterns for a time period. This alteration in activity may require some assessment in order for the interventionist to be able to provide suggestions for adapting the participant's physical activity program. A study clinician is available to advise the interventionists on the need to refer for medical care if necessary. Musculoskeletal problems that occur during Phase II and are brought to an interventionist's attention are handled similarly; an unblinded clinician is available to advise the interventionist as needed.

If there is any question about the etiology of an injury or the need for treatment, the participant is referred to a clinician for evaluation. If a participant is not willing to follow recommendations for referral care, a study clinician is notified and determines if further action is required. If appropriate, a serious adverse event record is created.

### **Nutrient Intake**

Calorie restriction can theoretically lead to inadequate nutrition. To minimize this risk, participants are encouraged to eat a variety of foods from all food groups and to maintain an adequate calorie level. Participants are instructed not to reduce caloric intake below 1200 calories per day. During the intensive weight-loss program in Phase I, an interventionist periodically reviews food records and provides feedback on the adequacy of nutrient intake. The issue of adequate nutrient intake is discussed in the group and individual sessions. If nutritional deficiency is suspected and unresponsive to advice from the interventionist, the site clinician counsels the participant.

Participants may use extreme measures to lose 4kg at the end of Phase I in order to be eligible for Phase II. Participants are reminded regularly of the importance of safe weight loss. Those who have a sudden, marked weight reduction are interviewed to determine if extreme measures have been taken. Interventionists are trained to detect evidence of extreme measures, and are given strategies for responding. The clinical site clinician is available to interview any participant if the interventionist or other study personnel suspects that the participant is using potentially unsafe methods.

### **Pregnancy and Other Exclusions**

If a participant becomes pregnant during the study, she is excluded immediately from further participation in all study activities. If she has not yet seen a clinician, she is immediately referred for standard prenatal care. If a participant develops any other exclusionary condition (e.g., cancer) following randomization, further participation is determined by a study clinician in conjunction with the participant's own health care provider.

### **Contact with Personal Providers**

The WLM investigators recognize the appropriateness and importance of securing the cooperation of personal providers. To this end, the personal health care providers of all participants are sent a letter describing the trial. These letters explain the study procedures and measures, and the circumstances that would lead to referral of a participant to her/his personal provider. At screening, persons with non-medicated diabetes, individuals with a prior history of a CVD event, and individuals with possible angina at baseline based on the Rose questionnaire require explicit approval of their health care provider and that provider's attestation of a negative and adequate stress test within the past 12 months (using the Eligibility PAL). The angina referral is made again at baseline if applicable. Potential participants who do not have a personal care provider are assisted in finding one.

All WLM participants will be on medication for hypertension and/or dyslipidemia. Weight loss and increased physical activity may necessitate reducing medications; other situations (e.g., new onset of one of these conditions; weight re-gain) may necessitate initiating or increasing medications. The decision to initiate or adjust drug therapy is a decision of the participant's personal clinician, not a WLM clinician.

### **Ascertainment of Medical Events and Vigorous Physical Activity Outside of Routine Data Collection Periods**

Due to the nature of the interventions in WLM, study personnel may become aware of medical conditions or events prior to formal data collection visits. Similarly, study personnel may become aware of a participant initiating or resuming vigorous physical activity outside of formal physical activity assessment periods. When study personnel become aware of a new medical condition or medical event (including Serious Adverse Events), or become aware of a participant initiating or resuming vigorous physical activity, they should immediately report the occurrence to a designated unmasked data collection individual. This designated individual will review safety procedures and, with the assistance of the study coordinator and local investigators, will decide on the appropriate course of action.

### **Study Oversight**

A Data and Safety Monitoring Board (DSMB) provides participant safety oversight for the trial. DSMB members, who include research scientists not otherwise connected with the study, are appointed by NHLBI. The expertise of members includes the disciplines and skills needed to initially review the protocol and then to monitor trial progress, quality of data, and safety of the participants by reviewing study reports. The DSMB serves in an advisory capacity to the NHLBI. Its members have access to unblinded outcome data during the trial and, to protect participants from unreasonable or unnecessary research risks, can recommend early termination of one or more arms of the trial if the data suggest significant adverse risk to participants, if the questions posed by the trial appear to have been answered and there are no ethical or other reasons to continue the trial, or if continuation of the trial is futile.

<b>TABLE 1</b>			
<b>Condition</b>	<b>Condition Present During Screening</b>	<b>Condition Identified During Phase I</b>	<b>Condition Identified During Phases II and III</b>
<b>Diabetes - diet treated</b>	Eligibility PAL	No Action	No Action
<b>Diabetes - med treated</b>	Exclude	Exclude	No Action
<b>CVD &gt; 12M</b>	Eligibility PAL	N/A	N/A
<b>CVD New or &lt; 12M*</b>	Exclude	Exclude	1. Stop physical activity 2. Follow up with personal provider prior to resuming PA
<b>Positive Rose Q</b>	Eligibility PAL	1. Stop physical activity 2. Eligibility PAL prior to randomization	1. Stop physical activity 2. Follow up with personal provider prior to resuming PA
<b>Performing VIGOROUS PA</b>	VPA-PAL not required; cleared for VPA	VPA-PAL for documentation	VPA-PAL for documentation
<b>PA PAL</b>		PA-PAL for documentation	VPA-PAL for documentation
<b>Pregnancy</b>	Exclude	Exclude	Stop study
<b>Other (e.g. cancer)</b>	Exclude	Exclude	PI discretion
<b>Weight Management Strategies</b>	N/A	N/A	Letter to participant advising them to discontinue unhealthy strategies
<b>BP escape</b>	N/A	See escape criteria	See escape criteria
<b>Serious AE</b>	N/A	See text of MOP section 8	See text of MOP section 8
<b>* CVD events = MI, stroke, angioplasty, CABG, heart failure, revascularization procedure</b>			

## **8.2 Serious Adverse Events**

### **Serious Adverse Events (SAE) Surveillance**

Surveillance for SAEs and other relevant clinical events that may be associated with study participation occurs during Phase I, at randomization (prior to Phase II) and at every follow-up visit thereafter.

Participants are queried at each follow-up visit about possible serious adverse events. Similar information can also be reported during interim contacts between data collection visits. Such events

trigger an adverse event (SAE) record, which completed locally and reviewed at the Coordinating Center to classify as gastrointestinal, cardiovascular, musculoskeletal, or “other” in nature. This information is then reported to the DSMB and NHLBI. Clinical centers also report SAEs to their IRB according to local guidelines.

### **Definition of Serious Adverse Events**

*SAEs* are defined as: an event that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/incapacity, results in congenital anomalies/birth defects, or, in the opinion of the investigator, represents other significant hazards or potentially serious harm to the research subject or others. These could include any of the following: heart attack, stroke, heart failure, coronary angioplasty or bypass surgery, angina pectoris, severe hypoglycemic episode, severe hypotensive episode, broken bone, torn ligament, and any other serious injury to the bone or muscle.

A positive Rose Angina questionnaire does not constitute an SAE. However, a positive Rose Angina questionnaire requires immediate cessation of physical activity and a referral to the participant’s primary care provider. If a participant has a positive Rose Angina questionnaire during screening or Phase I, an Eligibility PAL is required (see table 1). If a positive Rose Angina questionnaire occurs during Phase II, the participant must confer with their personal provider before resuming physical activity.

All other outcomes that may be construed as being an adverse consequence of study participation, such as an injury while performing a study measurement, are documented, reviewed, and followed up by a study clinician as needed.

### **Serious Adverse Events Reporting**

Information regarding SAEs is collected at each follow-up visit using the Medical Events Screening Form (Form #500). If there is a positive response on this form indicating that an SAE has occurred, or if any study personnel become aware of a potential SAE (as defined above) at any other time (e.g. during face-to-face sessions, phone call, email, etc.), a study clinician should be notified immediately. If a potential SAE is reported outside of usual data collection periods, a Medical Events Screening Form is completed to the extent possible. Any positive response to a Medical Events Screening Form, regardless of when it was completed, should be reported to the CC. If a death or life-threatening event occurs, a study investigator should notify the NHLBI within seven days of learning of the event. All other SAEs must be reported to the Coordinating Center within 15 days. All positive Medical Events Screening Forms must be entered by the sites (even if incomplete at the time of initial entry) within three days of collection and a copy of the form faxed to the CC. This assures prompt reporting to the NHLBI and IRBs. While local IRB reporting time frames are generally similar, each site should report SAEs to their local IRB within the time frames specified by their respective IRBs. The PI will have ultimate responsibility for reporting and confirming SAEs, but if temporarily unavailable, an interim report should be made to each entity described above by a co-investigator until the PI is able to confirm the event.

If a positive response on the Medical Events Screening Form is thought by a study investigator NOT to constitute an SAE, the Medical Events Screening Form should still be completed by an investigator, entered and faxed within the same time period specified in the forms instructions. In addition, the PI should document why, in their judgment, the positive response on the Medical Events Screening Form does not constitute an SAE.

Some reported events may be adjudicated and resolved by the physician members of the steering committee. If the adjudication committee cannot reach consensus, the event will be reported as an SAE to all appropriate entities.

Because of local and federal reporting time-lines for SAEs, it is not necessary to obtain independent or objective confirmation of an SAE. The occurrence of an SAE will be assumed to have occurred based on the self-report of a participant or the report from a friend or relative of the participant.

### **Phase III Safety Procedures**

Safety procedures in Phase III will continue as outlined for Phase II of WLM. Participants have been advised that if their physician's advice regarding physical activity is different from the WLM recommendation, they should follow their physician's advice. Participants who have medical conditions such as CVD events, cancer, and certain others will be sent a letter reminding them to consult with their physician and to follow their physicians' advice regarding diet and exercise.

#### *Surveillance Procedure*

1. Prior to re-enrollment in Phase III, the data coordinating center will provide a list of all prior Serious Adverse Events (SAEs) to each site, sorted by CVD, cancer, and other.
2. The Medical Events Screening Form (#500) is administered at each follow-up visit in Phase III.
3. Following the 30-month visit, the DCC provides a quarterly updated report that enumerates new SAEs.
4. Site clinicians review SAE lists and decide which participants in the 'other' SAE category should get a reminder letter stating that personal MD recommendations supersede WLM recommendations.

### **Unhealthy weight loss methods**

The Weight Management Strategies questionnaire (Form 210) can lead to the identification of participants who are using diuretics, laxatives or smoking for weight management. These participants promptly receive a letter from the site PI outlining the health risks of these strategies and advising against using them.

## **8.3 Berlin Sleep Questionnaire**

### **Referral Procedure**

1. The sleep questionnaire is scored in the clinic by staff before the participant leaves.
2. As with the WLM provider approval letters for study eligibility and exercise, a form letter stating that the questionnaire responses showed possible sleep apnea and that we recommend follow-up with a health care provider is given to the participant at the visit, or later mailed. A letter is not sent to the participant's personal medical provider.
3. The Coordinating Center will validate that referrals were made appropriately. To track participants who have been provided a sleep alert, the CC added the following fields to the footer of the Sleep Questionnaire form:

Sleep Apnea Alert needed?                      Yes or No  
Date alert letter sent/provided:              \_\_\_\_\_

### Scoring Procedure

An alert letter is given if:

- Both question 3 and question 5 are answered as “3-4 times a week” or “nearly every day”  
or (not and)
- Question 6 or question 7 are answered as “3-4 times a week” or “nearly every day” or question 8 is answered “Yes”

### Berlin Sleep Questionnaire Referral Letter for Participants

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Date \_\_\_\_\_

Dear \_\_\_\_\_,

During a data collection visit, you completed a form with questions related to sleep disorders. Your responses on this form raised the possibility of sleep apnea. For this reason, I suggest that you discuss the possibility of sleep apnea at your next doctor’s visit.

Thank you for your continued interest and participation in WLM.

Best Wishes,

Lawrence J. Appel, MD, MPH  
Principal Investigator, WLM  
Johns Hopkins University – ProHealth Clinic

# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.1 Program Structure

#### 9.1.1 Program Goals

##### Phase I Lifestyle Guidelines

**Study Goal:** Lose at least 9 pounds to be eligible for Phase II

**Personal Goal:** Attempt to lose 15 pounds during Phase I

<b>Guidelines (to achieve the goal)</b>	<b>Recommended Targets:</b>
1. Eat fewer calories	Women: Consume approximately 1500-1800 calories each day to lose weight.  Men: Consume approximately 2000-2300 calories each day to lose weight
2. Exercise regularly	Exercise a total 180 minutes of moderate-intensity activity each week in addition to your daily routine. (30 minutes on for 6 days per week)
3. Move more! Lose more!	In addition to your regular exercise, find at least 5 “extra” opportunities to move more each day.
4. Follow the DASH eating style <ul style="list-style-type: none"><li>• Eat a diet rich in fruits and vegetables</li><li>• Eat a diet rich in low-fat dairy foods</li><li>• Eat a diet low in fat</li></ul>	<ul style="list-style-type: none"><li>• Eat 9-12 servings of fruits and vegetables every day</li><li>• Eat 2-3 low-fat dairy foods every day</li><li>• Eat 25% or less of your total calories from fat</li></ul>
5. Eat a low-sodium diet	Eat 2400 mg or less of sodium each day
6. Limit alcohol consumption	Women: Drink no more than one drink per day Men: Drink no more the two drinks per day 1 drink = 12 ounces beer, 5 ounces wine or 1 jigger (1 ½ ounce) of 80-proof liquor
7. Record your daily food intake and physical activity	Keep daily records of the food you eat and drink. Keep daily records of your exercise minutes.
8. Be an active study participant	Attend intervention group sessions and clinic visits

#### 9.1.2 Program Format

- Phase I of Weight Loss Maintenance involves 20 weekly, facilitated group sessions, which will be completed in 23 to 24 weeks.
- Group sessions are approximately 1.5-2 hours in length.



### 9.1.3 Program Materials

#### **Leader's Guide:**

The Leader's Guide provides the resources for an interventionist to use to facilitate the intervention group sessions. Session outlines are part of the Leader's Guide and provide a standardized framework and structure for group sessions. There are 20 session outlines, one for each of 20 weekly group sessions. The outlines are sequenced topically with skill development emphasized in early sessions and reinforcement and support emphasized in later sessions. Resource materials, discussion ideas, content and activity ideas and participant worksheets and handouts are included in each session outline. Each session outline includes common group process elements including: Taste-it (food samples) or Do it! (group physical activity), Check-in (progress check), Try It! (discussion and activities), and Next steps (self-monitoring and goal setting). Separate specific curriculum outlines for Taste-it, Do it!, and Check-ins allow the facilitator to choose from a "menu" of options when planning for group sessions. Facilitating behavior change is prioritized over the delivery of content information.

#### **The Food & Fitness Guide**

- Provides a reference of nutrient values for commonly consumed food items to help participants self-monitor food intake and develop skills for making healthy food choices.
- Provides information about the study guidelines, nutrition topics such as nutrition labeling, fat gram guidelines, recipe modification and physical activity.
- Facilitates behavior change and the achievement and maintenance of the study Lifestyle Guidelines, i.e. intervention goals.

#### Description

- The *Food & Fitness Guide* is a reference book that lists the calories, grams of fat, and milligrams of sodium for standard serving sizes of commonly consumed food items, such as raw foods, processed and convenience foods, mixed dishes, and restaurant items. Additionally, the Food and Fitness Guide lists grams of saturated fat and contains a guide for what counts as a fruit, vegetable and dairy serving.
- The nutrient values listed in the *Food & Fitness Guide* are from the Nutrition Data System for Research (NDS-R) software, developed by the Nutrition Coordinating Center (NCC), University of Minnesota, Minneapolis, MN, Food and Nutrient Database 29, released in December 1998.
- The *Food & Fitness Guide* also includes a section on Physical Activity that provides information on the benefits of physical activity, how to calculate your target heart rate for moderate-intensity activity and general safety guidelines and precautions.
- The *Food & Fitness Guide* provides an alphabetical index of all listed foods.

In the "Food Listings" section of the guide, foods are grouped by category (for example, "Breads, Cereals and Other Grain Products"). Categories are arranged alphabetically and individual foods are arranged alphabetically within categories (for example, bagel, biscuit, bread...). There is also an alphabetical listing of foods (index) at the end of the book. To locate a particular food item, participants can use either the food category listing or alphabetical listing.

Nutrient values for prepared foods like macaroni and cheese, and spaghetti and meatballs are based on standard recipes and include fat and salt normally added during preparation. Salt added at the table is not included in the sodium values listed for a particular food.

Many of the food categories include Fat Gram Guidelines to help participants select lower-fat foods. A summary of the Fat Gram Guidelines is located on the back cover of the Food and Fitness Guide.

### **The Food and Fitness Diary:**

The diary for recording food intake and physical activity minutes contains enough space to record seven days of food records and enter the nutrient values for calories, servings of fruits and vegetables, and servings of dairy foods and an “optional” space to occasionally record nutrients like milligrams of sodium and/or grams of fat. There is a section in the diary to record physical activity. Participants can track daily minutes of moderate-intensity physical activity and weekly totals. Additionally, daily check boxes allow participants to track additional “extra” opportunities to “move more” and contribute to an active lifestyle. The back page of the diary allows participants to summarize daily totals and calculate weekly averages for calories, average servings of fruits, vegetables and dairy foods, and total minutes of moderate-intensity exercise. The diaries also include space to record weekly goals and action plans.

The participants are instructed to record calculations in whole numbers and not fractions using the following rounding rules: round up to the next whole number when the fraction/decimal is greater than 0.5 and round down the next whole number when the fraction/decimal is less than 0.5.

# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.2 Program Implementation

#### 9.2.1 Cultural adaptation of the Intervention

The initial weight loss program and weight loss maintenance interventions in WLM must be appropriate and effective for African Americans, a group at high risk for hypertension and obesity. A number of previous studies using weight loss interventions similar to those to be used in WLM have shown lower mean weight loss for African Americans compared to white participants. However, some recent studies have shown much better weight loss outcomes for African Americans when the intervention programs have addressed cultural issues of importance to African Americans.

Efforts to develop and implement cultural adaptation of the initial WLM weight loss program and the weight loss maintenance programs will include:

1. Advice from the WLM Minority Implementation Committee regarding the design of the weight loss and maintenance programs and the training of the WLM interventionists.
2. Inclusion of WLM Minority Implementation Committee members on all working groups in the intervention committee.
3. Review of all intervention materials by the Minority Implementation Committee.
4. Inclusion of African-American cultural training in the trial-wide training programs for WLM interventionists.
5. Inclusion of interventionists in the staff cultural sensitivity training programs at each clinical center.
6. Development of specific implementation strategies for enhancing intervention effectiveness for African Americans at each clinical center. These implementation strategies will be shared between the intervention teams at the clinical centers.

Previous studies have identified strategies that will be incorporated into the design of the WLM interventions. Most if not all of these strategies are effective and important for all study participants, but may require particular attention to ensure that the interventions are not inadvertently biased toward the dominant culture. These strategies include: 1) adequate minority representation at all levels of implementation (i.e., interventionists, investigators, etc.); 2) social support systems for participants; 3) effective communication, including demonstrations; 4) involvement of family and community; 5) participant input into study procedures and identification with study goals (“ownership”); 6) food guides and other intervention materials that are consonant with the various cultures represented among study participants; and 7) exercise guides that focus on the multiple health benefits of exercise and on individual tailoring on the type of physical activity in a participant’s personal plan.

# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.2 Program Implementation

#### 9.2.2 Calorie recommendations for weight loss

Weight Loss Maintenance (WLM) promotes a 15-pound of weight loss during the 20-session Phase 1 intervention (the eligibility requirement to enter into Phase II is a 9-pound loss). Participants receive a target daily calorie level at the first Phase 1 group session. The target calorie level is calculated using the Harris-Benedict equation (Harris & Benedict, 1919), using 1.2-activity factor, - 500 Kcal, rounded to nearest 50 Kcal, range of +/- 150 Kcal. By following an eating pattern close to the targeted weight loss calorie level, and increasing physical activity, participants will lose weight and reach the study weight loss goal.

#### 1 Maintenance Calorie Target

The Harris-Benedict equation uses height, weight, age, and gender to calculate basal metabolic rate (BMR or REE). The REE is Resting Energy Expenditure. The REE is then multiplied by an activity factor to calculate maintenance calorie needs. WLM uses a sedentary activity factor of 1.2, because it is assumed that most participants joining the study are sedentary.

Females	$REE^* = 655 + 9.6 (\text{wt in kg}) + 1.8 (\text{ht in cm}) - 4.7 (\text{age})$
Males	$REE^* = 66 + 13.7 (\text{wt in kg}) + 5.0 (\text{ht in cm}) - 6.8 (\text{age})$

$$\text{Calories} = (\text{REE} \times 1.2)$$

#### 2 Weight Loss Calorie Target

To lose weight participants need to ingest fewer calories than their maintenance calorie level. WLM subtracts 500 calories from the result of the Harris-Benedict calculation to yield a reasonable calorie deficit to initiate weight loss, but not present barriers to the participant following the program or maintaining a healthy diet.

Strategies to reduce calories and lose weight are outlined in the Leader's Guide, Section 9.4. To achieve weight loss, participants are encouraged to reduce their caloric consumption using the WLM weight loss calorie target, increase their physical activity, and eat healthier by eating less fat and more fruits, vegetables, and whole grains. Strategies to help participants reach these goals include recording what they eat daily, counting calories, and setting realistic short-term behavioral goals that help them eat less and exercise more.

# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.2 Program Implementation

#### 9.2.3 Incorporating the DASH diet

The WLM study uses the DASH dietary pattern in help participants achieve and/or maintain weight loss. The DASH dietary pattern emphasizes fruits, vegetables, and low-fat dairy products and is low in saturated and total fats and cholesterol. The DASH dietary pattern lowers blood pressure in men and women (with and without hypertension), young and old, and African Americans and non-African Americans. The DASH dietary pattern was the foundation of the dietary intervention in the PREMIER C intervention. The DASH dietary pattern is higher in potassium, magnesium, calcium, fiber, and protein and lower in saturated and total fats and cholesterol than typical US consumption. DASH dietary strategies used in WLM include increasing consumption of fruits, vegetables, low-fat dairy products, whole grains and nuts, seeds and legumes, and moderating intakes of animal products, fats, oils and dressings, and sweets and candies. WLM emphasizes lowering or balancing energy intake while aligning consumption closer to the DASH pattern.

Specifically, the following dietary guidelines help participants follow the DASH dietary pattern while attempting to lose or maintain weight:

- Eat 25% or less of their calories from fat.
- Eat 9 to 12 servings of fruits and vegetables per day.
- Eat 2 to 3 servings of dairy foods per day.
- Reduce their calories enough to lose weight (about -500 kcal/d).
- Eat 2400 mg or less per day of sodium.
- Drink no more than two alcoholic drinks per day for men and one for women.

Strategies used in the intervention to assist participant efforts to lose weight and following the DASH dietary pattern include:

- Substituting fruits and vegetables for high fat/high calorie foods.
- Incorporate low-fat dairy foods into daily patterns and meals.
- Use the FFG and/or food labels to select foods that are low in fat.
- Reduce calories by 500 calories per day to achieve weight loss.
- Keep records of food intake and calculate the number of servings of fruits, vegetable and dairy foods.

## Fat Contents of Menus at 3 Calorie Levels

Example of fat content of menus at 3 calorie levels that meet both B & C total fat targets.

### 1500 kcal menu:

	fat, g	kcal
<b>Breakfast</b>		
1 C milk, 1%	3	100
1 C oat bran flakes	2	110
1 slice wheat bread	1	65
1 tsp jam	0	20
6 oz OJ	0	85
<b>Lunch</b>		
3 oz water-pack tuna	1	100
1 TB LF mayo	5	50
2 sl wheat bread	2	130
12 oz diet cola	0	0
1 med apple	0	80
<b>Dinner</b>		
1/2 C salad	1	25
2 TB LF dressing	5	55
1.5 svg frozen entrée	12	495
1/2 C green beans	0	20
1 tsp tub margarine	4	35
1/2 C light ice cream	5	115
12 oz water	0	0
<b>Snacks</b>		
3 rye wafers	2	110
<b>TOTAL</b>	<b>43</b>	<b>1595</b>
<b>% fat</b>	<b>24.3%</b>	

### 2000 kcal menu:

	fat, g	kcal
<b>Breakfast</b>		
1 C milk, 1%	3	100
1 C Life	2	110
1 sl wheat bread	1	65
1 tsp tub margarine	4	35
1 tsp jam	0	20
6 oz OJ	0	85
<b>Lunch</b>		
3 oz drained tuna in oil	7	170
1 TB LF mayo	5	50
1 white hard roll, 3-1/2"	2	145
12 oz cola	0	155
1 large apple	0	125
<b>Dinner</b>		
1 C salad	1	45
2 TB LF dressing	5	55
1.5 svg frozen entrée	12	495
1/2 C pasta	1	110
1/4 C spaghetti sauce	2	65
1/2 C light ice cream	5	115
12 oz water	0	0
<b>Snacks</b>		
3 rye wafers	3	110
<b>TOTAL</b>	<b>53</b>	<b>2055</b>
<b>% fat</b>	<b>23.2%</b>	

### 2500 kcal menu:

	fat, g	kcal
<b>Breakfast</b>		
1 C milk, 1 %	3	100
1 C oat bran flakes	2	110
2 sl wheat bread	2	130
2 tsp tub margarine	8	70
1 TB jam	0	50
8 oz OJ	0	115
<b>Lunch</b>		
3 oz drained tuna in oil	7	170
2 TB LF mayo	10	100
1 white hamburger bun	4	250
12 oz diet cola	0	0
1 large apple	0	125
<b>Dinner</b>		
1 C salad	1	45
2 TB LF dressing	5	55
2 svg frozen entrée	16	660
1 C pasta	2	215
1/2 C spaghetti sauce	4	130
1/2 C light ice cream	5	115
12 oz water	0	0
<b>Snacks</b>		
3 rye wafers	3	110
<b>TOTAL</b>	<b>72</b>	<b>2550</b>
<b>% fat</b>	<b>25.4%</b>	

## What Counts as One Fruit or Vegetable Serving?

### Examples of What Counts as One Fruit or Vegetable Serving

Serving Size	Example
<b>FRUITS</b>	
1 medium fruit	apple, banana, orange, pear
$\frac{3}{4}$ C (6 oz) 100% fruit juice	apple juice, apricot nectar, orange juice,
$\frac{1}{2}$ C berries	blackberries, blueberries, strawberries
$\frac{1}{2}$ C chopped	melons (cantaloupe, honeydew, watermelon)
$\frac{1}{2}$ C canned, cooked, or frozen	applesauce, peach, pear, pineapple
$\frac{1}{4}$ C dried fruit	apples, apricots, figs, pears, prunes, raisins
<b>VEGETABLES</b>	
1 piece	medium tomato, medium baked potato
1 C raw leafy vegetables	green leaf lettuce, Romaine lettuce, spinach
$\frac{3}{4}$ C (6 oz) 100% vegetable juice	low-sodium V-8 juice, low-sodium tomato
$\frac{1}{2}$ C raw, chopped	carrots, green peppers, tomatoes
$\frac{1}{2}$ C canned, cooked, or frozen	beans, broccoli, cabbage, carrots, cauliflower, green peas, mustard greens, potatoes, spinach, squash, sweet potatoes, turnip greens

**Note:** Dried beans, peas, and legumes (chili beans, lentils, chickpeas, split peas) and soy products (tofu, garden burgers) do not count as a vegetable although they are considered part of a healthy diet.

## What Counts as a Fruit or Vegetable?

### Examples of Foods that Do Not or May Not Count as a Fruit or Vegetable

Certain foods do not count as fruits or vegetables because they are too high in fat or sugar, or because they contain very little fruit or vegetable. Highly processed vegetables, particularly those that are fried and highly salted, are not recommended.

- jams, jellies, and preserves
- fruit filling in pastry, cookies, or breakfast bars
- fruit-flavored alcoholic drink (strawberry daiquiris, pina coladas)
- fruit punch, Kool-Aid, fruit-aid, Tang, fruit seltzers
- fruit flavoring or bits of fruit in ice cream, sherbet, sorbet, frozen and regular yogurt
- fruit flavoring or bits of fruit in muffins, breads, pancakes
- fruit flavored candies (gummies, Sunkist gels)
- pickled vegetables (sweet or dill pickles, relish, pickled asparagus, mushrooms, or cabbage)
- sauerkraut
- olives (black, green)
- fried potatoes (including French fries and hash browns)
- fried and battered vegetables (Tempura, egg roll with skin)
- fried salted snacks (potato chips, corn chips, Doritos)
- tomato condiments (catsup, chili sauce, cocktail sauce)

Some foods may not count unless there is sufficient amount of fruits and vegetables and their fat content is not too high:

- avocado (vegetable is high in fat, but the fat is monounsaturated; should be within fat gram budget)
- soups must have at least ½ cup of vegetables per serving
- dehydrated meals in a cup must have at least ½ cup of vegetables per serving
- salsas must have at least ½ cup of vegetables or fruit per serving

## What Counts as One Dairy Serving?

### Examples of What Counts as One Dairy Serving

Serving size	Example
1 C (8 fl oz) milk	fat free milk, 1% milk
1 C yogurt	Nonfat or low-fat plain or fruited yogurt
½ C frozen yogurt	Nonfat or low-fat frozen yogurt
½ C pudding	pudding made with fat free or 1% milk
1.5 oz cheese (2 thin slices)	Nonfat, part skim, or low-fat cheese
4 TB grated cheese (1/4 cup)	Parmesan, Romano cheese
½ cup other cheese	Nonfat or 1% cottage cheese, nonfat or part-skim Ricotta cheese, farmer cheese

**Note:** All dairy foods count as a serving regardless of the fat content. However, nonfat and low-fat dairy foods are recommended.



## Mixed Dishes

Mixed Dishes- An Approach to Calculate Servings of Fruits, Vegetables, and Dairy.

Consumption of foods eaten as mixtures has grown dramatically in the past decade. Mixed dishes often cannot be placed easily into food group categories, which makes monitoring the number of servings of fruits, vegetables, and dairy difficult. To count servings of fruits, vegetables, or dairy, these mixtures must be disaggregated. The goal is to try to estimate fruits, vegetables, and dairy in terms of standard serving sizes. This may be done by visualizing how much of a standard 8-oz measuring cup the amount of fruit, vegetable, or dairy found in the mixed dish would fill. Fractions of servings ( $\frac{1}{4}$ ,  $\frac{1}{2}$ ,  $\frac{1}{3}$ ,  $\frac{2}{3}$ , and  $\frac{3}{4}$ ) may be used for individual components, as long as the total mixture provides at least  $\frac{1}{2}$  serving.

The following are examples of commonly consumed mixed dishes:

Mixed Dish	Description	Estimated serving amount	Tally of F, V, and D
1 C. lasagna	$\frac{1}{2}$ C. noodles $\frac{1}{4}$ Ricotta cheese 1 sl. Mozzarella cheese, part-skim $\frac{1}{4}$ C tomato sauce	$\frac{1}{2}$ svg dairy $\frac{1}{2}$ svg dairy $\frac{1}{2}$ svg veg	1 Dairy $\frac{1}{2}$ Veg
2 slices plain pizza (14" pie)	1 slice (1.5 oz) Mozzarella cheese, whole milk, shredded 1 Tbsp grated parmesan cheese 2 Tbsp ( $\frac{1}{8}$ C) tomato sauce	1 svg dairy $\frac{1}{4}$ svg dairy $\frac{1}{4}$ svg veg	1 Dairy 0 Veg
1 cheeseburger	1 hamburger roll 1 slice American cheese 3 oz ground beef	$\frac{1}{2}$ svg dairy	$\frac{1}{2}$ Dairy
1 C vegetable soup	$\frac{1}{2}$ C peas, carrots, potatoes, onion $\frac{1}{2}$ C broth	1 svg veg	1 Veg
1 C chicken pot pie	$\frac{1}{3}$ C peas, carrots, potatoes 2 oz chicken pastry dough	$\frac{2}{3}$ svg veg	$\frac{2}{3}$ Veg
bacon, lettuce & tomato sandwich	2 slices whole wheat bread 1 Tbsp mayonnaise, reg. 4 slice bacon 1 slice lettuce 1 slice tomato ( $\frac{1}{8}$ cup)	$\frac{1}{8}$ svg veg $\frac{1}{4}$ svg veg	0 Veg
grilled cheese sandwich	2 slices whole wheat bread 2 slices American cheese 2 sl. medium tomato ( $\frac{1}{4}$ C)	1 svg dairy $\frac{1}{2}$ svg veg	1 Dairy $\frac{1}{2}$ Veg
1 C cottage cheese with strawberries	$\frac{1}{2}$ C cottage cheese $\frac{1}{2}$ C strawberries	1 svg dairy 1 svg fruit	1 Dairy 1 Fruit

## DASH Eating Pattern Example

Example of an Eating Pattern that Meets WLM Goals for Fruits, Vegetables, and Dairy.

	Sample Menu	Number of Servings	
		F & V	Dairy
<b>Breakfast</b> (3 F&V; 1 Dairy)	6 oz. orange juice	1	
	8 oz. fat free milk		1
	1 cup bran cereal		
	1 medium banana	1	
	½ cup grapes	1	
<b>Lunch</b> (4 F&V; 1 Dairy)	1 cup salad greens	1	
	chicken salad sandwich with ½ cup sliced tomatoes		
	½ cup raw baby carrots	1	
	1 medium apple	1	
	8 oz. fat free milk		1
<b>Dinner</b> (4 F&V)	1 cup tossed salad	1	
	1 small baked potato	1	
	1 cup steamed broccoli	2	
	Baked flounder		
<b>Snacks</b> (1 F&V; 1 dairy)	8 oz. plain fat-free yogurt		1
	¼ cup raisins	1	
	<b>GOAL: 9-12 Servings F&amp;V 2-3 Servings Dairy</b>	<b>12</b>	<b>3</b>

# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.2 Program Implementation

#### 9.2.4

##### Physical activity goals

The WLM physical activity goals are congruent with national recommendations for physical activity and health. The WLM physical activity goal is to “exercise regularly” by engaging in physical activity a total of 180 minutes each week that is “in addition to your daily routine.” Recommended physical activity is moderate-intensity, aerobic in nature, purposeful (i.e., expends energy that is greater than that expended in daily activities), and after building up from shorter bouts, (see below), is at least 20 minutes in duration for each session.

WLM participants will enter the study at a variety of physical activity levels and abilities. For sedentary participants, regular participation in moderate-intensity exercise is an appropriate goal and the physical activity intervention specifically helps participants meet this goal. The exercise recommendation is for moderate-intensity, rather than vigorous physical activity

Incorporating ways to be more active (e.g., taking the stairs instead of the elevator, parking further away, etc.) contribute minimally to overall caloric expenditure. These minor types of activity are not the target of the physical activity goal to accumulate 180 minutes per week. The “move more” message, however, is included in the overall intervention. The intervention guideline in this area specifically recommends choosing to be more active in everyday situations, “in addition to your regular exercise program.” The “move more” guideline is subordinate in priority to the guidelines for regular exercise program of moderate-intensity exercise.

##### National guidelines for physical activity and weight management

Increasing physical activity is an important component of weight loss therapy since it increases energy expenditure. Increased physical activity may also inhibit food intake in overweight patients according to the NHLBI Guidelines on overweight and Obesity. Physical activity can also be helpful in maintaining a desirable weight. In addition, sustained physical activity has the benefit of reducing overall CHD risk beyond that produced by weight reduction alone.

Physical activity should be an integral part of weight loss therapy and weight maintenance. Initially, moderate levels of physical activity for 30 to 45 minutes, 3 to 5 days per week should be encouraged. All adults should set a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most, and preferably all, days of the week.

(Source: NHLBI Guidelines on Overweight and Obesity: Electronic Textbook  
[http://www.nhlbi.nih.gov/guidelines/obesity/e\\_txtbk/txgd/4322.htm](http://www.nhlbi.nih.gov/guidelines/obesity/e_txtbk/txgd/4322.htm).)

##### Description of WLM physical activity intervention

Participants primarily accumulate moderate-intensity physical activity minutes outside of the group sessions. However, during at least 50% of group sessions, participants engage in 20 or more minutes of moderate-intensity physical activity. Self-monitoring, problem-solving, skill-building, and social support are primary tools used in the intervention to help participants increase physical activity duration. The intervention starts with the participant's self-assessment of current physical activity level and aids the participant to slowly and progressively increase exercise bouts and duration.

The intervention focuses on sustained physical activity (i.e., at least 20 minutes of moderate or vigorous intensity activity). For sedentary participants, an adaptation time may be necessary to build up to this duration.

Group sessions include information on how to conduct a safe and effective physical activity program and develop the behavioral skills to meet study physical activity goals. Specific information covered during the intervention sessions include: target heart rate calculation, target ratings of perceived exertion, realistic expectations for physical activity, benefits of regular physical activity, proper shoes and clothing for different types of activity and weather conditions, importance of warm-up and cool-down activities, and safety issues. Specific behavioral strategies include identifying pleasurable activities, self-monitoring physical activity, time management skills, short- and long-term goal-setting, identifying barriers to physical activity, and problem solving to develop specific strategies to deal with barriers.

### **Moderate-intensity activity**

Moderate-intensity physical activity is defined as 40% to 60% of maximal aerobic power, which is equivalent to 50% - 69% of maximal heart rate. This corresponds to a rating of perceived exertion of 11 to 13 (see section 5). Activities requiring energy expenditure 3 to 6 times that expended at rest (i.e., 3 - 6 METs, or metabolic equivalents) is an objective determination of moderate-intensity activity. Brisk walking is a common activity that operationalizes this definition for most people. Brisk walking is walking 3 to 4 mph for most healthy adults (i.e., 15 to 20 minutes per mile). However, for elderly people or those who have poor cardiorespiratory fitness, walking at this speed may exceed moderate intensity. Conversely, for young people who are highly fit, walking at this speed may be a light intensity activity. Therefore, the actual speed for "brisk walking" will vary depending on the individual. Nonetheless, for most individuals and potential participants, brisk walking is likely to be a good marker for moderate intensity physical activity.

Examples of moderate intensity activity that expend 3 to 6 METs are:

- brisk walking
- hiking
- moderate bicycle riding
- swimming laps, slow to moderate pace
- dancing (e.g., "fast" dancing, square dancing, swing dancing)
- shooting baskets
- golf (walking, pulling or carrying clubs)
- ice-skating, roller-blading
- volleyball
- softball
- badminton
- racquetball

### **Definition of aerobic activity**

Aerobic physical activity, or activity "with oxygen," is that in which exercising muscles receive an adequate amount of oxygen to produce energy using oxidative pathways. Aerobic activity can continue for extended periods of time without fatigue. Physical activities that are continuous, rhythmic, use large muscle groups, and can be maintained over time are considered aerobic. Examples include walking, running, and bicycling. When muscles work at a level that is greater than can be sustained by the supply of oxygen that is delivered to them, waste products, such as lactic acid, accumulate in the muscles and fatigue results. This type of physical activity is called "anaerobic." Anaerobic activity is usually characterized by short, intense bouts of activity. Examples of anaerobic activity are running sprints and lifting weights.

The ability of an individual to exercise continuously depends on how effectively the heart, lungs, arteries, capillaries, cells, and veins can transfer oxygen, carbon dioxide, nutrients, and waste products to and from the exercising muscles. As an individual begins physical activity, the body adapts to the increased demand for energy. Energy stores of glycogen are mobilized from the muscles to provide an immediate source of fuel necessary, while at the same time, heart rate and respiration increase to provide more oxygen to the muscles so the activity can be sustained.

### **Vigorous intensity activity**

Vigorous-intensity activity is not recommended in WLM. Vigorous or hard intensity activity demands 60% to 84% of aerobic power. This is equivalent of 70% to 89% of maximal heart rate, and corresponds to rating of perceived exertion in the range between 14 and 17. Activities that expend more than 6 times the energy expended at rest (i.e., > 6 METs) provide an objective measure of vigorous activity. It can be operationalized by activity that is about as intense as jogging or running.

### **Estimation of maximal heart rate**

For the purposes of WLM maximal heart rate is estimated using the following formula for those aged 20-60 years.

$$220 - \text{Age} = \text{Estimated Maximal Heart Rate}$$

This method has a variability of about 10%, or about plus or minus 10 to 12 beats per minute. Older individuals (greater than 65 years of age) may have significantly greater maximal heart rates than that predicted by the formulas. So, calculating heart rate ranges for physical activity is only a guide for an individual's level of exertion rather than a precise measure.

Example: How to determine estimated maximal heart rate and target heart rate range for moderate and vigorous intensity activity.

To calculate heart rate for a 60-year old female participant:

$$220 - \text{Age} = \text{Estimated Maximal Heart Rate} = 220 - 60 = 160 \text{ beats/min}$$

Moderate intensity activity at 50% to 69% of maximal heart rate =

$$160 * 0.5 = 80 \text{ beats/min to } 160 * 0.69 = 110 \text{ beats/min}$$

This woman's target heart rate for moderate intensity is between 80 and 110 beats/min

### **How to count pulse rate**

Heart rate can be measured indirectly by placing the fingertips on a pulse site and counting for a period of time. This is termed "palpation." Areas where the pulse can be measured accurately are at the radial pulse on the wrist (on the thumb side) and the carotid artery on the side of the larynx (on the neck next to the "Adam's apple").

To measure pulse rate at the wrist, the radial artery is located at the inner wrist in line with the base of the thumb just inside the bony notch on the thumb side of the wrist. The tips of the other hand's index and middle fingers are then placed over the artery and light pressure is applied until the pulse is felt. The thumb is not used to palpate because the thumb has its own pulse. To measure pulse at the larynx, the carotid artery is palpated, which is located on either side of the larynx towards the throat. Heavy pressure should not be applied to the carotid arteries because baroreceptors are located in that region that can sense the pressure that is applied and will respond by slowing the heart rate. Both carotid arteries should never be pressed at the same time, as this can cause fainting. The pulse is counted for 15 seconds, counting the first pulse beat as zero at the start of the 15-second period. Multiplying the 15-second pulse count by 4 yields pulse rate in beats per minute.

## Determining Ratings of Perceived Exertion

In addition to heart rate, physical activity intensity is measured by assigning a numerical value to the subjective feelings of physical activity exertion. The Ratings of Perceived Exertion (RPE) Scale, developed by Dr. Gunner Borg, is sometimes called the Borg Scale. The scale takes into account overall exertion, including psychological, musculoskeletal, and environmental factors. Extensive research shows that the RPE correlates well with cardiorespiratory and metabolic factors such as heart rate, breathing rate, oxygen uptake, and overall fatigue. Numerous clinical studies have demonstrated that the RPE scale is a reproducible measure of exertion within a wide range of individuals regardless of age, gender, or cultural origin.

The advantage of using RPE scales to estimate level of exertion is that it doesn't rely on the skills of palpation and counting pulse. In general, heart rate approximates  $RPE * 10 + 10-20$  beats/min for RPEs between 11 and 16. In most cases, physical activity at a level of 11 to 13 RPEs is associated with moderate intensity physical activity. Physical activity in which RPE is between 14 and 17 is generally considered vigorous activity. RPE level above 17 is near maximal effort, and RPE level below 11 is light-intensity physical activity.

Standard instructions for administering the RPE are: "We want you to pay close attention to how hard you feel the work rate is. This feeling should be your total amount of exertion and fatigue, combining all sensations and feelings of physical stress, effort, and fatigue. Don't concern yourself with any one factor such as leg pain, shortness of breath or exercise intensity, but try to concentrate on your total, inner feeling of exertion. Don't underestimate or overestimate, just be as accurate as you can."

### Scale

#### Ratings of Perceived Exertion Scale

6	
7	Very, very light
8	
9	Very light
10	
11	Fairly light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Very, very hard
20	

## Physical Activity Initiation and Progression

The initiation and progression of physical activity differ by individual. Participants will set their own short-term goals. Selection of short-term goals allows for gradual implementation of physical activity in participants who are sedentary and unfit. This will help prevent injuries, gradually increase fitness, and allow for positive reinforcement to increase self-efficacy.

Participants falling roughly into several general categories based on initial physical activity levels:  
(1) sedentary – engaging in no moderate-to-vigorous activity (the office worker who goes home and watches TV all evening is an example)

- (2) irregularly active – engaging in some moderate, or some vigorous, activity (or some of both), but only sporadically (the occasional weekend golfer or tennis player is an example)
- (3) regularly moderately active – engaging in moderate-intensity activity for sustained durations (20-30 minutes) on most days of the week (the person who takes a daily brisk walk is an example).
- (4) regularly vigorously active – engaging in regular vigorous activity (the person who runs 3 times a week is an example)

### **(1) Sedentary participants**

For sedentary participants, the goal of walking briskly 10-15 minutes a day for five days a week is a recommended place to start. Once that is accomplished, then the participant is encouraged to increase the duration for the next week. This process continues until the minimum duration is 20 minutes. Once 20-minutes is accomplished, the participant is encouraged to maintain that duration. Once duration of 20 minutes is maintained, the participant is encouraged to work on frequency. For example, a participant might start at exercising 3 days a week, and over time, increases the number of days from 3 to 4, then to 5, then to 6. The increases in duration and frequency occur over a period of several weeks or months.

### **(2) Irregularly active participants**

Participants in this category are encouraged to make physical activity a regular part of their lives. Often, motivation is high but barriers exist, such as perceived lack of time. These participants are encouraged to add activity to currently inactive days in order to reach the study goal.

### **(3 & 4) Regularly active participants**

Participants who are already regularly active at a moderate intensity (third and fourth categories, above) are encouraged to continue at their current level. The goal for these participants is to maintain this level of activity.

## **Warm-up, Cool-down, and Flexibility Exercises**

Warm-up, cool-down, and flexibility exercises are part of a well-rounded physical activity program. They are beneficial when performed in conjunction with moderate intensity activity.

### **Warm-up exercises**

The purpose of warm-up exercises is to gradually increase heart rate, blood pressure, oxygen uptake, dilation of the blood vessels, and elasticity of the active muscles. By gradually increasing metabolic requirements and temperature of the muscles, it will reduce the likelihood of muscle injury, prevent the premature onset of blood lactic acid accumulation, and reduce the potential for myocardial ischemia. The warm-up phase includes a low-level (light) aerobic component followed by light stretching of the muscle groups that will be used during exercise.

### **Cool-down exercises**

The purpose of cool-down exercises is to slowly decrease cardiac work and overall metabolism that have been elevated during aerobic physical activity. It helps prevent sudden pooling of blood in the veins and ensures adequate circulation to the skeletal muscles, heart, and the brain. It also helps to prevent delayed muscle stiffness and reduces any tendency towards post-exercise dizziness or fainting.

### **Flexibility exercises**

Flexibility exercises increase and maintain the ability of a joint to move through a full and normal range of motion. Optimal joint flexibility minimizes risk of injury, reduces muscular soreness, and improves muscular balance. Static stretching, or a slow, gradual, and controlled elongation through a full range of motion, increases flexibility and has a low likelihood of causing injury. It requires slowly stretching a muscle to the point of mild discomfort and holding the position for 10 to 30 seconds.

Flexibility exercises should only be performed on muscles that have been warmed up. Easy stretching exercises performed prior to aerobic activity will help prevent muscular injury. Stretching exercises performed after the aerobic activity will ensure muscle relaxation, facilitate normal resting muscle length, and help to remove metabolic waste products.

## **Exercise Adherence**

Participant expectations about increasing physical activity level are kept realistic to avoid disappointment. Many of the benefits from moderate-intensity physical activity occur over time and are not noticeable in the early stages of a physical activity program. Benefits that may occur early on include: increased sense of well being after physical activity, feelings of accomplishment for reaching goals, and reduced feelings of stress. Health benefits, such as reduction in blood pressure and improvements in blood cholesterol take longer to accrue. Weight loss resulting from increased physical activity, without reducing daily caloric intake, is minimal. Over time, muscles firm up from exercise, and if a participant includes stretching in their regular routine, he/she may discern an increase in flexibility and range of motion.

Participants are additionally informed about potential discomfort from exercise -- they may have sore muscles early on as they initiate physical activity, increase duration, frequency, or intensity of a given activity, or add a new activity to their physical activity repertoire.

Sedentary participants will not accomplish the study goals immediately, so expectations such as completing a marathon or participating in a long-distance bicycle ride are likely unrealistic for most participants.

### **Self-monitoring, goal-setting, intrinsic/extrinsic reward systems**

In addition to monitoring and goal-setting for type and duration of physical activity, participants monitor and set goals for a variety of other physical activity-related processes. For example, achieved target heart rate during physical activity, feelings after completing a physical activity session (e.g., relaxation, sense of accomplishment), different places in which activity is performed, documentation of new social networks developed, and developing skills and proficiencies for new physical activities are all alternative physical activity goals that are self-monitored.

### **Enjoyment of activity**

It is established that individuals are more likely to continue activities that they enjoy. Many individuals may wish to identify a variety of activities they enjoy to reduce boredom. Although most WLM participants are likely to obtain their physical activity points from brisk walking, interventionists encourage experimentation in a wide variety of activities.

### **Identifying and overcoming barriers**

Listed below are common barriers associated with physical inactivity and specific strategies to avoid these barriers:

<b>Barriers</b>	<b>Strategies</b>
time constraints	make physical activity a priority develop effective time management skills



	<p>schedule specific time for exercise (i.e., appointment for activity)</p> <p>combine physical activity with other activities (e.g., socializing)</p>
boredom	<p>engage in a variety of physical activities</p> <p>alter location in which physical activity is performed</p> <p>learn a new skill</p> <p>be active with others to make it social</p> <p>combine with more interesting activities (reading, music, TV, etc.)</p>
travel	<p>plan ahead to ensure hotels are equipped with health clubs or are in locations suitable for outdoor activity</p> <p>use layover time at airports to do brisk walking</p> <p>schedule vacations that provide opportunities for physical activity</p>
being too tired	<p>schedule physical activity during times when energy level is high</p> <p>remember that post-exercise, most people feel refreshed even if they feel "too tired" to start</p> <p>engage in a fun activity</p> <p>if "tired" is a sign of stress, exercise will probably make you feel better</p>
inconvenience	<p>plan physical activity during work breaks</p> <p>do physical activity in home surroundings</p>
weather	<p>invest in cold weather exercise gear</p> <p>find an indoor place to exercise, like walking in a mall</p> <p>do physical activity in the home</p> <p>join an exercise class in the community</p>
perceived lack of coordination	<p>do physical activities that do not require coordination</p> <p>take a class to improve skill</p>

### **Environmental prompts**

A variety of prompts at work and home help remind participants to think about physical activity throughout the day. Prompts include scheduling physical activity in daily appointment books, laying out exercise gear so it is ready for the workout time, keeping an extra pair of walking shoes in the car or at the office, putting pictures of people exercising around the house, changing driving routes in order to pass by places to exercise (i.e., local parks, swimming pools, school tracks), putting on exercise clothes in the morning or after work and not changing clothes until after exercise.

### **Social support**

A strong predictor of adherence to physical activity programs is support from others. Support is achieved with buddy systems that developed between participants, friends and family of the participants. Support partners exercise with participants, provide reminders, discuss progress and goals, or take responsibility for other activities to provide time for the participant to exercise (e.g., watching the children, fixing dinner). Support also comes from those who maintain a long-term physical activity program and serve as mentors providing real-world strategies that have worked for them in the past.

### **Relapse prevention strategies**

Slips will happen. If slips are anticipated and seen as being temporary rather than a breakdown in the success of the program, adherence is more likely to be maintained.

Encourage Participants to defend against the “defeatist attitude” that often accompanies the erroneous belief that once an exercise program is disrupted, total relapse or quitting is inevitable. In fact, many people relapse numerous times before physical activity becomes routine. If physical activity becomes a process where there are undoubtedly times of less activity, then participants are less likely to consider themselves failures when a session or two are missed. Relapse prevention includes being aware of “high-risk” situations that decrease the likelihood of being active and pre-planning how to deal with these situations.

### **Safety Considerations in Adopting and Maintaining a Physical Activity Regimen**

Much of the participant’s success for exercise lies in being relatively comfortable and injury free. Before implementing a routine of regular exercise, a number of basic safety issues are considered.

1. Elements of the physical activity bout  
Specific attention paid to appropriate warm-up, main exercise bout, and cool-down components of a physical activity session.
2. Temperature:  
Physical activity during the warmer months is conducted during the cooler morning, evening hours, or indoors, whenever possible and light-colored, lightweight clothing is worn. If needed, short rest breaks during the activity are appropriate. Drinking as much water as comfortable (at least 2 cups) 15 to 20 minutes before exercise, a cup of water every 15 minutes during physical activity and more than thirst dictates after exercise will help to avoid dehydration. Water is the best replacement fluid unless the physical activity bouts exceed 60 minutes. Every pound lost during physical activity is replaced with 16 ounces of water. Physical activity is discontinued if dizziness, lightheadedness, chills, piloerection, or nausea (i.e., signs of heat illness) occur.  
During cold weather it is best to layer clothing. If physical activity is to be done in sub-freezing conditions, care is taken to protect the face, hands, or other normally exposed areas of the body.
2. Clothing  
In general, clothing worn is loose fitting and permit adequate flow of air over the body to assist cooling. For outdoor activities, bright colors and reflective materials are recommended. In warm weather, light colors that reflect solar heat are preferred. In cold weather, layers that can be taken off if necessary are best. For walking or running activities, appropriate shoes are necessary. Should be designed specifically for walking or running, be adequately cushioned, provide foot and ankle support, and not restrict the forefoot (toes should be unrestricted). The best way to get a proper fit for athletic footwear is to go to a reputable store that specializes in athletic shoes.
3. Nutritional and hydration status  
Participants are instructed to be adequately nourished and take appropriate liquids, especially water, liberally in conjunction with physical activity. Participants may wish to wait for 30 minutes to an hour before performing moderate physical activity after a full meal.
4. Disease status  
Participants do not engage in physical activity when running a significant fever, have musculo-skeletal pain, or other acute disease processes. It is fine to participate in physical activity if a mild upper respiratory tract infection is present, if the participant wishes to do so. Use of OTC pain relievers are helpful for general muscle soreness.

### **Injuries**

Muscle strains, pulls, or related complaints may occasionally occur. These typically are of minor significance and resolve in a few days. If a participant experiences such discomfort, physical activity is discontinued until the condition has improved. Cuts, blistering, or bruising are treated with appropriate padding or changes in clothing/shoes. Any condition that does not improve within 2-3 days are referred to a physician. More serious injuries to the muscles or skeleton require physician attention. Immediate treatment involves the principles of RICE:

- Rest - Limit the use of an injured muscle or joint. Do not place weight on an injured joint. Use crutches with physician approval.

- Ice - Apply ice wrapped in a towel, especially for the first 24-48 hours. Avoid hot water baths or heat applications in the first few hours after injury as these encourage swelling.
- Compression - Use an ace wrap to help reduce swelling. Do not apply too tightly to an upper limb to avoid distal swelling. Knee immobilizers are discouraged except for comfort.
- Elevation (for leg injuries) - Elevate the leg higher than your heart to decrease pain and swelling.

As a general precaution, if there is any doubt about the treatment of an injury, the participant is counseled to consult a physician.

# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.2 Program Implementation

#### 9.2.5 Guidelines for how to facilitate group sessions

##### Use of the Leader's Guide Session Outlines:

##### Use of the Leader's Guide Session Outlines:

Written group session outlines and materials provide a standardized framework and structure for group facilitation. There are 20 outlines used over the course of 20 weekly group sessions. All interventionists are thoroughly familiar with the entire leader's guide prior to use in the group sessions.

After the initial sessions when participants become familiar with the lifestyle guidelines, study goals, and expectations, the focus of the group sessions becomes mainly behavior change and problem solving for developing self-management skills. In general, there is a sequence to the order of topics from session to session, however, group leaders can re-order topics and activities according to the needs of the group (always keeping group process over content as a priority).

Group interventionists are flexible within the structure of the group session, consistently incorporating important behavior-change techniques outlined in the leader's guide (checking progress, problem-solving, action planning, goal setting, and self monitoring). Group process to facilitate behavior change is the priority over nutrition and exercise education (information delivery). Ample time is available for facilitated behavior change discussions and skill enhancement activities.

##### Group Session Purpose:

The purpose of the WLM group sessions is to use group process to help participants achieve the study 15-pound intervention weight loss target. The group setting was selected instead of individual visits because:

1. Groups allow participants to support each other
2. Groups are more efficient working with large numbers of people than individual visits
3. Participants have the opportunity to learn from each other
4. Groups build relationships, which are essential to long-term habit changes
5. Group discussions help participants be more open about the challenges they face making habit changes
6. Creates loyalty which supports attendance and retention
7. Gives the participants the opportunity to pass on information to each other instead of the interventionist, which is more effective
8. Groups provide opportunities for participants to build self-direction skill and create confidence

##### Group Session Objectives:

1. Group session time is balanced between knowledge enhancement and hands-on application
2. Use participant skill-building activities
  - a. Tailored goal setting
  - b. Specific and targeted action planning
  - c. Participant self-awareness through self-monitoring
  - d. Modification of goals and plans
  - e. Support and positive reinforcement
3. Practice the four general principles of motivational interviewing

- a. Express empathy
  - b. Develop discrepancy
  - c. Roll with resistance
  - d. Support self-efficacy
4. Promote proactive change plans by helping participants identify individually tailored desired choices BEFORE entering a powerfully tempting situation

### **Role of the Interventionist:**

The role of the WLM interventionist is to facilitate group discussions and not necessarily impart information. Good group facilitation techniques empower participants and help them increase their confidence that they can make habit changes. This is done by:

- Moderating the pace of the group discussion, one person speaks at a time
- Moderating the focus of the activity (one topic at a time)
- Exploring or inquire with the participants what is interfering with their progress
- Reframing when necessary
- Clarifying goals
- Generating and exploring options
- Refocusing discussion back to desired outcomes
- Focusing attention on what can be done to avoid the challenge or barrier in the future

Information is passed to the participant through the facilitation process. Techniques used are similar to the techniques listed above:

- Use open-ended questions to begin and continue discussions  
“Why does the study recommend and encourage you to eat lots of fruits and vegetables?”
- Rephrase to clarify a point
- Clarify goals
- Explore other options, etc

### **Description of group sessions:**

Group sizes vary according to site; however, the recommended size is 20-25 participants. Meeting rooms are easily accessed by all participants and are ready for use at least 30 minutes prior to the start of each session. Chairs, including chairs without side arms for larger participants and tables are set up and ready in the meeting room. The room contains necessary audio-visual equipment for conducting group sessions (at a very minimum, a white board is required). The group session length is approximately 1 1/2-2 hours. Qualified session facilitators (including, but not limited to interventionists and behavior specialists) arrive early and are present at all times during the group sessions.

Study participants may bring adult guests to group sessions, but are encouraged to plan ahead of time for such occasions, especially if meeting space is an issue. Guests are encouraged to participate in the group activities, when appropriate, and are expected to adhere to the group expectations of confidentiality and group process.

### **Lack of Group Session Time**

Because group dynamics is powerful, active group interaction takes precedent over tasks that solely impart information, such as didactic nutrition education presentations. If the group is focused on the session topic, going the direction the interventionist wants, dynamic and there is a high level of participation this is more important than making sure each session detail is completed.

When the interventionist finds that she/he is unable to complete all the group activities one option is to review the outstanding tasks with the group and ask them which agenda items are most important to them to complete at this session. If the interventionist finds that there are many groups that session activities that cannot be finished, the interventionist discusses the session outline with the site intervention team to brainstorm ways to make the session more efficient.

## Use of Behavior Change Strategies

Behavior change is not simple, and knowledge of facts alone is not sufficient to achieve and maintain healthful behaviors, particularly in an environment that counteracts healthful choices. The WLM intervention incorporates numerous behavior change strategies that have been successful in other studies.

Behavior change strategies encompass those lifestyle-change intervention methods that enhance participant motivation, select targets for behavior change, and assist participants in making and maintaining the dietary and exercise changes.

Behavioral intervention strategies come from Bandura's (1986) social cognitive theory, Watson & Tharp's (1989) behavioral self-management model, Marlatt & Gordon's (1985) relapse prevention model and Prochaska et al.'s (1986) Tran theoretical model of behavior change. Using the specific techniques outlined below help facilitate participant adherence to the study goals and enhance the likelihood of participants reaching the eligibility weight loss criteria for randomization into Phase II of the WLM study.

Group facilitators use a variety of behavior modification and social learning theory approaches during the interventions sessions. The intervention introduces simple and important behavioral approaches early and incorporates advanced techniques over time. These behavioral techniques allow participants to effectively manage their diet and physical activity programs when confronted with the full spectrum of daily environmental challenges. A client-centered approach is prioritized to help participants learn to control his/her behavior and achieve and maintain the dietary and exercise goals. Group sessions provide hands-on activities (real-time practice) that employ behavioral strategies for eating and physical activity behaviors.

## Description of Key Behavior Strategies

**Self-monitoring:** Includes encouraging participants to accurately observe and record diet and physical activity behaviors. The goal is to increase awareness of the amounts and types of foods eaten and minutes of continuous physical activity to provide feedback and reinforcement toward achieving study and personal goals.

**Goal setting:** Techniques for helping participants set and achieve realistic, attainable goals and tailor goals according to individual motivation and situation

**Action Planning:** Participants set realistic short-term action steps that modify their behaviors a little at a time to eventually achieve long-term goals.

**Social Support:** This method helps participants learn how to appropriately solicit and attain support from friends, family, and peers for their behavioral changes (Marlatt & Gordon, 1985)

**Self-Assessment:** Periodic self-assessments that help participants look at food and exercise-related patterns, behaviors, triggers, thoughts, and attitudes. Self-assessment occurs through activities that use the completed food diaries, group discussions, and various worksheets

**Problem Solving:** Subsequent to the step of barrier definition is the generation, evaluation, and implementation of alternative responses that help the participant overcome barriers to reaching or maintaining behavioral goals.

**Modifying Environmental Influences (stimulus control):** This approach alters the environmental circumstances usually present at time unwanted behaviors occur. The purpose is to modify the stimulus for a particular health behavior.

**Making Choices/Substitutions Decision Making:** This approach encourages participants to choose the more healthful choice every time they have a choice, or to substitute a more healthful option for a lesser healthful option.

**Identification of negative triggers:** This form of self-assessment identifies specific circumstances that precipitate undesired dietary or exercise choices.

**Behavioral prompts:** Using “prompts” or reminders for desired behaviors. Examples include:

- Placing food diaries on the table while eating
- Posting program goals on the refrigerator
- Taking a “heart-healthy” grocery list to the grocery store
- Posting a schedule for exercise in a visible location (like on a daily/monthly calendar posted on a bulletin board)
- Putting out exercise clothes or walking shoes in a visible location as a reminder to exercise that day.

**Utilization of competing behaviors:** This technique involves teaching the participant to choose the healthful behaviors that compete with less healthful behaviors.

**Reinforcement:** Techniques that provide positive or negative consequences contingent on engaging in the targeted healthful behavior. Another technique is extrinsic reinforcement, where others, like program staff and family or friends, provide rewards.

**Modeling/Role play:** Exposing the participant to individuals who demonstrate the desired behaviors. This approach provides “vicarious reinforcement” for behaviors (Bandura, 1986), particularly if the role model shares characteristics with the participant (for example, the same race or gender). Particularly useful is modeling that demonstrates realistic examples of overcoming barriers. Role-playing is another form of modeling, which is used for skill practice. For example, a participant can role-play asking a spouse or friend to provide social support for exercise, or a participant can role-play various tempting dining situations while the instructor, and then the participant, demonstrate healthful responses.

**Identification of Barriers and Overcoming Obstacles:** This technique involves identifying tempting, problem, or high-risk situations, or other factors that the participant finds “gets in the way” of doing the targeted behaviors. Perceived barriers can include lack of time, lack of skills, lack of knowledge, and times of emotional distress.

**Time Management:** Learning to adjust plans and schedule activities in advance in order to insure that ample time is available for both required and desired activities.

**Social and Communication Skills enhancement:** Increasing a person’s ability to express desires and interact with others in an honest and straightforward manner.

**Relapse Prevention:** Techniques that anticipate, and plan for, the fact that participants will occasionally “slip” back into old behavior patterns, as well as those techniques that promote generalization of behavior change patterns. It is important for participants and interventionists both to recognize that lapses and relapses are common in health behavior change (they are the rule, rather than the exception). Lapses/relapses are temporary and not considered a “failure” if the participant is motivated to getting “back on track.”

**Cognitive Methods:** Knowledge, although often necessary is usually not sufficient for behavior change. Cognitive techniques are aimed at modifying knowledge, thoughts, feelings, and behavior about lifestyle changes by identifying and altering incorrect or illogical patterns of thinking.

**Values Clarification:** This approach provides the participant with an opportunity to reflect on long-held values regarding health and lifestyle in order to compare and contrast beliefs and values with behaviors and actions.

**Motivational Interviewing:** A method or style of counseling used in group facilitation that helps to assess the participants readiness for change, explore importance and confidence levels about specific changes, explores motivation, uncovers resistance and helps move the participant toward client-centered decisions to change.

## **General Guidelines for Debriefing and Facilitating Group Discussions**

Adapted from: *J. Am Diet Assoc.* 1999;99:72-76

1. Build the group from within. Assure participants that the group will be structured to fit their needs and concerns.
2. Have the group establish ground rules early on and stick to them.
3. Use icebreaker-type exercises to help participants start talking.
4. Ask open-ended questions: Ask questions that cannot be answered by “yes” or “no” and involve participants in describing their own experiences.
5. Ask for more information when clarity is needed, avoid making assumptions about what is not said.
6. Guide the discussion: Allow group participants to speak, keep discussion on track, and gently bring topics to a conclusion.
7. Avoid doing the problem solving for the participants.
8. Encourage full participation by making the group session a safe place: Encourage quiet participants to voice their ideas, listen intently to each participant, repeat comments when necessary, give positive feedback verbally and/or physically.
9. Focus the conversation: Clarify different views, restate the objectives of the session when necessary, summarize the important points of the discussion.
10. Correct misconceptions artfully: Avoid turning into the “lecturer”, emphasize the worth of participants’ experiences, use responses such as “I am glad this worked for you, what have other people found...”, and ask what other group participants think about the statement.
11. Create an atmosphere of acceptance: Accept and respect each participant’s feelings, even when you disagree with that viewpoint.
12. Summarize the discussion: Bring ideas together and repeat relevant information, strive to make the summary the result of the participants’ discussion, not your own analysis, and repeat and clarify the solution to any specific problem that participants discussed.
13. Be patient: Remember, it takes time for a group to grow and develop trust.
14. Have fun: Keep a smile and enjoy sharing and learning from the group.

## **Site Specific Materials**

Materials developed at the local site for the intervention complement and enhance, but do not replace, study-wide materials. Prior approval is not necessary for providing additional materials, but sites are encouraged to share locally developed materials with other sites.

## **Use of External Resources**

The following are guidelines for using cookbooks, field trips, videos, etc., for the WLM intervention.

### **Cookbooks**

1. Cookbooks recommended to participants should follow the study dietary guidelines.
2. Participants are encouraged to bring recipes/cookbooks to the intervention session for discussion/sharing.
3. WLM study staffs do not sell books to participants.



**Videos**

Videos enhance (but do not replace) intervention sessions to reinforce WLM study guidelines, demonstrate activities, illustrate principles, and/or provide role model behaviors. Interventionists preview all videos prior to using.

# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.2 Program Implementation

#### 9.2.6 Guidelines for Taste-It, Do-It, and Check-In Session Components

##### **Purpose**

The WLM Phase 1 sessions include Taste It, Do It and Check In activities. Each session includes a Check In, while the Taste It and Do It typically alternate every other session. The general purpose and overall objectives of these activities is described here. The curriculum for the Taste It, Do It and Check In activities are part of the leader's guide, but separate from the session outlines. This provides the interventionist with a menu of options to use for these particular session components and provides maximum flexibility to meet each groups' needs within the site's capabilities.

The Leader's Guide provides a standardized framework and structure for Taste-It, Do-It, and Check-In activities and includes instructions for the interventionist conducting the activity.

- All WLM interventionists read and become familiar with the activities for each component.
- The written materials found in the Leader's Guide guides group facilitation of activities.
- Priority is given to behavior change discussions and activities over advice and education.

## **WLM Taste-it!**

### **Purpose:**

1. Help participants develop skills for selecting and eating foods that fit the WLM guidelines
  - Have participant's taste, be shown or prepare WLM appropriate foods
  - Emphasize techniques to reduce calories and eat more fruits, vegetables, dairy and whole grain/high fiber foods
2. Make the group session fun and provide variety to improve retention and adherence
3. Serve and demonstrate foods that are easy, convenient, practical, and culturally appropriate
4. Provide foods that are simple to prepare and require few ingredients
5. Limit the use of recipes to no more than two at a given time

**Note:** Sites will determine the exact food items (within the predetermined theme) to present with input from their group participants.

### **Taste-it Objectives**

#### **Interventionist:**

1. Help participants change their eating pattern in the next 7 weeks
2. Prepares, or demonstrates foods that meet WLM study targets prioritizing techniques to eat fewer calories, eat more fruits, vegetables, dairy foods and whole grain/high fiber foods
3. Serves food that is familiar and culturally appropriate and likely to appear in participants food diaries
4. Serves food that is easy, convenient and/or practical to prepare and familiar to the participant
5. Makes the session fun
6. Enhance social support by facilitating participant's interaction and participation by encouraging participants to discuss their food planning, purchasing and preparation behavior changes and challenges
7. Creates change talk
8. Uses few recipes, but when do use ingredients that are familiar to participants and culturally appropriate

#### **Participants:**

The participants will be more likely to:

1. Achieve and adhere to the WLM dietary guidelines
2. Purchase or prepare featured foods
3. Stay involved in the study (retention)
4. Find healthier ways to prepare new and common foods
5. Reflect and discuss their behavior change progress

### **Including Participants in the Taste-it Plans**

#### 1. Purpose

At the session prior to each Taste-it the interventionist facilitates a discussion with the participants to involve them in the next session Taste-it plans. The purpose is to help the participants identify foods to discuss at the next Taste-it. Depending on the group dynamic this discussion can occur verbally or ideas can be generated using worksheets.

- Common foods they eat that are related to the Taste-it food subject
- Fruits and vegetables, low-fat dairy foods, reduced calories foods they want to try
- Recipes or food products they eat and might want to discuss

#### 2. Explain how elaborate/simple the Taste-its are: what can and cannot be done.

3. Ask participants to either purchase the food or make a recipe (to be reimbursed for cost).
4. Sample Facilitation Questions
  - *At session \_\_\_\_ (group session number) we are going to talk about \_\_\_\_ (food subject).*
  - *Tell me about some of the \_\_\_\_ (food subject) foods that you eat.*
  - *What have been some of the challenges that you have run into trying to eat healthier \_\_\_\_ (food subject)?*
  - *What particular foods are difficult to change?*
  - *Who might be interested in bringing some \_\_\_\_ (food subject) products or recipes you have found helpful and easy and that you enjoy related to \_\_\_\_ (food subject)?*
5. Work out with the participant at the end of the session the food product they will purchase and bring, or the food they will prepare.
6. Discuss the budget your site has set for this and information you need from the participants, such as receipts for reimbursement, recipes, etc.

**Leader’s Guide for Taste-it! includes:**

1. The purpose
2. Materials and/or equipment needed, including handouts/questionnaires
3. Facilitation questions to generate discussion among participants
4. Ideas on how to present the Taste It, including ways to address portion size, calories, etc
5. Special instructions for the interventionist (if needed)
6. Suggested handouts or questionnaires (if needed or appropriate)
7. Recipes (optional)

**WLM Taste-it Themes**

Session	Theme	Suggested Taste-it Activity
3	DASH and Fruits and Vegetables	<ul style="list-style-type: none"> <li>• Review DASH eating pattern</li> <li>• Show DASH fruit and vegetable servings to demonstrate DASH serving sizes</li> </ul>
5	Breakfast	<ul style="list-style-type: none"> <li>• Ways to include dairy products and serve sample products</li> <li>• Ways to reduced fat at breakfast and serve sample products</li> <li>• Value and demo of high fiber and whole grain cereals and serve samples.</li> <li>• Compare fat and calories in common breakfast foods with alternatives</li> </ul>
7	Dinners	<ul style="list-style-type: none"> <li>• Ways to modify frozen and prepared entrees to make lower in fat, higher in fiber</li> <li>• Ways to add fruits and vegetables to evening meals</li> <li>• Ways to eat less fat and calories at dinner</li> <li>• Soups made with vegetables and legumes</li> </ul>
9	Desserts	<ul style="list-style-type: none"> <li>• Ways to eat smaller dessert portions, lower calorie desserts, and reduce the fat in desserts. Serve examples</li> <li>• Fruits for dessert</li> <li>• Sample different yogurts served with fruit and/or fruit smoothies</li> </ul>

Session	Theme	Suggested Taste-it Activity
11	Quick Snacks Quick Meals	<ul style="list-style-type: none"> <li>• Low-fat cheeses</li> <li>• Quick meals using a ready-made product or salad mix embellished with tuna, etc</li> <li>• Sandwiches</li> <li>• One dish meals; embellishing common foods to make a one dish meal</li> <li>• Discuss and compare calories and fat in common snacks. Show and serve some alternatives</li> <li>• Discuss ways and serve foods to reduce cravings</li> </ul>
13	Fast Food and/or Dining Out	<ul style="list-style-type: none"> <li>• Embellishing fast foods to make them healthier (add fruits, vegetables, whole grain foods to make complete meal)</li> <li>• Foods and ways to help you eat less when dining out</li> </ul>
15	Lunch	<ul style="list-style-type: none"> <li>• Discuss ways to eat low fat and reduced calorie lunch and serve some samples</li> <li>• Discuss ideas for quick lunches and serve samples</li> <li>• Ways to add whole grains to lunches and serve samples</li> </ul>
17	Party Foods	<ul style="list-style-type: none"> <li>• Reduced fat, high fruit and vegetable holiday foods</li> <li>• Reduced fat, high fruit and vegetable party foods</li> </ul>

# WLM Do-It!

## **Purpose:**

### **To help the participants:**

1. Develop physical activity skills and behaviors.
2. Build confidence in their abilities to exercise.
3. Practice and try new exercise activities.
4. Achieve the study physical activity goals by participating in aerobic physical activity.
5. Do activity during the session that will count toward physical activity minutes to record.
6. Establish physical activity as a “normal” thing to do.

## **Do-It! Objectives**

### **Interventionist:**

During the Do-It! activities, the interventionist will:

1. Provide a safe and fun environment for participants to exercise (“Do-It”)
2. Encourage participants exercise regularly, in addition to their daily routine
3. Emphasize aerobic physical activity (at least 80% of the Do-It activities are aerobic, 20% can be non-aerobic but should address overall fitness)
4. Model, demonstrate and reinforce the correct and safe ways to exercise

### **Participants:**

During the Do-It! Activity, participants will:

1. Actively participate in a group exercise activity
2. Become more comfortable exercising
3. Develop confidence in their abilities to exercise
4. Increase the duration of their physical activity bouts
5. Participate in physical activities to expand their options for realistic physical activity
6. Practice increasing the intensity of their exercise

## **Each Do-It! Activity includes:**

1. Setting the stage – introduce the session Do-It! goals
2. Warm-up (includes stretching)
3. Aerobic exercise
4. Pulse check at least once during the aerobic portion of the activity
5. Perceived exertion check at least once during the aerobic portion of the activity
6. Cool-down (includes stretching)
7. Hydration, drink water before, during and after
8. Summarizing and tying the Do-It! activity to the participant’s physical activity plans

### **Leader’s Guide for the Do-It! includes:**

1. Title
2. Objectives
3. Materials/Equipment (handouts, exercise equipment, etc)
4. Instructions for interventionist

## Do It! Activities

<b>Type of Physical Activity</b>	<i>Aerobic: Y/N</i>
Group walk: <ul style="list-style-type: none"> <li>• Neighborhood</li> <li>• Park</li> <li>• Parking lot</li> <li>• High school track</li> <li>• Fitness center</li> </ul>	Y
Destination walking	Y
Exercise videos: <ul style="list-style-type: none"> <li>• Walking by Leslie Sansone: 1, 2 and 4 mile walk</li> <li>• Richard Simmons “Sweating to the Oldies”</li> <li>• Donna Richardson and Gilad</li> <li>• Participant recommended</li> </ul>	Y
Visit to fitness center to learn about exercise equipment	N
Group aerobic class <ul style="list-style-type: none"> <li>• with fitness instructor</li> <li>• at local recreation center</li> <li>• with martial arts instructor</li> <li>• with exercise/physical therapist or personal trainer</li> </ul>	Y
Power walking	Y
Strength training (Dynabands or dumbbells)	N
Interval Training	Y
Walking program to increase duration over time	Y
Stretching	N

## **WLM Check-In**

### **Purpose:**

**To help participants be aware of study goals and reflect on their progress.**

### **Check-In Objectives**

#### **Interventionist:**

1. Find out how participant has been doing since last group session
2. Provide accountability for goals and plans announced at the previous meeting
3. Use motivational interviewing skills to help participants
  - a. Explore ambivalence and develop confidence
  - b. Develop positive perspectives and emphasize benefits
  - c. Move from pre-contemplation or contemplation to action
  - d. Tell you what you want to tell them (draw advice from the participants)
  - e. Problem solve
  - f. Use change talk
4. Provide variety and continued interest in the process by focusing on specific and different behaviors at each session (self-monitoring, PA, portions, etc)
5. Encourage each participant to discuss progress for a particular behavior based on the previous week's session
6. Make the session fun
7. Create social support by getting participants to interact with each other

#### **Participants:**

During the check-in process, participants:

1. Share successes and challenges they face losing weight
2. Discuss progress for a particular behavior based on the previous week's session
3. Problem solve
4. Bond with others in the group and develop social support skills
5. Be accountable
6. Increase change talk
7. Verbalize positive aspects of their effort in WLM

#### **Each Check-In Activity takes at least 15 minutes and includes:**

- *Open-ended questions (O)* – Open-ended questions leave room for a response; they require more than a yes/no answer, a specific fact, or number. Open-ended questions encourage the participants to do more of the talking. More talking = greater engagement.
- *Affirming statements (A)* - Affirming statements are words of appreciation and understanding to help build rapport and encourage greater participation in the group.
- *Reflections (R)* - A reflection is a brief statement which offers a reasonable guess as to what the speaker means, in order to check rather than assume understanding. Interventionists should reflect and emphasize participant “change talk.”
- *Summary (S)* - Summaries link together and reinforce material that has been discussed. This shows you've been listening carefully and prepares the participant to elaborate further. And it also allows them to hear their own change talk for a third time.



**Leader’s Guide for the Check-In includes:**

1. Title
2. Objectives
3. Materials/Equipment
4. Instructions for the interventionist

**Check-In Activities**

<b>Check-In Activity</b>	<b>Brief Description</b>
<b>Motivational Interviewing scale</b>	“On a scale of 1-10, how happy are you with how your progress this week?”
<b>Food records</b>	Participants use their food record to look at how they did in particular areas (f/v servings, fat content, sodium intake, etc)
<b>Action plan/Check-In partner</b>	Participants partner-up for action planning at one session and check-in at the next group session.
<b>Question/concerns/challenges</b>	As participants are entering the classroom, they fill out slips of paper with questions they have concerning the previous session and/or challenges they faced over the past week. The Interventionist pulls slips at random and address questions raised with the help of participants (brainstorm possible solutions to identified problems, etc).
<b>Names in a bag</b>	Place participants names in a bag at the beginning of each session, pull a name and have that person answer an open-ended question (What kind of successes or challenges did you encounter this week?)
<b>Ball toss</b>	Participants stand up and toss a ball around. The participant with the ball talks about their progress. The ball then gets tossed to another participant and so on.
<b>Question and answer</b>	Interventionist asks open-ended questions and participants who are willing talk about their progress.
<b>Questions on chairs</b>	Sheets of paper with progress check questions are placed on several chairs in the room. Ask the participant to share their answers with the group.
<b>Musical chairs</b>	The participant who is left standing says something about their progress for the past week or has the option of asking someone in the group about their progress.
<b>Participant-led progress check</b>	Participant volunteers to facilitate the progress check.
<b>Group Feedback</b>	Participants volunteer to discuss their challenges and successes from the last week and the group provides feedback.
<b>Partner or small group check-in</b>	Participants receive a short list of questions to ask each other in a small group or with one partner as a check-in. One person takes notes and summarizes their discussion for the larger group.

# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.2 Program Implementation

#### 9.2.7 Phase I Intervention Data Collection

##### Description

Attendance, weight, adherence and self-monitoring data are collected for all participants using the forms 200, 201, and 202. Instructions for completing each form are located in the forms section of this manual.

##### 1. Intervention attendance and weight form #200

Attendance and weight status are the key components of Phase I that contribute to maximizing the yield of participants eligible for randomization into Phase II. Form 200 purposely collects limited information to allow for timely and continuous monitoring of group attendance and weight. Information collected on Form 200 assists with local triage and case management and overall study quality control monitoring for the Phase I weight loss program. Form 200 is a report generated by the local site. The report contains the names and study ID numbers of all participants assigned to the group. Space is available to record attendance and weight.

##### 2. Food and Fitness Diary form #201

A key behavioral self-management tool used in WLM Phase I weight loss program is self-monitoring of food intake and physical activity minutes using the Food and Fitness Diary. Participants keep records of daily food intake and minutes of moderate-intensity exercise. Participants track calories, servings of fruits, vegetables, and dairy from the foods they record on their daily food records. Each week, the participant summarizes the data from each day, onto Form #201 (which is the front and back cover of the Food and Fitness Diary). Data from this form is self-reported intervention process data and used for providing graphed feedback to the participant at Phase I group sessions.

A current version of this form is only available on the Food and Fitness Diary.

This form is not a required form. However, this data is critical for participants to track and every effort is made to encourage participants to complete this form weekly.

##### 3. Missed group session form #202

Study triage guidelines and local case management procedures specifically address the follow-up procedures for participants who miss group session visits. However, to maximize the yield of participant's becoming eligible for Phase II, aggressive and immediate follow-up after a missed group session is recommended in most circumstances.

Form 202 captures information about they type of absence (planned or unplanned) and documents the type of contact made with the participant after a missed session. Additionally, Form 202 captures scale weight information (if available) *even when a participant missed the scheduled group session.*

# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.3 Program Quality Assurance

#### 9.3.1 Quality Control

##### Overview

This chapter describes the quality control procedures that assure standard delivery of the WLM interventions. These quality control procedures help the interventionists and investigators maintain quality interventions. Additionally, this chapter describes the ongoing monitoring of intervention progress to identify potential quality and adherence issues. Procedures include:

- Use of written guidelines for each session
- Identification of an intervention director at each site
- Training meetings for all interventionists
- Frequent telephone conference calls for all interventionists
- Monthly review of key intervention adherence measures
- Annual intervention site visits at each clinical center by the CC
- Local quality control procedures

##### Written intervention materials

Written intervention goals (lifestyle guidelines) are the basis for content and delivery of each group session. Interventionists use the written session outlines, lifestyle guidelines, and group facilitation standards to provide consistent intervention messages. Intervention materials provide the framework for delivering the common intervention goal of weight loss and healthy lifestyle habits.

##### Intervention Staffing:

###### *Intervention directors*

Each clinical center PI identifies an intervention director. The intervention directors oversee all local intervention activities insure that the intervention delivered messages are consistent with the WLM protocol and manual of procedures. Intervention directors are knowledgeable and experienced in behavior change and group facilitation.

Intervention directors are responsible for training all intervention staff hired during the course of the study. Local training includes (but is not limited to) the following elements.

1. Reading all related Intervention materials, including the study protocol.
2. Observing (using the observation checklist located in this chapter) an experienced interventionist facilitating group sessions. Debrief with the interventionist after each observation.
3. Co-facilitate group sessions with an experienced interventionist and debriefing after each session.
4. Be observed (using the observation checklist) facilitating group sessions by an experienced interventionist. Debrief after each observation.
5. Participate in training focused on "Motivational Interviewing" including self-education by reading "Health Behavior Change, a Guide for Practitioners." Rollnick, Mason and Butler.

Intervention directors, along with site PIs assure the interventionists have the tools necessary to function at a high level within the aspects of a multi-site trial. Such tools include (but are not limited

to) an individual e-mail account and phone numbers. Intervention directors keep the coordinating center up-to-date about intervention staff contact information.

#### *Interventionists*

Highly skilled facilitators lead the intervention group sessions. Interventionists are experienced group facilitators with skills in behavior change and both group and individual-level counseling. Additionally, interventionists have at least a general background in nutrition and physical activity.

#### **Trial-wide training meetings**

The coordinating center organizes and conducts intervention trainings for all WLM interventionists. Trainers are knowledgeable about the study and have expert knowledge in the area for which they are training. Trainers include, but are not limited to, PIs and site intervention staff with specialized intervention experience and knowledge, study consultants and outside experts.

#### *The goals of the intervention training include:*

- Enhance group facilitation skills.
- Understand and practice high-priority, high-leverage activities that lead to participant behavior change.
- Incorporate intervention goals and priority messages into group facilitation skill set.
- Advance personal understanding of cultural differences with regard to health and weight loss.
- Practice challenging group facilitation scenarios.
- Understand data monitoring systems for quality control and randomization yield.
- Form intervention support networks across sites to enhance case management.

Interventionist become familiar with the details of session outlines during site-specific training and orientation.

#### *Training Topics:*

Topics will include but not be limited to the following:

- Intervention Related Screening Activities
- Group Session Implementation and Group Facilitation Skills
- Motivational Enhancement Counseling
- Behavior Change
- Physical Activity
- Minority Participants
- Data Collection

Proposed/planned training dates are:

June, 2003 - phase I weight loss  
November, 2003 - randomization visit and phase II interventions  
Fall, 2004 - phase II interventions  
Fall, 2005 - phase II interventions

#### **Telephone conference calls**

The coordinating center schedules regular conference calls for all WLM interventionists. The purpose of these calls is to review and answer questions regarding the written materials and plans for intervention sessions, discuss problems encountered in delivering the intervention, review intervention adherence reports, and help each other develop plans for difficult intervention problems. Conference calls are lead by an experienced study intervention director (as appointed by the Steering Committee) and are regularly held twice per month.

#### **Monthly review of intervention adherence data:**

The coordinating center prepares intervention yield reports (broken down by clinical center, race and gender) using intervention weight data. Reports indicate the percentage of participant within a specified weight loss category at each group session. The minimum target for participants losing at

least 9 pounds by G20 is 50%. These reports are available to all project investigators and interventionists on the WLM Web site at regular intervals (no less than monthly).

Additional intervention adherence data reports (based on data obtained from the self-reported Food and Fitness Diary information) are available and discussed on regularly scheduled conference calls. The content of these reports includes:

- Meeting attendance
- Mean weight change
- Mean number of minutes of exercise per week
- Mean number of food diaries per week
- Kcal/day from food diaries
- Mean number of servings of F,V, & D from food diaries

#### **Intervention site visits**

Each clinical center receives annual intervention site visits from the coordinating center. An intervention expert from the coordinating center leads the site visit. Site visits may include an interventionist from another clinical center in a “cross-site visitor” capacity. The site visitors review a number of procedures including record keeping, data collection and entry, and delivery of the intervention. Observation of at least one group session occurs during the visit. The site visit team produces written reports for the steering committee as well as the intervention director and PI of the visited center.

#### **Local quality control procedures**

Each site is responsible for the development and implementation of local quality control procedures. These should include but not be limited to: interventionist observation of each other, regular observation by the site PI, observation and regular involvement by the site intervention director, behavior-change skills development, and regular access and consultation with a behavior change expert. See attached observation form and procedure.

#### **Local Case Management Procedures**

Each site is responsible to develop effective intervention case management procedures to use along with the triage system (See MOP chapter 9.3.2 for Triage and Case Management).

## Phase I Group Session Observation

To what extent did the interventionist:	Completely --- Not at all
	1    2    3    4    5
1.     Ask a general open-ended question about progress <i>“How has it been going? What things are working for you?”</i>	1    2    3    4    5
2.     Seek elaboration and clarification of responses <i>“Tell me more about that? Can you explain it again?”</i>	1    2    3    4    5
3.     Elicit input from non-responders directly <i>“Sam, how about you, how did your week go?”</i>	1    2    3    4    5
4.     Summarize and synthesize responses	1    2    3    4    5
5.     Elicit participant input about the purpose and value of the activity <i>“So, why do you think that this particular activity is part of our session today?”</i>	1    2    3    4    5
6.     Plan activities that focus on behavior change	1    2    3    4    5
7.     Provide opportunity for individuals to create a personal plan	1    2    3    4    5
8.     Encourages participants to evaluate goals as doable, seeable, and reachable.	1    2    3    4    5
9.     Encourage support among group members <i>Provides opportunities for group members to talk directly with each other</i> <i>Models providing support in a non-judgmental manner</i>	1    2    3    4    5
10.    Allow members to solve own problems <i>Provides opportunity for participants to generate ideas, causes, and solutions to problems and concerns</i> <i>Provides potential solutions only after a direct request or exhausting the participant’s own ideas</i>	1    2    3    4    5

**Purpose:**

Interventionists and session observers use this evaluation tool as a guide to provide feedback and enhance group facilitation skill.

**Uses:**

1.     Interventionist uses this tool prior to conducting group sessions as a reminder or trigger for what to keep in mind.
2.     Interventionist uses this tool after conducting a group session to evaluate personal skill and focus on areas in need of enhancement.
3.     Observer uses this tool during a group session to provide feedback to an interventionist in a debriefing session after a group session.

**Schedule of use:**

While this tool is used at any time, the following schedule is required by the study (per WLM steering committee vote).

At least four (4) observations (including a personal debrief) per interventionist by a PI, Co-PI or Intervention Director during the first 3 months of Phase I interventions.

# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.3 Program Quality Assurance

#### 9.3.2 Triage System and Local Case Management

##### WLM Triage System for Weight Loss and Attendance

**Background:**

The measure of success for the WLM Phase I weight loss intervention is the percent of participants meeting (or exceeding) the weight loss criteria for randomization (i.e. the percent of people who are weight-eligible for Phase II).

**Purpose:**

These guidelines, used in conjunction with sound clinical judgment, help focus and prioritize intervention activities on participants most likely to benefit and become eligible for randomization into Phase II.

**Determining priority according to weight:**

Weight status by this group session:	Lower priority	<b>High priority</b> “High probable” range of making weight eligibility for Phase II:	Meeting or exceeding weight loss target:
<b>G5</b>	gained weight	0-3	4+
<b>G10</b>	lost 3 lbs or less	4-7	8+
<b>G15</b>	lost 4 lbs or less	5-11	12+
<i>G18 participants who have lost 4+kgs (8.8 lbs) are eligible to begin Phase II screening</i>			
<b>G20</b>			15+

**Procedures per priority status:**

Weight loss status	Procedure:
At or exceeding target	<ul style="list-style-type: none"> <li>• Participant doing very well.</li> <li>• Continue regular follow-up at group sessions</li> </ul>
<b>High priority</b> (Within “high probable” range)	<ul style="list-style-type: none"> <li>• High priority for additional intervention effort per local case management procedures.</li> </ul>
<b>Lower priority</b> (Below “high probable” range)	<ul style="list-style-type: none"> <li>• May not benefit from any additional intervention effort.</li> <li>• Continue regular encouragement at group sessions</li> </ul>

## Suggested guidelines for “missed visits”

### **Background and purpose:**

Given the large intervention caseload and weekly session frequency, there is no intent to conduct content-driven make-up sessions. Phone contacts, when they occur, are behavior oriented, brief and generally limited to the following brief elements:

- Encouragement to attend group sessions
- Progress on record-keeping and weight loss

### **Procedures for missed sessions:**

<b>Missed visit status:</b>	<b>Interventionist Responsibility</b>
<b>1. PLANNED ABSENCE</b> Participant notifies site of a planned absence prior to scheduled group session.	<b>At the time participant notifies the site:</b> <ul style="list-style-type: none"><li>• Encourage participant to attend another group session sometime before the next scheduled group session.</li><li>• If appropriate, briefly review participant’s progress (record keeping, exercise, and weight loss).</li></ul>
<b>2. UNPLANNED ABSENCE</b> Participant contacts site after an unplanned absence.	<b>At the time participant contacts site about the missed session:</b> <ul style="list-style-type: none"><li>• Encourage participant to attend another group session sometime before the next scheduled group session</li><li>• Solicit participant’s commitment to attend the next regularly scheduled group session.</li><li>• If appropriate, briefly review participant’s progress (record keeping, exercise, and weight loss).</li></ul>
<b>3. UNPLANNED ABSENCE</b> Participant misses a group session and does not contact the site, “no show, no call.”	<b>Use local case management procedures to determine appropriate next step.</b> Recommendations: <ul style="list-style-type: none"><li>• Timely (next day) phone contact after an unplanned absence to encourage participant to attend another group session that week and/or come the next weekly group session. (<i>local sites to determine the extent of the follow-up effort</i>)</li><li>• If first group session is an unplanned absence, consider no further follow up.</li><li>• If participant has three consecutive unplanned absences, consider no further follow up.</li></ul>

## Local Case Management

To maximize the yield of Phase I participants entering Phase II, each site implements an effective local case management system. Local systems include (but are not limited to) the following:

- Regular and timely review of all participants weight and attendance progress
- Regular and timely case conferencing between intervention staff and behavior specialists.
- Documentation of case management plans and outcomes
- Documentation of case conferencing meetings

(This section still to be expanded)



# Weight Loss Maintenance MOP

## 9 Phase I Weight Loss Program

### 9.3 Program Quality Assurance

#### 9.3.3 Participant Safety Issues

##### Too rapid of weight loss

WLM recommends all participants to lose at least 9 pounds during phase I. A mean weight loss of ½ to 2 pounds per week over 5-6 months, or 10 percent of body weight over 6 months, is considered a healthy reasonable pace (1,2). The working definition of too rapid weight loss in WLM will be a mean weight loss greater than 2 pounds per week for women and 3 pounds per week for men over a 4-week period. Weight loss greater than this amount may pose health risk to the participants and will trigger a case review by the intervention staff. The only exception to this guideline will be the first two weeks of intervention in which a greater weight loss will be acceptable.

##### Nutrient Adequacy

##### Definition of Nutritional Inadequacy

Rapid weight loss may be an indication of inadequate nutrition. The initial target calorie level for weight loss in WLM is 1500 Kcal/day for women and 2000 Kcal for men. These values are based upon an estimated weight maintenance level of 2100 Kcal for women and 2600 Kcal/day for men (based on the DASH studies). The 1500kcal for women and 2000 kcal for men guideline was selected so that participants can lose weight safely while maintaining adequate intakes of essential vitamins and minerals. The issue of adequate nutrient intake will be discussed during phase I group sessions. A mean caloric intake of less than 1,000 Kcal/day for women and 1,500 Kcal/day for men over a four week period as documented by self-monitoring (i.e. FFD) may indicate inadequate intakes of essential vitamins and minerals and thus may pose health risk. A case review should be conducted by the intervention staff when nutrient inadequacy is suspected or detected.

Procedures for handling rapid weight loss and nutrient inadequacy:

1. Body weight is measured during screening and at each visit, and weight, and dietary intake data are collected at each subsequent intervention session. These data will be monitored by the coordinating center, and the intervention director at each clinic will be notified when their participants reach alert levels for weight loss, and caloric intake risk.
2. When a participant reaches an alert level, the intervention director will be responsible for conducting a case review with the local intervention team and recording the results of that review in an alert log. The intervention team will be responsible for evaluating the case and developing a plan that might include an individual visit with the participant, a special plan for helping that participant in the context of the regularly scheduled group meetings, follow-up contacts by telephone, some other action, or taking no further action.
3. Nutrition and weight alerts – Case reviews should include all of the information available to the interventionists. In some cases the reported caloric intake may not be representative of the participants true mean intake (e.g., they are reporting eating 500 Kcal/day but are not losing weight). However, if a case review indicates that the participant may have a mean caloric intake below 1,000 Kcal/day for women or 1,500 Kcal/day for men, an individual visit with the participant should be scheduled. That visit may be conducted by any of the WLM interventionists familiar with the case. The purpose of the individual visit will be to review with the participant their recent food diaries and to discuss the importance of eating an adequate diet. Dietary recommendations will focus on a pattern including grains and cereals, fruits and vegetables, dairy, and meat and/or meat substitutes as suggested by the DASH eating pattern and consistent with the participant's WLM intervention group assignment.
4. The disposition of each intervention alert should be recorded in a log. This log will be reviewed during the intervention site visits.

## **Participants with Diabetes**

Although dietary recommendations used in the WLM for weight loss and management are appropriate for diabetes patients taking diabetes medications, and these patients would benefit from a weight loss program, they are not qualified to enter the WLM study. There is a significant risk of hypoglycemia induced by weight loss and increased physical activity in diabetics treated with oral medication or insulin. The monitoring and clinical oversight that would be required to ensure their safety is beyond the scope of this project.

## **Extreme dieting patterns**

Participants may use extreme measures to lose 4 kg at the end of Phase 1 in order to be eligible for Phase II. Extreme dieting patterns include using diet pills or severe energy restriction to lose weight rapidly. These practices are not recommended and supported by WLM. Data regarding severe energy restricted diets, such as very low calorie diets (VLCDs), show that despite the short-term success of achieving significant weight losses, there is poor long-term maintenance of the weight loss (3). Another type of severe energy restriction is starvation diets include fasting, which has been used for centuries and results in a loss of lean body mass and mineral loss due to diuresis. VLCDs are protein-sparing modified fasts using either a premixed liquid of meat, fish, or poultry. VLCDs come and go in popularity often according to the push of a commercial program or book. Generally, in a medical environment, they are reserved for patients who have BMIs > 30 and have failed other approaches. Patients should be under medical supervision and must receive supplemental vitamins and minerals (3). It has been established that the weight losses over time are not greater than a mixed diet of equal caloric content, and the resumption of eating solid foods frequently disrupts maintenance efforts (4,5). In fact, data from the Continuing Survey of Food Intakes by Individuals 1994-1996 was analyzed to look at dietary patterns and selected measures of nutritional status and Body Mass Index. This analysis found that individuals on a moderate fat, high-carbohydrate diet as recommended by the Food Pyramid Guide were more likely to maintain weight loss (6).

During WLM intervention, participants are reminded regularly of the importance of safe weight loss. Interventionists are trained to detect evidence of extreme measures and trained with strategies for responding. If participants are found to follow any extreme dieting patterns, an individual visit will be scheduled by the interventionist to provide counseling to the participants. Follow up visits may also need to be scheduled depending on the cases.

## **Nutrition Supplements**

WLM offers reliable and healthy eating recommendations to participants in all intervention groups. Nutrition guidelines for WLM, which are based on the DASH study results, emphasize fruits, vegetables and dairy products. In general, following these guidelines/advice is the best way to get all the vitamins, minerals and other nutrients that a person may need for cardiovascular health. However, some participants may choose to take certain vitamin/mineral/herbal supplements on their own. WLM policies on supplement usage include:

1. Participants may continue to take vitamin/mineral/herbal supplements that they have been taking at entry to the study. Participants will be asked about their supplement usage at various times during the trial (specify) (Form #XX).
2. WLM participants may request information regarding supplement usage. If such questions come up during intervention sessions, interventionists should gently point out to those participants that the DASH diet was based on dietary patterns using various food groups and no one knows exactly which, if any, nutrients are the key to blood pressure reduction. Interventionists should emphasize the message that the best sources of nutrients are from foods, and eating a variety of foods is the best way to ensure adequate nutrition.

3. Since diet supplements are not the focus of the WLM intervention, interventionists should advise participants using guideline listed in #4 (below) and try to avoid extended discussion on this topic. Participants can be informed that written material about supplements is available and they can pick up the material at the end of session. Participants should also be encouraged to discuss use of supplements with their physicians.

4. Specific recommendations regarding supplements.

**Multiple vitamins/minerals (One a day, Centrum or Thera type), single vitamins/minerals (for example, vitamin C, vitamin E, folate, calcium, selenium, zinc or iron), and antioxidants supplements.**

These supplements may help certain populations meet their special nutritional needs. For example, osteoporosis patients that have difficulty getting adequate calcium from foods may need calcium supplements. Iron supplements are recommended for pregnant women or individuals with anemia. However, the effectiveness of using these supplements in preventing or treating chronic diseases such as heart disease and cancer is not known. In general, eating a wide variety of foods is the best way to obtain essential nutrients. The WLM study recognizes the interest of some participants in using supplements in promoting their health. Participants should be advised to use these supplements at or below the Recommended Dietary Allowances (RDA) and under their physician's supervision. It is possible that overdosage of these supplements may result in toxicity symptoms or negative outcomes.

**Calcium fortified foods**

Calcium fortified foods are good sources of calcium. However, they do not contain other essential nutrients that are present in dairy products. For the WLM study, calcium fortified foods should not be used as a substitute for dairy products.

**Herbal and botanical supplements, energy supplements**

These supplements have received very little scientific study regarding safety and effectiveness. They are not regulated by FDA and their quality during their manufacture is not checked. Furthermore, these products have frequently been associated with unfounded or misleading health claims on the label and in books. Participants should be advised to consult their physician before taking these supplements. Examples of common herbal and botanical supplements and their claimed functions are listed below:

Aloe vera Cleansing/laxative  
Chamomile indigestion  
Echinacea Increase immunity  
Ephedra (Ma Juang) Weight loss/appetite control/Nasal decongestant/asthma/  
Feverfew Migrane  
Garlic Reduce cholesterol/arteriosclerosis  
Ginkgo Improve circulation  
Ginseng Tonic/reduce fatigue/increase stamina  
Golden Seal Root Increase immunity  
Hawthorn Congestive heart failure  
Milk thistle Hepatitis/cirrhosis  
Saw Palmetto Antiinflammatory  
St. John's Wort Antidepressant

**Non-prescription weight loss supplements/fat burners**

The display of these supplements always look extremely appealing—not much effort and quick results. Examples of such products include *hydroxycitric acid*, *chitosan*, *conjugated linoleic acid*, *ephedrine*, *pyruvate* and *cellasene*. Most of these products are claimed to increase weight loss, decrease fat absorption or formation. Very few human studies have been conducted to examine the effectiveness and safety of these products. In fact, about three dozen deaths have been linked to

ephedra. Participants should be discouraged from taking them and be aware that the claims used for these products are not supported by scientific investigation. They should consult their physicians before taking them.

#### References

1. Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults, The Evidence Report, National Institutes of Health, National Heart, Lung, and Blood Institute. *Obesity Research* 1998;6(Supp2):515-2095.
2. Position of the American Dietetic Association: Weight Management, *J Am Diet Assoc* 1997;97:71-84
3. National Task Force on the Prevention and Treatment of Obesity, National Institutes of Health. Very low-calorie diets. *JAMA*. 1993;270:967-974.
4. Wadden TA, Foster GD, Letizia KA. One-year behavioral treatment of obesity: comparison of moderate and severe caloric restriction and the effects on weight maintenance therapy. *J Consult Clin Psychol*. 1994;62:165- 171.
5. Stein K. High-protein, low carbohydrate diets: Do they work? *JADA*. 2000,100:760-761.  
Kant AK. Consumption of energy-dense, nutrient-poor foods by adult Americans: nutritional and health implications. The third National Health and Nutrition Examination Survey, 1988-1994. *Am J Clin Nutr*. 2000;72:929-936.

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# Weight Loss Maintenance MOP

## Summary of edits between version 1.0 and 1.1

- The process to transfer a file has been rewritten and moved from 11.4 to 12.5 section 3.

## Summary of edits between version 1.1 and 1.2

- The prefix <https://> has been added to the secure website information.
- Added that IE 5.0 and Netscape 6.0 are required for proper viewing of the IT website.

## 11 Communication and Internet Websites

The WLM study uses the Internet to communicate information about the study to the general public, to study personnel and participants, for data entry, and to deliver an intervention. Knowledge of, and about the Internet is necessary for participants and for sites to effectively participate in the WLM study.

There are four broad areas of Internet use in the WLM study 1) a recruitment website where potential participants can find out more about the study and demonstrate their ability to use the Internet, 2) a project website for use by study staff which encompasses all aspects of study administration, including data entry, 3) a separate website to be used by participants randomized to the “Innovative Technology” (IT) arm of the intervention during Phase II and 4) a “file transfer” (FT) website where accelerometry datasets will be moved and stored. While not all study staff are expected to know all things about all websites, at least one site staff person should be assigned the responsibility to be familiar with each website, in case questions arise and the CC is unavailable to help.

### 11.1 Website for Recruitment Information

The URL for the WLM recruitment website is <http://www.wlmtrial.org>. Note that [wlmtrial.com](http://www.wlmtrial.com) will also direct the user to this website; the study has purchased both domain names for use. This site is in the public domain and is not password protected.

While potential participants may find this website through web “surfing”, it is more likely that they will encounter it as a result of being directed there by a local recruitment flyer or brochure. The purpose of the website is to provide potential participants with basic information about the study, a way for them to assess potential eligibility, and the ability to contact a local site for more information.

The recruitment website contains basic information about the WLM study; its goals, where the study is being conducted, and how it is funded. It is purposefully broad in scope, and it is hoped that the site will stimulate interest in participating in the WLM study.

A brief eligibility quiz may be taken over the website. No data are collected from this quiz, and the results are not considered final. However, basic eligibility questions like “Do you take prescription drugs for high cholesterol or high blood pressure” are a part of the quiz, as this is a relatively easy question for participants to assess, and is a necessary part of screening for the WLM trial. If participants can self-select out of screening, knowing they are ineligible, it will save the clinic sites time and money to concentrate on participants more likely to be eligible for study participation. A brief note is displayed on the screen indicating whether the participant is potentially eligible or not. If they are eligible, they are encouraged to contact a local clinical site for follow-up.

While site contact information is provided on the recruitment website, potential participants may also opt to e-mail the site closest to them directly if they click on the “Contact Us” link on the website. Doing this displays a screen into which they enter basic contact information. When they send this information, an e-mail is sent to the recruitment coordinator at each clinical site (or their designee), informing them that a new person has requested information from the website. The recruitment staff then should go to the study data entry website, where they can run the “Recruitment – Contact Us” report that will display the contact information for that participant. It is important to know that this information is **not** archived at the CC; it is deleted after two weeks.

As a part of the “Contact Us” information, the participant provides the state in which they live. For states in which there is no obvious way they participant could take part in the study (e.g. Iowa, Florida, New Hampshire, etc.), their e-mail is directed to the CC, where staff will communicate with the sender to explain that there is not a WLM site in their area. In addition, the CC receives a copy of every e-mail sent to each site from this website, to assure that the system is working and the sites are receiving the necessary information from the site.

## **11.2 Secure Websites: Study Administration, Randomization and Data Entry**

The URL for the WLM administrative website is <https://www.wlmtrial.org/manage> or <https://www.kpchr.org/wlmmanage>. Note that this is a secure website, and is subject to a higher security standard than the recruitment or intervention websites. This website will house all study-related documents, information, reports and data. Access is granted by the CC and is authenticated by username and password.

It is absolutely necessary that study staff using this website be signed on under their own username and password while using any facet of this site. WLM site staff should work to assure that all users of the WLM study site are login in using their own CC-supplied username and password. Sites should **never** allow other site staff to sign on with any username but their own. If the CC determines that users are operating under a different signon than their own, or have given their username and password to other staff to use, their access to the website will be terminated, and a report will be made to their site PI, CC PI and NHLBI Project Officer to determine further action.

*Username and Passwords:* WLM staff persons are supplied with a username and password by the CC. The site must make an initial request to the CC for this to occur. The contact person at the CC for assigning new accounts is Rina Smith (Rina.Smith@kpchr.org). The site must provide the following information to the CC in order to get a username/password for a staff person:

- Name
- Role on WLM
- Blinding status (Is the staff person blinded to any portion of the study? If so, which?)
- E-mail and phone number

Delay in providing this information will result in a delay in assigning a username/password. In most cases, these will be assigned by the CC within 24 hours of complete receipt of information from the site.

The username will define to the administration website what functions the user can complete on the website. For instance, staff who are not identified as “data entry” will not be allowed to go to the part of the website that pertains to data entry. Likewise, various documents and folders will only be available to users who have been given permission to view them. This will allow the CC to post to a central area any number of private communications (e.g. DSMB reports, Steering Committee information, NHLBI reports) without having to construct entirely new areas or applications to hold them. If a user believes that they should have access to a certain area on the website, they should contact their site coordinator to a) check to assure that they should indeed have access to that area and then b) have the site coordinator contact the CC to arrange for access.

*Logging On:* In order to log onto the study administration website, the user **must** be using version 5.0 or higher of the Internet Explorer browser. Using a version of the Netscape browser will cause the website to not be fully functional for the user.

Users should proceed to the URL noted above and they will be prompted to enter their username and password. Usernames are **not** case sensitive, however, passwords **are** case sensitive. If the site is not allowing login to proceed, site personnel are asked to double-check their “caps-lock” key to assure that it is not accidentally depressed.

The first time study staff log onto the site, study staff will be asked to change their password. It is important to note that the CC does not keep an accessible record of staff passwords. This is done to enhance security. If staff lose or forget their passwords, they will be assigned a new one by the CC, and staff will need to change it once they log into the site.

*Confidentiality of Data:* All data are stored in password-protected datasets at the CC. Access to data by the site staff is restricted by their username; the user’s site is embedded so that they may only view data from their site. Access to folders and reports is restricted as described above.

*General Instructions:* When staff first log into the website, they are presented with a menu of options that run along the left-hand side of the screen. These options are:

- All Track
- Bulletin Board
- Document Management
- E-mail Groups
- My Information
- Reports
- Calendar
- Data Entry/Management

Not every user will have access to all of these options, and these options may in fact be further limited once you enter them. For example, intervention staff will have access to the Data Entry/Management section of the website, but will be limited to viewing, entering and reading reports that specifically pertain to Phase I and Phase II intervention.

A brief description of these items is as follows:

All Track: This is primarily used by the CC to track internal administrative and analytical procedures. Some site staff may be granted access to all or part of All Track to assist the CC with such tracking. As a general rule, most website users will not have access to this application.

Bulletin Board: All staff will have access to the study bulletin board.

Document Management: This is where all study documents are filed. When you open document management, those folders you have access to will be displayed. Clicking on those folders will open them up, displaying files that may be opened and viewed, or perhaps other subfolders. The WLM administrative website will support many file types (e.g. PowerPoint, Excel, Acrobat, Word, etc.) which can be opened just by double clicking on them. It’s important to remember that the user must have the software on their computer in order to open the file. For example, the staff must have PowerPoint installed on their computer in order to open a PowerPoint file.



E-Mail Groups: Users are organized into “groups”, for example, D&A, Clinic Coordinators and Recruitment. Usually these groups correspond to a Committee on WLM, but not always. Any WLM group can be created by notifying the CC of who is in the group, the group’s name, and their purpose. To e-mail the group, click on the “Click Here to e-mail the group now” link at the bottom of the screen. In most cases, your e-mail program will create an unsent e-mail with the distribution list of the group you have selected. You may type in your text and then send. You may also use attachments from this screen.

My Information: This allows you to change your a) name, and b) e-mail as they change throughout the study. Please be aware that this is the primary way the website knows who you are. If your e-mail is incorrect, you will not receive any e-mails from the system. This screen also lists your site and your group membership(s). You may also change your password here by clicking on the “Change Password” button. This may be done at any time.

Reports: This option will not be available to all users. Most reports will be filed under “Document Management”, however, there are some dynamic reports that are available to a select group of users, usually CC staff. As dynamic reports are built and made available, non-CC staff will increasingly use this option as the study progresses.

Calendar: All study-based events (meetings, conference calls, site visits, etc.) may be posted on the calendar. These events may be restricted to individuals (e.g. Svetkey, Vollmer, Heinith) or groups (e.g. D&A Committee). You may view all events posted on the calendar, or click on “View only my events” to see the ones you are involved in.

Be aware that as new events are created, an e-mail reminder is sent to all participants of the event if the organizer wishes to do so.

Data Entry/Management: This link opens the WLM data entry/management application (DEMA), including randomization and Phase I group assignment. All study data are entered through this site. The full set of data entry options and capabilities are described in section 12.

### **11.3 Secure Website: IT Intervention**

One study arm in WLM is the “Innovative Technology” (IT) arm where participants will receive a weight loss management intervention entirely over the Internet at a website designed and hosted by the CC. Participants randomized to this arm of the study should check into the site regularly to receive tips on how to maintain their Phase I weight loss, participate in discussions with other participants, and ask questions of weight-loss and exercise experts. Participants randomized to this intervention should have at a minimum either 1) IE 5.0 or higher, or 2) Netscape 6.0 or higher.

When a participant is randomized to the IT arm, the DEMA will print a report with the website URL, the participant’s username, and their initial password to get into the site. Participants will need to set aside at least 30 minutes to complete their initial check-in phase of this intervention. A site-designee should be available to assist participants logging in for the first time. Subsequent questions regarding the website will be directed to the CC via the website itself. If sites have questions regarding the site, they should contact Kristy Funk (Kristine.Funk@kpchr.org).

### **11.4 Secure Website: File Transfer System**

The accelerometer used in the WLM study will download a small data file for each participant. Please refer to Section 7.5 for instructions on how to download and name these files.

Once these files are ready, they must be sent to the CC for analysis. This will be done using a File Transfer (FT) website. The web address for this site is <https://secure2.kpchr.org/wlmft>. This website is a secure site that will allow sites to transfer their accelerometry files to the CC electronically via the Internet, rather than by floppy disk transfer via regular ground delivery.

Only certain staff may have access to this site, and they must first have an authentication certificate (Digital ID) installed on their computer in order to transfer data files. Failure to have this certificate installed will result in the data not being transferred to the CC. Since the certification process is somewhat complicated, it is recommended that only two persons from each site complete the process. Ideally these two people will be able to serve as back-up to each other. If a site knows initially that they will need more than two people, it is permissible to have up to four certificates installed at each site.

Sites should begin this process as soon as they identify their FT people. These should be staff who are at home with using the Internet, and who understand the basic tenets of copying files on the computer. Once staff are identified, transmit their names, role and e-mail to Rina Smith (Rina.Smith@kpchr.org) and Carrie Meeks (Carrie.S.Meeks@kpchr.org) at the CC. The process to have the certificate installed can take as little as a few days, or as long as a month, depending upon the computer set-up at the site. Sites are encouraged to begin this process as soon as possible.

Once the certificate is installed, the staff may reach the FT site at the above address. The procedure to transfer a file is outlined in Chapter 12 under section 12.5 Accelerometer file transfer website.

Notify Rina Smith and Carrie Meeks at the CC via phone or e-mail once the file transfer is complete.

# Weight Loss Maintenance MOP

## 12 Data Management

### Summary of edits between Version 1.0 and Version 1.1:

- Section reorganized to add 4 new sections; old sections re-named
- The process to transfer a file has been rewritten and moved from 11.4 to 12.5 section 3.

### Summary of edits between Version 1.1 and Version 1.2:

- Section 12.1 completed.

### Summary of edits between Version 1.2 and Version 1.3:

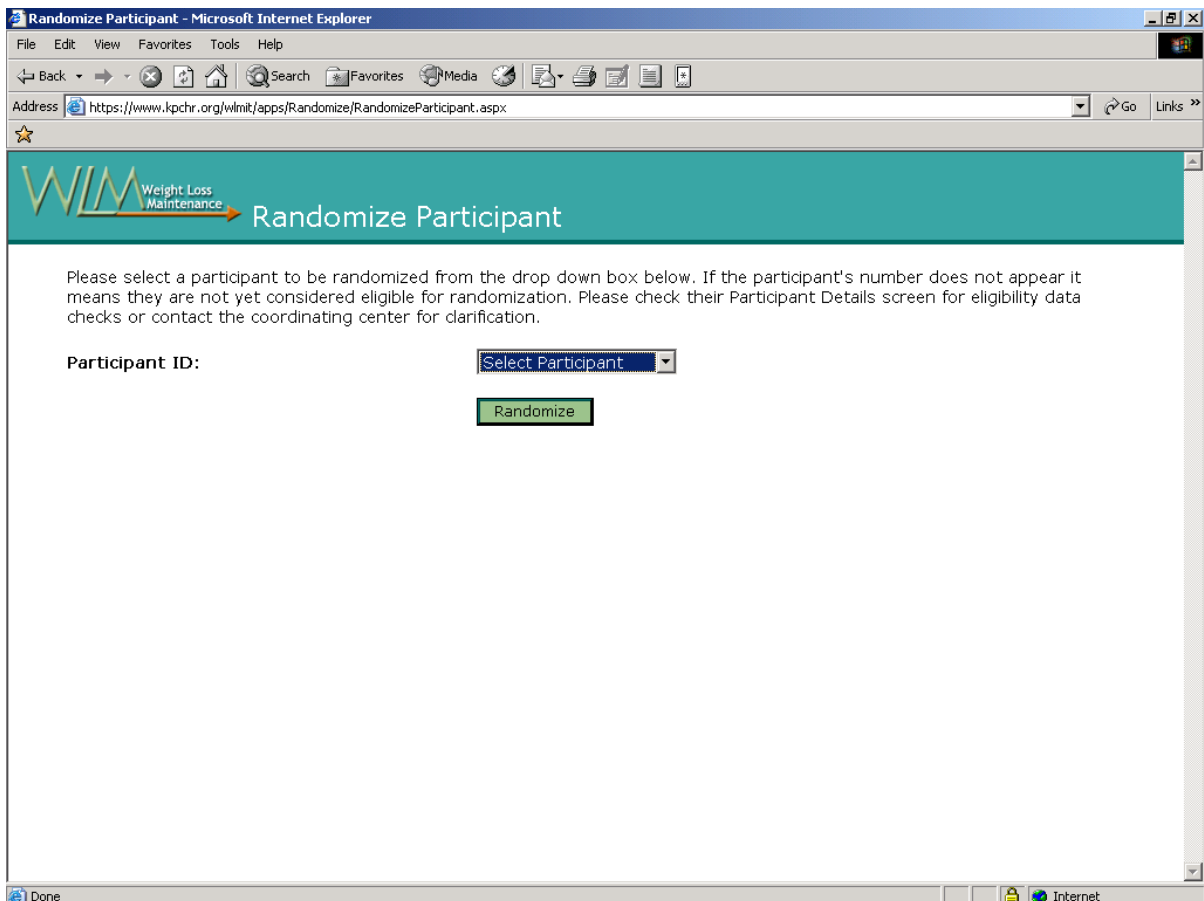
- Section 12.7 updated for Data Query Report instructions

## 12.1 Randomization into Phase II

Prior to randomization, the site should verify that all eligibility data items have been entered into the DEMA, and that no outstanding eligibility checks are present. Missing eligibility data forms, or outstanding eligibility checks will prevent the site from randomizing a participant.

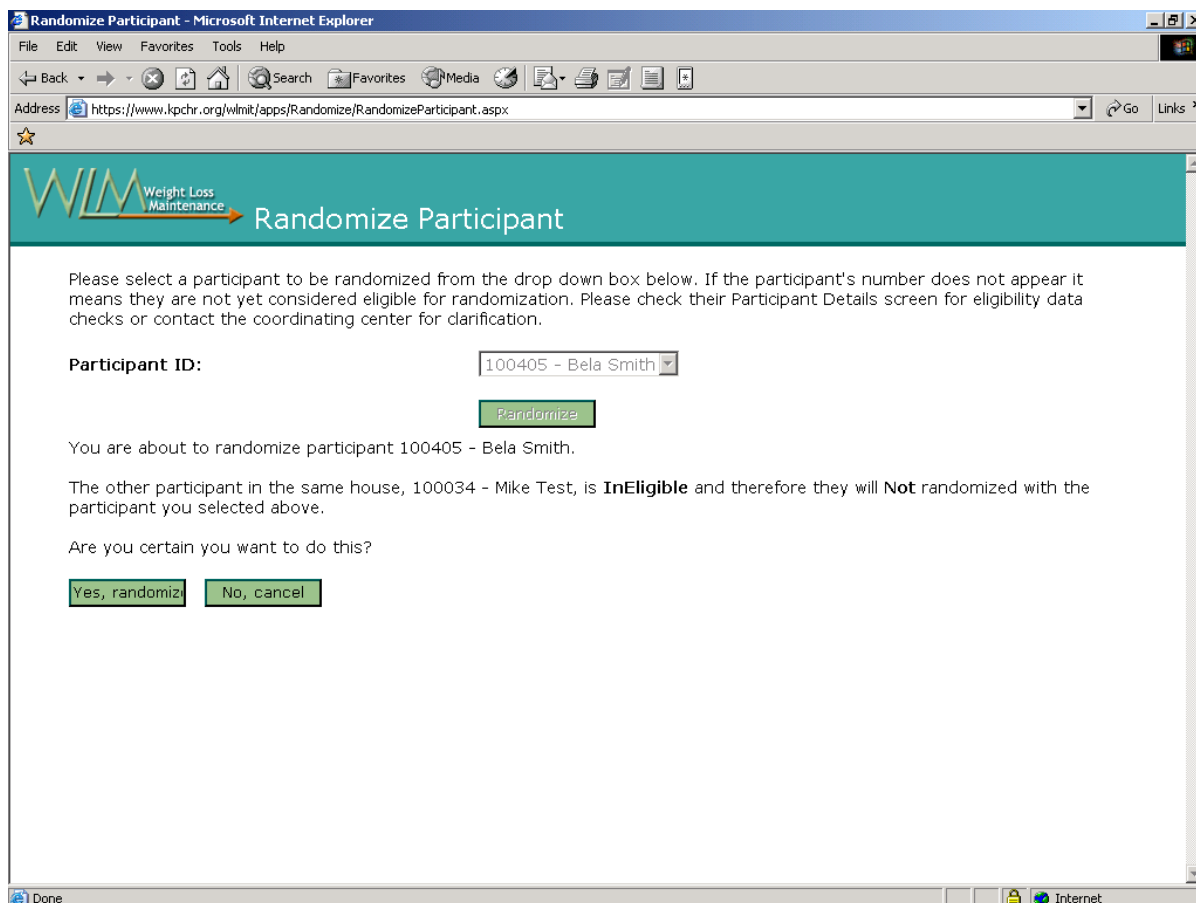
To randomize a participant, log onto the WLM IT website at <https://www.kpchr.org/wlmit>. If you only have randomization privileges, you will be directed after logging in directly to the randomization screen. If you are an interventionist, you must first proceed to the WLM IT Home Page, and then select “Site Admin” and then “Randomize A Participant”.

The WLM randomization Screen looks as follows:

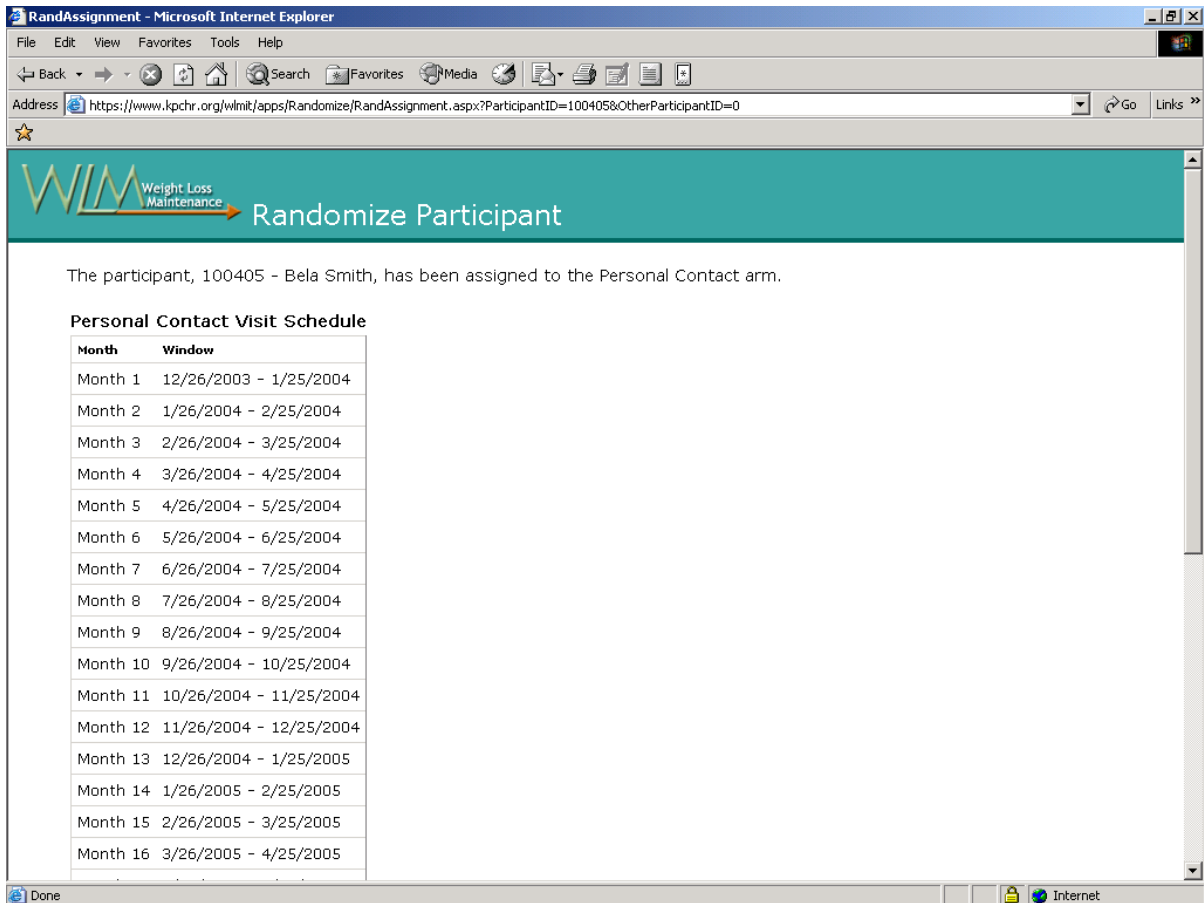


To randomize a WLM participant, choose their name from the drop down box. If the participant's name does not appear, then they are not yet eligible for randomization. Check to assure that all eligibility forms have been entered, and that no outstanding eligibility checks are present.

When you are ready to randomize the selected participant, click on the "Randomize" button. You will receive a message asking if you wish to truly randomize the participant. Click "Yes" to randomize the participant, "No" to cancel and start over.



After randomization, the participant's randomization assignment and clinic visit schedule will appear. You have the option of printing this schedule at this time.



You may choose to randomize another participant or logging out of the system at this time.

If a participant is randomized to the PC arm, a print out will be available that also has their PC contact schedule. If they are randomized to IT, then an introductory letter with initial login information will be available and should be printed out at that time.

If any problems occur with randomization, contact the CC immediately.

## 12.2 Data Entry Using the WLM Secure Website

All WLM staff must have an approved username and password to access the WLM data entry and management program (DEMA). Details for how to obtain logon privileges are located in detail in Section 11 of the MOP.

Specific coding and entry instructions are provided for each WLM form as a part of that form and should be referred to when collecting and entering study data.

General principles of data entry for the WLM study are as follows:

- Data should be entered as soon as possible following collection. Doing so will allow the WLM data checks to operate and identify sources of possible error within the data so that they may be corrected in a timely manner.
- All WLM forms have codes next to checkboxes (e.g. Yes  1), which indicate the code that should be entered for the associated answer. In the example above, a “1” should be entered to denote a “Yes” answer to the question.
- Only data fields that need to be entered are displayed on the data entry screen. If codes are not provided on the forms for checkbox answers, then the question does not have to be entered into the system.

- In some cases, text entry is required. Please do not use abbreviations (e.g. BTW) when typing text, although basic medical abbreviations (e.g. qd) are allowed.
- Access to specific DEMA forms is limited by your user role. If you are an interventionist, then you may only view and/or enter intervention forms. If you are a full data entry person, you will have access to all forms.

To access the DEMA, log onto the WLM main website at <https://www.kpchr.org/wlmmanage>. If you have data entry privileges, the link “Data Entry/Management” will appear at the bottom of the list of website options on the left. Click to enter the DEMA.

The home page of the DEMA has four links that comprise the system. These are:

- **Forms:** Click here to enter data. A list of all forms for which you have data entry privileges will appear. You may add (enter new data), edit (modify existing data), verify (reenter data as a part of a QC check), view (look at data only with no modification privileges), or delete records. To perform any function on a form, you must first *select* the form by clicking the “select” link to the left of the form name. The buttons at the bottom will activate and allow you to perform the stated functions.
- **Participant Management:** This is the main area where participant information is stored. You may search for a participant by name (first or last), or by their WLM ID number. Clicking on the “select” link allows you to work on that participant. You may also edit the participant’s name, assign them to a Phase I group, and run their eligibility and form checks here. Additionally, you may also add participants to the DEMA through this screen.
- **Groups:** In order to identify a participant with a Phase I group, that group needs to be entered into the system. Use the “Groups” link to do so. *Note that there is no form to capture this information.* This is entered and maintained by the site. You may add, edit or view groups, and enter all necessary information concerning them on this screen.
- **Reports:** All reports that run off of the “real time” study database may be run from this screen. In most cases, these are eligibility reports, or reports that show the forms status for participants at your site.

### 12.3 Procedure for WLM Study Participants to Submit Study ID to the Webtest Website for Internet Eligibility Requirements

1. Sites should prepare participants about internet eligibility requirements prior to sending them an e-mail about the Webtest website.
2. Sites may e-mail the following text to participants. Please ensure the correct study participant ID is stated in the e-mail.

Dear <insert participant name here>,

Thank you for your participation in the Weight Loss Maintenance Study (WLM).

As part of the eligibility requirements, we require you to access a WLM Study website. When you click on the website address below, it will take you to the WLM Web Test Website. On the website, please type your 6 digit study ID <insert participant study id here> in the WLM Number box and then click on the “Send” button. You will only need to enter your study ID once on this website. Please contact me if you have problems submitting this information to the website. Otherwise, please do not reply to this message.

<http://www.wlmtrial.org/Anonymous/WLMWebTest.aspx>

<insert staff signature and contact details here>

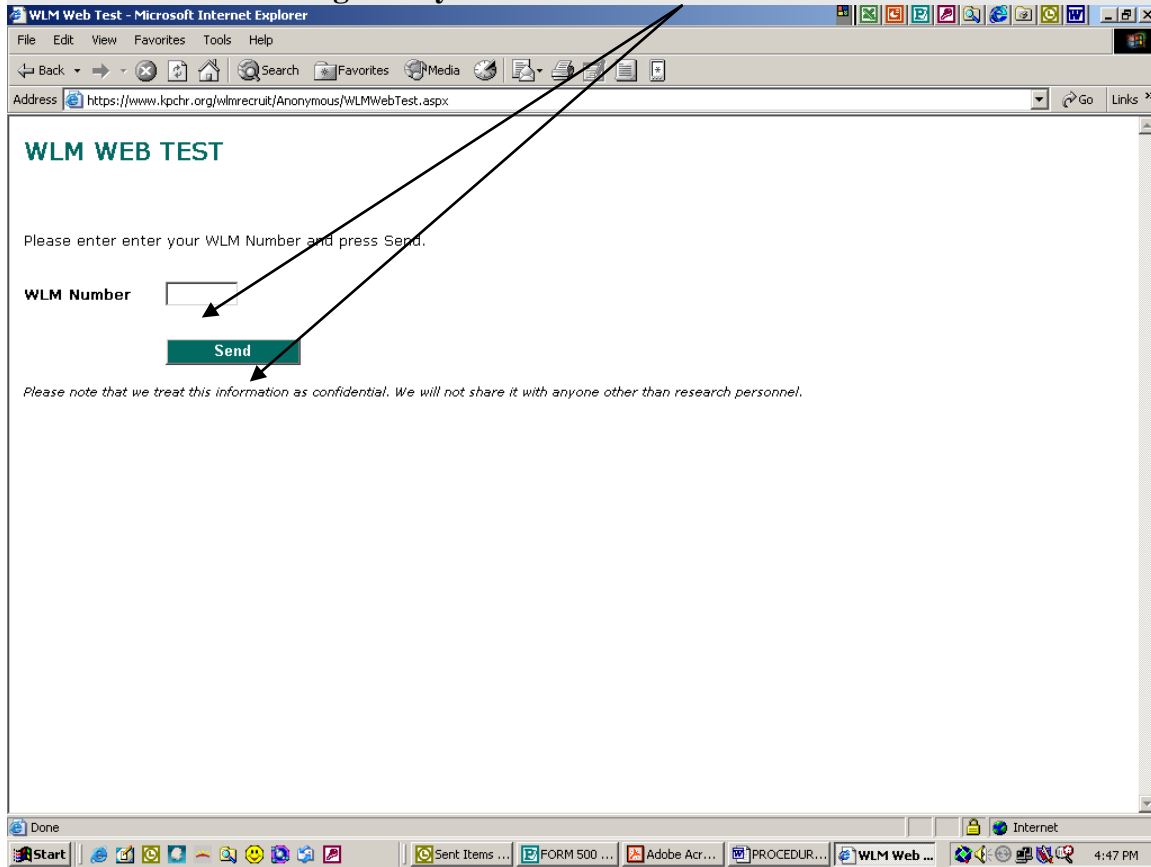
3. A participant may click on the website link directly from the e-mail message to go to the test website. They should then enter the 6 digit study ID and click the “Send” button (see Web shot 1).

4. Once the participant has submitted their study ID to the website successfully, sites should go the online report in WLM project website under Data Entry Management called **'Recruitment - Confirm web access'** to get a listing of participants who have successfully completed this task. Sites should review this report regularly for updated confirmations.
5. A confirmation that the participant has completed this task should be noted in Form 119 Phase 1 Eligibility, question 3.4 for data entry.

Problems:

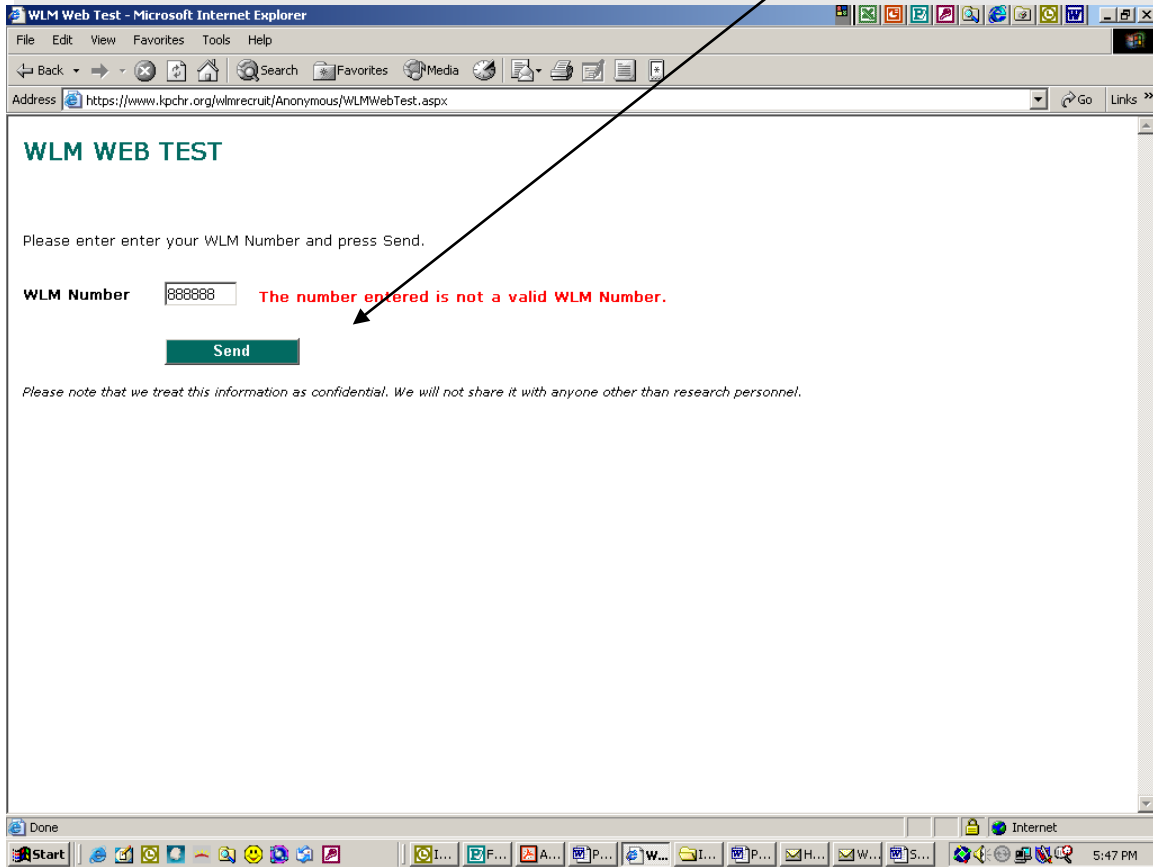
1. If the participant experiences problems submitting their participant Study ID on the website, sites may contact the participant to step them through the process.
2. If the participant tries to enter a 6 digit study ID that is not a legitimate WLM id, they will get back an error message saying **"The number entered is not a valid WLM Number"** (see Web shot 2). In this instance sites should ensure that the participant has been provided with the correct participant study ID number.
3. If the participant is not able to click on the website link straight from the e-mail message i.e. if they move their mouse over the website address and a hand does not appear, they may copy and paste the exact website address (with upper and lower case letters into the internet browser i.e. it must be exactly as the following address  
<http://www.wlmtrial.org/Anonymous/WLMWebTest.aspx>
4. If the participant encounters a website error message, get as much information including the error message before contacting the Coordinating Center. For eligibility requirements participant should be able to perform this test without difficulty. If a participant encounters difficulties that indicate their level of internet competence may pose a problem for their continued participation in WLM, or their internet browser may not support the needs of the WLM study, then it is left up to the sites to determine whether the participant should continue in the study.

## Web Shot 1: Enter 6 digit study ID and click "Send" button





## Web Shot 2: Error message if participant puts in the wrong participant study ID and clicks "Send"



## 12.4 Procedure for Repeat Accelerometer

Minimum data collection standard for accelerometer data must include at least one weekend day and four days of activity data. (94 hours or 5640 minutes). Participants not meeting this standard of data collection must be asked to repeat the measurement. This applies to screening, baseline, 12 and 30 months data collection.

For participants requiring a repeat accelerometer, the process for data collection is as follows:

1. Do not data enter the original, unsuccessful form 116. File the original in the participant chart.
2. Save the unsuccessful .csv data file on site local PC. DO NOT transfer to CC.
3. Fill out a new, repeat form 116 for the repeat accelerometer.
4. Once you get a repeat .csv data file from participant that meets the required standard, delete the old .csv data file and replace with the repeat .csv file on your local PC.
5. Data enter only the repeat form 116 and file in participant chart.
6. Transmit only the new repeat data that now meets the standard to CC via file transfer website.

Upon review, if the repeat .csv data file does not meet the required standard, a 3<sup>rd</sup> or subsequent attempt is being left up to sites to determine based on a participant's window and availability of accelerometers. The number of repeat attempts is not stated in the protocol.

After a repeat measurement if a site determines it cannot get a file from a participant that meets the standard, contact the Coordinating Center

## 12.5 WLM Accelerometer File Transfer Website Procedure

### 1. General Instructions

These instructions apply once a site person has been given authorized access to the File Transfer Website from the WLM Study Coordinating Center.

- Accelerometer files must be zipped before being posted to the File Transfer Website.
- Each accelerometer file enclosed in the WinZip file should follow the following agreed WLM accelerometer file naming convention with underscores: XX\_XX\_XXXXXX
  - First 2 digits is the site identifier. For Baltimore this is 01, Baton Rouge 02, Duke 04, Portland 09.
  - Second 2 digits is the visit code (02 = screening, 04 = baseline, 07= 12 months, 11 = 30 months)
  - Last 6 digits is the 6-digit participant ID.
  - Separate the site, visit and participant ID with underscores, i.e., 01\_02\_103826
- The maximum number of accelerometer files in a WinZip file should be a week's worth.
- A WinZip file should be posted weekly to the WLM File Transfer Website and an e-mail notification sent to Rina Smith [rina.smith@kpchr.org](mailto:rina.smith@kpchr.org) and Carrie Meeks at [carrie.meeks@kpchr.org](mailto:carrie.meeks@kpchr.org)
- Quality Control checks will be done on WinZip files once they are downloaded at the Coordinating Center.
- Sites should therefore store WinZip files on a designated file directory for the life of the WLM Project.
- Sites should also store the original, unzipped accelerometer files on disks or on a designated file directory for the life of the WLM Project.

### 2. Instructions for Creating a WinZip File

1. Click on the **WinZip icon**. This will open the work area.
2. Click on **"New"**. This will open up a new archive area.
3. Then select the file directory where you want your WinZip file to be stored.
4. In the **"File Name"**, specify the WinZip file name according to the following naming convention:

## ACC\_XX\_MMDDYYYY

XX is the site identifier and MMDDYYYY is the date you are creating the WinZip file name. Example ACC\_02\_08012003 for Baton Rouge on August 01, 2003.

5. Then click “**Ok**” This will open up an Add screen.
6. Click on “**Add**” and from the drop down list find the directory that has the accelerometer files stored.
7. Hold down the **CONTROL** key and select the accelerometer files from the directory to be copied over to the WinZip file
8. Click ‘**Add**’. You will now see the files you have added to the WinZip folder.
9. Go to the “File” menu and select “**Close Archive**”.
10. There will now be a file called **ACC\_XX\_MMDDYYYY.zip** on your designated directory.
11. Save the original accelerometer files that you have added to the WinZip File. A WinZip file will ensure that the accelerometer files you have copied are included in only one archive and are posted only once. Keeping only the WinZip file stored on your hard drive will give you more storage space on your hard drive. However if something does go wrong with WinZip and uploading/downloading process, sites need to ensure they have a copy of the original, unzipped file available for uploading again.

If you find you need to do the following:

Add a missed accelerometer file to an existing WinZip file BEFORE you post to the website:

Open saved WinZip file. Click “**ADD**” and select relevant file to be added from the directory. Then click “**Add**” to copy file. The missed file should now be displayed in WinZip fold. Go to “**File**” menu and select “**Close Archive**”

To delete a file from an existing WinZip file BEFORE you post to the website:

Open saved WinZip file. Highlight the accelerometer file you want to delete. Go to “**Actions**” and click on “**Selected file**” and then click on “**delete**”.

12. Upload the saved WinZip file to the file transfer web site.
13. Store the WinZip file on a designated directory for the life of the WLM Project.

### 3. Instructions for uploading WinZip file to the WLM File Transfer Website

1. Logon to WLM File Transfer site <https://secure2.kpchr.org/wlmft> with your assigned username and password.
2. Click on “**project name**” link under "Select a content area" on the main page.
3. Click on the "Post New File" icon on the right hand side of the page.
4. This will bring up the "Post a New File" page. If this is first time you have used the site, then you will be prompted to download an active X control. Say yes to this prompt. After the control downloads you will be presented with an empty box with buttons labeled "Add", "Delete", "Start Upload". Click on the "Add" button to browse for the zipped file you want to upload. Once you have selected the file it will be placed in the box. Click on the "Start Upload" button to start the upload process.
5. Once the transfer is complete, you will be presented with a page that asks for a title and summary of the file you are uploading. **Enter a title and summary** and then press the "Add" button at the bottom of the screen.
6. The file should now be posted in the "specified" folder on the secure web site.
7. Notify Rina Smith and Carrie Meeks at the CC via phone or e-mail once the file transfer is complete.

**If required: To delete a WinZip file on the WLM File Transfer Website, please perform the following steps:**

1. From the home page, click on File Management
2. In the list of all files, locate your file to delete. You can only view & delete files YOU posted.
3. Click on the “radio button” (small circle/dot) to select that file.
4. At the bottom of the page, click “delete”.

**If required: To download a file from the WLM File Transfer Website that CC may sent you, please perform the following steps:**

1. Click on your “**Project/Site/Folder**” link under “**Select a content area**” on the main page.
2. Double-click on the file icon next to the file you want to download, and select the “**SAVE**” option. Select a location for the file and then click the “**Save**” button. **OR, you can Right Click** on the file icon and select “**save target as**”.

## **12.6 Data Flow From Clinical Screening Forms to Phase I Intervention Forms**

In general, please note that all WLM staff who has access to the WLM website, will not have access to the Data Entry Management Application (DEMA) part of the WLM website. If access to DEMA is required for entering group information, Phase 1 data entry, running Form 200 and triage reports, send an updated WLM Website Access/Staff ID Request Form to Rina Smith and Carrie Meeks at the Coordinating Center so the correct access privileges can be assigned. If staff already have access to DEMA but are seeing the word “*Training*” at the top of the screen and will be doing the above tasks, please send an updated Website Access/Staff ID form. Ensure any relevant training has been provided to the site staff before they proceed to enter data on the ‘live’ database.

### How to Add A Phase 1 Group to DEMA

Ensure that the site staff entering group information has been assigned the correct access privileges **i.e. the staff person is NOT seeing the word “*Training*” when they access the DEMA application.**

1. Log onto the WLM website at <https://www.kpchr.org/wlmmanage/>
2. Select *Data Entry Management* then *Groups*.  
*See Webshot 1, 2.*
3. Select *Add* and enter all the relevant group information for a group that is ready to start i.e. *Group Name, Group Description, Start Date, Completed Date* (if known), *Interventionist* running that group, *Group Composition, Notes* (if needed). Then click *save* to store this information. The minimum fields that must be populated are: Group Name, Start Date, Interventionist, and Group Composition. *See Webshot 3, 4.*
4. To view the Group ID # for an assigned group. Go back to the *Groups* screen after a group’s information has been saved and the Group ID # will be displayed in the Group ID column.  
*See Webshot 5.*

### How to assign a Participant to a Group, Generate and Enter a Form 200

1. Ensure participant has met all screening eligibility criteria **before** being assigned to a Phase 1 Group. Clinical Form 119 Phase 1 Eligibility Review lists all the eligibility criteria for a participant.
2. Assign a participant to a group by filling out Form 126 Initial Group Assignment. Make sure the correct Group ID # for the relevant group is noted on the form.
3. Go to the WLM website/*Data Entry Management* and select *Participant Management* screen. Enter *Participant ID* and click on *Search* to bring up their record. *See Webshot 6,7.*

4. Select **Edit Details** and then **Group**. From the drop down list, select the group the participant is being assigned to. Then click on **Save**. *See Webshot 8.*  
Note well that the **Group** you assigned the participant to in the **Participant Management** screen must match the Group ID # the participant is assigned to on Form 126 Initial Group Assignment.
5. Data enter Form 126 Initial Group Assignment (this step can be delayed until after Form 200 is generated for a group session). However data entry of Form 126 is critical for Trial Monitoring Reports.
6. To generate Form 200 for use at a group session, go to **Data Entry Management/Reports** and select **Phase I-Intervention Attendance report**. Click on **Run Report** and then select the relevant **Group** you are interested in from the drop down list. Click **run with parameters** and a report for the relevant group will be displayed. To print, select from the print icon (see top of report, 3rd option) and then follow prompts to print all pages. Use this Form 200 report to collect attendance and weight data for the relevant group and session. *See Webshot 9,10,11,12.*
7. To do data entry of Form 200 Report, go to **Data Entry/Management** then **Forms**. Select Form 200 from the forms list. Then select **Add a record**.

*See Webshot 13,14.*

Proceed with data entry of form. Enter the **Group Session Date, Group Session # G, Group ID #, Interventionist ID #** and **Participant ID** from the first row. Then enter their attendance and weight information and click on **Accept**. To enter the next participant ID information, click the **continue** button each time and then enter the next participant ID in the top part of the form, before entering their attendance and weight data. Once all the data are entered, click on **Accept** to save Form 200 to the database. *See Webshot 15, 16.*

### How to Change a Participant's Group Assignment once they have already been assigned to a group

These instructions only apply whenever there is a **permanent change** to a participant's group assignment. The changes below should be done prior to the participant's next group session so that the participant is showing up under the correct group on a Form 200 report for the next session

1. Assign the participant to the new group by filling out Form 206 Change of Group Assignment.
2. Go to the WLM website/**Data Entry Management** and select **Participant Management** screen. Enter **Participant ID** and click on **Search** to bring up their record.
3. Select **Edit Details** and then **Group**. From the drop down list, select the new group the participant is being assigned to. Then click on **Save**.  
Note well that the **Group** you assigned the participant to in the **Participant Management** screen must now match the new Group the participant is assigned to on Form 206 Change of Group Assignment.
4. Data enter Form 206 Change of Group Assignment. This step can be delayed until after Form 200 report is generated.
5. To generate Form 200 report for use at a group session, go to **Data Entry Management/Reports** and select **Phase I-Intervention Attendance report**. Click on **Run Report** and then select the relevant **Group** you are interested in from the drop down list. Click **Run with parameters** and a report for the relevant group will be displayed. For any permanent changes to a group, the participant should now show up under the new group. To print, select from the print icon (see top of report, 3rd option) and follow prompts to print all pages. Use this report to collect attendance and weight data for the relevant group and session.

6. Data enter Form 200.

## How to Change information for an Interventionist leading a Group

These instructions only apply whenever there is a **permanent change** to the main interventionist leading an assigned group. The changes below should be done prior to the affected group's next group session so that the correct interventionist is showing up under the interventionist information on a Form 200 report for the next session.

1. Assign the new interventionist to an existing group by filling out Form 207 Change of Main Interventionist.
2. Go to the WLM website/Data Entry Management and select Groups and then the group that is affected by the permanent change in main interventionist.
3. Select Edit and under Interventionist drop down list, select the new name of main interventionist that will be leading this group. Then click save to store this information.
4. Note well that the new Interventionist you have assigned to lead a group in the Group screen must match the new Interventionist details on Form 207 Change of Main Interventionist.
5. Data enter Form 207 Change of Main Interventionist. This step can be delayed until after form 200 report is generated.
6. To generate Form 200 report for use at a group session, go to Data Entry Management/Reports and select Phase I-Intervention Attendance report. Click on Run Report and then select the relevant Group you are interested in from the drop down list. Click Run with parameters and a report for the relevant group will be displayed. For any permanent changes to an interventionist leading an existing group, the new interventionist should now show up for the group affected by the change. To print, select from the print icon (see top of report, 3rd option) and then follow prompts to print all pages. Use this report to collect attendance and weight data for the relevant group and session.
7. Data enter Form 200.

### Web Shot 1: Log onto the WLM website and then select Data Entry/Management

Default - Microsoft Internet Explorer

Address <https://www.kpchr.org/wlmanage/apps/default.aspx>

**WLM** Weight Loss Maintenance

Welcome to the new Weight Loss Maintenance project website!

Use the menu options to the left (above the calendar) to explore the many areas available to you on the site. Please be sure to check the "My Information" area to assure that we have your correct e-mail address and that your name is spelled correctly. We hope this site will be useful to you in tracking the many goings-on in WLM.

If you have any questions or problems with the website, please contact Rina Smith at [rina.smith@kpchr.org](mailto:rina.smith@kpchr.org) or (503) 335-6378.

All Track  
Bulletin Board  
Calendar  
Documents  
Email Groups  
My Information  
Reports  
Site Management  
**Data Entry/Management**

August 2003

Sun	Mon	Tue	Wed	Thu	Fri	Sat
> 27	28	29	30	31	1	2
> 3	4	5	6	7	8	9
> 10	11	12	13	14	15	16
> 17	18	19	20	21	22	23
> 24	25	26	27	28	29	30
> 31	1	2	3	4	5	6

## Web Shot 2: Go to Groups

DEMA Main - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://www.kpchr.org/wlm/manage/apps/dema/default.aspx>

WLM HOME • All Track • BB • Calendar • Data Entry/Manage • Documents • Email Groups • My Info • Reports • Site Admin

DEMA HOME • Forms • Participant Management • Groups • Reports • Show Main Menu

### Data Entry/Management

[Forms](#)  
[Participant Management](#)  
[Groups](#)  
[Reports](#)

### DEMA Updates and News

08/21/2003 - 09/04/2003 **What's New with DEMA**  
Changes to DEMA were made and they include:

- Updated the report, "Phase I - Intervention - Participant Feedback" with several small changes.
- Updated the calculation of starting weight to exactly match the algorithm provided by Bill Vollmer.
- Updated the calculation of screening status to catch InEligible outcomes on form 105.

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08/15/2003 - 09/02/2003 **What's New with DEMA**  
Changes to DEMA were made and they include:

- The following forms are now available for Data Entry:
  - Form 200: Phase 1: Attendance and Weight Log Form
  - Form 201: Phase 1: Self Monitoring Data Collection
  - Form 202: Phase 1 Missed Session Form
  - Form 205: Short Physical Activity Form
  - Form 206: Change of Group Assignment Form
  - Form 207: Change of Main Intervention Form

---

08/15/2003 - 09/01/2003 **What's New with DEMA**  
Changes to DEMA were made and they include:

- Updated the report, "Phase I - Intervention - Triage Group", with multiple small formatting and layout changes.
- Updated the report, "Phase I - Intervention - Participant Targets", with change to calculation of

Start | Internet | 11:13 AM

### Web Shot 3: Click on Add to enter details for a new group.

The screenshot shows a Microsoft Internet Explorer browser window displaying a web application titled "WLM DEMA - Group List". The browser's address bar shows the URL: <https://www.kpchr.org/wlmmanage/Apps/DEMA/GroupList.aspx>. The page content includes a navigation menu with "DEMA HOME", "Forms", "Participant Management", "Groups", "Reports", and "Show Main Menu". Below the navigation is the heading "WLM DEMA - Group List" and a sub-heading "Number of groups: 12". A table lists 12 groups with columns for Group ID, Group Name, Interventionist, Start Date, Completed Date, and Site. Each row has a "Select" link in the first column. Below the table are five buttons: "Add", "Edit", "View", "Delete", and "Exit DEMA". A black arrow points from the top of the page down to the "Add" button. The Windows taskbar at the bottom shows the Start button, several application icons, and the system clock displaying 11:43 AM on 03/26/04.

	Group ID	Group Name	Interventionist	Start Date	Completed Date	Site
Select	12	ACHIEVE #1	Dana Larson	08/19/2003	01/20/2004	Portland
Select	27	ACHIEVE #10	Pam Evans	02/11/2004	06/30/2004	Portland
Select	28	ACHIEVE #11	Dana Larson	02/26/2004	07/26/2004	Portland
Select	29	ACHIEVE #12	Pam Evans	03/09/2004	08/03/2004	Portland
Select	13	ACHIEVE #2	Pam Evans	09/03/2003	02/04/2004	Portland
Select	14	ACHIEVE #3	Dana Larson	09/18/2003	02/19/2004	Portland
Select	15	ACHIEVE #4	Pam Evans	09/30/2003	03/02/2004	Portland
Select	22	ACHIEVE #5	Kathy Schwab	10/15/2003	03/17/2004	Portland
Select	23	ACHIEVE #6	Kathy Schwab	10/30/2003	04/08/2004	Portland
Select	24	ACHIEVE #7	Kathy Schwab	01/07/2004	05/26/2004	Portland
Select	25	ACHIEVE #8	Kathy Schwab	01/07/2004	05/26/2004	Portland
Select	26	ACHIEVE #9	Dana Larson	01/27/2004	06/15/2004	Portland



## Web Shot 4: Add details for a group ready to start and then save.

The screenshot shows a Microsoft Internet Explorer browser window displaying a web application titled "WLM DEMA - Group Detail - Add Mode". The browser's address bar shows the URL "https://www.kpchr.org/wimmanage/Apps/DEMA/GroupDetail.aspx". The page has a blue header with navigation links: "DEMA HOME", "Forms", "Participant Management", "Groups", "Reports", and "Show Main Menu".

The main content area contains a form with the following fields and values:

- GroupID:** (empty)
- Group Name:** ACHIEVE #1
- Group Description:** Tuesdays 6-8 pm, demo classroom
- Start Date:** 8/19/2003
- Completed Date:** 1/20/2004
- Interventionist:** Larson, Dana
- Group Composition:**  All African American  Not All African American
- Notes:** Meets Tuesdays 6-8 pm, demo classroom

At the bottom of the form, there are three buttons: "Save", "Cancel", and "Exit DEMA". A red arrow points from the top of the page to the "Save" button.

The Windows taskbar at the bottom shows the Start button, several application icons, and the system tray with the time "11:41 AM".

## Web Shot 5: To find out group id # of group you have just entered.

WLM DEMA - Group List

Number of groups: 12

	Group ID	Group Name	Interventionist	Start Date	Completed Date	Site
<a href="#">Select</a>	12	ACHIEVE #1	Dana Larson	08/19/2003	01/20/2004	Portland
<a href="#">Select</a>	27	ACHIEVE #10	Pam Evans	02/11/2004	06/30/2004	Portland
<a href="#">Select</a>	28	ACHIEVE #11	Dana Larson	02/26/2004	07/26/2004	Portland
<a href="#">Select</a>	29	ACHIEVE #12	Pam Evans	03/09/2004	08/03/2004	Portland
<a href="#">Select</a>	13	ACHIEVE #2	Pam Evans	09/03/2003	02/04/2004	Portland
<a href="#">Select</a>	14	ACHIEVE #3	Dana Larson	09/18/2003	02/19/2004	Portland
<a href="#">Select</a>	15	ACHIEVE #4	Pam Evans	09/30/2003	03/02/2004	Portland
<a href="#">Select</a>	22	ACHIEVE #5	Kathy Schwab	10/15/2003	03/17/2004	Portland
<a href="#">Select</a>	23	ACHIEVE #6	Kathy Schwab	10/30/2003	04/08/2004	Portland
<a href="#">Select</a>	24	ACHIEVE #7	Kathy Schwab	01/07/2004	05/26/2004	Portland
<a href="#">Select</a>	25	ACHIEVE #8	Kathy Schwab	01/07/2004	05/26/2004	Portland
<a href="#">Select</a>	26	ACHIEVE #9	Dana Larson	01/27/2004	06/15/2004	Portland

[Exit DEMA](#)

## Web Shot 6: Select Participant Management

DEMA Main - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://www.kpchr.org/wimmanage/apps/dema/default.aspx>

WLM HOME • All Track • BB • Calendar • Data Entry/Manage • Documents • Email Groups • My Info • Reports • Site Admin

DEMA HOME • Forms • Participant Management • Groups • Reports • Show Main Menu

Data Entry/Management

- Forms
- Participant Management**
- Groups
- Reports

### DEMA Updates and News

08/21/2003 - 09/04/2003 What's New with DEMA  
Changes to DEMA were made and they include:

- Updated the report, "Phase I - Intervention - Participant Feedback" with several small changes.
- Updated the calculation of starting weight to exactly match the algorithm provided by Bill Vollmer.
- Updated the calculation of screening status to catch InEligible outcomes on form 105.

---

08/15/2003 - 09/02/2003 What's New with DEMA  
Changes to DEMA were made and they include:

- The following forms are now available for Data Entry:
  - Form 200: Phase 1: Attendance and Weight Log Form
  - Form 201: Phase 1: Self Monitoring Data Collection
  - Form 202: Phase 1 Missed Session Form
  - Form 205: Short Physical Activity Form
  - Form 206: Change of Group Assignment Form
  - Form 207: Change of Main Intervention Form

---

08/15/2003 - 09/01/2003 What's New with DEMA  
Changes to DEMA were made and they include:

- Updated the report, "Phase I - Intervention - Triage Group", with multiple small formatting and layout changes.
- Updated the report, "Phase I - Intervention - Participant Targets", with change to calculation of

Done

Start | Internet | Inb... | Microso... | INHOU... | DATA F... | DEMA ... | 5:33 PM

## Web Shot 7: Enter Participant ID, click on search, then select participant and click edit details.

Participant Management - Microsoft Internet Explorer

Address: https://www.kpchr.org/wlmmanage/Apps/DEMA/ParticipantList.aspx

DEMA HOME Forms Participant Management Groups Reports Show Main Menu

### WLM DEMA - Participant Management - \*\*\* Training \*\*\*

Participant Name:  The search is exclusive. For example, if you enter both a Participant ID and some or all of a name it will only find a participant if both the name and ParticipantID match.

ParticipantID:

Number of participants found: 1

	ParticipantID	Name	Phase	Pre-Randomization Status	Site
Select	100056	Duck, Daffy	Phase I		Portland

Start | Internet | 5:38 PM

## Web Shot 8: Select group participant is being assigned to and click save.

Participant Detail - Microsoft Internet Explorer

Address: <https://www.kpchr.org/wlmmanage/apps/DEMA/ParticipantDetail.aspx>

DEMA HOME Forms Participant Management Groups Reports Show Main Menu

WLM DEMA - Participant - Detail - \*\*\* Training \*\*\*

ParticipantID: 100056

SurName/Title:

First Name: Daffy

Last Name: Duck

Group: B - Orange

Cohort Number:

Study ARM:

Phase:

Screening Status:

Eligible for Randomization:

Eligibility Check Last Run:

Data Check Problems

Post-Randomization Status:

Save Cancel Check Eligibility Randomize Exit DEMA

## Web Shot 9: Select Reports.

DEMA Main - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://www.kpchr.org/wimmanage/Apps/DEMA/Default.aspx>

DEMA HOME Forms Participant Management Groups Reports Show Main Menu

Data Entry/Management

Forms  
Participant Management  
Groups  
Reports

### DEMA Updates and News

08/21/2003 - 09/04/2003 **What's New with DEMA**  
Changes to DEMA were made and they include:

- Updated the report, "Phase I - Intervention - Participant Feedback" with several small changes.
- Updated the calculation of starting weight to exactly match the algorithm provided by Bill Vollmer.
- Updated the calculation of screening status to catch InEligible outcomes on form 105.

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08/15/2003 - 09/02/2003 **What's New with DEMA**  
Changes to DEMA were made and they include:

- The following forms are now available for Data Entry:
  - Form 200: Phase 1: Attendance and Weight Log Form
  - Form 201: Phase 1: Self Monitoring Data Collection
  - Form 202: Phase 1 Missed Session Form
  - Form 205: Short Physical Activity Form
  - Form 206: Change of Group Assignment Form
  - Form 207: Change of Main Intervention Form

---

08/15/2003 - 09/01/2003 **What's New with DEMA**  
Changes to DEMA were made and they include:

- Updated the report, "Phase I - Intervention - Triage Group", with multiple small formatting and layout changes.
- Updated the report, "Phase I - Intervention - Participant Targets", with change to calculation of calories to lose 1 pound per week.

Start | Internet | 5:41 PM

## Web Shot 10: Select Phase 1 Intervention Attendance Report (Online Form 200 Report).

DEMA HOME » Forms » Participant Management » Groups » Reports » Show Main Menu

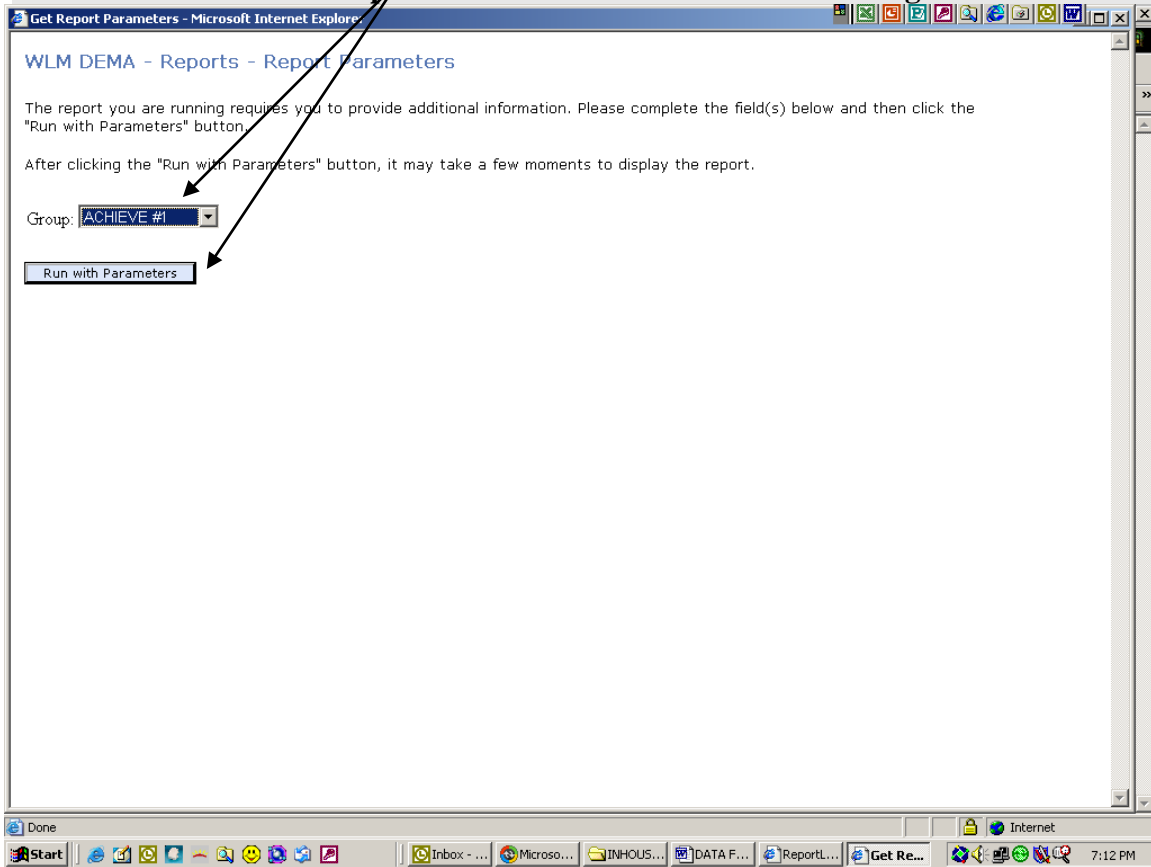
### WLM DEMA - Reports

Number of reports: 11

Report Name	Report Short Description	Creation Date	Last Modified
<a href="#">Select</a> Clinical - MD Permission	Participants who must have MD permission to take part in WLM.	05/21/2003	05/21/2003
<a href="#">Select</a> Clinical - Screening Eligibility Window	Participants actively in eligibility screening with the window of time they need the eligibility screening done within.	06/11/2003	07/21/2003
<a href="#">Select</a> Clinical - Screening Eligible	Participants who have completed their Screening Eligibility and are eligible for Phase I.	05/23/2003	05/23/2003
<a href="#">Select</a> Clinical - Screening Forms	A list of participants and what screening forms have been entered.	05/23/2003	05/23/2003
<a href="#">Select</a> Clinical - Screening Pending	Participants who have Not completed their Screening Eligibility and are not yet eligible for Phase I.	05/23/2003	05/23/2003
<a href="#">Select</a> Phase I - Intervention - Attendance	List of participants assigned to a given group, presented as Form200.	07/17/2003	08/13/2003
<a href="#">Select</a> Phase I - Intervention - Participant Feedback	Generates a individualized feedback for participants on their Phase I progress.	08/13/2003	08/21/2003
<a href="#">Select</a> Phase I - Intervention - Participant Targets	Generates individualized lifestyle targets for each participant in a group.	08/01/2003	08/15/2003

[Run Report](#)   [Exit DEMA](#)

## Web Shot 11: Select Group and click on Run with Parameters to generate Form 200.





**Web Shot 12: Example of Online Form 200 Report. Print this report by selecting the print icon (3rd left )**

DEMA Report - Microsoft Internet Explorer

Close Window View Without Pages

1 of 2 100% powered by crystal

**WIM** Weight Loss Maintenance

**Form 200: Attendance/Weight Log (by group) Form**

Group Session Date: \_\_\_/\_\_\_/\_\_\_ Y M M D D Y Y Y Y Group Session # G: \_\_\_

Site: Portland

Group ID #: 6 Group Name: Orange

Interventionist ID #: 88 Interventionist Name: Erma Levy

Row	ACTIVE Participants		Attended?		Weight Available?		If Yes enter Weight
1	Flinstone, Fred, Mr.	100001	Yes=1	No=2	Yes=1	No=2	_____
2	Flinstone, Junior	100135	Yes=1	No=2	Yes=1	No=2	_____
3	Flinstone, Pebbles	100113	Yes=1	No=2	Yes=1	No=2	_____
4	Flinstone, Wilma, Mrs.	100012	Yes=1	No=2	Yes=1	No=2	_____
5	Smith, Sally	100179	Yes=1	No=2	Yes=1	No=2	_____
6	Test, Mike	100034	Yes=1	No=2	Yes=1	No=2	_____
7			Yes=1	No=2	Yes=1	No=2	_____
8			Yes=1	No=2	Yes=1	No=2	_____
9			Yes=1	No=2	Yes=1	No=2	_____
10			Yes=1	No=2	Yes=1	No=2	_____

Done Internet

Start Inbo... Microso... INHOUS... DATA F... ReportL... DEMA ... 7:16 PM

## Web Shot 13: For data entry of Form 200 Report, go to Forms.

DEMA Main - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://www.kpchr.org/wimmanage/Apps/DEMA/Default.aspx>

DEMA HOME Forms Participant Management Groups Reports Show Main Menu

### Data Entry/Management

- Forms
- Participant Management
- Groups
- Reports

### DEMA Updates and News

08/21/2003 - 09/04/2003 **What's New with DEMA**  
Changes to DEMA were made and they include:

- Updated the report, "Phase I - Intervention - Participant Feedback" with several small changes.
- Updated the calculation of starting weight to exactly match the algorithm provided by Bill Vollmer.
- Updated the calculation of screening status to catch InEligible outcomes on form 105.

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08/15/2003 - 09/02/2003 **What's New with DEMA**  
Changes to DEMA were made and they include:

- The following forms are now available for Data Entry:
  - Form 200: Phase 1: Attendance and Weight Log Form
  - Form 201: Phase 1: Self Monitoring Data Collection
  - Form 202: Phase 1 Missed Session Form
  - Form 205: Short Physical Activity Form
  - Form 206: Change of Group Assignment Form
  - Form 207: Change of Main Intervention Form

---

08/15/2003 - 09/01/2003 **What's New with DEMA**  
Changes to DEMA were made and they include:

- Updated the report, "Phase I - Intervention - Triage Group", with multiple small formatting and layout changes.
- Updated the report, "Phase I - Intervention - Participant Targets", with change to calculation of calories to lose 1 pound per week.

Start | Internet | 7:20 PM

## Web Shot 14: Select Form 200 and then add record.

WLM DEMA - Form List

Number of forms: 29

<a href="#">Select</a>	Screening	Form121AcceleroActivity	Form 121: Physical Activity Form	Clinical
<a href="#">Select</a>	Screening	Form122BeliefsAttitudes	Form 122: Beliefs and Attitudes of WLM Participant	Clinical
<a href="#">Select</a>	Screening	Form123PerceptClinResearch	Form 123: Perceptions of Participants in Clinical	Clinical
<a href="#">Select</a>	Screening	Form124WeightLossHist	Form 124: Weight Loss History Questionnaire	Clinical
<a href="#">Select</a>	Screening	Form125PatientHistoryQx	Form 125: Patient History Questionnaire	Clinical
<a href="#">Select</a>	Screening	Form126InitialPhaseIGroupAssign	Form 126: Initial Phase I Group Assignment Form	Clinical
<a href="#">Select</a>	Phase I	Form200Phase1AttendWeight	Form 200: Phase 1: Attendance and Weight Log Form	Intervention
<a href="#">Select</a>	Phase I	Form201Phase1SelfMonit	Form 201: Phase 1: Self Monitoring Data Collection	Intervention
<a href="#">Select</a>	Ad Hoc	Form202Phase1MissSession	Form 202: Phase 1 Missed Session Form	Intervention
<a href="#">Select</a>	Phase I	Form205ShortPhyActForm	Form 205: Short Physical Activity Form	Clinical
<a href="#">Select</a>	Ad Hoc	Form206ChangeGroupAssignment	Form 206: Change of Group Assignment Form	Intervention
<a href="#">Select</a>	Ad Hoc	Form207ChangeMainInterventionist	Form 207: Change of Main Intervention Form	Intervention
<a href="#">Select</a>	Ad Hoc	Form502StudySuspension	Form 502: Study Suspension Form	Clinical

As a member of the coordinating center you need to choose which site's data you wish to access:

Baltimore  Baton Rouge  Durham  NHLBI  Portland

[Add Record](#) [Edit Record](#) [Verify Record](#) [View Record](#) [Delete Record](#) [Statistics](#) [Exit DEMA](#)

**Web Shot 15: Data Entry screen for Form 200. Enter header information from online Form 200 Report here, then attendance and weight data for first participant then click on Accept.**

**Form 200: Phase 1: Attendance and Weight Log Form**  
Protocol: WLM  
Add Mode

Site ID  1  
Group Session Date  2  
Group Session # G  3  
Group ID #  4  
Interventionist ID#  5  
Participant ID  6

Attended?  7  
Weight Available?  8  
If Yes, enter Weight  9  
Completed by (Staff ID)  10

Accept Cancel Close Staff ID: testcarrie

**Web Shot 16 Click on continue to enter next participant id and relevant row data.**

Form 200: Phase 1: Attendance and Weight Log Form  
Protocol: WLM  
Add Mode

Site ID  1  
Group Session Date  2  
Group Session # G  3  
Group ID #  4  
Interventionist ID#  5  
Participant ID  6

Record Update Succeeded with the following form checks...

Close Continue Staff ID: testcarrie

## 12.7 Data Query Reports

When forms are entered into the WLM\_Manage DEMA database, the data will be reviewed for completeness and accuracy at the Coordinating Center. Where data are missing, out of range, or have logic check errors, the Coordinating Center will send out Data Query Reports to clarify the data. The Data Query Report will be posted on the WLM File Transfer website <https://secure2.kpchr.org/wlmft> at regular intervals determined by the Coordinating Center. Sites will be notified of report postings by e-mail. The Data Query Report will provide information about the error, the reason for the data query and the information that is required to resolve it. The report will show Participant ID, the form and visit date, field affected, the type of error and a description of the correction necessary. The Data Assistant/Data Manager at each site will need to download the Data Query Report, review charts and make corrections to forms and to the WLM\_Manage DEMA database where necessary. Then they should document a resolution code and resolution description, the date the error was resolved and the staff id of the person resolving the query on the Data Query Report.

Each site should retain a copy of the Data Query Reports for their records and should send the Query Reports back to the Coordinating Center by the due date using the file transfer system.

### Instructions for Resolving Data Queries

- 1) Download a copy of the Data Query Report to your machine by right clicking (mouse) on your sites data query report and choosing "Save Target As" to save a copy of the data query on your machine. These reports cannot be accessed directly from the website.
- 2) Open the Data Query Report by double clicking on the html file. From the file menu, choose Edit with Microsoft Word for Windows. Ensure the version of word being used is Word 2000. Type in for each record a resolution code, a description of the resolution, the date resolved and the staff ID of the person resolving the query. Save changes to the corrected report by choosing save on the file menu. To view your edits, click the refresh button.
- 3) Ensure the relevant chart/form has been reviewed and updated for the correct data as per instructions further below.
- 4) Ensure the relevant form's data has been updated on the WLM\_Manage DEMA database.
- 5) Upload the corrected Data Query Report to the Coordinating Center via FTP website.

### To complete missing data:

- Locate the relevant chart and form and enter the information that is missing as per data query. If there is a reason why data is not available, please state the reason.
- Put staff initials and date and reason next to the amendment.
- Enter any new data on the WLM\_Manage DEMA database
- State what action was done to resolve the query in the '*Description of Resolution*' column.

### To correct data:

- Make the corrections to the form, providing a reason for the change.
- Put staff initials and date next to the amendment.
- Enter changed data on the WLM\_Manage DEMA database
- State what action was done to resolve the query in the '*Description of Resolution*' column.

### To confirm queried data is correct:

- Put initials, date and the words "*confirmed correct*" on the form next to the queried data.
- State 'confirmed correct' in the '*Description of Resolution*' column.

### Overdue Forms

A form is considered overdue if the Coordinating Center has not received any database date within an agreed time frame, depending on form type, usually 1-2 months after the visit was due. Requests for

any missing or overdue forms will be sent with the Data Query Reports. Please respond to these requests promptly by entering the requested data forms into the WLM\_Manage DEMA database.

### **Overdue Form 500 Medical Events Screening Forms**

Tracking of Serious Adverse Events is done on Form 500. The total number of Serious Adverse Event forms entered should total the number of Serious Adverse Events reported by your site. If any are missing, the Coordinating Center will request these either through Data Query Reports or via phone/e-mail. Please respond to these requests promptly by entering the requested Form 500 into WLM\_Manage DEMA database and sending a faxed copy to the Coordinating Center. If edits have been made to any Form 500 data after you have already faxed form 500 to the CC, then please update WLM\_Manage DEMA database and send any updated information to the Coordinating Center as soon as possible for further adjudication and reporting to NHLBI.

The number and proportion of WLM Forms that are missing, have data queries and overdue data queries at each site will be reported on regularly.

## **12.8 Participant Closeout**

If a participant refuses to participate in the study or becomes ineligible prior to randomization, the following procedures should be followed.

*At a screening visit:* If refusal/ineligibility is determined at a screening visit, the participant can simply be closed out by marking “ineligible” on the bottom of the relevant screening visit form and then entering that form into the system. All completed data collection forms for that participant for that visit should be entered into the WLM data entry system for that participant, regardless of eligibility status.

*Between screening visits:* If refusal/ineligibility is determined between screening visits, the participant can be closed out using the Study Suspension Form (#502). For example, a participant may call in to cancel the next screening visit and refuse to participate any further. All prior screening data collection forms that have been collected should be entered before closing out the participant. Once refusal or ineligibility is determined, no additional data collection is required. There are reports located in the data management system can be run at any time to identify any non-randomized participants that still have an “eligible” code in the system and need to be closed out. All participants will eventually need a final outcome of “eligible” or “ineligible”.

*For any randomized participant who doesn't complete the intervention,* the Study Suspension Form (#502) should be completed and entered into the WLM data entry system. Be sure to review the coding instructions on the form for additional termination codes. If the suspension reason is coded as “other”, the clinic coordinator should fax a copy of the termination form to the CC data manager for review. The CC will add additional codes if necessary or recode the “other” response if possible. Also, before entering the suspension form, be sure that all other remaining data have been entered.

### *End of Study Closeout*

To close out participants from the WLM data management system, confirm that all data collection forms have been entered into the WLM data entry system. Next, the 30-month visit data completeness report should be run and checked to verify that all data has been entered. Finally, the 30-month Visit Form (#404) can be entered. This closes out the participant and no further data can be entered.

## **12.9 Editing Data**

From time to time it will become necessary to change the data entered into the data entry system. This is done by selecting the form you wish to edit, and then clicking on “edit”. After entering the necessary header information (e.g. ID, date), the participant’s data will appear on the screen. Click on the field you wish to edit and enter the new value into the field. When you are finished, a pop-up box will appear asking you for the reason you wish to edit the form. You may choose one of the

drop down options, or type in a reason in the box provided.

The system will store the before edit value, the after edit value, the date the edit was performed, and who made the edit.

## **12.10 Missing or Overdue Forms**

Sites are expected to enter all data for participants within a week of collection. This gives ample time to adjudicate discrepancies and contact the participant for clarification, if necessary. There will be some cases where a week is not adequate; the form should then be entered as soon as the relevant data are captured.

Sites will not be allowed to enter participants into Phase I, or to randomize participants without the requisite eligibility data having been entered into the data entry system.

Missing and/or overdue forms will be noted as such on the data query reports system (see section 12.3).

## **12.11 Quality Control Methods**

Patient identification and record linkages. The WLM participant ID is a unique, six digit numeral. A check-digit is inserted into the ID at the time of creation to minimize the risk of inadvertent ID numeral transposition. Nevertheless, the ID on each form needs to be checked for transposition errors. Each page of multi-page forms must have the same ID number.

Legibility. All data must be checked for illegible handwritten replies, spelling errors, etc. All checked response boxes must have checks within designated spaces. Check to be sure that the forms are filled out in pen. Forms filled out in pencil are often difficult to read.

Form admissibility. All forms must be checked to determine if the form was completed within the specified time window. All forms must be checked to assure that the completed form is the correct one for the indicated visit or activity.

Missing information. All forms must be checked for unanswered items or sections of an otherwise completed form. The Clinic Coordinator must assure that all necessary forms have been completed for the indicated visit or activity before entry of the individual's data can begin. There are a few forms that are allowed to have missing data (e.g., patient history, psychosocial forms). This is indicated in the coding instructions for these forms. All other WLM data collection forms must be complete prior to data entry.

Consistency. All data must be checked to assure that information supplied in one section is consistent with data in another section of the same form. All forms for the same participant for a given visit must be checked to assure consistency. Skip patterns on forms should be checked for the correct data flow.

Range and inadmissible codes. All data must be checked to assure they do not contain values either outside specified ranges or undefined alphabetic or numeric codes.

The individual coding instructions attached to the relevant forms provide detailed instructions for coding and review procedures for each study form. Review the coding instructions for the form before completing the review process.

Override Functions: While certain data may be required on a form, various circumstances may occur that causes a response to be blank, or to be out of the expected range for that answer. In each case, the site may be given the ability to "override" the check and enter the reason that the answer was missing or out of range. Overriding a data check is the same as resolving the check. Two things are important to note about overrides: 1) they are reported to the WLM Steering Committee and



reviewed by the study Chair, and 2) certain eligibility criterion may NOT be overridden. For example, you may not override the criterion regarding BP/hyperlipidemia medications.

## **12.12 Data Validation and Quality Assurance**

Quality Control Methods Following Data Entry. As the data entry technician enters the data, any values that do not pass the range or logic checks defined by the system will trigger a prompt to the data entry technician to confirm that it was correctly entered. At this point the technician can either flag the form for review, or in some cases, the override function can be used to enter the values as is.

Data Validation. The primary measures of data integrity rely on the verification of data. Verification is a comparison of data before a transition (data entry) to the result after the transition to assure a one-to-one correspondence and assure that the transition process was “true”. In order to assure the accuracy of the WLM data, the Coordinating Center has set up a two-step process. 1) Validation of the data by the Coordinating Center completed at predetermined times and as a part of a site visit, and 2) validation completed by the individual sites.

### *Data Validation at the CC*

Data validation will be done by the Coordinating Center to assure validity of the data. The Coordinating Center will request the following at specified times during the study:

- All weight forms
- Three charts chosen at random from randomized participants. This includes all clinical, Phase I and intervention forms entered into the DEMA.

Additional validation will occur as a part of site visits. The Coordinating Center will request a random set of forms (from both randomized and non-randomized participants), as well as three random charts from each site.

The site should copy the requested forms and send to the Data Clerk at the Coordinating Center. A summary error report and a detailed error report will be compiled for the site. The Clinic Coordinator at the site and the Data Clerk and Data Manager at the Coordinating Center will then work together to solve any discrepancies that may have occurred. The Clinic Coordinator is responsible for seeing that corrections are made to the forms if needed (see data edits on forms section). Corrected copies of the forms should be faxed or mailed to the Coordinating Center. Changes that need to be made to the database should be clearly noted on the form. The Coordinating Center will file all copies of the forms in the Coordinating Center’s participant chart.

### *Data Validation by the Site*

Sites may opt to validate certain portions of their data as they see fit. This would be done under the “verify” option on the forms list of the DEMA.

The following list is a guideline for the amount of data validation to be conducted at the individual sites:

- All screening data for randomized participants
- A random sample of other forms for randomized participants

### **12.13 DEMA Instruction Sheet for New Staff Certification and Training**

The following are procedures for training and certifying a new staff member who will be doing data entry and data management activities at a WLM site. A new staff member cannot do data entry and data management activities unless the following procedures are completed.

- 1) The site coordinator will fill out the WLM Website Access/Staff ID Request Form to get the new staff member access to the WLM website and data entry application. Once completed the WLM Access form should be e-mailed to Rina Smith and Carrie Meeks at the coordinating center. The website access form is located on the WLM website under Forms and Rina and Carrie's e-mail addresses are given on the form.
- 2) The coordinating center notifies the coordinator that a staff ID has been assigned and the training database account has been set up with appropriate access privileges.
- 3) The new staff member enters the test data from the test data packet sent by the coordinating center. To enter test data into the training database, enter a fake participant name, DOB, and cohort number (if applicable) in the Participant Management screen (add a participant). The training system will assign a fake participant ID. Enter the test data using this fake ID for all test forms.
- 4) Site coordinators should ensure any problems on paper copies have been flagged for appropriate errors.
- 5) Site coordinators send the coordinating center a copy of the completed data entry/data management test with score.
- 6) The coordinating center confirms test data matches what is in the training database tables with the correct problems flagged and stored in override and edit tables.
- 7) The coordinating center moves new staff from training to the production database and notifies them they can start entering real participant data.

## **13 Forms**

### **Summary of edits between Version 1.0 and Version 1.1:**

- Forms editing and error correction instructions added
- Forms list updated

# Weight Loss Maintenance MOP

## 13 Forms

This section includes information to assist with the completion of forms. General points relevant to all the forms are given first, followed by specific points relevant to individual Forms. Additional information about the visits at which these forms are completed is given in Section 6. When completing the forms carefully consider the phrasing of questions; try not to lead the participant and try to use consistent wording with all participants. In addition to these notes, there are instructions and definitions attached to the forms. If your question is not answered, please contact the Coordinating Center.

### 13.1 Confidentiality of Data

All Forms containing confidential information about the participant are identified by a unique Participant ID Number. The Prescreen Visit Form is further identified by Date of Birth and participant name in order to obtain the unique Participant ID number. Form 100 Participant Contact Form is used to collect detailed participant contact information and will not be entered onto the Coordinating Center data systems but stored in participant folders in a secure area at the sites. All confidential information is therefore both transferred and stored in an anonymised format. Merging of participant identifiers with other data will be performed only when essential for follow-up communication with the participant. Access to such data will be restricted to essential Coordinating Center or site personnel where applicable.

### 13.2 Form Completion

#### General Completion Notes

When completing the forms:

- Write clearly using a black or blue ball point pen
- Fill in the participant ID field on the top right hand corner on every form. It will be 6 digits long and is the unique identifying number for that participant. Each page of multi-page forms must have the same ID number A label can be used to indicate the Participant ID or simply go to the electronic copy of the form stored on the website and click on the participant ID area. This will give you the ability to type the 6 digit participant ID straight onto the first page of the form and it will automatically replicate the same ID number onto the remaining pages of that form You can then print the form for the participant's visit.
- Fill in the visit date on every form. Each page of multi page form must have the same date.
- Complete every section and answer every question on every form unless specifically instructed otherwise.
- Check  boxes or write numbers or text in spaces.

#### Forms Editing and Error Corrections on Paper Forms.

It is important to use the following process when making corrections to study forms to assure the accuracy and validity of the data.

- Participant responses should never be obliterated.
- Staff corrections/edits should be made with a red or green ball point pen.
- A single slash should be made through the incorrect answer and the correct answer written next to it.
- The reviewer's initials, date of correction and an explanation of the edit should be written next to the data field that is being edited.
- Do not use correction fluid.

For example:

~~92~~ *90 RL 8/5/03 Addition error*

If a participant makes a correction to a form, the Clinic Coordinator should

- Verify that the answer is clearly written.
- Make a single slash through the old answer
- The reviewer's initials, date of correction and the notation "participant correction" should be written next to the data field.

For example:

**YES NO**

RL 8/5/03 participant correction

If a change has been made to the paper copy of the form after the form has been entered into the data entry application, make sure the changes are passed to the data entry staff as soon as possible so the database can be updated for the new information and data checks run. You do not have to send paper copies of data edits to the Coordinating Center unless the Coordinating Center specifically makes a request. The one exception to this is Form 500s that are positive for SAE. Corrections to SAEs must be faxed to the CC. Corrections to Form 500s where there is no SAE should NOT be faxed to the CC.

### 13.3 Form List

The following forms are administered during various phases of the WLM Trial (Screening, Phase 1, Baseline, Phase II). The relevant follow up visit periods that a form should be administered are stated on the forms. Data collection forms can be found on the WLM website under the documents/forms link except for the Food Frequency questionnaires and Form 201 Food and Fitness diaries that are shipped to sites by the Coordinating Center.

The following 100 series forms are administered during the screening phase and in the case of forms 103,104,106,108,109,110,111,112,113,114(if applicable), Food Frequency Questionnaire, 116,117,120,121 are additionally administered at baseline and during Phase II of the WLM Trial.

#### Screening Phase:

- Form 100: Participant Contact Form
- Form 101A: PSV Form Participant ID Registration (interviewer administered)
- Form 101B: PSV Form Participant ID Registration (self administered)
- Form 102: Eligibility Questionnaire
- Form 103: Medication Tracking Form
- Form 104: Summary Medication Use Form
- Form 105: BMI Eligibility Form
- Form 106: Weight Form
- Form 107 Eligibility Follow up Questionnaire (administered if exceeded 120 day screening window from PSV Form)
- Form 108: Rose Questionnaire—Angina
- Form 109 SF-36 Questionnaire
- Form 110: Social Support and Eating Habits Questionnaire
- Form 111: Social Support and Exercise Questionnaire
- Form 112: Perceived Stress Questionnaire
- Form 113: Patient Health Questionnaire PHQ-8
- Form 114: Depression Alert Form
- Food Frequency Questionnaire

Form 116: Accelerometry Form  
Form 117: Lab Collection Form—Fasting Blood  
Form 118: Motivational Assessment Interview  
Form 119: Phase 1 Eligibility Review  
Form 120: Physician Approval Form.  
Form 121: Physical Activity Form  
Form 122: Beliefs and Attitudes of WLM Participants  
Form 123: Perception of Participant in Clinical Research  
Form 124: Weight Loss History Questionnaire  
Form 125: Patient History Questionnaire  
Form 126: Initial Phase 1 Group Assignment

### **Phase I and at Baseline**

Form 200: Phase I Attendance/Weight Form  
Form 201: Food and Fitness Diary Instructions  
Form 202: Phase I Missed Group Session Form  
Form 203: Baseline Eligibility Questionnaire  
Form 204: Blood Pressure – Visit 1  
Form 205: Short Physical Activity Form  
Form 206: Change of Group Assignment  
Form 207: Change of Main Interventionist  
Form 208: Phase II Eligibility Checklist  
Form 209: Blood Pressure – Visit 2

Forms 103,104,106,108,109,110,111,112,113,114(if applicable),  
Food Frequency Questionnaire, 116,117,120,121, 500 are additionally administered at baseline

### **Phase II:**

Form 210: Weight Management Strategies Qx. – 30 months  
Form 211: Berlin Sleep Questionnaire – 30 months  
Form 212: Phase III Eligibility Weight – 30 months (if needed)  
Form 300: PC Attendance Form  
Form 301: PC Process Form  
Form 302: PC Make-up Form  
Form 303: IT Intervention Orientation Assessment Form  
Form 304: Intervention Extra Contacts Form  
Form 305: IT Reorientation and Transition Visit  
Form 400: Clinic Visit Form – 6 months  
Form 401: Clinic Visit Form – 12 months  
Form 400: Clinic Visit Form – 18 months  
Form 400: Clinic Visit Form – 24 months  
Form 402: Clinic Visit Form – 30 months

Forms 103,104,106,108,109,110,111,112,113,114(if applicable),  
Food Frequency Questionnaire, 116,117,120,121, 204, 205, 209, 500 are additionally  
administered during Phase II

### **Adverse Event and Ad Hoc Forms**

Form 500: Medical Events Screening Form  
Form 502: Study Suspension Form  
Form 503: Participant Transfer Form

Form 504: Recruitment Activity Form (For Recruitment Committee Use)

**Staff & Equipment Certification Forms:**

- Form 600: Weight Certification Form
- Form 601: Weight Observation Checklist
- Form 602: Weight Scales Accuracy Check and Yearly Certification log
- Form 603: Height Certification Form
- Form 604: Height Observation Checklist
- Form 605: Stadiometer Accuracy Check
- Form 606 ABP Monitor Blood Pressure Certification Form
- Form 607: Blood Pressure (ABPM) Observation Checklist
- Form 608: Blood Pressure Written Examination (ABPM)
- Form 608ak: Blood Pressure Test answer key (*sent to clinic coordinators only*)
- Form 609: Space Lab Device and Cuffs Inspection and Maintenance Log
- Form 610: Accelerometry Certification Form
- Form 611: RT3 Accelerometry Written Test
- Form 611ak: RT3 Accelerometry Written Test Answer Key (*sent to clinic coordinators only*)
- Form 612: Data Entry and Data Management Certification Form
- Form 613: Data Entry and Data Management Written Test
- Form 613ak Data Entry and Data Management Answer Key (*sent to clinic coordinators only*)

**Data Analysis & Publication Forms:**

- Form 700: Proposal for a WLM Paper
- Form 701: PASC Review Form for a WLM Publication Proposal
- Form 702: Manuscript Review Form (Ballot)
- Form 703: Ancillary Study Request Form
- Form 704: Abstract Review Form
- Form 705: Analysis Request Form
- Form 706: Data Release Request Form

# Weight Loss Maintenance MOP

## 14 Trial Monitoring

The primary aim of trial monitoring is to ensure the Study is conducted safely and scientifically, in accordance with the Study Protocol and in line with local recommendations for good clinical research practice. In addition, this process will provide an opportunity to identify areas for training, for discussion of matters related to the Study and for the establishment of a good working relationship between the sites and the Coordinating Center.

### 14.1 Monitoring Program

The monitoring program consists of two main areas; trial monitoring reports and site visits. Trial monitoring reports are ongoing reports produced on a regular schedule by the CC to monitor key areas of interest. Site visits are special, annual visits to each site to assure that the protocol is being implemented correctly.

### 14.2 Trial Monitoring Reports

During the trial's course, the Coordinating Center produces a variety of reports summarizing the characteristics of the study as a whole and of individual clinical centers. These reports are distributed to the members of the Steering Committee, to appropriate subcommittees, and to the Data Safety & Monitoring Board in order to monitor the progress of the trial. Selected reports are also available on the WLM website.

Additional reports, produced for the DSMB only, permit the DSMB to monitor the efficacy and safety of the interventions. These reports include not only standardized reports issued at regular intervals but also ad hoc reports as requested.

The reports prepared for the Steering Committee focus on the recruitment and retention of participants. Recruitment reports allow the Steering Committee to ensure that recruitment is proceeding in a timely manner and to identify potential recruitment problems. Retention reports focus on clinic follow-up rates to help ensure scientific validity of the study outcomes. In addition, the Steering Committee also receives reports summarizing the completeness and quality of the study database.

The other committees receive reports relevant to their areas of expertise.

### 14.3 Site Visit Monitoring Procedures

The Coordinating Center will visit each site as close as possible to the commencement of the study and at a minimum, will have annual site visits until follow-up is completed, with additional visits if needed. The visits focus on issues such as adherence to the study Protocol, data collection procedures, validity, completeness and documentation of data.

The visits focus in more detail on laboratory procedures; informed consent; certification and calibration of staff and equipment; screening and follow-up visit observations, MOP, and forms manuals; observation of automated systems and their use; staff training and certification; and site-identified problems. These site visits also cover intervention delivery, including observation of intervention sessions, observing selected individual counseling and telephone contacts, and interviewing local staff and/or participants as necessary.

In summary, site visit activities include, but are not limited to:

- Clinic Visit and Interventionist Observations
- Review of Clinic/Intervention Space
- Review of Equipment
- Review of Laboratory Procedures
- Review of Clinic & Intervention Procedures



- Review of Site Study Manuals & Documentation
- Review of Selected Data Forms and Data Management Systems