Asthma
Clinical
Research
Network
NIH/NHLBI

CLINICAL AND LABORATORY ADVERSE EVENTS

(Clinic Coordinator completed)

Subject ID: ___ ___ - ___ ___ - ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: ___ ___ ___

Complete this log if the subject experienced any clinical adverse events (including intercurrent events) since the last visit. Check the "None" box and instruct the subject to initial and date the source documentation box if the subject has not experienced any clinical adverse events since the last visit.

❑0 None

Subject's Initials:___ ___ ___
Date: __ __ / __ __ / __ __ __ __

* Please complete a Serious Adverse Event Reporting (SERIOUS) form.

** Please complete the appropriate Change in Medications form.

*** Please complete the Concomitant Medications (CMED) form.

DESCRIPTION OF ADVERSE EVENT **(1000)**	1. ICD9 CODE **(1010)**	2. DATE STARTED (Top Line) **(1020)** / 3. DATE STOPPED (Bottom Line) **(1030)** MONTH / DAY / YEAR	4. ONGOING at current visit **(1040)**	5. TYPE **(1050)** 1 - INTERMITTENT 2 - CONTINUOUS	6. SEVERITY **(1060)** 1 - MILD 2 - MODERATE 3 - SEVERE	7. SERIOUS **(1070)** 1 - YES * 0 - NO	8. LIKELIHOOD OF RELATIONSHIP TO STUDY DRUG(S) **(1080)** 1 - NONE 2 - UNLIKELY (REMOTE) 3 - POSSIBLE 4 - PROBABLE	9. CHANGE IN STUDY DRUG(S) **(1090)** 1 - UNCHANGED 2 - ALTERED**	10. OUTCOME *(Skip if #3 is missing.)* **(1100)** 1 - COMPLETELY RECOVERED 2 - RECOVERED, BUT WITH LASTING EFFECTS 3 - DEATH *	11. TREATMENT REQUIRED **(1110)** 1 - NONE 2 - MEDICATION *** 3 - HOSPITALIZATION * 4 - OTHER	12. ONGOING at final visit **(1120)**
___ ___	_ _ _ . _ _	_ _ / _ _ / _ _ _ _ _ _ / _ _ / _ _ _ _	❑1								❑1
___ ___	_ _ _ . _ _	_ _ / _ _ / _ _ _ _ _ _ / _ _ / _ _ _ _	❑1								❑1
___ ___	_ _ _ . _ _	_ _ / _ _ / _ _ _ _ _ _ / _ _ / _ _ _ _	❑1								❑1
___ ___	_ _ _ . _ _	_ _ / _ _ / _ _ _ _ _ _ / _ _ / _ _ _ _	❑1								❑1
___ ___	_ _ _ . _ _	_ _ / _ _ / _ _ _ _ _ _ / _ _ / _ _ _ _	❑1								❑1

Asthma Clinical Research Network
NIH/NHLBI

ASTHMA EVALUATION QUESTIONNAIRE

Subject ID: __ __ - __ __ - __ __ __
Subject Initials: __ __ __
Visit Number: __ __ __
Visit Date: __ __ / __ __ / __ __
Month Day Year
Coordinator ID: __ __ __ __ __ __

(Subject Interview Completed)

Coordinator Instructions: Before administering this questionnaire, give the subject his or her diary cards from the two weeks immediately preceding the visit. The subject should refer to the diary cards when answering each question. The AEQ must be the last asthma questionnaire completed at a given visit.

Subject Instructions: Please consider your last two weeks of asthma control in answering these questions. Check the box next to the response that best describes your average weekly asthma symptoms, rescue use and nighttime awakenings in the past two weeks.

1. In the past two weeks, how often have you experienced asthma symptoms?

- ❑0 Less than or equal to 2 days a week
- ❑1 3 to 5 days per week
- ❑2 6 or more days per week, but not continual
- ❑3 Continual (multiple times every day) **(1000)**

2. In the past two weeks, how often have you used your rescue beta-agonist medicine (e.g., albuterol (Proventil, Ventolin)), aside from preventative use prior to exercise?

- ❑0 Less than or equal to 2 days per week
- ❑1 3 to 5 days per week
- ❑2 6 days per week
- ❑3 At least once per day (daily) **(1010)**

3. In the past two weeks, how often have you awakened at night due to asthma symptoms?

- ❑0 No awakenings or awakened 1 night during the 2 weeks
- ❑1 1 night per week
- ❑2 2 or 3 nights per week
- ❑3 4 or more nights per week **(1020)**

Subject Source Documentation

Subject's Initials: __ __ __ **(1030)**

Date: __ __ / __ __ / __ __ __ __ **(1040)**

Time: __ __ __ __ *(based on a 24-hour clock)* **(1050)**

Asthma Clinical Research Network
NIH/NHLBI

AM1® QUALITY CONTROL

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

1. Serial Number of AM1® being tested ___ ___ ___ ___ ___ ___ ___ ___ **(1000)**

2. Serial Number of turbine being tested ___ ___ - ___ ___ ___ **(1010)** **(1020)**

3. Test date ___ ___ / ___ ___ / ___ ___ ___ ___ **(1030)** *month day year*

4. Is a new AM1® device being tested for this subject? ❑1 Yes ❑0 No **(1040)**

   If ***YES***, indicate the primary reason.
   - ❑1 First issuing
   - ❑2 "Old" device failed QC testing
   - ❑3 "Old" device had display problems
   - ❑4 "Old" device experienced battery failure
   - ❑5 "Old" device was recalled
   - ❑6 "Old" device was lost
   - ❑7 Other **(1050)**

	AM1® (L/Min)	Jones FVC (L/Min)	Clinic Use Only: Relative Bias (AM1 - Jones FVC) / Jones FVC * 100 %	Clinic Use Only: Rank (smallest to largest)
5. Trial 1 **(1060/1070)**	___ ___ ___	___ ___ ___ . ___	___ ___ ___ . ___ %	___
6. Trial 2 **(1080/1090)**	___ ___ ___	___ ___ ___ . ___	___ ___ ___ . ___ %	___
7. Trial 3 **(1100/1110)**	___ ___ ___	___ ___ ___ . ___	___ ___ ___ . ___ %	___
8. Trial 4 **(1120/1130)**	___ ___ ___	___ ___ ___ . ___	___ ___ ___ . ___ %	___
9. Trial 5 **(1140/1150)**	___ ___ ___	___ ___ ___ . ___	___ ___ ___ . ___ %	___

Clinic Use Only

Median Relative Bias ___ ___ ___ . ___ % **Inter-quartile Range** ___ ___ . ___ %

*The **Median Relative Bias** is the third largest value of the 5 measures of relative bias.*

*The **Inter-quartile Range** is determined by subtracting the relative bias of rank 2 from the relative bias of rank 4.*

***When a subject receives a new AM1® or turbine for the first time,** the median relative bias must be between -15% and +15%, AND the inter-quartile range must be less than 10%.*

***When a subject returns to the clinic with a used AM1®:** (i) subtract the original median relative bias (the median relative bias when the AM1® or turbine was first dispensed) from the current median relative bias, and (ii) subtract the original inter-quartile range (the inter-quartile range when the AM1® or turbine was first dispensed) from the current inter-quartile range. The difference for (i) must be between -5% and +5% and the difference for (ii) must be less than +5% for the AM1® to be reissued to the subject.*

10. Did the AM1® pass? ❑1 Yes ❑0 No **(1160)**
11. If ***NO***, is this the second test with this turbine at this visit? ❑1 Yes ❑0 No **(1170)**

➔ *If **NO**, retest the AM1® with the same turbine and complete another AM1® Quality Control form.*

➔ *If **YES**, issue a new turbine and complete another AM1® Quality Control form. If 2 turbines have been tested with this device, issue a new device and turbine and complete another AM1® Quality Control form.*

Asthma Clinical Research Network
NIH/NHLBI

ASTHMA CHARACTERIZATION QUESTIONNAIRE

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Subject Interview completed)

ASTHMA HISTORY

1. Approximately how old were you when chest symptoms suggesting asthma first appeared? ____ ____ years **(1000)**
   (Enter '00' if subject was under 1 year.)

   1a. Did these symptoms appear immediately after or as a result of a respiratory infection such as a cold or pneumonia? ❑1 Yes ❑0 No ❑8 Don't Recall **(1010)**

2. How old were you when a doctor first diagnosed you with asthma? ____ ____ years **(1020)**

   2a. What caused you to seek medical care?
   ❑1 Acute Symptoms
   ❑2 Chronic Symptoms
   ❑3 Other _____ **(1030)**

3. Have any of your immediate blood relatives been told by a physician that they have asthma? (*Check the 'N/A' box if the subject does not have biological siblings or children.*)

   3a. Mother ❑1 Yes ❑0 No ❑8 Don't Know **(1040)**

   3b. Father ❑1 Yes ❑0 No ❑8 Don't Know **(1050)**

   3c. Brother(s) or Sister(s) ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A **(1060)**

   3d. Child(ren) ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A **(1070)**

ASTHMA SYMPTOMS

4. On average, over the last 4 weeks, how often have you experienced each of the following asthma symptoms:

   4a. Cough (deep chest)
   ❑0 Never
   ❑1 Less than or equal to twice a week
   ❑2 More than twice a week but not daily
   ❑3 Daily
   ❑4 Continuously **(1080)**

   4b. Sputum (phlegm or mucous from the lungs)
   ❑0 Never
   ❑1 Less than or equal to twice a week
   ❑2 More than twice a week but not daily
   ❑3 Daily
   ❑4 Continuously **(1090)**

4c. Chest tightness (difficulty taking a deep breath, pressure in the chest)

- ❑0 Never
- ❑1 Less than or equal to twice a week
- ❑2 More than twice a week but not daily
- ❑3 Daily
- ❑4 Continuously **(1100)**

4d. Wheezing (whistling or musical sound in the chest)

- ❑0 Never
- ❑1 Less than or equal to twice a week
- ❑2 More than twice a week but not daily
- ❑3 Daily
- ❑4 Continuously **(1110)**

4e. Shortness of breath

- ❑0 Never
- ❑1 Less than or equal to twice a week
- ❑2 More than twice a week but not daily
- ❑3 Daily
- ❑4 Continuously **(1120)**

4f. Nighttime symptoms (waking due to asthma)

- ❑0 Never
- ❑1 One or two nights a month
- ❑2 More than two nights per month but at most one night a week
- ❑3 More than one night a week but not frequently
- ❑4 Frequently **(1130)**

5. How often do you use your rescue beta-agonist medicine (e.g., Albuterol (Proventil, Ventolin)) other than to pretreat prior to exercise?

- ❑0 Less than or equal to twice a week
- ❑1 Greater than twice a week but not daily
- ❑2 Daily but not four times a day
- ❑3 Greater than or equal to four times a day

(1140)

6. How do you categorize your asthma symptoms throughout the course of the year?

- ❑1 Relatively the same all year
- ❑2 Vary by season(s) **(1150)**

➔ If 'Vary by season(s)', do your asthma symptoms worsen during the...

6ai. Winter? ❑1 Yes ❑0 No **(1160)**

6aii. Spring? ❑1 Yes ❑0 No **(1170)**

6aiii. Summer? ❑1 Yes ❑0 No **(1180)**

6aiv. Fall? ❑1 Yes ❑0 No **(1190)**

7. In the last 12 months, how many... (*Enter '00' if none*)

7a. Asthma episodes have you had that required emergency care or an unscheduled office visit? ____ ____ **(1200)**

7b. Hospitalizations have you had due to asthma? ____ ____ **(1210)**

7c. Courses of oral corticosteroid therapy (e.g., Prednisone) for asthma have you taken? ____ ____ **(1220)**

7d. Days of work, school or housework have you missed due to asthma? ____ ____ ____ days **(1230)**

➔ ***If Question #7d > 0, complete Question #7di.***

7di. In the past 3 months, how many days of work, school, or housework have you missed due to asthma? ____ ____ days **(1240)**

ASTHMA TRIGGERS

8. Do any of the following currently provoke your asthma?

8a. Exercise/Sports ❑1 Yes ❑0 No ❑8 Don't Know **(1250)**

8b. Menstrual cycle (If subject is male or postmenopausal, check N/A) ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A **(1260)**

8c. Aspirin or non-steroidal anti-inflammatory drugs (e.g., Aleve, Motrin) ❑1 Yes ❑0 No ❑8 Don't Know **(1270)**

8d. Colds, upper respiratory infections, sinus infections ❑1 Yes ❑0 No ❑8 Don't Know **(1280)**

8e. Irritants (e.g., smoke, pollution, odors, perfumes, chemicals) ❑1 Yes ❑0 No ❑8 Don't Know **(1290)**

8f. Weather conditions (e.g., cold, humidity) ❑1 Yes ❑0 No ❑8 Don't Know **(1300)**

8g. Emotional stress ❑1 Yes ❑0 No ❑8 Don't Know **(1310)**

8h. Food additives/preservatives (e.g., MSG, etc.) ❑1 Yes ❑0 No ❑8 Don't Know **(1320)**

8i. Other (please specify)_____ ❑1 Yes ❑0 No **(1330)**

ALLERGIES

9. Do you have allergies to pets, pollen, dust, etc.? ❑1 Yes ❑0 No ❑8 Don't Know **(1340)**

If ***YES***,

9a. Do your allergies provoke your asthma? ❑1 Yes ❑0 No ❑8 Don't Know **(1350)**

9b. Were your allergies diagnosed by a doctor? ❑1 Yes ❑0 No **(1360)**

9c. How do you categorize your allergies? ❑1 Relatively the same all year
❑2 Vary by season(s) **(1370)**

➔ If 'Vary by season(s)', do your allergies worsen during the...

9ci. Winter? ❑1 Yes ❑0 No **(1380)**

9cii. Spring? ❑1 Yes ❑0 No **(1390)**

9ciii. Summer? ❑1 Yes ❑0 No **(1400)**

9ciii. Fall? ❑1 Yes ❑0 No **(1410)**

10. Have you ever had eczema (i.e., prolonged itchy, scaly, weepy skin rash)? ❑1 Yes ❑0 No ❑8 Don't Know **(1420)**

10a. If ***YES***, was your eczema diagnosed by a doctor? ❑1 Yes ❑0 No **(1430)**

11. Have any of your immediate blood relatives been told by a physician that they have allergies/eczema/hay fever? (*Check the 'N/A' box if the subject does not have biological siblings or children.*)

11a. Mother ❑1 Yes ❑0 No ❑8 Don't Know **(1440)**

11b. Father ❑1 Yes ❑0 No ❑8 Don't Know **(1450)**

11c. Brother(s) or Sister(s) ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A **(1460)**

11d. Child(ren) ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A **(1470)**

SMOKING HISTORY

12. Were you ever a smoker? ❑1 Yes ❑0 No **(1472)**

12a. If ***YES***, how many years did you smoke? (total number of years) ___ ___ years **(1474)**

13. Did you grow up in a household where you were exposed to tobacco smoke? ❑1 Yes ❑0 No **(1480)**

14. In an average week, approximately how many hours are you exposed to other people's tobacco smoke in all environments? ___ ___ ___ hours **(1490)**

Subject Source Documentation

Subject's Initials: __ __ __ **(1500)**

Date: __ __ / __ __ / __ __ __ __ **(1510)**

Asthma Clinical Research Network
NIH/NHLBI

CONCOMITANT MEDICATIONS FOR ASTHMA/ALLERGY AND ADVERSE EVENTS

Subject ID: ___ ___ - ___ ___ ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: ___ ___ ___

(Coordinator completed)

Instructions: Since signing the informed consent or last study visit, list all prescription and over-the-counter (OTC) concomitant medications used to treat asthma/allergy symptoms and adverse events. Do not list routine use of study drugs or rescue medications. Check the "None" box if the subject has not started taking any medications since signing the informed consent or last study visit. If the medication is not related to an adverse or laboratory event, leave the event number missing and check the "N/A" box. If the subject is still taking the medication at the end of the current visit, check the "ongoing at current visit" check box and leave the stop date missing. All ongoing medications should be reviewed at subsequent visits to document the stop date of a medication. At the last study visit or an early termination visit, review all ongoing medication and indicate a stop date or check the "ongoing at final visit" check box on the data collection form and update the medication data in the ACRN data entry application.

At the final study visit or early termination visit, forward all concomitant medications for asthma/allergy-related medications and adverse events forms to the DCC.

❑0 None

NAME OF MEDICATION **(1000)**	CODE **(1010)**	RELATED EVENT **(1020)**	DOSE **(1030)**	UNITS **(1040)**	FREQUENCY **(1050)**	ROUTE	START DATE (MM/DD/YYYY) **(1060)**	STOP DATE (MM/DD/YYYY) **(1070)**	ONGOING AT CURRENT VISIT **(1080)**	ONGOING AT FINAL VISIT **(1090)**
___ ___		Event ___ ___ ❑0 NA					___ / ___ / _____	___ / ___ / _____	❑1	❑1
___ ___		Event ___ ___ ❑0 NA					___ / ___ / _____	___ / ___ / _____	❑1	❑1
___ ___		Event ___ ___ ❑0 NA					___ / ___ / _____	___ / ___ / _____	❑1	❑1
___ ___		Event ___ ___ ❑0 NA					___ / ___ / _____	___ / ___ / _____	❑1	❑1
___ ___		Event ___ ___ ❑0 NA					___ / ___ / _____	___ / ___ / _____	❑1	❑1
___ ___		Event ___ ___ ❑0 NA					___ / ___ / _____	___ / ___ / _____	❑1	❑1

UNITS and FREQUENCY CODES FOR CONCOMITANT MEDICATIONS

Asthma Clinical Research Network
NIH/NHLBI

Codes for Units	
Code	Units
1	mg
2	mcg (μg)
3	ml
4	mg/ml
5	mEq
6	g
7	U
8	teaspoon
9	patch
10	puffs (oral inhalation)
11	nasal spray
12	no units
13	packet
14	1 drop
15	mm
16	other

Codes for Frequency		
Code	Frequency	
1	QD	1 time a day
2	BID	2 times a day
3	TID	3 times a day
4	QID	4 times a day
5	q4h	every 4 hours
6	q5h	every 5 hours
7	q6h	every 6 hours
8	q8h	every 8 hours
9	q12h	every 12 hours
10	q24h	every 24 hours
11	hs	every night at bedtime
12	PRN	as required
13	qod	every other day
14	qw	once a week
15	biw	2 times per week
16	tiw	3 times per week
17	5 times per week	
18	every 5 days	
19	once a month	
20	taper dose	
21	other	

Asthma Clinical Research Network
NIH/NHLBI

EXHALED BREATH CONDENSATE COLLECTION

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___ ___

(Technician Completed)

1. Has the subject had anything other than water to drink or eat in the past hour? ❑1 Yes ❑0 No **(1000)**

   ➔ ***If YES, STOP HERE. Subject is ineligible to continue with ebc collection. If possible, wait until the full hour has passed, then proceed with collection.***

2. Was ebc collection attempted at this visit? ❑1 Yes ❑0 No **(1010)**

   ➔ ***If NO, complete Question #2a and STOP.***
   ➔ ***If YES, proceed to Question #3***

   2a. Check the primary reason ebc collection was not attempted.
   ❑1 Subject Refusal
   ❑2 Equipment Unavailable
   ❑3 Clinic Oversight
   ❑4 Other_____ **(1020)**

3. Time ebc collection started (based on 24-hour clock). ___ ___ ___ ___ **(1030)**

4. Time ebc collection stopped (based on 24-hour clock). ___ ___ ___ ___ **(1040)**

   ➔ ***If collection time exceeds ten minutes, please provide an explanation below.***

_____

_____

_____

_____

_____

5. Did the subject experience any of the following during the collection process...
   5a. Sneezing? ❑1 Yes ❑0 No **(1050)**
   5b. Coughing? ❑1 Yes ❑0 No **(1060)**
   5c. Burping? ❑1 Yes ❑0 No **(1070)**

6. Were six eppendorf tubes aliquoted at this visit? ☐ 1 Yes ☐ 0 No **(1080)**

If YES, proceed to Question #7.

6a. Which of the following explain why six tubes were not collected?

Equipment Malfunction ☐ 1 Yes ☐ 0 No **(1090)**
If YES, explain _____

Low Yield ☐ 1 Yes ☐ 0 No **(1100)**

Subject could not tolerate procedure ☐ 1 Yes ☐ 0 No **(1110)**

Other ☐ 1 Yes ☐ 0 No **(1120)**
If YES, explain _____

6b. Record the number of tubes aliquoted. ___ tubes **(1130)**

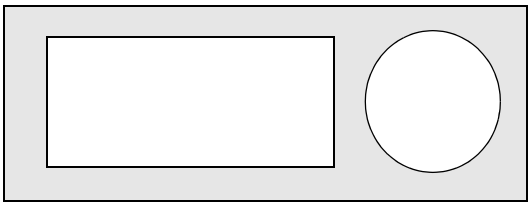
➔ ***If '0', STOP HERE.***

7. Was nitrogen gas layered on the tubes before closing them? ☐ 1 Yes ☐ 0 No **(1150)**

8. Were the tubes stored immediately at -70° Celsius or colder? ☐ 1 Yes ☐ 0 No **(1160)**

8a. If ***NO***, at what temperature were the tubes stored? ___ ___ ___ ° C **(1170)**

9. Attach one barcode label/dot pair from the subject's visit-specific strip here. Write the barcode number from the label in the spaces provided.



___ ___ ___ ___ ___ ___ ___ ___ **(1180)**

Comments:_____

_____

_____

_____

Asthma Clinical Research Network
NIH/NHLBI

EXHALED NITRIC OXIDE

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

Complete this form only if the subject is eligible according to the appropriate Pulmonary Procedures Checklist (PULMONARYCHK) form.

1. Was the exhaled nitric oxide (ENO) procedure performed? ☐1 Yes ☐0 No **(1000)**

   ➔ ***If NO, complete Question #1a and STOP.***

   ➔ ***If YES, proceed to Question #1b.***

1a. What was the reason the ENO procedure could not be performed?

☐1 Equipment failure, please specify

_____

_____

_____

☐2 Equipment not calibrated

☐3 Subject refusal

☐4 Clinic oversight

☐5 Other _____ **(1010)**

1b. Was the exhaled nitric oxide (ENO) procedure performed on the NIOX Mino? ☐1 Yes ☐0 No **(1015)**

   ➔ ***If YES, do not complete Question #11 on the next page since only 1 acceptable maneuver was obtained.***

For each maneuver, record the time and FE_{NO} value. If the maneuver was not accepted by the NIOX machine, record the time and select the 'Maneuver Not Acceptable' check box.

For a procedure done on the ACRN NIOX Machine, when TWO reproducible measurements are achieved, select the 'Reproducible Measurements' check box for both maneuvers. The two measurements are considered reproducible when they are within 5% of their mean or 1.25 ppb of their mean.

		Time (based on 24 - hour clock)	**Measured FE_{NO}**	**Maneuver Not Acceptable**	**Clinic Use Only** **Reproducible Measurements**
2.	Maneuver #1	___ ___ ___ ___ **(1020)**	___ ___ ___ . ___ ppb **(1030)**	☐ 1 **(1050)**	☐
3.	Maneuver #2	___ ___ ___ ___ **(1060)**	___ ___ ___ . ___ ppb **(1070)**	☐ 1 **(1090)**	☐
4.	Maneuver #3	___ ___ ___ ___ **(1100)**	___ ___ ___ . ___ ppb **(1110)**	☐ 1 **(1130)**	☐
5.	Maneuver #4	___ ___ ___ ___ **(1140)**	___ ___ ___ . ___ ppb **(1150)**	☐ 1 **(1170)**	☐
6.	Maneuver #5	___ ___ ___ ___ **(1180)**	___ ___ ___ . ___ ppb **(1190)**	☐ 1 **(1210)**	☐
7.	Maneuver #6	___ ___ ___ ___ **(1220)**	___ ___ ___ . ___ ppb **(1230)**	☐ 1 **(1250)**	☐
8.	Maneuver #7	___ ___ ___ ___ **(1260)**	___ ___ ___ . ___ ppb **(1270)**	☐ 1 **(1290)**	☐
9.	Maneuver #8	___ ___ ___ ___ **(1300)**	___ ___ ___ . ___ ppb **(1310)**	☐ 1 **(1330)**	☐
10.	Maneuver #9	___ ___ ___ ___ **(1340)**	___ ___ ___ . ___ ppb **(1350)**	☐ 1 **(1370)**	☐

11. Did the subject achieve two reproducible outcomes? ☐ 1 Yes ☐ 0 No **(1380)**

If ***NO***, explain _____

_____

_____

Asthma Clinical Research Network
NIH/NHLBI

METHACHOLINE CHALLENGE TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

Complete this form only if the subject is eligible according to the Methacholine Challenge Testing Checklist (METHACHK) form.

Clinic Use Only *(Technician completed)*
Use the FEV_1 value from the appropriate spirometry testing form as the baseline reference.

A. Baseline FEV_1 prior to methacholine challenge ___ . ___ ___ L

B. Methacholine Reversal Reference Value (Question A x 0.90 = ___ . ___ ___ L)

C. Diluent FEV1 Reference Value (Question 1000 x 0.8049 = ___ . ___ ___ L)

1. Post Diluent FEV_1 ___ . ___ ___ L **(1000)**

2. Did the subject drop ≥ 20% at the diluent stage? ❑ 1 Yes ❑ 0 No **(1010)**
   ➔ If ***YES,*** proceed to Question #5 and record 0 for Question #5a.

3. Last concentration of methacholine administered ___ ___ ___ . ___ ___ ___ ___ mg/ml **(1020)**

4. FEV_1 after last concentration of methacholine administered ___ . ___ ___ L **(1030)**

5. Did the subject achieve a PC_{20}? ❑ 1 Yes ❑ 0 No **(1040)**
   ➔ If ***NO***, proceed to Question #6.
   5a. PC_{20} ___ ___ ___ . ___ ___ ___ ___ mg/ml **(1050)**

6. Time methacholine challenge ended *(based on 24-hour clock)* ___ ___ ___ ___ **(1060)**

7. Subject's FEV_1 after standard reversal from methacholine challenge
   If subject is continuing with sputum induction, standard reversal = 4 puffs albuterol.
   If subject is not continuing with sputum induction, standard reversal = 2 puffs albuterol.
   7a. FEV_1 ___ . ___ ___ L **(1070)**
   7b. Time of FEV_1 in Question #7a (*based on 24-hour clock*) ___ ___ ___ ___ **(1090)**
   7c. Was the FEV_1 from Question #7a ≥ the methacholine reversal reference value (B) in the gray box above? ❑ 1 Yes ❑ 0 No **(1100)**
   ➔ ***If YES, STOP HERE and continue with remaining visit procedures.***
   ➔ ***If NO, proceed to the Additional Treatment for Methacholine Challenge Testing (METHA_ADD_TRT) form.***

Asthma Clinical Research Network
NIH/NHLBI

ADDITIONAL TREATMENT POST METHACHOLINE CHALLENGE TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

Complete this form only if the subject did not reverse to 90% of baseline FEV_1 after the first post-challenge treatment of albuterol.

1. Was an additional treatment used in the first hour? ❑1 Yes ❑0 No **(1000)**
   ➔ ***If NO, skip to Question #3.***

   1a. Additional albuterol by MDI ❑1 Yes ❑0 No **(1010)**
   ➔ ***If NO, skip to Question #1b.***
   Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four **(1020)**

   1b. Nebulized Beta-agonist ❑1 Yes ❑0 No **(1030)**

   1c. Subcutaneous epinephrine ❑1 Yes ❑0 No **(1040)**

   1d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No **(1050)**

   1e. Other *(specify)* _____ ❑1 Yes ❑0 No **(1060)**

2. Subject's FEV_1 after additional treatment within first hour.

   2a. FEV_1 ___ . ___ ___ L **(1070)**

   2b. FEV_1 (% predicted) ___ ___ ___ % predicted **(1080)**

   2c. Time of FEV_1 in Question #2a (*based on 24-hour clock*) ___ ___ ___ ___ **(1090)**

   2d. Was the FEV_1 from Question #2a ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form? ❑1 Yes ❑0 No **(1100)**

   ➔ ***If YES, STOP HERE and continue with remaining visit procedures.***

   ➔ ***If NO, proceed to Question #3.***

3. Was additional treatment used after one hour? ❑1 Yes ❑0 No **(1110)**

➔ ***If NO, skip to Question #4.***

3a. Additional albuterol by MDI ❑1 Yes ❑0 No **(1120)**

➔ ***If NO, skip to Question #3b.***

Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four **(1130)**

3b. Nebulized Beta-agonist ❑1 Yes ❑0 No **(1140)**

3c. Subcutaneous epinephrine ❑1 Yes ❑0 No **(1150)**

3d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No **(1160)**

3e. Treatment in the emergency room ❑1 Yes ❑0 No **(1170)**

3f. Overnight hospitalization ❑1 Yes ❑0 No **(1180)**

➔ ***If YES, please complete the Serious Adverse Event (SERIOUS) form.***

3g. Other *(specify)* _____ ❑1 Yes ❑0 No **(1190)**

4. Subject's final FEV_1 after methacholine challenge.

4a. FEV_1 ___ . ___ ___ L **(1200)**

4b. FEV_1 (% predicted) ___ ___ ___ % predicted **(1210)**

4c. Time of FEV_1 from Question #4a (*based on 24-hour clock*) ___ ___ ___ ___ **(1220)**

4d. Was the FEV_1 from Question #4a ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form? ❑1 Yes ❑0 No **(1230)**

➔ ***If NO, complete the source documentation box below.***

Physician Source Documentation

Physician's signature: _____ **(1240)**

Date: __ __ / __ __ / __ __ __ __ **(1250)**

Time: __ __ __ __ *(based on 24-hour clock)* **(1260)**

Asthma Clinical Research Network
NIH/NHLBI

METHACHOLINE CHALLENGE TESTING CHECKLIST

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

Complete this form only if the subject is eligible according to the appropriate Pulmonary Procedure Checklist form and successfully completed baseline spirometry session(s).

1. Has the subject had any severe acute illness in the past 4 weeks? ☐ 1 Yes ☐ 0 No **(1000)**

   If ***YES***, has the subject received permission from the supervising physician to proceed with the methacholine challenge testing? ☐ 1 Yes ☐ 0 No **(1010)**
   Physician's Signature: _____ **(1015)**

2. Does the subject have a baseline (pre-diluent) FEV_1 less than 55% of predicted? ☐ 1 Yes ☐ 0 No **(1020)**
   Use the FEV_1 value from the appropriate spirometry testing form as the baseline reference.

3. Does the subject have a history of urinary retention? ☐ 1 Yes ☐ 0 No **(1030)**

   ➔ If ***NO***, proceed to Question #4.

   3a. If ***YES***, is the subject randomized? ☐ 1 Yes ☐ 0 No **(1040)**

   ➔ If ***NO***, proceed to Question #4 and complete the appropriate Termination of Study Participation form.

   3b. Was written medical clearance obtained from the study physician? ☐ 1 Yes ☐ 0 No **(1050)**

   If ***YES,*** obtain physician's signature:

   _____ **(1055)**

4. Is there any other reason the subject should not proceed with the methacholine challenge testing? ☐ 1 Yes ☐ 0 No **(1060)**
   If ***YES,*** explain _____

5. Is the subject eligible to proceed with the diluent (solution #0) spirometry testing for the methacholine challenge? ☐ 1 Yes ☐ 0 No **(1070)**
   If any of the shaded boxes are completed, the subject is NOT eligible for the methacholine challenge.

   ➔ ***If YES, proceed to the Methacholine Challenge Testing (METHA) form.***

Asthma Clinical Research Network
NIH/NHLBI

BASALT/TALC RUNIN ALLOCATION CHECKLIST

Subject ID: 1 6 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 3
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Since Visit 1, has the subject experienced a significant asthma exacerbation as defined in the protocol? ☐ 1 Yes ☐ 0 No **(1000)**

2. Since Visit 1, has the subject received treatment with any excluded medications (P16_EXCLDRUG)? ☐ 1 Yes ☐ 0 No **(1010)**

3. Using the history stored in the DOSER™, did the subject take at least 75% of the required puffs from his or her QVAR inhaler during the interval between Visits 2 and 3? ☐ 1 Yes ☐ 0 No **(1020)**

   ➔ Use Question #3 from P16_COMPLY to answer this question

4. Using the history stored in the DOSER™, did the subject take 4 puffs per day (correct daily dose) on at least 75% of the days during the interval between Visits 2 and 3? ☐ 1 Yes ☐ 0 No **(1030)**

   ➔ Use Question #6 from P16_COMPLY to answer this question

5. Did the subject record <u>both</u> AM and PM peak flow measurements <u>and</u> symptoms on his or her Diary Cards (P16_DIARY) on at least 75% of the days during the interval between Visits 2 and 3? ☐ 1 Yes ☐ 0 No **(1040)**

6. Did the subject measure his or her AM and PM peak flow on schedule and accurately transcribe the measurements on his or her Diary Cards (P16_DIARY) on at least 75% of the days during the interval between Visits 2 and 3? ☐ 1 Yes ☐ 0 No **(1050)**

7. Is the subject's prebronchodilator FEV_1 > 40% of predicted? ☐ 1 Yes ☐ 0 No **(1060)**

8. Does the subject wish to withdraw consent from the study? ☐ 1 Yes ☐ 0 No **(1070)**

9. Is there any new information that makes the subject ineligible according to the eligibility criteria? ☐ 1 Yes ☐ 0 No **(1080)**
   If ***YES,*** describe: _____

10. Is there any other reason why this subject should not be allocated to the BASALT or TALC study? ☐ 1 Yes ☐ 0 No **(1090)**
    If ***YES,*** describe: _____

11. Is the subject eligible for allocation? ☐ 1 Yes ☐ 0 No **(1100)**

If any of the shaded boxes is completed, the subject is ineligible.

➔ ***If YES, continue with rest of form.***

➔ ***If NO, complete the BASALT/TALC RUNIN Termination of Study Participation (P16_TERM) form.***

12. Is the subject's prebronchodilator FEV_1 > 70% of predicted? ☐ 1 Yes ☐ 0 No **(1110)**

➔ If ***NO***, skip to Question # 14.

13. Did the subject answer 0 or 1 for each of the three questions on the ACRN Asthma Evaluation Questionnaire (AEQ) at this visit? ☐ 1 Yes ☐ 0 No **(1120)**

➔ If ***YES***, skip to Question # 15. Subject should be allocated to the BASALT study.

14. Does the subject have any medical contraindications for tiotropium use (i.e., narrow angle glaucoma, prostatic hypertrophy, bladder-neck obstruction, renal insufficiency)? ☐ 1 Yes ☐ 0 No **(1130)**

➔ If ***YES***, subject is ineligible to continue in the BASALT/TALC studies. Complete a BASALT/TALC RUNIN Termination of Study Participation (P16_TERM) form.

➔ If ***NO***, subject should be allocated to the TALC study.

15. Indicate the study into which the subject is enrolling. ☐ 17 BASALT ☐ 18 TALC **(1140)**

16. Record the date on which the subject originally signed the informed consent document for the study to which he or she has been allocated. ___ ___ / ___ ___ / ___ ___ ___ ___ **(1150)** Month Day Year

After study allocation, complete the following procedures:

➔ ***Record study to which the subject was allocated (P16_LOG).***

➔ ***Enroll subject in appropriate protocol.***

Asthma Clinical Research Network
NIH/NHLBI

BASALT/TALC RUNIN COMPLIANCE CHECKLIST

Subject ID: 1 6 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Check the following compliance criteria at Visits 2 and 3.

DOSER™ Compliance for QVAR MDI

1. Total number of scheduled puffs since the last visit ___ ___ ___ puffs **(1000)**

   ➔ Value obtained from Question #1 on P16_COMPLY_WKS

2. Total number of puffs in DOSER™ history ___ ___ ___ puffs **(1010)**

   ➔ Value obtained from Question #2 on P16_COMPLY_WKS

3. Percent compliance = $\frac{\textit{Question \#2}}{\textit{Question \#1}}$ *x 100* ___ ___ ___ . ___ % **(1020)**

   ➔ ***If the subject took less than 75% of the scheduled QVAR puffs, re-emphasize the importance of maintaining the daily dosing schedule.***

4. Total number of full days since the last visit ___ ___ **(1030)**

   ➔ Value obtained from Question #4 on P16_COMPLY_WKS

5. Total number of compliant days ___ ___ **(1040)**

   ➔ Value obtained from Question #5 on P16_COMPLY_WKS

6. Percent compliance = $\frac{\textit{Question \#5}}{\textit{Question \#4}}$ *x 100* ___ ___ ___ . ___ % **(1050)**

   ➔ ***If the subject took the correct daily dose less than 75% of the days, re-emphasize the importance of maintaining the daily dosing schedule.***

Asthma Clinical Research Network
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BASALT/TALC RUNIN DIARY CARD

Subject's Initials: __ __ __
Date: __ __ / __ __ / __ __ __ __

Subject ID: 1 6 - __ __ - __ __ __
Subject Initials: __ __ __
Return Visit Number: __ __
Return Visit Date: __ __ / __ __ / __ __
Month Day Year

To the subject: If your peak flow is below ___ ___ ___ (1000) liters/minute, use your RESCUE albuterol inhaler as instructed in the handout "If Your Asthma Gets Worse." Contact study personnel if your peak flow does not increase to this value after 1 hour of RESCUE use, or if you are experiencing extreme symptoms. If you have taken at least 10 puffs/24 hours for the past 48 hours from your RESCUE inhaler, contact study personnel.

Please use black ink to complete.		Day 1: ____	Day 2: ____	Day 3: ____	Day 4: ____	Day 5: ____	Day 6: ____	Day 7: ____
Date (ddate)		___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day
MORNING EVALUATION (Between 5 AM and 10 AM)								
1. Number of times you woke up last night due to asthma (1010)		__ __	__ __	__ __	__ __	__ __	__ __	__ __
2. Time of AM Peak Flow (within 15 minutes of awakening) (1020)		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
3. AM Peak Flow (liters/min)** (1030) / (1035)		___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
4. Total number of puff(s) from QVAR Inhaler **(AM)** (1040)		___	___	___	___	___	___	___
Symptoms++ during the night	5. Shortness of Breath (1050)							
	6. Chest Tightness (1060)							
	7. Wheezing (1070)							
	8. Cough (1080)							
	9. Phlegm/Mucus (1090)							
NIGHT-TIME EVALUATION (Between 8 PM and 1 AM)								
10. Time of PM Peak Flow (between 8 PM and 1 AM) (1100)		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
11. PM Peak Flow (liters/min)** (1110) / (1115)		___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
12. Total number of puff(s) from QVAR Inhaler **(PM)** (1120)		___	___	___	___	___	___	___
Symptoms++ since you woke	13. Shortness of Breath (1130)							
	14. Chest Tightness (1140)							
	15. Wheezing (1150)							
	16. Cough (1160)							
	17. Phlegm/Mucus (1170)							
24 HOUR EVALUATION								
18. Total number of puffs from albuterol (RESCUE) inhaler during past 24 hours. *(Do not record preventive use.)* (1180)		__ __	__ __	__ __	__ __	__ __	__ __	__ __
19. Total number of times you dosed from your albuterol (RESCUE) inhaler during past 24 hours. *(Do not record preventive use.)* (1190)		__ __	__ __	__ __	__ __	__ __	__ __	__ __

****** Record the best of three attempts. Circle the value if you have taken any medication from your RESCUE albuterol inhaler in the last 2 hours.

++ Symptom Severity Rating Scale

0 = Absent	No symptom
1 = Mild	Symptom was minimally troublesome, i.e. not sufficient to interfere with normal daily activity or sleep.
2 = Moderate	Symptom was sufficiently troublesome to interfere with normal daily activity or sleep.
3 = Severe	Symptom was so severe as to prevent normal activity and/or sleep.

Asthma Clinical Research Network
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BASALT/TALC RUNIN ELECTROCARDIOGRAM REPORT

Subject ID: 1 6 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 3
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

The subject should rest quietly for at least five minutes before the electrocardiogram.

1. Time electrocardiogram started *(based on 24-hour clock)* ___ ___ ___ ___ **(1000)**

2. Ventricular heart rate ___ ___ ___ beats/min **(1010)**

3. Cardiac cycle measurements

   3a. P - R Interval ___ ___ ___ milliseconds **(1020)**

   3b. QRS Duration ___ ___ ___ milliseconds **(1030)**

   3c. Q - T Interval ___ ___ ___ milliseconds **(1040)**

Physician Source Documentation

Physician's signature: _____ **(1050)**

Date: __ __ / __ __ / __ __ __ __ **(1060)**

Asthma Clinical Research Network
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BASALT/TALC RUNIN ELIGIBILITY CHECKLIST 1

Subject ID: 1 6 - __ __ - __ __ __
Subject Initials: __ __ __
Visit Number: 1
Visit Date: __ __ / __ __ / __ __
Month Day Year
Interviewer ID: __ __ __ __ __ __

(Subject Interview completed)

1. ***Did the subject sign either (or both) of the BASALT/TALC Informed Consent(s)?*** ☐ 1 Yes ☐ 0 No **(1000)**

   If ***YES***, record the date the form(s) was (were) signed. __ __ / __ __ / __ __ __ __ **(1010)**
   month day year

   ➔ ***Consent should be reviewed and signed on the day Visit 1 is performed.***

2. Are you planning to move away from this clinical center in the <u>upcoming year</u> such that your ability to complete the study will be jeopardized? ☐ 1 Yes ☐ 0 No **(1020)**

3. Have you had a respiratory tract infection in the past **4 weeks**? ☐ 1 Yes ☐ 0 No **(1030)**

4. Have you experienced a significant asthma attack in the past **4 weeks**? ☐ 1 Yes ☐ 0 No **(1040)**

5. Do you work the night shift or have an altered day/night cycle for other reasons? ☐ 1 Yes ☐ 0 No **(1050)**

6. Is the subject eligible to proceed? ☐ 1 Yes ☐ 0 No **(1060)**
   If any of the shaded boxes are completed, the subject is ineligible.

   ➔ ***If YES, proceed with remaining Visit 1 procedures.***

Subject Source Documentation
Subject Initials: __ __ __ **(1070)**
Date: __ __ / __ __ / __ __ __ __ **(1080)**

P16 ELIG1

Asthma Clinical Research Network
NIH/NHLBI

BASALT/TALC RUNIN ELIGIBILITY CHECKLIST 2

Subject ID: 1 6 - __ __ - __ __ __
Subject Initials: __ __ __
Visit Number: 1
Visit Date: __ __ / __ __ / __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __ __

(Clinic Coordinator completed)

1. Is the subject 18 years of age or older? ☐ 1 Yes ☐ 0 No **(1000)**

2. Does the subject have current evidence of any of the conditions listed on the Exclusionary Medical Conditions (P16_EXCLMED) reference card? ☐ 1 Yes ☐ 0 No **(1010)**
   If ***YES***, describe _____

   2a. Does the subject have unstable or severe coronary artery disease or a history of myocardial infarction within 6 months of Visit 1? ☐ 1 Yes ☐ 0 No **(1020)**

3. Has the subject taken any medications listed on the Exclusionary Drugs (P16_EXCLDRUG) reference card within the specified time periods? ☐ 1 Yes ☐ 0 No **(1030)**
   If ***YES***, describe _____

4. Is the subject currently taking prescription or over-the-counter medication(s) other than those listed on the Allowed Medications (P16_MEDALLOW) reference card ? ☐ 1 Yes ☐ 0 No **(1040)**
   If ***YES***, describe _____

5. Based on input from the subject and the study physician, will the subject need to use intranasal steroids at any time during the study? ☐ 1 Yes ☐ 0 No **(1050)**

   5a. If ***YES***, is the subject willing to use a single intranasal steroid at a stable dose continuously for the duration of the study? ☐ 1 Yes ☐ 0 No **(1060)**

6. Is the subject regularly using inhaled corticosteroids? ☐ 1 Yes ☐ 0 No **(1070)**

   ➔ If ***NO***, skip to Question #7 and complete rest of form.

   ➔ If ***YES***, answer Questions #6a and 6b, then skip to Question #8.

   6a. Has the subject been on a stable dose of inhaled corticosteroids for at least **2 weeks**? ☐ 1 Yes ☐ 0 No **(1080)**

   6b. Has the subject been using greater than the equivalent of 1000 µg inhaled fluticasone daily? ☐ 1 Yes ☐ 0 No **(1090)**

   ➔ Refer to the ICS Equivalency (P16_ICS_EQUIV) reference card.

7. Has the subject used or received a prescription for an asthma controller (inhaled corticosteroids, leukotriene modifier, and/or long-acting beta-agonist) during the past year? ☐ 1 Yes ☐ 0 No **(1100)**

   7a. If ***NO***, does the subject report experiencing asthma symptoms more than twice a week? ☐ 1 Yes ☐ 0 No **(1110)**

8. Is the subject currently receiving hyposensitization therapy (e.g., allergy shots) other than an established maintenance regimen implemented continuously for a minimum of **3 months**? ☐ 1 Yes ☐ 0 No **(1120)**

9. Has the subject experienced a life-threatening asthma exacerbation requiring treatment with intubation and mechanical ventilation in the past **5 years**? ☐ 1 Yes ☐ 0 No **(1130)**

10. Has the subject smoked cigarettes, a pipe, cigar, marijuana, or any other substance in the past year? ☐ 1 Yes ☐ 0 No **(1140)**

11. Record smoking history in pack-years. (Enter 00.0 if subject never smoked.) ___ ___ . ___ **(1150)**

    Is Question #11 ≥ 10? ☐ 1 Yes ☐ 0 No **(1160)**

12. Is the subject potentially able to bear children? ☐ 1 Yes ☐ 0 No ☐ 9 N/A **(1170)**
    (If subject is male, check N/A and go to Question #13.)

    12a. If ***YES***, is the subject using one of the approved methods indicated on the Birth Control (BIRCTRL) reference card? ☐ 1 Yes ☐ 0 No **(1180)**

    12b. If ***YES***, is the subject currently pregnant or lactating? ☐ 1 Yes ☐ 0 No **(1190)**

13. Is the subject eligible to proceed? ☐ 1 Yes ☐ 0 No **(1200)**
    If any of the shaded boxes are completed, the subject is ineligible.

    ➔ ***If YES, proceed with remaining Visit 1 procedures.***

Subject Source Documentation
Subject Initials: __ __ __ **(1210)**
Date: __ __ / __ __ / __ __ __ __ **(1220)**

Asthma Clinical Research Network
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BASALT/TALC RUNIN ELIGIBILITY CHECKLIST 3

Subject ID: 1 6 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Section 1

1. Is the subject's prebronchodilator FEV_1 > 40% of predicted? ☐ 1 Yes ☐ 0 No **(1000)**

   ➔ If ***NO***, **STOP** here. Subject is ineligible for the study.

2. Does the subject have valid source documentation for a methacholine challenge (ACRN systems and procedures only) within the past 6 months? ☐ 1 Yes ☐ 0 No **(1001)**

   ➔ If ***NO***, skip to Question #3.

   ➔ If ***YES***, record values below:

   PC_{20}: ___ ___ ___ . ___ ___ ___ ___ mg/ml **(1002)**

   Source Documentation Date: ___ ___ / ___ ___ / ___ ___ ___ ___ **(1003)**

   Technician ID: ___ ___ ___ ___ ___ ___ **(1004)**

   Supervisor ID: ___ ___ ___ ___ ___ ___ **(1005)**

   2a. Was the subject using ICS regularly at the time the challenge was performed? ☐ 1 Yes ☐ 0 No **(1006)**

   ➔ If ***YES***, complete Question #2b and skip to Question #2d.

   ➔ If ***NO***, complete Question #2c and continue with rest of form.

   2b. Does the subject have source documentation of a methacholine $PC_{20} \leq 16$ mg/ml? ☐ 1 Yes ☐ 0 No **(1007)**

   2c. Does the subject have source documentation of a methacholine $PC_{20} \leq 8$ mg/ml? ☐ 1 Yes ☐ 0 No **(1008)**

2d. Is the subject eligible to proceed? ☐ 1 Yes ☐ 0 No **(1009)**

If either shaded box in Question # 2b or 2c is completed, the subject must complete testing at Visit 1 to confirm eligibility.

➔ ***If YES, continue with remaining visit procedures and complete Section 4.***

➔ ***If NO, complete Question #3 on the next page and proceed accordingly.***

3. Is the subject's prebronchodilator $FEV_1 \geq 55\%$ of predicted and he/she qualifies for methacholine challenge? ☐ 1 Yes ☐ 0 No **(1010)**

   ➔ If ***YES***, complete Section 2.

   ➔ If ***NO***, complete Section 3.

Section 2

4. Is the subject regularly using ICS at this time? ☐ 1 Yes ☐ 0 No **(1020)**

   ➔ If ***YES***, complete Question #5 and skip to Question #7.

   ➔ If ***NO***, complete Question #6 and continue with rest of form.

5. Does the subject have a methacholine $PC_{20} \leq 16$ mg/ml? ☐ 1 Yes ☐ 0 No **(1030)**

6. Does the subject have a methacholine $PC_{20} \leq 8$ mg/ml? ☐ 1 Yes ☐ 0 No **(1040)**

7. Is the subject eligible to proceed? ☐ 1 Yes ☐ 0 No **(1050)**

   If either shaded box in Section 2 is completed, the subject is ineligible at this point.

   ➔ ***If YES, continue with remaining visit procedures and complete Section 4.***

   ➔ ***If NO, the subject may return at a later date for a continuation visit to perform albuterol reversibility testing to qualify. Complete Question #8 and proceed accordingly.***

8. Will the subject complete reversibility testing? ☐ 1 Yes ☐ 0 No **(1060)**

   ➔ If ***NO***, STOP here. Subject is ineligible for the study.

   ➔ If ***YES***, continue with visit procedures on the P16_VISITA checklist and complete Section 3.

Section 3

9. Did the subject's FEV_1 improve $\geq 12\%$ in response to four puffs of albuterol? ☐ 1 Yes ☐ 0 No **(1070)**

   ➔ ***If YES, continue with remaining visit procedures and complete Section 4 on the next page.***

   ➔ ***If NO, STOP here. Subject is ineligible for the study.***

Section 4

10. Is the subject able to use the AM1® device correctly, as evidenced by achieving a satisfactory rating on the AM1® Performance Checklist (PERF_AM1)? ☐ 1 Yes ☐ 0 No **(1080)**

11. Is the subject able to use a metered dose inhaler (MDI) properly, as evidenced by achieving a score of 6 on two consecutive, separate inhalations using the MDI Inhalation Technique Checklists (SCORE, TECH_MDI)? ☐ 1 Yes ☐ 0 No **(1090)**

12. Is the subject eligible to proceed? ☐ 1 Yes ☐ 0 No **(1100)**

If either shaded box in Section 4 is completed, the subject is ineligible.

➔ ***If YES, continue with remaining visit procedures.***

➔ ***If NO, STOP here. Subject is ineligible for the study.***

Asthma Clinical Research Network
NIH/NHLBI

BASALT/TALC RUNIN LABORATORY MEASUREMENTS

Subject ID: 1 6 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 2
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Eosinophils (absolute count) ___ ___ ___ ___ /mm^3 **(1000)**

Asthma Clinical Research Network
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BASALT/TALC RUNIN MEDICAL HISTORY

Subject ID: 1 6 - __ __ - __ __ __
Subject Initials: __ __ __
Visit Number: 1
Visit Date: __ __ / __ __ / __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __ __

(Subject Interview completed)

COLD HISTORY

1. On average, how many respiratory tract infections/colds do you experience per year? __ __ **(1000)**

2. How severe are your colds usually?
   - ❑1 Extremely severe
   - ❑2 Very severe
   - ❑3 Severe
   - ❑4 Moderate
   - ❑5 Mild
   - ❑6 Extremely mild **(1010)**

3. When you get colds, how often do they make your asthma worse?
   ➔ ***If NEVER, skip to Question # 5.***
   - ❑1 Always
   - ❑2 Usually
   - ❑3 Sometimes
   - ❑4 Rarely
   - ❑5 Never **(1020)**

4. When colds make your asthma worse, how severe does your asthma usually get?
   - ❑1 Extremely severe
   - ❑2 Very severe
   - ❑3 Severe
   - ❑4 Moderate
   - ❑5 Mild
   - ❑6 Extremely mild **(1030)**

PRIOR ASTHMA TREATMENT

I will read a list of medications. Indicate if you have <u>ever used</u> each medication. If you have, please indicate, to the best of your knowledge, the date last taken.

				If Yes, indicate date medication was last taken month / day / year
5. Non-long-acting Inhaled Beta-Agonists (**Bronkaid Mist, Duo-Medihaler, Medihaler-Epi, Primatene Mist, Alupent, Brethaire, Brethine, Bronkometer, Maxair, Metaprel, Proventil, Tornalate, Ventolin, Xopenex and others)**	❑1 Yes **(1040)**	❑0 No	❑8 Unknown	__ __ / __ __ / __ __ __ __ **(1050) (1060) (1070)**
5a. If ***YES***, indicate average daily puffs in the past month. (Enter '00' if none used.)	__ __ puffs **(1080)**			
6. Long-acting Inhaled Beta-Agonists (**Serevent, Foradil, Advair Diskus Symbicort Turbuhaler)**	❑1 Yes **(1090)**	❑0 No	❑8 Unknown	__ __ / __ __ / __ __ __ __ **(1100) (1110) (1120)**

If Yes, indicate date medication was last taken month / day / year

7.	Asthma medication via a Nebulizer Machine	❑1 Yes	❑0 No	❑8 Unknown (1130)	__ __ / __ __ / __ __ __ __ (1140) (1150) (1160)
8.	Oral Beta-Agonists (**Alupent, Brethine, Bricanyl, Metaprel, Proventil, Ventolin, Repetabs, Volmax and others**)	❑1 Yes	❑0 No	❑8 Unknown (1170)	__ __ / __ __ / __ __ __ __ (1180) (1190) (1200)
9.	Short-acting Oral Theophylline (**Aminophylline, Slo-Phyllin and others**)	❑1 Yes	❑0 No	❑8 Unknown (1210)	__ __ / __ __ / __ __ __ __ (1220) (1230) (1240)
10.	Sustained release Oral Theophylline (**Slo-bid, Theo-Dur, Uniphyl and others**)	❑1 Yes	❑0 No	❑8 Unknown (1250)	__ __ / __ __ / __ __ __ __ (1260) (1270) (1280)
11.	Inhaled Anticholinergic (**Atrovent, Combivent, Spiriva**)	❑1 Yes	❑0 No	❑8 Unknown (1290)	__ __ / __ __ / __ __ __ __ (1300) (1310) (1320)
12.	Anti-allergic Inhaled Medications (**Intal, Tilade and others**)	❑1 Yes	❑0 No	❑8 Unknown (1330)	__ __ / __ __ / __ __ __ __ (1340) (1350) (1360)
13.	Anti-allergic Nasal Medications (**Nasalcrom, Astelin and others**)	❑1 Yes	❑0 No	❑8 Unknown (1370)	__ __ / __ __ / __ __ __ __ (1380) (1390) (1400)
14.	Anti-allergic Oral Medications (**Allegra, Claritin, Zyrtec, Chlor-Trimeton and others**)	❑1 Yes	❑0 No	❑8 Unknown (1410)	__ __ / __ __ / __ __ __ __ (1420) (1430) (1440)
15.	Leukotriene Antagonist / 5LO Inhibitors (**Accolate, Zyflo, Singulair**)	❑1 Yes	❑0 No	❑8 Unknown (1450)	__ __ / __ __ / __ __ __ __ (1460) (1470) (1480)
16.	IgE Blocker (**Xolair**)	❑1 Yes	❑0 No	❑8 Unknown (1490)	__ __ / __ __ / __ __ __ __ (1500) (1510) (1520)
17.	Topical Steroids - Prescription (**Synalar, Lidex, Dermacin, Fluocinonide and others**)	❑1 Yes	❑0 No	❑8 Unknown (1530)	__ __ / __ __ / __ __ __ __ (1540) (1550) (1560)
18.	Topical Steroids - OTC (**Hydrocortisone - multiple strengths and products)**	❑1 Yes	❑0 No	❑8 Unknown (1570)	__ __ / __ __ / __ __ __ __ (1580) (1590) (1600)
19.	Nasal Steroids (**Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Rhinocort, Nasonex and others)**	❑1 Yes	❑0 No	❑8 Unknown (1610)	__ __ / __ __ / __ __ __ __ (1620) (1630) (1640)
20.	Oral Steroids (**Prednisone, Medrol and others**)	❑1 Yes	❑0 No	❑8 Unknown (1650)	__ __ / __ __ / __ __ __ __ (1660) (1670) (1680)

If Yes, indicate date medication was last taken month / day / year

21. Inhaled Steroids (**Azmacort, Beclovent, Vanceril, AeroBid, QVAR, Flovent, Pulmicort, Advair Diskus and others**) ❑1 Yes ❑0 No ❑8 Unknown **(1690)** __ __ / __ __ / __ __ __ __ **(1700) (1710) (1720)**

➔ ***If NO or unknown, skip to Question #22.***

➔ ***If YES, complete Questions #21a - 21c.***

21a. Indicate most recent type of inhaled steroid taken

- ❑1 beclomethasone MDI (1 puff = 42 µg) (**e.g., Beclovent, Vanceril**)
- ❑2 beclomethasone MDI (1 puff = 84 µg) (**e.g., Vanceril-DS**)
- ❑3 beclomethasone HFA (1 puff = 40 µg) (**e.g., QVAR**)
- ❑4 beclomethasone HFA (1 puff = 80 µg) (**e.g., QVAR**)
- ❑5 budesonide DPI (1 puff = 80 µg) (**e.g., Symbicort Turbuhaler**)
- ❑6 budesonide DPI (1 puff = 160 µg) (**e.g., Symbicort Turbuhaler**)
- ❑7 budesonide DPI (1 puff = 200 µg) (**e.g., Pulmicort Turbuhaler**)
- ❑8 budesonide DPI (1 puff = 320 µg) (**e.g., Symbicort Turbuhaler**)
- ❑9 flunisolide MDI (1 puff = 250 µg) (**e.g., Aerobid, Aerobid - M**)
- ❑10 fluticasone MDI (1 puff = 44 µg) (**e.g., Flovent**)
- ❑11 fluticasone MDI (1 puff = 110 µg) (**e.g., Flovent**)
- ❑12 fluticasone MDI (1 puff = 220 µg) (**e.g., Flovent**)
- ❑13 fluticasone DPI (1 puff = 50 µg) (**e.g., Flovent Rotadisk**)
- ❑14 fluticasone DPI (1 puff = 100 µg) (**e.g., Advair Diskus**)
- ❑15 fluticasone DPI (1 puff = 250 µg) (**e.g., Advair Diskus**)
- ❑16 fluticasone DPI (1 puff = 500 µg) (**e.g., Advair Diskus**)
- ❑17 mometasone DPI (1 puff = 220 µg) (**e.g., Asmanex Twisthaler**)
- ❑18 triamcinolone acetonide MDI (1 puff = 100 µg) (**e.g., Azmacort**)
- ❑19 other _____ **(1730)**

21b. Indicate number of daily puffs used ___ ___ puffs **(1740)**

21c. Indicate how long you used the inhaled steroid(duration of use)

- ❑1 less than 1 month
- ❑2 1 - 6 months
- ❑3 greater than 6 months **(1750)**

PRIOR CHOLESTEROL TREATMENT WITH STATIN DRUGS

Indicate if you have ever used statin medications. If you have, please indicate, to the best of your knowledge, the most recent drug taken, date last taken, and the total daily dose.

22. Statin medications (**Lipitor, Baycol, Lescol, Advicor, Mevacor, Pravachol, Vytorin, Zocor and Crestor**) ❑1 Yes ❑0 No ❑8 Unknown **(2030)**

If Yes, indicate date medication was last taken month / day / year __ __ / __ __ / __ __ __ __ **(2040) (2050) (2060)**

➔ ***If NO or unknown, skip to Question #23.***

➔ ***If YES, complete Questions #22a - 22b.***

22a. Indicate most recent type of statin medication taken

- ❑1 atorvastatin (**e.g., Lipitor**)
- ❑2 cerivastatin (**e.g., Baycol**)
- ❑3 fluvastatin (**e.g., Lescol**)
- ❑4 lovastatin (**e.g., Advicor, Mevacor**)
- ❑5 pravastatin (**e.g., Pravachol**)
- ❑6 simvastatin (**e.g., Vytorin, Zocor**)
- ❑7 rosuvastatin (**e.g., Crestor**) **(2070)**

22b. Indicate the total daily dose used (If dosage is unknown enter '999') ___ ___ ___ . ___ mg **(2080)**

PRIOR DISEASES, ILLNESSES AND SURGERIES

Have you had any diseases, illnesses, conditions or surgeries related to the following areas?

				If Yes, Comment
23.	Skin	❑1 Yes	❑0 No	_____ **(1760)**
24.	Blood, Lymph, or Immune Systems	❑1 Yes	❑0 No	_____ **(1770)**
25.	Eyes	❑1 Yes	❑0 No	_____ **(1780)**
26.	Ears, Nose, or Throat	❑1 Yes	❑0 No	_____ **(1790)**

26a. Have you ever had nasal polyps? ❑1 Yes ❑0 No ❑9 Don't know **(1800)**

26ai. If ***YES,*** have you ever had any nasal polyps removed? ❑1 Yes ❑0 No **(1810)**

26b. Do you have chronic or recurrent sinusitis (treated with antibiotics)? ❑1 Yes ❑0 No ❑9 Don't know **(1820)**

27. Breasts ❑1 Yes ❑0 No _____ **(1830)**

28. Endocrine Systems ❑1 Yes ❑0 No _____ **(1840)**

29. Lung - other than asthma ❑1 Yes ❑0 No _____ **(1850)**

29a. Have you ever had pneumonia? ❑1 Yes ❑0 No ❑9 Don't know **(1860)**

29b. Have you ever had bronchitis? ❑1 Yes ❑0 No ❑9 Don't know **(1870)**

30. Heart and Blood Vessels ❑1 Yes ❑0 No _____ **(1880)**

31. Liver or Pancreas ❑1 Yes ❑0 No _____ **(1890)**

32. Kidneys or Urinary Tract System ❑1 Yes ❑0 No _____ **(1900)**

33. Reproductive System ❑1 Yes ❑0 No _____ **(1910)**

34. Stomach or Intestines ❑1 Yes ❑0 No _____ **(1920)**

34a. Do you have gastroesophageal reflux disease (GERD)? ❑1 Yes ❑0 No ❑9 Don't know **(1930)**

35. Muscles or Bones ❑1 Yes ❑0 No _____ **(1940)**

36. Nervous System ❑1 Yes ❑0 No _____ **(1950)**

37. Psychiatric ❑1 Yes ❑0 No _____ **(1960)**

38. Other _____ ❑1 Yes ❑0 No _____ **(1970)**

39. Drug Allergies ❑1 Yes ❑0 No _____ **(1980)**

_____

_____

40. Food Allergies ❑1 Yes ❑0 No _____ **(1990)**

_____

_____

SUBJECT'S WEIGHT

(Clinic Coordinator completed)

41. Weight (*without shoes or heavy clothing*) ___ ___ ___ . ___ kg **(2000)**

Subject Source Documentation

Subject's Initials: __ __ __ **(2010)**

Date: __ __ / __ __ / __ __ __ __ **(2020)**

BASALT/TALC RUNIN PULMONARY PROCEDURE CHECKLIST (Visits 1-3)

Subject ID: 1 6 - __ __ - __ __ __
Subject Initials: __ __ __
Visit Number: __
Visit Date: __ __ / __ __ / __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __ __

(Subject Interview completed)

Please reference the Drug Classifications list for a complete list of examples for the questions below. If any medications <u>other than</u> study QVAR or rescue albuterol were used, record the medication(s) on the Concomitant Medications for Asthma/Allergies and Adverse Events (CMED) form.

1. Have you consumed caffeine in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1000)**
   ***Examples**: Pepsi, Coke, Coffee, Mountain Dew, Tea, Rootbeer, Red Bull*

2. Have you used medications with caffeine in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1010)**
   ***Examples**: Anacin, Darvon compound, Esgic, Excedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*

3. Have you used any weight loss medications in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1020)**
   Examples: bitter orange, Xenadrine EFX, Thermorexin

4. Have you consumed any food containing alcohol or beverages containing alcohol in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1030)**

5. Have you used any oral antihistamines in the past **48** hours? ☐ 1 Yes ☐ 0 No **(1040)**
   ***Examples**: Allegra, Chlor-Trimeton, Claritin, Tylenol PM*

6. Have you used any nasal antihistamines in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1045)**
   ***Examples**: Astelin, Livostin, Patanase*

7. Have you used any oral decongestants or cold remedies in the past **48** hours? ☐ 1 Yes ☐ 0 No **(1050)**
   ***Examples**: pseudoephedrine (Sudafed), Tylenol Allergy*

8. Have you used any nasal decongestants in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1060)**
   ***Examples**: oxymetazoline (Afrin)*

9. Have you used any cough medicines, anti-tussives, or expectorants in the past **48** hours? ☐ 1 Yes ☐ 0 No **(1070)**
   ***Examples**: guaifenesin, dextromethorphan, Duratuss, Benylin, Triaminic expectorant, Dayquil Anti-Cough*

10. Have you used a rescue intermediate-acting inhaled beta-agonist in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1080)**
    ***Example**: albuterol (Ventolin or Proventil), study RESCUE*

11. Have you used any nasal steroids in the past **48** hours? ☐ 1 Yes ☐ 0 No **(1090)**
    ***Examples**: Flonase, Rhinocort, Nasonex*

12. Have you used any smokeless tobacco products today? ☐ 1 Yes ☐ 0 No **(1095)**
***Examples**: chewing tobacco, snuff*

13. At this time, is your asthma worse because of recent exposure to triggers? ☐ 1 Yes ☐ 0 No **(1100)**
***Examples**: cold air, smoke, allergens, recent exercise, a recent respiratory tract infection, or other pulmonary infection*

14. Is there any other reason you should not proceed with spirometry testing? ☐ 1 Yes ☐ 0 No **(1110)**

If ***YES***, explain _____
_____

15. Is the subject eligible to proceed with the spirometry testing? ☐ 1 Yes ☐ 0 No **(1120)**

If any of the shaded boxes are filled in, the subject is ineligible for spirometry and exhaled nitric oxide testing.

➔ ***If YES, proceed to Question #16 or the next form/procedure listed on the visit procedure checklist.***

Complete for all subjects at Visit 1.

If subject is less than 21 years old, complete Question #16 at each visit.

16. Height (*without shoes*) ___ ___ ___ cm **(1130)**

Asthma Clinical Research Network
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BASALT/TALC RUNIN TERMINATION OF STUDY PARTICIPATION

Visits 1-3

Subject ID: 1 6 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete this form only for subjects who have successfully completed Visit 1 and have been terminated or deemed ineligible prior to the completion of Visit 3.

1. Who initiated termination of the subject?

   ❑1 Subject
   ❑2 Clinical Staff **(1000)**

   ➔ ***If subject withdrew due to impending clinical staff termination, please indicate termination by clinical staff.***

   ➔ ***If Clinical Staff, skip to Question #3.***

2. Indicate the **primary** reason the subject has withdrawn from the study.

   ❑1 no longer interested in participating *****
   ❑2 no longer willing to follow protocol *****
   ❑3 difficult access to clinic (location, transportation, parking)
   ❑4 unable to make visits during clinic hours
   ❑5 moving out of the area
   ❑6 unable to continue due to personal constraints *****
   ❑7 unable to continue due to medical condition unrelated to asthma *****
   ❑8 side effects of runin study medications *****
   ❑9 dissatisfied with asthma control during the runin
   ❑10 other ***** **(1010)**

*** Additional explanation required:**

_____

_____

_____ **(1020)**

➔ ***Skip to the SIGNATURES section.***

3. Did clinical staff terminate the subject due to ...

3a.	pregnancy? *(Check N/A if the subject is male.)*	☐ 1 Yes	☐ 0 No	☐ 9 N/A	**(1030)**
3b.	loss to follow-up? *****	☐ 1 Yes	☐ 0 No		**(1040)**
3c.	an asthma-related adverse event? *****	☐ 1 Yes	☐ 0 No		**(1050)**
3d.	a medication-related adverse event? *****	☐ 1 Yes	☐ 0 No		**(1060)**
3e.	an adverse event not related to asthma or medications? *****	☐ 1 Yes	☐ 0 No		**(1070)**
3f.	non-compliance with QVAR dosing? *****	☐ 1 Yes	☐ 0 No		**(1080)**
3g.	non-compliance with diary completion? *****	☐ 1 Yes	☐ 0 No		**(1090)**
3h.	non-compliance with visit attendance? *****	☐ 1 Yes	☐ 0 No		**(1100)**
3i.	non-compliance with peak flow monitoring? *	☐ 1 Yes	☐ 0 No		**(1110)**
3j.	significant asthma exacerbation?	☐ 1 Yes	☐ 0 No		**(1120)**
3k.	ineligibility during the BASALT/TALC common runin period for reasons other than compliance or exacerbation? *****	☐ 1 Yes	☐ 0 No		**(1130)**
3l.	subject allocated to TALC prior to study start date	☐ 1 Yes	☐ 0 No		**(1132)**
3m.	subject allocated to TALC after recruitment closed	☐ 1 Yes	☐ 0 No		**(1134)**
3n.	subject allocated to BASALT after recruitment closed	☐ 1 Yes	☐ 0 No		**(1136)**
3o.	other reason? *****	☐ 1 Yes	☐ 0 No		**(1140)**

*** Additional explanation required:**

_____

_____

_____ **(1150)**

3p. Indicate the letter corresponding to the primary reason the subject was terminated. ____ **(1160)**

SIGNATURES

Please complete the following section regardless of the reason for termination of study participation.

I verify that all information collected on the ACRN BASALT/TALC RUNIN data collection forms for this subject is correct to the best of my knowledge and was collected in accordance with the procedures outlined in the study protocol.

_____ **(1170)** ___ ___ /___ ___ /___ ___ ___ ___ **(1180)**

Clinic Coordinator Signature — month day year

_____ **(1190)** ___ ___ /___ ___ /___ ___ ___ ___ **(1200)**

Principal Investigator Signature — month day year

Asthma Clinical Research Network
NIH/NHLBI

TALC CLINIC COORDINATOR STUDY TREATMENT QUESTIONNAIRE (Visits 3-6, 7-10, 11-14)

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This questionnaire is to be completed at Visits 6, 10, and 14 by the ACRN study coordinator who was primarily responsible for the subject's TALC visits during the preceding 14 weeks. If a randomized subject terminates prior to Visit 14, this form should be completed at the time of the termination visit. Do not complete this form for subjects terminating during runout periods.

1. **Blinded Scheduled Diskus®**

Subjects in the TALC study were randomized to receive either an active salmeterol Diskus or a placebo Diskus. You were blinded to the actual treatment assignment. Please check the box that most closely represents your feelings about the treatment the subject received **over the past 14 weeks.**

- ☐ 1 I am certain the Diskus contained placebo. **(1000)**
- ☐ 2 I think the Diskus probably contained placebo.
- ☐ 3 I have no idea which type of Diskus the subject received, but my best guess would be:
  - ☐ 1 Placebo
  - ☐ 2 Active Salmeterol **(1010)**
- ☐ 4 I think the Diskus probably contained active salmeterol.
- ☐ 5 I am certain the Diskus contained active salmeterol.

2. **Blinded Scheduled HandiHaler®**

Subjects in the TALC study were randomized to receive either active tiotropium capsules or placebo capsules to be administered with their scheduled HandiHaler®. You were blinded to the actual treatment assignment. Please check the box that most closely represents your feelings about the capsules the subject received **over the past 14 weeks.**

- ☐ 1 I am certain the capsules contained placebo. **(1020)**
- ☐ 2 I think the capsules probably contained placebo.
- ☐ 3 I have no idea what was in the subject's capsules, but my best guess would be:
  - ☐ 1 Placebo
  - ☐ 2 Active Tiotropium **(1030)**
- ☐ 4 I think the capsules probably contained active tiotropium.
- ☐ 5 I am certain the capsules contained active tiotropium.

3. **Blinded QVAR MDIs**

Subjects in the TALC study were randomized to receive either low dose QVAR (40 micrograms per puff) or high dose QVAR (80 micrograms per puff). You were blinded to the actual treatment assignment. Please check the box that most closely represents your feelings about the treatment the subject received **over the past 14 weeks.**

☐ 1 I am certain the subject was on low dose QVAR. **(1040)**

☐ 2 I think the subject probably was on low dose QVAR.

☐ 3 I have no idea what dose of QVAR the subject received, but my best guess would be:

- ☐ 1 Low Dose
- ☐ 2 High Dose **(1050)**

☐ 4 I think the subject was probably on high dose QVAR.

☐ 5 I am certain the subject was on high dose QVAR.

4. Please comment with respect to any observations you made that helped you make your choices in Questions #1 - #3.

Clinic Coordinator Source Documentation

Coordinator's Initials: __ __ __ **(1060)**

Date: __ __ / __ __ / __ __ __ __ **(1070)**

Asthma Clinical Research Network
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TALC CHANGE IN MEDICATIONS

(Visits 3-14, 6A-6H, 10A-10H)

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete this form if the subject has experienced an adverse event that resulted in altering the dose of any of the subject's study medications.

1. Related Adverse Event Number ___ ___ **(1000)**

2. QVAR MDI
   - ❑ 1 Discontinued
   - ❑ 2 Reduced
   - ❑ 3 Increased
   - ❑ 4 Unchanged **(1010)**

➔ If ***Unchanged***, proceed to Question #3.

2a. Date change began ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) **(1020)**

2b. Date change ended ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) **(1030)**

2c. Ongoing at current visit ❑ 1 **(1040)**

3. Scheduled Diskus®
   - ❑ 1 Discontinued
   - ❑ 2 Reduced
   - ❑ 3 Increased
   - ❑ 4 Unchanged
   - ❑ 5 Not Applicable **(1050)**

➔ If ***Unchanged or Not Applicable,*** *proceed to Question #4.*

3a. Date change began ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) **(1060)**

3b. Date change ended ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) **(1070)**

3c. Ongoing at current visit ❑ 1 **(1080)**

4. Scheduled HandiHaler®/Study capsules

- ☐ 1 Discontinued
- ☐ 2 Reduced
- ☐ 3 Increased
- ☐ 4 Unchanged
- ☐ 5 Not Applicable **(1090)**

➔ If ***Unchanged or Not Applicable,*** stop here.

4a. Date change began ___ ___ / ___ ___ / ___ ___ ___ ___ **(1100)**
Month Day Year

4b. Date change ended ___ ___ / ___ ___ / ___ ___ ___ ___ **(1110)**
Month Day Year

4c. Ongoing at current visit ☐ 1 **(1120)**

Asthma Clinical Research Network
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TALC COMPLIANCE CHECKLIST

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Check the following compliance criteria at all scheduled Visits 4-15, 6A-6H, and 10A-10H.

1. **DOSER™ Compliance for QVAR MDI**

If the interval between visits exceeds 30 days, complete Questions #1a - #1f using data for the 30 days prior to the visit.

1a. Total number of scheduled puffs since the last visit ___ ___ ___ puffs **(1000)**

➔ Value obtained from Question #1 on P18_COMPLY_WKS

1b. Total number of puffs in DOSER™ history ___ ___ ___ puffs **(1010)**

➔ Value obtained from Question #2 on P18_COMPLY_WKS

1c. Percent compliance = $\frac{\textit{Question \#1b}}{\textit{Question \#1a}}$ *x 100* ___ ___ ___ . ___ % **(1020)**

➔ ***If the subject took less than 75% of the scheduled QVAR puffs, re-emphasize the importance of maintaining the daily dosing schedule.***

1d. Total number of full days since the last visit ___ ___ **(1030)**

➔ Value obtained from Question #4 on P18_COMPLY_WKS

1e. Total number of compliant days ___ ___ **(1040)**

➔ Value obtained from Question #5 on P18_COMPLY_WKS

1f. Percent compliance = $\frac{\textit{Question \#1e}}{\textit{Question \#1d}}$ *x 100* ___ ___ ___ . ___ % **(1050)**

➔ ***If the subject took the correct daily dose less than 75% of the days, re-emphasize the importance of maintaining the daily dosing schedule.***

2. **Scheduled Diskus® Compliance (Visits 4 - 6, 8 - 10, 12 - 14 ONLY*)***

2a. Number of scheduled puffs since the last visit ___ ___ ___ puffs **(1060)**

➔ ***Do not include puffs during the 12 hour hold period prior to the visit***

2b. Number of remaining puffs reflected on scheduled Diskus® counters ___ ___ ___ puffs **(1070)**

➔ Total the values reflected on the two returned scheduled Diskuses®

2c. Number of puffs taken ___ ___ ___ puffs **(1080)**

➔ Compute 120 - Question #2b

2d. Percent compliance = $\frac{\textit{Question \#2c}}{\textit{Question \#2a}}$ *x 100* ___ ___ ___ . ___ % **(1090)**

➔ ***If the subject took less than 75% of the scheduled Diskus puffs, re-emphasize the importance of maintaining the daily dosing schedule.***

3. **Scheduled HandiHaler®/Study capsule Compliance (Visits 4 - 6, 8 - 10, 12 - 14 ONLY*)***

3a. Number of scheduled capsules since the last visit ___ ___ capsules **(1100)**

➔ ***Do not include doses during the 24 hour hold period prior to the visit***

3b. Number of used blisters returned ___ ___ blisters **(1110)**

3c. Percent compliance = $\frac{\textit{Question \#3b}}{\textit{Question \#3a}}$ *x 100* ___ ___ ___ . ___ % **(1120)**

➔ ***If the subject took less than 75% of the scheduled doses, re-emphasize the importance of maintaining the daily dosing schedule.***

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TALC DIARY CARD

Subject's Initials: ___ ___ ___
Date: ___ ___ / ___ ___ / ___ ___ ___ ___

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Return Visit Number: ___ ___ ___
Return Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year

To the subject: If your peak flow is below ___ ___ ___ (1000) liters/minute, use your RESCUE albuterol inhaler as instructed in the handout "If Your Asthma Gets Worse." Contact study personnel if your peak flow does not increase to this value after 1 hour of RESCUE use, or if you are experiencing extreme symptoms. If you have taken at least 10 puffs/24 hours for the past 48 hours from your RESCUE inhaler, contact study personnel.

Please use black ink to complete.		Day 1: ____	Day 2: ____	Day 3: ____	Day 4: ____	Day 5: ____	Day 6: ____	Day 7: ____
Date (ddate)		___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day
MORNING EVALUATION (Between 5 AM and 10 AM)								
1. Number of times you woke up last night due to asthma (1010)		___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
2. Time of AM Peak Flow (within 15 minutes of awakening) (1020)		___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___
3. AM Peak Flow (liters/min)** (1030) / (1035)		___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
4. Total number of puff(s) from QVAR Inhaler **(AM)** (1040)		___	___	___	___	___	___	___
Symptoms++ during the night	5. Shortness of Breath (1050)							
	6. Chest Tightness (1060)							
	7. Wheezing (1070)							
	8. Cough (1080)							
	9. Phlegm/Mucus (1090)							
NIGHT-TIME EVALUATION (Between 8 PM and 1 AM)								
10. Time of PM Peak Flow (between 8 PM and 1 AM) (1100)		___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___
11. PM Peak Flow (liters/min)** (1110) / (1115)		___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
12. Total number of puff(s) from QVAR Inhaler **(PM)** (1120)		___	___	___	___	___	___	___
Symptoms++ since you woke	13. Shortness of Breath (1130)							
	14. Chest Tightness (1140)							
	15. Wheezing (1150)							
	16. Cough (1160)							
	17. Phlegm/Mucus (1170)							
24 HOUR EVALUATION								
18. Total number of puffs from albuterol (RESCUE) inhaler during past 24 hours. *(Do not record preventive use.)* (1180)		___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
19. Total number of times you dosed from your albuterol (RESCUE) inhaler during past 24 hours. *(Do not record preventive use.)* (1190)		___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___

****** Record the best of three attempts. Circle the value if you have taken any medication from your RESCUE albuterol inhaler in the last 2 hours.

++ Symptom Severity Rating Scale

0 = Absent	No symptom
1 = Mild	Symptom was minimally troublesome, i.e. not sufficient to interfere with normal daily activity or sleep.
2 = Moderate	Symptom was sufficiently troublesome to interfere with normal daily activity or sleep.
3 = Severe	Symptom was so severe as to prevent normal activity and/or sleep.

Asthma Clinical Research Network
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TALC DIARY CARD

Subject's Initials: __ __ __
Date: __ __ / __ __ / __ __ __ __

Subject ID: 1 8 - __ __ - __ __ __
Subject Initials: __ __ __
Return Visit Number: __ __
Return Visit Date: __ __ / __ __ / __ __
Month Day Year

To the subject: If your peak flow is below _____ (1000) liters/minute, use your RESCUE albuterol inhaler as instructed in the handout "If Your Asthma Gets Worse." Contact study personnel if your peak flow does not increase to this value after 1 hour of RESCUE use, or if you are experiencing extreme symptoms. If you have taken at least 10 puffs/24 hours for the past 48 hours from your RESCUE inhaler, contact study personnel.

Please use black ink to complete.	Day 1: _____	Day 2: _____	Day 3: _____	Day 4: _____	Day 5: _____	Day 6: _____	Day 7: _____
Date (ddate)	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day
MORNING EVALUATION (Between 5 AM and 10 AM)							
1. Number of times you woke up last night due to asthma (1010)	__ __	__ __	__ __	__ __	__ __	__ __	__ __
2. Time of AM Peak Flow (within 15 minutes of awakening) (1020)	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
3. AM Peak Flow (liters/min)** (1030) / (1035)	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __
4. Total number of puff(s) from QVAR Inhaler **(AM)** (1040)	___	___	___	___	___	___	___
5. Total number of puff(s) from Scheduled Diskus® **(AM)** (1043)	___	___	___	___	___	___	___
6. Total number of capsule(s) taken with Scheduled HandiHaler® **(AM)** (1048)	___	___	___	___	___	___	___
Symptoms++ during the night — 7. Shortness of Breath (1050)							
8. Chest Tightness (1060)							
9. Wheezing (1070)							
10. Cough (1080)							
11. Phlegm/Mucus (1090)							
NIGHT-TIME EVALUATION (Between 8 PM and 1 AM)							
12. Time of PM Peak Flow (between 8 PM and 1 AM) (1100)	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
13. PM Peak Flow (liters/min)** (1110) / (1115)	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __
14. Total number of puff(s) from QVAR Inhaler **(PM)** (1120)	___	___	___	___	___	___	___
15. Total number of puff(s) from Scheduled Diskus® **(PM)** (1125)	___	___	___	___	___	___	___
Symptoms++ since you woke — 16. Shortness of Breath (1130)							
17. Chest Tightness (1140)							
18. Wheezing (1150)							
19. Cough (1160)							
20. Phlegm/Mucus (1170)							
24 HOUR EVALUATION							
21. Total number of puffs from albuterol (RESCUE) inhaler during past 24 hours. *(Do not record preventive use.)* (1180)	__ __	__ __	__ __	__ __	__ __	__ __	__ __
22. Total number of times you dosed from your albuterol (RESCUE) inhaler during past 24 hours. *(Do not record preventive use.)* (1190)	__ __	__ __	__ __	__ __	__ __	__ __	__ __

** Record the best of three attempts. Circle the value if you have taken any medication from your RESCUE albuterol inhaler in the last 2 hours.

++ Symptom Severity Rating Scale

0 = Absent	No symptom
1 = Mild	Symptom was minimally troublesome, i.e. not sufficient to interfere with normal daily activity or sleep.
2 = Moderate	Symptom was sufficiently troublesome to interfere with normal daily activity or sleep.
3 = Severe	Symptom was so severe as to prevent normal activity and/or sleep.

Asthma Clinical Research Network
NIH/NHLBI

TALC ELIGIBILITY CHECKLIST

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 3
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Is the subject able to use a Diskus® properly, as evidenced by achieving a score of 8 on two consecutive, separate inhalations using the Diskus® Inhalation Technique Checklist (TECH_DISKUS)? ☐ 1 Yes ☐ 0 No **(1000)**

2. Is the subject able to use a HandiHaler® correctly, as evidenced by achieving a score of 11 when practicing with two consecutive placebo capsules using the HandiHaler® Inhalation Technique Checklist (TECH_HANDIHALER)? ☐ 1 Yes ☐ 0 No **(1010)**

3. Is the subject able to use a metered dose inhaler (MDI) properly, as evidenced by achieving a score of 6 on two consecutive, separate inhalations using the MDI Inhalation Technique Checklist (TECH_MDI)? ☐ 1 Yes ☐ 0 No **(1020)**

4. Is there any other reason why this subject should not be randomized in the TALC study? ☐ 1 Yes ☐ 0 No **(1030)**
   If ***YES,*** describe: _____

5. Is the subject eligible to proceed? ☐ 1 Yes ☐ 0 No **(1040)**
   If any shaded box is completed, the subject is ineligible.

   ➔ ***If the subject is eligible and will participate in TALC, randomize the subject. Record the subject's Period 1 drug kit number on P16_LOG .***

   ➔ ***If the subject is ineligible, complete the TALC Termination of Study Participation (P18_TERM) form.***

Asthma Clinical Research Network
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TALC HEART RATE MONITORING

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

The subject should rest quietly for at least five minutes before monitoring resting heart rate.

1. Which heart rate monitoring method was used at this visit?
   ❑ 1 ECG
   ❑ 2 Pulse oximeter **(1000)**

   ➔ ***If pulse oximeter was used, complete questions #2 and #3 and continue with remaining visit procedures***

2. Time heart rate monitoring started *(based on 24-hour clock)* ___ ___ ___ ___ **(1010)**

3. Ventricular heart rate ___ ___ ___ beats/min **(1020)**

4. Cardiac cycle measurements

   4a. P - R Interval ___ ___ ___ milliseconds **(1030)**

   4b. QRS Duration ___ ___ ___ milliseconds **(1040)**

   4c. Q - T Interval ___ ___ ___ milliseconds **(1050)**

5. Have there been any clinically important changes from Visit 3 in the subject's ECG measurements?
   ❑ 1 Yes ❑ 0 No **(1060)**

   ➔ ***If YES, please complete the Clinical and Laboratory Adverse Events (AECLIN) form.***

Asthma Clinical Research Network
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TALC SCHEDULED MEDICATIONS (Visits 3-14, 6A-6H, 10A-10H)

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Type of scheduled medications dispensed
   - ❑ 1 Regular
   - ❑ 2 Backup **(1000)**

   ➔ ***If backup medications were dispensed, fax this form immediately to the Project Coordinator at the DCC at (717) 531-4359. Explain circumstances:*** _____

2. Number of scheduled QVAR® inhalers dispensed
   - ❑ 0 None
   - ❑ 1 One
   - ❑ 2 Two **(1010)**

3. Number of scheduled Diskus® units dispensed
   - ❑ 0 None
   - ❑ 1 One
   - ❑ 2 Two **(1020)**

4. Number of study capsule blister cards (6 blisters per card) dispensed with scheduled HandiHaler®
   ___ Blister Cards **(1030)**

If this is a dispensation at Visits 3-5, 7-9, or 11-13, affix the drug label below.

Note: No drug label will be available for dispensations at Visits 6, 6A-6H, 10, 10A-10H, 14.

Copy the drug label number below.

1 8 - ___ ___ ___
(1040) **(1050)**

Coordinator's Signature: _____ **(1070)**

Date: ___ ___ / ___ ___ / ___ ___ ___ ___ **(1080)**

By signing in the source documentation box you are:

1) confirming that the label on the medications matches the number on the outside of the treatment period kit.
2) confirming that the subject initials and ID number written on the outside of the kit correspond to the person receiving the medications.
3) confirming that the dates of use for QVAR® inhalers and Diskus® units have been calculated correctly and accurately transcribed onto the inhaler labels.
4) confirming that the correct medications were distributed at this visit.

(Subject Interview completed)

Please reference the Drug Classifications list for a complete list of examples for the questions below. If any medications <u>other than</u> study drugs or rescue albuterol were used, record the medication(s) on the Concomitant Medications for Asthma/Allergies and Adverse Events (CMED) form.

1. Have you consumed caffeine in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1000)**
   Examples: *Pepsi, Coke, Coffee, Mountain Dew, Tea, Rootbeer, Red Bull*

2. Have you used medications with caffeine in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1010)**
   Examples: *Anacin, Darvon compound, Esgic, Excedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*

3. Have you used any weight loss medications in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1020)**
   Examples: *bitter orange, Xenadrine EFX, Thermorexin*

4. Have you consumed any food containing alcohol or beverages containing alcohol in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1030)**

5. Have you used any oral antihistamines in the past **48** hours? ☐ 1 Yes ☐ 0 No **(1040)**
   Examples: *Allegra, Chlor-Trimeton, Claritin, Tylenol PM*

6. Have you used any nasal antihistamines in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1045)**
   Examples: *Astelin, Livostin, Patanase*

7. Have you used any oral decongestants or cold remedies in the past **48** hours? ☐ 1 Yes ☐ 0 No **(1050)**
   Examples: *pseudoephedrine (Sudafed), Tylenol Allergy*

8. Have you used any nasal decongestants in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1060)**
   Examples: *oxymetazoline (Afrin)*

9. Have you used any cough medicines, anti-tussives, or expectorants in the past **48** hours? ☐ 1 Yes ☐ 0 No **(1070)**
   Examples: *guaifenesin, dextromethorphan, Duratuss, Benylin, Triaminic expectorant, Dayquil Anti-Cough*

10. Have you used a rescue intermediate-acting inhaled beta-agonist in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1080)**
    Example: *albuterol (Ventolin or Proventil), study RESCUE*

11. Have you used any nasal steroids in the past **48** hours? ☐ 1 Yes ☐ 0 No **(1090)**
    Examples: *Flonase, Rhinocort, Nasonex*

12. Have you used any smokeless tobacco products today? ☐ 1 Yes ☐ 0 No **(1095)**
***Examples**: chewing tobacco, snuff*

13. **(Do not complete for Visits 6A-6H, 7, 10A-10H, 11 and 15)**
Have you used your scheduled Diskus in the past **12** hours? ☐ 1 Yes ☐ 0 No **(1100)**

14. **(Do not complete for Visits 6A-6H, 7, 10A-10H, 11 and 15)**
Have you used your scheduled HandiHaler in the past **24** hours? ☐ 1 Yes ☐ 0 No **(1110)**

15. At this time, is your asthma worse because of recent exposure to triggers? ☐ 1 Yes ☐ 0 No **(1120)**
***Examples**: cold air, smoke, allergens, recent exercise, a recent respiratory tract infection, or other pulmonary infection*

16. Is there any other reason you should not proceed with spirometry testing? ☐ 1 Yes ☐ 0 No **(1130)**

If ***YES***, explain _____

_____

17. Is the subject eligible to proceed with the spirometry testing? ☐ 1 Yes ☐ 0 No **(1140)**

If any of the shaded boxes are filled in, the subject is ineligible for spirometry and exhaled nitric oxide testing.

➔ ***If YES, proceed to Question #18 or the next form/procedure listed on the visit procedure checklist.***

If subject is less than 21 years old, complete Question #18 at each visit.

18. Height (*without shoes*) ___ ___ ___ cm **(1150)**

Asthma Clinical Research Network
NIH/NHLBI

TALC SIGNIFICANT ASTHMA EXACERBATION (Visits 3-15, 6A-6H, 10A-10H)

Subject ID: 1 8 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form must be completed each time a subject experiences an asthma exacerbation according to the definition below.

1. Did the subject experience an increase in cough, phlegm/mucus, chest tightness, wheezing, and/or shortness of breath? ☐ 1 Yes ☐ 0 No **(1000)**

2. Did the subject require an increase in asthma medications (oral, inhaled, and/or intravenous corticosteroids or other controller medications) as a result of rescue intervention or by the opinion of the treating physician? ☐ 1 Yes ☐ 0 No **(1010)**

   ➔ ***If YES, please complete the CMED form.***

3. Did the subject experience a significant asthma exacerbation? ☐ 1 Yes ☐ 0 No **(1020)**
   If BOTH of the shaded boxes are completed, the subject has experienced a significant asthma exacerbation.

   ➔ ***If NO, STOP HERE. DO NOT SUBMIT THIS FORM TO THE DCC.***

4. Date significant asthma exacerbation occurred ___ ___ / ___ ___ / ___ ___ ___ ___ (*month / day / year*) **(1030)**

5. Did the subject seek care for the asthma exacerbation? ☐ 1 Yes ☐ 0 No **(1040)**

   ➔ ***If NO, skip to Question #8.***

6. What type of care was sought?

   6a. Study Investigator? ☐ 1 Yes ☐ 0 No **(1050)**

   If ***YES***, indicate type of contact.
   ☐ 1 Scheduled clinic visit
   ☐ 2 Unscheduled clinic visit
   ☐ 3 Phone contact **(1060)**

   6b. Primary Care or Other Physician? ☐ 1 Yes ☐ 0 No **(1070)**

   If ***YES***, name of physician: _____

   If ***YES***, indicate type of contact.
   ☐ 1 Scheduled clinic visit
   ☐ 2 Unscheduled clinic visit
   ☐ 3 Phone contact **(1080)**

6c. Emergency Room visit? ❑ 1 Yes ❑ 0 No **(1090)**

If ***YES,*** name of hospital: _____

7. Was the subject hospitalized? ❑ 1 Yes ❑ 0 No **(1100)**

➔ ***If YES, please complete the Serious Adverse Event Reporting (SERIOUS) Form.***

If ***YES***,

7a. Duration of hospital stay? ___ ___ . ___ days **(1110)**

7b. Was intubation or ventilation assistance required? ❑ 1 Yes ❑ 0 No **(1120)**

7c. Name of hospital: _____

8. Please indicate whether the following medications were used to treat the asthma exacerbation:

8a. Albuterol rescue inhaler (RESCUE) ❑ 1 Yes ❑ 0 No **(1130)**

8b. Nebulized beta-agonist ❑ 1 Yes ❑ 0 No **(1140)**
➔ ***If YES, please complete the CMED form.***

8c. Inhaled corticosteroids ❑ 1 Yes ❑ 0 No **(1150)**
➔ ***If YES, please complete the CMED form.***

8d. Oral corticosteroids ❑ 1 Yes ❑ 0 No **(1160)**
➔ ***If YES, please complete the CMED form.***

8e. Intravenous corticosteroids ❑ 1 Yes ❑ 0 No **(1170)**
➔ ***If YES, please complete the CMED form.***

9. Was the asthma exacerbation treated as outlined in the protocol? ❑ 1 Yes ❑ 0 No **(1180)**

If ***NO***, explain _____

_____

10. Was the asthma exacerbation related to routine pulmonary function testing, including the collection of exhaled nitric oxide? *(Check one box only)*

❑ 1 Definitely related
❑ 2 Probably related
❑ 3 Relationship undetermined
❑ 4 Probably not related
❑ 5 Definitely not related **(1190)**

11. Was the asthma exacerbation related to the collection of exhaled breath condensates? *(Check one box only)*

- ☐ 1 Definitely related
- ☐ 2 Probably related
- ☐ 3 Relationship undetermined
- ☐ 4 Probably not related
- ☐ 5 Definitely not related **(1200)**

12. Was the asthma exacerbation related to sputum induction? *(Check one box only)*

- ☐ 1 Definitely related
- ☐ 2 Probably related
- ☐ 3 Relationship undetermined
- ☐ 4 Probably not related
- ☐ 5 Definitely not related **(1210)**

Asthma Clinical Research Network
NIH/NHLBI

TALC SUBJECT STUDY TREATMENT QUESTIONNAIRE (Visits 3-6, 7-10, and 11-14)

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Subject completed)

This questionnaire is to be completed by the TALC subject at the end of Visits 6, 10, and 14. If a randomized subject terminates prior to Visit 14, please ask him or her to complete this form during the termination visit. This form should <u>not</u> be completed if a subject terminates during a runout period.

1. **Blinded Scheduled Diskus®**

As a TALC study subject you were randomized to receive either a real (i.e., active) salmeterol Diskus or a look-alike placebo (i.e., inactive) Diskus®.

1a. Please check the box that most closely represents your feelings about the **scheduled Diskus®** you used **over the past 14 weeks**.

- ☐ 1 I am certain the Diskus® contained placebo **(1000)**
- ☐ 2 I think the Diskus® probably contained placebo
- ☐ 3 I have no idea which type of Diskus® I received, but my best guess would be:
  - ☐ 1 Placebo
  - ☐ 2 Active Salmeterol **(1010)**
- ☐ 4 I think the Diskus® probably contained active salmeterol
- ☐ 5 I am certain the Diskus® contained active salmeterol

1b. Please comment with respect to any observations you may have made regarding your scheduled Diskus® (e.g., taste, smell, physical sensations, etc.).

- ☐ 1 I have no comments
- ☐ 2 I observed the following *(Describe below)* **(1020)**

_____
_____
_____
_____

2. Blinded Scheduled HandiHaler®

As a TALC study subject you were randomized to receive either real (i.e., active) tiotropium capsules or look-alike placebo (i.e., inactive) capsules to be taken with your scheduled HandiHaler®.

2a. Please check the box that most closely represents your feelings about the capsules you used **over the past 14 weeks**.

- ☐ 1 I am certain the capsules contained placebo **(1030)**
- ☐ 2 I think the capsules probably contained placebo
- ☐ 3 I have no idea which type of capsules I received, but my best guess would be:
  - ☐ 1 Placebo
  - ☐ 2 Active Tiotropium **(1040)**
- ☐ 4 I think the capsules probably contained active tiotropium
- ☐ 5 I am certain the capsules contained active tiotropium

2b. Please comment with respect to any observations you may have made regarding your study capsules (e.g., taste, smell, physical sensations, etc.).

- ☐ 1 I have no comments
- ☐ 2 I observed the following *(Describe below)* **(1050)**

_____

_____

_____

_____

3. Blinded QVAR MDIs

As a TALC study subject you were randomized to receive either low dose QVAR (40 micrograms per puff - equivalent to the runin/runout dose) or high dose QVAR (80 micrograms per puff).

3a. Please check the box that most closely represents your feelings about the QVAR inhalers you used **over the past 14 weeks**.

- ☐ 1 I am certain the inhalers contained low dose QVAR **(1060)**
- ☐ 2 I think the inhalers probably contained low dose QVAR
- ☐ 3 I have no idea which type of QVAR inhalers I received, but my best guess would be:
  - ☐ 1 Low Dose
  - ☐ 2 High Dose **(1070)**
- ☐ 4 I think the inhalers probably contained high dose QVAR
- ☐ 5 I am certain the inhalers contained high dose QVAR

3b. Please comment with respect to any observations you may have made regarding your QVAR inhalers (e.g., taste, smell, physical sensations, etc.).

- ☐ 1 I have no comments
- ☐ 2 I observed the following *(Describe below)* **(1080)**

_____

_____

_____

_____

4. Considering your study treatment over the past 14 weeks:

4a. How well do you feel the study drugs controlled your asthma symptoms?

- ☐ 1 Not at all
- ☐ 2 Hardly at all
- ☐ 3 Somewhat
- ☐ 4 Fairly well
- ☐ 5 Very well **(1090)**

4b. How would you rate the status of your asthma today as compared to 14 weeks ago (i.e. prior to starting your current treatment)?

- ☐ 1 A lot better today
- ☐ 2 A little better today
- ☐ 3 About the same
- ☐ 4 A little worse today
- ☐ 5 A lot worse today **(1100)**

4c. Would you use the study treatment regimen if it were available to you?

- ☐ 1 Yes
- ☐ 0 No
- ☐ 9 Don't know **(1110)**

Subject Source Documentation

Subject's Initials: __ __ __ **(1120)**

Date: __ __ / __ __ / __ __ __ __ **(1130)**

Asthma Clinical Research Network
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TALC TERMINATION OF STUDY PARTICIPATION (Visits 3-15, 6A-6H, 10A-10H)

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete this form only for subjects who have been allocated to the TALC protocol.

1. Has the subject completed the study through Visit 15? ❑1 Yes ❑0 No **(1000)**
   ➔ ***If YES, skip to the SIGNATURES section.***

2. Who initiated termination of the subject? ❑1 Subject ❑2 Clinical Staff **(1010)**
   ➔ ***If subject withdrew due to impending clinical staff termination, please indicate termination by clinical staff.***
   ➔ ***If Clinical Staff, skip to Question #4.***

3. Indicate the **primary** reason the subject has withdrawn from the study.
   - ❑1 no longer interested in participating *****
   - ❑2 no longer willing to follow protocol *****
   - ❑3 difficult access to clinic (location, transportation, parking)
   - ❑4 unable to make visits during clinic hours
   - ❑5 moving out of the area
   - ❑6 unable to continue due to personal constraints *****
   - ❑7 unable to continue due to medical condition unrelated to asthma *****
   - ❑8 side effects of study medications *****
   - ❑9 dissatisfied with asthma control
   - ❑10 other ***** **(1020)**

*** Additional explanation required:**

_____

_____

_____ **(1030)**

➔ ***Skip to the SIGNATURES section.***

4. Did clinical staff terminate the subject due to ...

4a.	pregnancy? *(Check N/A if the subject is male.)*	❑ 1 Yes	❑ 0 No	❑ 9 N/A **(1040)**
4b.	loss to follow-up? *****	❑ 1 Yes	❑ 0 No **(1050)**	
4c.	an asthma-related adverse event? *****	❑ 1 Yes	❑ 0 No **(1060)**	
4d.	a medication-related adverse event? *****	❑ 1 Yes	❑ 0 No **(1070)**	
4e.	an adverse event not related to asthma or medications? *****	❑ 1 Yes	❑ 0 No **(1080)**	
4f.	non-compliance with medication dosing? *****	❑ 1 Yes	❑ 0 No **(1090)**	
4g.	non-compliance with diary completion? *****	❑ 1 Yes	❑ 0 No **(1100)**	
4h.	non-compliance with visit attendance? *****	❑ 1 Yes	❑ 0 No **(1110)**	
4i.	non-compliance with peak flow monitoring? *	❑ 1 Yes	❑ 0 No **(1120)**	
4j.	three significant asthma exacerbations during a treatment period?	❑ 1 Yes	❑ 0 No **(1130)**	
4k.	ineligibility post-allocation at Visit 3? *	❑ 1 Yes	❑ 0 No **(1140)**	
4l.	other reason? *****	❑ 1 Yes	❑ 0 No **(1150)**	

*** Additional explanation required:**

_____

_____

_____ **(1160)**

4m. Indicate the letter corresponding to the primary reason the subject was terminated. ____ **(1170)**

SIGNATURES

Please complete the following section regardless of the reason for termination of study participation.

I verify that all information collected on the ACRN TALC data collection forms for this subject is correct to the best of my knowledge and was collected in accordance with the procedures outlined in the study protocol.

_____ **(1180)** ___ ___ /___ ___ /___ ___ ___ ___ **(1190)**

Clinic Coordinator Signature — month day year

_____ **(1200)** ___ ___ /___ ___ /___ ___ ___ ___ **(1210)**

ACRN Investigator Signature — month day year

Asthma Clinical Research Network
NIH/NHLBI

TALC
VISIT 7/11 SCHEDULING CHECKLIST 1
(Visits 6, 10)

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the subject experienced a significant asthma exacerbation during the TALC trial? ☐ 1 Yes ☐ 0 No **(1000)**

   1a. If **YES**, record the date of the subject's *latest* significant asthma exacerbation from Question #4 on the TALC Significant Asthma Exacerbation (P18_SIGEX) form: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1010)**

   1b. If **YES**, did the subject experience his/her last significant asthma exacerbation at least **2 weeks** prior to today's date? ☐ 1 Yes ☐ 0 No **(1020)**

2. Has the subject taken prednisone (for any reason) during the TALC trial? ☐ 1 Yes ☐ 0 No **(1030)**

   2a. If **YES**, record the date of the subject's last dose of prednisone from the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1040)**

   2b. If **YES**, was the subject's last dose of prednisone taken at least **2 weeks** prior to today's date? ☐ 1 Yes ☐ 0 No **(1050)**

3. During the TALC trial, has the subject taken open-label inhaled corticosteroids (ICS) other than 2 puffs QVAR BID during the runin/runout periods (any dose, any brand, for any reason)? ☐ 1 Yes ☐ 0 No **(1060)**

   3a. If **YES**, record the date of the subject's last dose of open-label ICS from the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1070)**

   3b. If **YES**, was the subject's last dose of open-label ICS taken prior to today's date? ☐ 1 Yes ☐ 0 No **(1080)**

      3bi. If **NO**, will the subject discontinue use of these medications today? ☐ 1 Yes ☐ 0 No **(1085)**

4. Is the subject prepared to schedule Visit 7 or 11 at this time? ☐ 1 Yes ☐ 0 No **(1090)**
   If any of the shaded boxes are completed, the subject is NOT prepared to schedule Visit 7 or 11.

   ➔ ***If YES, schedule Visit 7 or 11.***
   ➔ ***If NO, schedule the subject for Visit 6A or 10A to occur 2 weeks from today.***

Asthma Clinical Research Network
NIH/NHLBI

TALC
VISIT 7/11 SCHEDULING CHECKLIST 2
(Visits 6A - 6H, 10A - 10H)

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the subject experienced a significant asthma exacerbation during the TALC trial? ☐ 1 Yes ☐ 0 No **(1000)**

   1a. If **YES**, record the date of the subject's *latest* significant asthma exacerbation from Question #4 on the TALC Significant Asthma Exacerbation (P18_SIGEX) form: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1010)**

   1b. If **YES**, did the subject experience his/her last significant asthma exacerbation at least **2 weeks** prior to today's date? ☐ 1 Yes ☐ 0 No **(1020)**

2. Has the subject taken prednisone (for any reason) during the TALC trial? ☐ 1 Yes ☐ 0 No **(1030)**

   2a. If **YES**, record the date of the subject's last dose of prednisone from the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1040)**

   2b. If **YES**, was the subject's last dose of prednisone taken at least **2 weeks** prior to today's date? ☐ 1 Yes ☐ 0 No **(1050)**

3. During the TALC trial, has the subject taken open-label inhaled corticosteroids (ICS) other than 2 puffs QVAR BID during the runin/runout periods (any dose, any brand, for any reason)? ☐ 1 Yes ☐ 0 No **(1060)**

   3a. If **YES**, record the date of the subject's last dose of open-label ICS from the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1070)**

   3b. If **YES**, was the subject's last dose of open-label ICS taken prior to today's date? ☐ 1 Yes ☐ 0 No **(1080)**

      3bi. If **NO**, will the subject discontinue use of these medications today? ☐ 1 Yes ☐ 0 No **(1085)**

4. Has a study investigator assessed the subject at this visit? ☐ 1 Yes ☐ 0 No **(1090)**

   4a. If **YES**, does the study investigator allow the subject to schedule Visit 7 or 11 at this time? ☐ 1 Yes ☐ 0 No **(1100)**

5. Is the subject prepared to schedule Visit 7 or 11 at this time? ☐ 1 Yes ☐ 0 No **(1110)**
   If any of the shaded boxes are completed, the subject is NOT prepared to schedule Visit 7 or 11.

   ➔ ***If YES, schedule the subject for Visit 7 or 11 to occur 2 weeks from today.***
   ➔ ***If NO, schedule the subject for another intermediate visit to occur 2 weeks from today .***

Asthma Clinical Research Network
NIH/NHLBI

TALC
VISIT 7/11 SCHEDULING CHECKLIST 3
(Visits 7, 11)

Subject ID: 1 8 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the subject experienced a significant asthma exacerbation during the TALC trial? ☐ 1 Yes ☐ 0 No **(1000)**

   1a. If **YES**, record the date of the subject's *latest* significant asthma exacerbation from Question #4 on the TALC Significant Asthma Exacerbation (P18_SIGEX) form: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1010)**

   1b. If **YES**, did the subject experience his/her last significant asthma exacerbation at least **4 weeks** prior to today's date? ☐ 1 Yes ☐ 0 No **(1020)**

2. Has the subject taken prednisone (for any reason) during the TALC trial? ☐ 1 Yes ☐ 0 No **(1030)**

   2a. If **YES**, record the date of the subject's last dose of prednisone from the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1040)**

   2b. If **YES**, was the subject's last dose of prednisone taken at least **4 weeks** prior to today's date? ☐ 1 Yes ☐ 0 No **(1050)**

3. During the TALC trial, has the subject taken open-label inhaled corticosteroids (ICS) other than 2 puffs QVAR BID during the runin/runout periods (any dose, any brand, for any reason)? ☐ 1 Yes ☐ 0 No **(1060)**

   3a. If **YES**, record the date of the subject's last dose of open-label ICS from the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1070)**

   3b. If **YES**, was the subject's last dose of open-label ICS taken at least **2 weeks** prior to today's date? ☐ 1 Yes ☐ 0 No **(1080)**

4. Is the subject prepared to complete Visit 7 or 11 at this time? ☐ 1 Yes ☐ 0 No **(1090)**
   If any of the shaded boxes are completed, the subject is NOT prepared to complete Visit 7 or 11.

   ➔ ***If YES, complete Visit 7 or 11 today.***
   ➔ ***If NO, complete an intermediate visit today.***

Asthma Clinical Research Network
NIH/NHLBI

POST-ALBUTEROL (4 puffs) SPIROMETRY TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

Complete this form only if the subject is eligible according to the appropriate Pulmonary Procedure Checklist form and successfully completed baseline spirometry session(s).

➔ ***Administer 4 puffs of albuterol and wait 15 minutes, then perform spirometry.***

1. Time albuterol administered *(based on 24-hour clock)* ___ ___ ___ ___ **(1000)**

2. Time post-albuterol spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ **(1010)**

The best effort reflects the trial where the sum of FEV_1 and FVC is maximized.

3. Results of best effort post-albuterol:

   3a. FVC ___ . ___ ___ L **(1020)**

   3b. FEV_1 ___ . ___ ___ L **(1030)**

   3c. FEV_1 (% predicted) ___ ___ ___ % predicted **(1040)**

   3d. PEFR ___ ___ . ___ ___ L/S **(1050)**

   3e. FEF_{25-75} ___ . ___ ___ L/S **(1060)**

4. In your judgment, was the subject's spirometry technique acceptable? ❑ 1 Yes ❑ 0 No **(1070)**

   4a. If **NO**, why was it unacceptable?

   Inadequate inspiratory effort ❑ 1 Yes ❑ 0 No **(1080)**

   Inadequate expiratory effort ❑ 1 Yes ❑ 0 No **(1090)**

   Inadequate duration of expiration ❑ 1 Yes ❑ 0 No **(1100)**

   Cough during procedures ❑ 1 Yes ❑ 0 No **(1110)**

   Other *(specify)* _____ ❑ 1 Yes ❑ 0 No **(1120)**

Asthma Clinical Research Network
NIH/NHLBI

POST-IPRATROPIUM (4 Puffs) SPIROMETRY TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

Complete this form only if the subject is eligible according to the appropriate Pulmonary Procedure Checklist form and successfully completed baseline spirometry session(s).

Note: Ipratropium should NOT be administered to subjects who have a hypersensitivity/allergy to soy or peanuts.

➔ ***Administer 4 puffs of ipratropium and wait 30 minutes, then perform spirometry.***

1. Time ipratropium administered *(based on 24-hour clock)* ___ ___ ___ ___ **(1000)**

2. Time post-ipratropium spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ **(1010)**

The best effort reflects the trial where the sum of FEV_1 and FVC is maximized.

3. Results of best effort post-ipratropium:

   3a. FVC ___ . ___ ___ L **(1020)**

   3b. FEV_1 ___ . ___ ___ L **(1030)**

   3c. FEV_1 (% predicted) ___ ___ ___ % predicted **(1040)**

   3d. PEFR ___ ___ . ___ ___ L/S **(1050)**

   3e. FEF_{25-75} ___ . ___ ___ L/S **(1060)**

4. In your judgment, was the subject's spirometry technique acceptable? ❑1 Yes ❑0 No **(1070)**

   4a. If **NO**, why was it unacceptable?

   Inadequate inspiratory effort ❑1 Yes ❑0 No **(1080)**

   Inadequate expiratory effort ❑1 Yes ❑0 No **(1090)**

   Inadequate duration of expiration ❑1 Yes ❑0 No **(1100)**

   Cough during procedures ❑1 Yes ❑0 No **(1110)**

   Other *(specify)* _____ ❑1 Yes ❑0 No **(1120)**

Asthma Clinical Research Network
NIH/NHLBI

URINE PREGNANCY TEST

Subject ID: __ __ - __ __ - __ __ __
Subject Initials: __ __ __
Visit Number: __ __ __
Visit Date: __ __ / __ __ / __ __
Month Day Year
Coordinator ID: __ __ __ __ __ __

(Clinic Coordinator Completed)

Complete this form for female subjects only.

1. Is the subject unable to bear children due to any of the following reasons?

1a. Post-menopausal (at least one year since last menses)	☐ 1 Yes	☐ 0 No **(1000)**
1b. Hysterectomy	☐ 1 Yes	☐ 0 No **(1010)**
1c. Tubal ligation	☐ 1 Yes	☐ 0 No **(1020)**

➔ ***If any of the shaded boxes are filled in, a pregnancy test is not required. Proceed to the source documentation box.***

2. Pregnancy test results
   - ☐ 1 Positive
   - ☐ 2 Negative **(1030)**

➔ ***If pregnancy test results are positive, the subject must be terminated from study participation. Complete the appropriate Termination of Study Participation form and follow study termination procedures.***

Subject Source Documentation
Subject's Initials: __ __ __ **(1040)**
Date: __ __ / __ __ / __ __ __ __ **(1050)**

"Attach Registry Form Label Here"

ACRN REGISTRY

Subject's Last Name: _____

Subject's First Name: _____

Subject's Initials: ___ ___ ___

Social Security Number: ___ ___ ___ ___ (Last 4 digits)

Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator/Subject Interview Completed)

Search the ACRN Registry. If the subject is either incomplete or not found in the Registry, complete the Registry form and enter/update the subject's information appropriately.

ADMINISTRATIVE

1. Did the subject sign an ACRN Protocol Informed Consent and HIPAA Authorization form? ☐1 Yes ☐0 No **(1000)**

   If ***NO***, stop here. Data cannot be entered into the ACRN Registry.

   If ***YES***, record the signature date. ___ ___ / ___ ___ / ___ ___ ___ ___ **(1010)**
   Month Day Year

DEMOGRAPHICS

2. Subject's date of birth ___ ___ / ___ ___ / ___ ___ ___ ___ **(1020)**
   (Ask the subject his/her date of birth.) Month Day Year

3. Subject's gender ☐1 Male
   ☐2 Female **(1030)**

4. Subject's Race and Ethnicity

   4a. Subject's ethnic background
   (Ask the subject to identify his/her ethnic background.) ☐1 Hispanic or Latino
   ☐2 Not Hispanic or Latino **(1040)**

   4b. Subject's racial background
   (Ask the subject to identify all that apply.)

   American Indian or Alaskan Native ☐1 Yes ☐0 No **(1050)**

   Asian ☐1 Yes ☐0 No **(1060)**

   Black or African American ☐1 Yes ☐0 No **(1070)**

   White ☐1 Yes ☐0 No **(1080)**

   Native Hawaiian or Other Pacific Islander ☐1 Yes ☐0 No **(1090)**

   Other *(specify)*_____ ☐1 Yes ☐0 No **(1100)**

* R E G I S T R Y *

5. Subject's primary racial identification
(This identification will be used for spirometry testing. Ask the subject which category best describes him or her and check only one box.)

- ☐ 1 American Indian or Alaskan Native
- ☐ 2 Asian or Pacific Islander
- ☐ 3 Black, not of Hispanic Origin
- ☐ 4 White, not of Hispanic Origin
- ☐ 5 Hispanic
- ☐ 6 Other _____ **(1110)**

Subject Source Documentation

Subject's Initials: __ __ __

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

Administrative Use Only

Does the subject recall participating in any of the ACRN I protocols? *(Circle all that apply)*

BAGS (1)	CIMA (2)	SOCS/SLIC (3)	DICE (6)	MICE (7)
BARGE (8)	IMPACT (9)	SMOG (10)	SLiMSIT (11)	PRICE (12)

Registry Form Storage Instructions:

Upon printing the subject's label sheet, print the subject's name on the upper right hand label. Attach the Registry form label to the upper left hand corner of the form. Lastly, attach the Registry Log label to the next available row on the Registry Log and complete the required fields. The Registry form should be stored alphabetically by subject's last name in the ACRN Registry Binder. The label sheet should then be filed directly behind the Registry form.

REGISTRY FORMS SHOULD NOT BE SENT TO THE DCC.

Asthma Clinical Research Network
NIH/NHLBI

SLEEP AND DAYTIME ALERTNESS QUESTIONNAIRE

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Subject completed)

ABOUT YOUR SLEEP

The questions below apply to the last 6 months.

Some people work the night shift or rotating shifts. Other people have a bedtime that changes a lot. If these apply to you, then questions about the time of day refer to the time when you awaken from your longest sleep and become active. Questions about time of night refer to the time when you have your longest sleep.

Please check only one box for each question.	**Never**	**Rarely**	**Sometimes**	**Usually**	**Always**
1. I am told I snore loudly and bother others.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 **(1000)**
2. I am told I stop breathing ("hold my breath") in sleep.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 **(1010)**
3. I awake suddenly gasping for breath, unable to breathe.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 **(1020)**

➔ If this ***never*** happens to you, please skip to question #4.

➔ If this happens to you ***even rarely,*** please answer questions #3a and 3b.

3a. It takes just a couple of breaths to fully recover.	❑ 1 Yes	❑ 0 No **(1030)**
3b. It happens when I have chest tightness, wheezing, or cough and takes more than a couple of breaths to fully recover.	❑ 1 Yes	❑ 0 No **(1040)**

4. I sweat a great deal at night.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 **(1050)**
5. I have high blood pressure (or once had it).	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 **(1060)**
6. I have a problem with my nose blocking up when I am trying to sleep.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 **(1070)**
7. My snoring or my breathing problem is much worse if I sleep on my back.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 **(1080)**
8. My snoring or my breathing problem is much worse if I fall asleep right after drinking alcohol.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 **(1090)**

ABOUT YOUR DAYTIME ALERTNESS

9. Do you feel that you are excessively (overly) sleepy during the day? ❑ 1 Yes ❑ 0 No **(1100)**

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you.

Please check one box that best represents the likelihood of your dozing off in each situation.

	Likelihood of Dozing			
	Never	**Slight**	**Moderate**	**High**
10. Sitting and reading	❑ 0	❑ 1	❑ 2	❑ 3 **(1120)**
11. Watching TV	❑ 0	❑ 1	❑ 2	❑ 3 **(1130)**
12. Sitting, inactive in a public place (for example, a theater or a meeting)	❑ 0	❑ 1	❑ 2	❑ 3 **(1140)**
13. As a passenger in a car for an hour without a break	❑ 0	❑ 1	❑ 2	❑ 3 **(1150)**
14. Lying down to rest in the afternoon when circumstances permit	❑ 0	❑ 1	❑ 2	❑ 3 **(1160)**
15. Sitting and talking to someone	❑ 0	❑ 1	❑ 2	❑ 3 **(1170)**
16. Sitting quietly after a lunch without alcohol	❑ 0	❑ 1	❑ 2	❑ 3 **(1180)**
17. In a car, while stopped for a few minutes in traffic	❑ 0	❑ 1	❑ 2	❑ 3 **(1190)**

18. During the past 2 months, on average, how many hours of <u>*actual sleep*</u> (including daytime naps) did you get in a 24-hour period? This may be different than the number of hours you spent in bed. ___ ___ hours **(1200)**

CURRENT WEIGHT

19. What is your current weight in pounds? ___ ___ ___ pounds **(1205)**

Subject Source Documentation
Subject's Initials: __ __ __ **(1210)**
Date: __ __ / __ __ / __ __ __ __ **(1220)**

Asthma Clinical Research Network
NIH/NHLBI

SERIOUS ADVERSE EVENT REPORTING FORM

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form and a final resolution report (including relevant documents) written by the Principal Investigator should be faxed to the DCC at (717) 531-4359 within 72 hours of notification of a serious event. Also fax the Clinical Adverse Events form (AECLIN), the appropriate Concomitant Medications for Asthma and Allergies (CMED) form, and any relevant source documents.

1. Date of Adverse Event ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) **(1000)**

2. Description of Adverse Event (ICD9 Code) ___ ___ ___ . ___ ___ **(1010)**

   Describe: _____

3. Time interval between taking the study drug (last dose before symptoms) and subsequent onset of symptoms. ___ ___ **(1020)**

4. Unit of time for above interval **(1030)**
   - ☐ 1 second(s)
   - ☐ 2 minute(s)
   - ☐ 3 hour(s)
   - ☐ 4 day(s)

5. Why was the event serious?

   5a. Fatal Event ☐ 1 Yes ☐ 0 No **(1040)**

   5b. Life-threatening event ☐ 1 Yes ☐ 0 No **(1050)**

   5c. Inpatient hospitalization required ☐ 1 Yes ☐ 0 No **(1060)**
   ➔ ***If NO, skip to Question #5d.***

   Admission date ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) **(1070)**

   Discharge date ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) **(1080)**

   5d. Hospitalization prolonged ☐ 1 Yes ☐ 0 No **(1090)**

   5e. Disabling or incapacitating ☐ 1 Yes ☐ 0 No **(1100)**

   5f. Overdose ☐ 1 Yes ☐ 0 No **(1110)**

   5g. Cancer ☐ 1 Yes ☐ 0 No **(1120)**

   5h. Congenital anomaly ☐ 1 Yes ☐ 0 No **(1130)**

   5i. Serious laboratory abnormality with clinical symptoms ☐ 1 Yes ☐ 0 No **(1140)**

   5j. Other *(specify)* _____ ☐ 1 Yes ☐ 0 No **(1150)**

6. What, in your opinion, caused the event?

6a. Toxicity of study drug(s) ☐ 1 Yes ☐ 0 No **(1160)**

6b. Withdrawal of study drug(s) ☐ 1 Yes ☐ 0 No **(1170)**

6c. Concurrent medication ☐ 1 Yes ☐ 0 No **(1180)**
If ***YES***, describe _____

6d. Concurrent disorder ☐ 1 Yes ☐ 0 No **(1190)**
If ***YES***, describe _____

6e. Other event ☐ 1 Yes ☐ 0 No **(1200)**
If ***YES***, describe _____

DO NOT ENTER QUESTIONS #7 - 8: FOR REPORTING PURPOSES ONLY.

7. If subject died, cause of death: _____
_____

8. Was an autopsy performed? ☐ 1 Yes ☐ 0 No

If YES, attach report or send as soon as possible.

REPORTING INVESTIGATOR:

Comments (discuss any relevant laboratory data or other assessments which help explain the event):

Name: _____

Signature: _____

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

Asthma Clinical Research Network
NIH/NHLBI

ALLERGY SKIN TEST RESULTS

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Since August 2004, has the subject had an acceptable skin test for an ACRN protocol within three years of the visit date? ☐ 1 Yes ☐ 0 No **(1000)**

   ➔ If ***NO***, proceed to Question #2.

   1a. Date of previous skin test ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1010)**

   1b. Coordinator ID who performed the skin test ___ ___ ___ ___ ___ ___ **(1020)**

   1c. Time test sites pricked/punctured *(based on 24-hour clock)* ___ ___ ___ ___ **(1030)**

   1d. Time test sites evaluated *(based on 24-hour clock)* ___ ___ ___ ___ **(1040)**

   ➔ **STOP HERE** and attach a photocopy of pages 3 and 4 from the previous Allergy Skin Test Results (SKIN) form to this page for data entry purposes.

2. Has the subject had dermatographia **or** a significant adverse reaction to skin testing previously (e.g., anaphylaxis, angioedema, asthma, hypotension, etc.)? ☐ 1 Yes ☐ 0 No **(1050)**

   ➔ If ***YES***, do not proceed with allergy skin testing.

   ➔ If ***YES***, and the subject has acceptable ACRN skin testing results from a prior ACRN protocol (ACRN I or II), record Subject ID associated with the most recent acceptable test. ___ ___ - ___ ___ - ___ ___ ___ **(1052) (1054) (1060)**

3. Has the subject taken any of the medications listed in the ACRN Skin Testing MOP within the exclusionary periods? ☐ 1 Yes ☐ 0 No **(1070)**

   ➔ If ***YES***, the allergy skin testing procedure should be rescheduled.

4. Was the subject's most recent FEV1 below 60% predicted? ☐ 1 Yes ☐ 0 No **(1072)**

➔ If ***NO***, proceed to Question #5.

4a. Has the subject received permission from the supervising physician to proceed with the skin testing? ☐ 1 Yes ☐ 0 No **(1074)**

➔ If ***YES***, obtain physician's signature:

_____ **(1076)**

➔ If ***NO***, allergy skin testing procedure should be rescheduled.

5. Is the subject eligible for allergy skin testing? ☐ 1 Yes ☐ 0 No **(1080)**

If any of the shaded boxes are completed, the subject is ineligible for allergy skin testing. STOP HERE.

➔ ***Allergy Skin testing may be rescheduled for the next visit if the subject is ineligible due to Question #3 or Question #4a.***

6. Time test sites pricked/punctured *(based on 24-hour clock)* ___ ___ ___ ___ **(1090)**

7. Time test sites evaluated *(based on 24-hour clock)* ___ ___ ___ ___ **(1100)**

ALLERGY SKIN TEST RESULTS

Subject ID: ___ ___ - ___ ___ - ___ ___ ___

Visit Number: ___ ___ ___

Transfer the tracing of each measurable wheal and record the longest diameter and the diameter at the perpendicular midpoint in mm. If the wheal is not measurable, record '0' for both diameters.

1. Positive Control	Largest Wheal Diameter: ___ ___ ___ mm (1110) Perpendicular Wheal Diameter: ___ ___ ___ mm (1120)	2. Negative Control	Largest Wheal Diameter: ___ ___ ___ mm (1130) Perpendicular Wheal Diameter: ___ ___ ___ mm (1140)
3. Mite Mix	Largest Wheal Diameter: ___ ___ ___ mm (1150) Perpendicular Wheal Diameter: ___ ___ ___ mm (1160)	4. Cockroach Mix	Largest Wheal Diameter: ___ ___ ___ mm (1170) Perpendicular Wheal Diameter: ___ ___ ___ mm (1180)
5. Mouse	Largest Wheal Diameter: ___ ___ ___ mm (1190) Perpendicular Wheal Diameter: ___ ___ ___ mm (1200)	6. Rat	Largest Wheal Diameter: ___ ___ ___ mm (1210) Perpendicular Wheal Diameter: ___ ___ ___ mm (1220)
7. Penicillium	Largest Wheal Diameter: ___ ___ ___ mm (1230) Perpendicular Wheal Diameter: ___ ___ ___ mm (1240)	8. Alternaria	Largest Wheal Diameter: ___ ___ ___ mm (1250) Perpendicular Wheal Diameter: ___ ___ ___ mm (1260)

9. Aspergillus	Largest Wheal Diameter: ___ ___ ___ mm **(1270)** Perpendicular Wheal Diameter: ___ ___ ___ mm **(1280)**	10. Cladosporium	Largest Wheal Diameter: ___ ___ ___ mm **(1290)** Perpendicular Wheal Diameter: ___ ___ ___ mm **(1300)**
11. Cat	Largest Wheal Diameter: ___ ___ ___ mm **(1310)** Perpendicular Wheal Diameter: ___ ___ ___ mm **(1320)**	12. Dog	Largest Wheal Diameter: ___ ___ ___ mm **(1330)** Perpendicular Wheal Diameter: ___ ___ ___ mm **(1340)**

13. Is the mean diameter for the 'Negative Control' < 3 mm? ☐ 1 Yes ☐ 0 No **(1350)**

➔ If ***YES***, go to Question #14.

➔ If ***NO***, administer the negative control on the opposite hand and complete Question #13a and #13b.

13a. Record the measurements for the 'Negative Control' administered on the opposite hand:

Largest Wheal Diameter: ___ ___ ___ mm **(1352)**

Perpendicular Wheal Diameter: ___ ___ ___ mm **(1354)**

13b. Is the mean diameter calculated from the measurements in Question #13a < 3 mm? ☐ 1 Yes ☐ 0 No **(1360)**

➔ If **NO,** go to Question #15. The subject has dermatographia and therefore, do not repeat skin testing on this subject.

14. Is the mean diameter for 'Positive Control' ≥ 3 mm more than the mean diameter from the 'Negative Control'? ☐ 1 Yes ☐ 0 No **(1370)**

15. Was this test acceptable? ☐ 1 Yes ☐ 0 No **(1380)**

If any of the gray shaded boxes are checked, this test was not acceptable.

➔ ***Allergy Skin testing may be rescheduled for the next visit if the subject's test was unacceptable due to the use of exclusionary medications.***

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SPIROMETRY TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

Complete this form only if the subject is eligible according to the appropriate Pulmonary Procedure Checklist form.

1. Time spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ **(1000)**

The best effort reflects the trial where the sum of FEV_1 and FVC is maximized.

2. Results of best effort:

   2a. FVC ___ . ___ ___ L **(1010)**

   2b. FEV_1 ___ . ___ ___ L **(1020)**

   2c. FEV_1 (% predicted) ___ ___ ___ % predicted **(1030)**

   2d. PEFR ___ ___ . ___ ___ L/S **(1040)**

   2e. FEF_{25-75} ___ . ___ ___ L/S **(1050)**

3. In your judgment, was the subject's spirometry technique acceptable? ❑1 Yes ❑0 No **(1060)**

   3a. If **NO**, why was it unacceptable?

   Inadequate inspiratory effort ❑1 Yes ❑0 No **(1070)**

   Inadequate expiratory effort ❑1 Yes ❑0 No **(1080)**

   Inadequate duration of expiration ❑1 Yes ❑0 No **(1090)**

   Cough during procedures ❑1 Yes ❑0 No **(1100)**

   Other *(specify)* _____ ❑1 Yes ❑0 No **(1110)**

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SPUTUM INDUCTION LAB VALUES

Subject ID: ___ ___ -___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Slide #: ___

(Technician completed)

Processing Sample

1. Technician ID ___ ___ ___ ___ ___ ___ **(1000)**
2. Processing Date ___ ___ / ___ ___ / ___ ___ ___ ___ **(1010)**
   month day year
3. Time processing started *(based on 24-hour clock)* ___ ___ ___ ___ **(1020)**
4. Total Cell Count ___ ___ ___ ___ . ___ x 10^4 cells/ml **(1030)**

Differential Cell Counts

5. Technician ID ___ ___ ___ ___ ___ ___ **(1040)**
6. Read Date ___ ___ / ___ ___ / ___ ___ ___ ___ **(1050)**
   month day year
7. Squamous Cells ___ ___ . ___ % **(1060)**

8. Did the subject's sputum sample reveal ≥ 80% squamous cells? ☐ 1 Yes ☐ 0 No **(1070)**
   - ➔ ***If NO, please complete Question #9 through Question #14 and send the sputum sample for overreading***.
   - ➔ ***If YES, STOP HERE and mark the samples as excluded from shipment to San Francisco in the Sample Tracking Module***.

The parameters below are calculated following exclusion of squamous cells.

9. Total Cell Count ___ ___ ___ ___ . ___ x 10^4 cells/ml **(1080)**
10. Epithelial Cells ___ ___ . ___ % **(1090)**
11. Macrophages ___ ___ . ___ % **(1100)**
12. Neutrophils ___ ___ . ___ % **(1110)**
13. Eosinophils ___ ___ . ___ % **(1120)**
14. Lymphocytes ___ ___ . ___ % **(1130)**

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SPUTUM INDUCTION UCSF OVER-READ

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Slide #: ___
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

1. Date of Over-Read ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) **(1000)**

2. Is the slide quality acceptable? ☐ 1 Yes ☐ 0 No **(1010)**
   ➔ If ***NO***, please comment below. If a back-up slide is required, update the Sample Tracking Module.

_____
_____
_____
_____
_____

Differential Cell Counts

3. Squamous Cells ___ ___ . ___ % **(1020)**

The parameters below are calculated following exclusion of squamous cells.

4. Epithelial Cells ___ ___ . ___ % **(1030)**
5. Macrophages ___ ___ . ___ % **(1040)**
6. Neutrophils ___ ___ . ___ % **(1050)**
7. Eosinophils ___ ___ . ___ % **(1060)**
8. Lymphocytes ___ ___ . ___ % **(1070)**

SPUTUM INDUCTION

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

Complete this form only if the subject is eligible according to the Sputum Induction Checklist (SPUTUMCHK) form.

1. ***(If attempting sputum induction for the first time in this protocol or subject has not had an adequate sample at prior attempts, do not complete Question #1.)***

   What was the duration of sputum induction the first time the subject's sample was processed and had < 80% squamous cells for this protocol? ___ ___ . ___ minutes **(1000)**

   Duration of sputum induction at current visit should not exceed this.

2. Sputum induction start time *(based on 24-hour clock)* ___ ___ ___ ___ **(1010)**

3. Sputum induction stop time *(based on 24-hour clock)* ___ ___ ___ ___ **(1020)**

4. Duration of sputum induction collection phase at this visit ___ ___ . ___ minutes **(1030)**

   4a. Was the duration ≥ 4 minutes? ☐ 1 Yes ☐ 0 No **(1040)**

5. Volume of sputum sample at this visit ___ ___ ___ . ___ ml **(1050)**

   5a. Is the volume of the sample ≥ 1 ml? ☐ 1 Yes ☐ 0 No **(1060)**

6. Is the sample adequate for laboratory analysis? ☐ 1 Yes ☐ 0 No **(1070)**
   If either shaded box in Question #4a or #5a are completed, the sputum sample is not adequate and should not be sent for analysis of squamous cell counts.

   ➔ ***If YES, the technician reading the slide should complete the Sputum Induction Lab Values (SPUTLAB) form.***

7. Subject's FEV_1 immediately after completion of sputum induction

7a. FEV_1 ___ . ___ ___ L **(1080)**

7b. FEV_1 (% predicted) ___ ___ ___ % predicted **(1090)**

7c. Time of FEV_1 in Question #7a (*based on 24-hour clock*) ___ ___ ___ ___ **(1100)**

7d. Percent difference in FEV_1 $\frac{(Reference - Question\ \#7a)}{Reference}$ x 100 ___ ___ . ___ % **(1110)**

Reference = FEV_1 used for assessment of eligibility for SI.

7e. Did the subject's FEV_1 drop > 10% (from post-albuterol baseline) as indicated in Question #7d? ❑ 1 Yes ❑ 0 No **(1120)**

➔ ***If NO, STOP HERE and continue with remaining visit procedures.***

➔ ***If YES, proceed to the Additional Treatment for Sputum Induction (SPUTUM_ADD_TRT) form.***

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ADDITIONAL TREATMENT POST SPUTUM INDUCTION

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

Complete this form only if the subject has experienced > 10% fall in FEV_1 from post-albuterol baseline immediately after completion of sputum induction.

Clinic Use Only

Sputum Induction Reversal Reference Value: *Reference x 0.90 =* ___ . ___ ___ *L*

Reference = FEV_1 used for assessment of eligibility for Sputum Induction.

➔ Administer 2 puffs of albuterol and wait 15 minutes, then perform spirometry.

1. Subject's FEV_1 after initial 2 puffs of albuterol

   1a. FEV_1 ___ . ___ ___ L **(1000)**

   1b. FEV_1 (% predicted) ___ ___ ___ % predicted **(1010)**

   1c. Time of FEV_1 from Question #1a (*based on 24-hour clock*) ___ ___ ___ ___ **(1020)**

   1d. Was the FEV_1 from Question #1a ≥ the sputum induction reversal reference value in the gray box above? ❑1 Yes ❑0 No **(1030)**

   ➔ ***If YES, stop here and continue with remaining visit procedures.***
   ➔ ***If NO, administer 2 puffs of albuterol and wait 15 minutes, then perform spirometry. Proceed to Question #2.***

2. Subject's FEV_1 after 2 additional puffs of albuterol

   2a. FEV_1 ___ . ___ ___ L **(1040)**

   2b. FEV_1 (% predicted) ___ ___ ___ % predicted **(1050)**

   2c. Time of FEV_1 from Question #2a (*based on 24-hour clock*) ___ ___ ___ ___ **(1060)**

   2d. Was the FEV_1 from Question #2a ≥ the sputum induction reversal reference value in the gray box above? ❑1 Yes ❑0 No **(1070)**

   ➔ ***If NO, complete the source documentation box below.***

Physician Source Documentation

Physician signature: _____ **(1080)**

Date: __ __ / __ __ / __ __ __ __ **(1090)**

Time: __ __ __ __ *(based on 24-hour clock)* **(1100)**

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SPUTUM INDUCTION CHECKLIST

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

Complete this form only if the subject successfully completed baseline spirometry session(s).

1. ***(If attempting Sputum Induction for the first time in this protocol, do not complete Question #1)***

   Was the subject's sputum sample processed and had < 80% squamous cells the first time a sputum induction was attempted for this protocol? ☐ 1 Yes ☐ 0 No **(1000)**

2. ***(Only for subjects who completed a methacholine challenge at this visit.)***

   Was the subject's FEV_1 after reversal from the methacholine challenge ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form? ☐ 1 Yes ☐ 0 No **(1010)**

   2a. If ***NO***, has the subject received permission from the supervising physician to proceed with sputum induction testing? ☐ 1 Yes ☐ 0 No **(1020)**
   Physician's Signature: _____ **(1030)**

3. Subject's FEV_1 used for assessment of eligibility for sputum induction ___ . ___ ___ L **(1040)**

4. Subject's FEV_1 (% predicted) used for assessment of eligibility for sputum induction ___ ___ ___ % predicted **(1050)**

5. Was the subject's FEV_1 (% predicted) from Question #4 ≥ 60% predicted? ☐ 1 Yes ☐ 0 No **(1060)**

6. Is there any other reason the subject should not proceed with sputum induction? ☐ 1 Yes ☐ 0 No **(1070)**
   If ***YES***, explain _____

7. Is the subject eligible for sputum induction? ☐ 1 Yes ☐ 0 No **(1080)**
   If any of the shaded boxes are completed, the subject is NOT eligible for sputum induction.

   ➔ ***If YES, proceed to the Sputum Induction (SPUTUM) form.***