**CLINICAL AND LABORATORY ADVERSE EVENTS**

(Clinic Coordinator completed)

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.

- **None**

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<table>
<thead>
<tr>
<th>DESCRIPTION OF ADVERSE EVENT (1000)</th>
<th>1. ICD9 CODE (1010)</th>
<th>2. DATE STARTED (Top Line) (1020)</th>
<th>3. DATE STOPPED (Bottom Line) (1030)</th>
<th>4. ONGOING at current visit</th>
<th>5. TYPE (1050)</th>
<th>6. SEVERITY (1060)</th>
<th>7. SERIOUS (1070)</th>
<th>8. LIKELIHOOD OF RELATIONSHIP TO STUDY DRUG(S) (1080)</th>
<th>9. CHANGE IN STUDY DRUG(S) (1090)</th>
<th>10. OUTCOME (Skip if #3 is missing) (1100)</th>
<th>11. TREATMENT REQUIRED (1110)</th>
<th>12. ONGOING at final visit (120)</th>
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* Please complete a Serious Adverse Event Reporting (SERIOUS) form.

** Please complete the appropriate Change in Medications form.

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

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___ ___ ___

Subject’s Initials: ___ ___ ___
Date: ___ ___ ___ ___ ___ ___
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)  

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)  

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  

Subject Source Documentation

Subject’s Initials:  
Date:  
Time:  (based on a 24-hour clock)
AM1® QUALITY CONTROL

(Technician completed)

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

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

3. Test date
   __ __ / __ __ / __ __ __ __ (1030)

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)

<table>
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<tr>
<th>AM1® (L/Min)</th>
<th>Jones FVC (L/Min)</th>
</tr>
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<tbody>
<tr>
<td>__________</td>
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</table>

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.
(Subject Interview completed)

ASTHMA HISTORY

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

   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 mucus 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
- 4 Frequently (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)

6a(ii). Spring?
- 1 Yes
- 0 No (1170)

6a(iii). Summer?
- 1 Yes
- 0 No (1180)

6a(iv). 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?

7b. Hospitalizations have you had due to asthma?

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

7d. Days of work, school or housework have you missed due to asthma?

→ 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?

ASTHMA TRIGGERS

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

8a. Exercise/Sports

8b. Menstrual cycle
(If subject is male or postmenopausal, check N/A)

8c. Aspirin or non-steroidal anti-inflammatory drugs (e.g., Aleve, Motrin)

8d. Colds, upper respiratory infections, sinus infections

8e. Irritants (e.g., smoke, pollution, odors, perfumes, chemicals)

8f. Weather conditions (e.g., cold, humidity)

8g. Emotional stress

8h. Food additives/preservatives (e.g., MSG, etc.)

8i. Other (please specify)
ALLERGIES
9. Do you have allergies to pets, pollen, dust, etc.?
   If YES,
   9a. Do your allergies provoke your asthma?
   9b. Were your allergies diagnosed by a doctor?
   9c. How do you categorize your allergies?
   → If 'Vary by season(s)', do your allergies worsen during the...
   9ci. Winter?
   9cii. Spring?
   9ciii. Summer?
   9ciii. Fall?

10. Have you ever had eczema (i.e., prolonged itchy, scaly, weepy skin rash)?
   10a. If YES, was your eczema diagnosed by a doctor?

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
   11b. Father
   11c. Brother(s) or Sister(s)
   11d. Child(ren)

SMOKING HISTORY
12. Were you ever a smoker?
   12a. If YES, how many years did you smoke? (total number of years)

13. Did you grow up in a household where you were exposed to tobacco smoke?

14. In an average week, approximately how many hours are you exposed to other people’s tobacco smoke in all environments?
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.

<table>
<thead>
<tr>
<th>NAME OF MEDICATION (1000)</th>
<th>CODE (1010)</th>
<th>RELATED EVENT (1020)</th>
<th>DOSE (1030)</th>
<th>UNITS (1040)</th>
<th>FREQUENCY (1050)</th>
<th>ROUTE</th>
<th>START DATE (MM/DD/YYYY) (1060)</th>
<th>STOP DATE (MM/DD/YYYY) (1070)</th>
<th>ONGOING AT CURRENT VISIT (1080)</th>
<th>ONGOING AT FINAL VISIT (1090)</th>
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### Codes for Frequency

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<td>21</td>
<td>other</td>
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</table>
1. Has the subject had anything other than water to drink or eat in the past hour?  
   → 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?  
   → 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

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

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

   → 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

5b. Coughing?  
1. Yes  
0. No

5c. Burping?  
1. Yes  
0. No
6. Were six eppendorf tubes aliquoted at this visit?  
   □  Yes  □  No (1080)

   **If YES, proceed to Question #7.**

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

   Equipment Malfunction
   □  Yes  □  No (1090)
   If YES, explain ________________________________

   Low Yield
   □  Yes  □  No (1100)

   Subject could not tolerate procedure
   □  Yes  □  No (1110)

   Other
   □  Yes  □  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?  
   □  Yes  □  No (1150)

8. Were the tubes stored immediately at -70° Celsius or colder?  
   □  Yes  □  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:___________________________________________________________________________

__________________________
__________________________
__________________________
__________________________
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?  
   ➤ 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?  
   ➤ 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 $F_{ENO}$ 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.

<table>
<thead>
<tr>
<th>Maneuver</th>
<th>Time (based on 24-hour clock)</th>
<th>Measured $F_{ENO}$</th>
<th>Maneuver Not Acceptable</th>
<th>Clinic Use Only Reproducible Measurements</th>
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<td>6. Maneuver #5</td>
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<td>[1190]</td>
<td>[1210]</td>
<td>[1250]</td>
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<td>7. Maneuver #6</td>
<td>[1220]</td>
<td>[1230]</td>
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<td>[1290]</td>
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<td>8. Maneuver #7</td>
<td>[1260]</td>
<td>[1270]</td>
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<td>9. Maneuver #8</td>
<td>[1300]</td>
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<td>10. Maneuver #9</td>
<td>[1340]</td>
<td>[1350]</td>
<td>[1370]</td>
<td>[1380]</td>
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</tbody>
</table>

11. Did the subject achieve two reproducible outcomes?
   If NO, explain ________________________________

   ☐ 1 Yes  ☐ 0 No (1380)
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\textsubscript{1} value from the appropriate spirometry testing form as the baseline reference.

A. Baseline FEV\textsubscript{1} prior to methacholine challenge \underline{__} . \underline{__} \underline{__} L
B. Methacholine Reversal Reference Value (Question A \times 0.90 = \underline{__} . \underline{__} \underline{__} \underline{__} L)
C. Diluent FEV\textsubscript{1} Reference Value (Question 1000 \times 0.8049 = \underline{__} . \underline{__} \underline{__} \underline{__} L)

1. Post Diluent FEV\textsubscript{1} \underline{__} . \underline{__} \underline{__} L (1000)
2. Did the subject drop \geq 20\% at the diluent stage?
   ➔ If YES, proceed to Question #5 and record 0 for Question #5a.
   \square_1 Yes \square_0 No (1010)
3. Last concentration of methacholine administered \underline{__} \underline{__} \underline{__} \underline{__} mg/ml (1020)
4. FEV\textsubscript{1} after last concentration of methacholine administered \underline{__} . \underline{__} \underline{__} L (1030)
5. Did the subject achieve a PC\textsubscript{20}?
   ➔ If NO, proceed to Question #6.
   \square_1 Yes \square_0 No (1040)
   5a. PC\textsubscript{20} \underline{__} \underline{__} \underline{__} \underline{__} mg/ml (1050)
6. Time methacholine challenge ended (based on 24-hour clock) \underline{__} \underline{__} \underline{__} \underline{__} (1060)
7. Subject’s FEV\textsubscript{1} after standard reversal from methacholine challenge
   \textbf{If subject is continuing with sputum induction, standard reversal = 4 puffs albuterol.}
   \textbf{If subject is not continuing with sputum induction, standard reversal = 2 puffs albuterol.}
   7a. FEV\textsubscript{1} \underline{__} . \underline{__} \underline{__} L (1070)
   7b. Time of FEV\textsubscript{1} in Question #7a (based on 24-hour clock) \underline{__} \underline{__} \underline{__} \underline{__} (1090)
   7c. Was the FEV\textsubscript{1} from Question #7a \geq the methacholine reversal reference value (B) in the gray box above?
      ➔ 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.
**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 FEV₁ after the first post-challenge treatment of albuterol.*

1. Was an additional treatment used in the first hour?
   - If NO, skip to Question #3.

1a. Additional albuterol by MDI
   - If NO, skip to Question #1b.

   - Number of additional puffs of albuterol administered
     - 1 Yes
     - 0 No
     - 2 four
     - 3 > four

1b. Nebulized Beta-agonist
   - 1 Yes
   - 0 No

1c. Subcutaneous epinephrine
   - 1 Yes
   - 0 No

1d. Implementation of clinic emergency protocol or algorithm
   - 1 Yes
   - 0 No

1e. Other (specify) ________________________________
   - 1 Yes
   - 0 No

2. Subject’s FEV₁ after additional treatment within first hour.

2a. FEV₁
   - __ . ___ ___ L

2b. FEV₁ (% predicted)
   - ___ ___ % predicted

2c. Time of FEV₁ in Question #2a (based on 24-hour clock)
   - ___ ___ ___

2d. Was the FEV₁ from Question #2a ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form?
   - If YES, STOP HERE and continue with remaining visit procedures.
   - If NO, proceed to Question #3.
3. Was additional treatment used after one hour?
   ➔ If NO, skip to Question #4.
   
   3a. Additional albuterol by MDI
       ➔ If NO, skip to Question #3b.
       Number of additional puffs of albuterol administered
       
       |   |   |   |
       | 1 | Yes | 0 | No (1110) |
       | 2 | Yes | 0 | No (1120) |
       | 3 | Yes | 0 | No (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
       ➔ If YES, please complete the Serious Adverse Event (SERIOUS) form.
       
       |   |   |   |
       | 1 | Yes | 0 | No (1180) |

   3g. Other (specify) ___________________________
       
       |   |   |   |
       | 1 | Yes | 0 | No (1190) |

4. Subject’s final FEV₁ after methacholine challenge.

   4a. FEV₁
       
       |   |   |   |
       | __ | . | __ | __ | L (1200) |

   4b. FEV₁ (% predicted)
       
       |   |   |   |
       | __ | __ | % predicted (1210) |

   4c. Time of FEV₁ from Question #4a (based on 24-hour clock)
       
       |   |   |   |
       | __ | __ | __ | __ | (1220) |

   4d. Was the FEV₁ from Question #4a ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form?
       ➔ If NO, complete the source documentation box below.
       
       |   |   |   |
       | 1 | Yes | 0 | No (1230) |

   Physician Source Documentation

   Physician’s signature: ___________________________ (1240)
   Date: ___ / ___ / ___ ___ (1250)
   Time: ___ ___ (based on 24-hour clock) (1260)
**METHACHOLINE CHALLENGE TESTING CHECKLIST**

**Subject ID:**

**Subject Initials:**

**Visit Number:**

**Visit Date:**

**Month / Day / Year**

**Supervisor ID:**

**Technician ID:**

---

(Physician’s Signature: __________________________) (1055)

---

**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?
   - [ ] Yes
   - [ ] No

   If **YES**, has the subject received permission from the supervising physician to proceed with the methacholine challenge testing?

   **Physician’s Signature:** __________________________ (1015)

2. Does the subject have a baseline (pre-diluent) FEV₁ less than 55% of predicted?
   - [ ] Yes
   - [ ] No

   *Use the FEV₁ value from the appropriate spirometry testing form as the baseline reference.*

3. Does the subject have a history of urinary retention?
   - [ ] Yes
   - [ ] No

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

3a. If **YES**, is the subject randomized?
   - [ ] Yes
   - [ ] No

   ➔ 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?

   - [ ] Yes
   - [ ] No

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

   __________________________ (1055)

4. Is there any other reason the subject should not proceed with the methacholine challenge testing?

   If **YES**, explain __________________________

5. Is the subject eligible to proceed with the diluent (solution #0) spirometry testing for the methacholine challenge?

   - [ ] Yes
   - [ ] No

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

2. Since Visit 1, has the subject received treatment with any excluded medications (P16_EXCLDRUG)? □ Yes □ 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? □ Yes □ 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? □ Yes □ No (1030)
   ➔ Use Question #6 from P16_COMPLY to answer this question

5. Did the subject record both AM and PM peak flow measurements and symptoms on his or her Diary Cards (P16_DIARY) on at least 75% of the days during the interval between Visits 2 and 3? □ Yes □ 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? □ Yes □ No (1050)

7. Is the subject’s prebronchodilator FEV₁ > 40% of predicted? □ Yes □ No (1060)

8. Does the subject wish to withdraw consent from the study? □ Yes □ No (1070)

9. Is there any new information that makes the subject ineligible according to the eligibility criteria? If YES, describe: ____________________________

10. Is there any other reason why this subject should not be allocated to the BASALT or TALC study? If YES, describe: ____________________________
11. Is the subject eligible for allocation?

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 FEV₁ > 70% of predicted?

- 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?

- 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)?

- 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.

- BASALT
- TALC

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.

After study allocation, complete the following procedures:

- Record study to which the subject was allocated (P16_LOG).
- Enroll subject in appropriate protocol.
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
   
   ➔ Value obtained from Question #1 on P16_COMPLY_WKS

2. Total number of puffs in DOSER™ history
   
   ➔ Value obtained from Question #2 on P16_COMPLY_WKS

3. Percent compliance = \( \frac{\text{Question #2}}{\text{Question #1}} \times 100 \)

   ➔ 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
   
   ➔ Value obtained from Question #4 on P16_COMPLY_WKS

5. Total number of compliant days
   
   ➔ Value obtained from Question #5 on P16_COMPLY_WKS

6. Percent compliance = \( \frac{\text{Question #5}}{\text{Question #4}} \times 100 \)

   ➔ If the subject took the correct daily dose less than 75% of the days, re-emphasize the importance of maintaining the daily dosing schedule.
To the subject: If your peak flow is below [___ ___ ___] 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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Day 1:</th>
<th>Day 2:</th>
<th>Day 3:</th>
<th>Day 4:</th>
<th>Day 5:</th>
<th>Day 6:</th>
<th>Day 7:</th>
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**MORNING EVALUATION (Between 5 AM and 10 AM)**

1. Number of times you woke up last night due to asthma (1000)
   
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.
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)
(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)
   ➔ 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 upcoming year 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?
   If any of the shaded boxes are completed, the subject is ineligible.
   ➔ If YES, proceed with remaining Visit 1 procedures.
   ☐ 1 Yes ☐ 0 No (1060)

Subject Source Documentation
Subject Initials: ___ ___ ___ (1070)
Date: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ (1080)
BASALT/TALC RUNIN
ELIGIBILITY
CHECKLIST 2

(Clinic Coordinator completed)

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

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

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

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

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? If YES, describe ________________________________
   □ Yes □ No (1040)

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? □ Yes □ 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? □ Yes □ No (1060)

6. Is the subject regularly using inhaled corticosteroids? □ Yes □ 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? □ Yes □ No (1080)

6b. Has the subject been using greater than the equivalent of 1000 μg inhaled fluticasone daily? □ Yes □ 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?
   - Yes 0 No (1100)
7a. If NO, does the subject report experiencing asthma symptoms more than twice a week?
   - 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?
   - 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?
   - Yes 0 No (1130)
10. Has the subject smoked cigarettes, a pipe, cigar, marijuana, or any other substance in the past year?
    - Yes 0 No (1140)
11. Record smoking history in pack-years. (Enter 00.0 if subject never smoked.)
    - Is Question #11 ≥ 10?
      - Yes 0 No (1150)
12. Is the subject potentially able to bear children? (If subject is male, check N/A and go to Question #13.)
    - Yes 0 No 9 N/A (1160)
12a. If YES, is the subject using one of the approved methods indicated on the Birth Control (BIRCTRL) reference card?
    - Yes 0 No (1170)
12b. If YES, is the subject currently pregnant or lactating?
    - Yes 0 No (1180)
13. Is the subject eligible to proceed?
    - If any of the shaded boxes are completed, the subject is ineligible.
    - If YES, proceed with remaining Visit 1 procedures.
Section 1

1. Is the subject’s prebronchodilator FEV1 > 40% of predicted?   
   - Yes  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?   
   - Yes  No (1001)
   ➔ If NO, skip to Question #3.
   ➔ If YES, record values below:

   PC20: ______ 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?   
   - Yes  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 PC20 ≤ 16 mg/ml?   
   - Yes  No (1007)

2c. Does the subject have source documentation of a methacholine PC20 ≤ 8 mg/ml?   
   - Yes  No (1008)

2d. Is the subject eligible to proceed?   
   - Yes  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 FEV₁ ≥ 55% of predicted and he/she qualifies for methacholine challenge?
   - If YES, complete Section 2.
   - If NO, complete Section 3.

Section 2
4. Is the subject regularly using ICS at this time?
   - 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 PC₂₀ ≤ 16 mg/ml?
   - Yes 0 No (1030)

6. Does the subject have a methacholine PC₂₀ ≤ 8 mg/ml?
   - Yes 0 No (1040)

7. Is the subject eligible to proceed?
   - 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?
   - 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 FEV₁ improve ≥ 12% in response to four puffs of albuterol?
   - 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.
Subject Initials: ____
Visit Number: 2
Visit Date: _____ / ____ / ______
Coordinator ID: _______ _______ _______
COLD HISTORY

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

2. How severe are your colds usually?
   - Extremely severe
   - Very severe
   - Severe
   - Moderate
   - Mild
   - Extremely mild (1010)

3. When you get colds, how often do they make your asthma worse?
   - Always
   - Usually
   - Sometimes
   - Rarely
   - Never (1020)

   → If NEVER, skip to Question # 5.

4. When colds make your asthma worse, how severe does your asthma usually get?
   - Extremely severe
   - Very severe
   - Severe
   - Moderate
   - Mild
   - Extremely mild (1030)

PRIOR ASThma TREATMENT

I will read a list of medications. Indicate if you have ever used 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, Medihaier-Epi, Primatene Mist, Alupent, Brethaire, Brethine, Bronkometer, Maxair, Metaprel, Proventil, Tornalate, Ventolin, Xopenex and others)
   - Yes
   - No
   - Unknown
   ___ ___ / ___ / ___ ___ (1040) (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)
   - Yes
   - No
   - Unknown
   ___ ___ / ___ / ___ ___ (1090) (1100) (1110) (1120)
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>1</th>
<th>0</th>
<th>8</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Asthma medication via a Nebulizer Machine</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>(1130) - (1140) - (1150) - (1160)</td>
</tr>
<tr>
<td>8</td>
<td>Oral Beta-Agonists (Alupent, Brethine, Bricanyl, Metaprel, Proventil, Ventolin, Repetabs, Volmax and others)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
</tr>
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<td></td>
<td></td>
<td>(1170) - (1180) - (1190) - (1200)</td>
</tr>
<tr>
<td>9</td>
<td>Short-acting Oral Theophylline (Aminophylline, Slo-Phyllin and others)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
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<tr>
<td></td>
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<td>(1210) - (1220) - (1230) - (1240)</td>
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<td>10</td>
<td>Sustained release Oral Theophylline (Slo-bid, Theo-Dur, Uniphyl and others)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
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<tr>
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<td>(1250) - (1260) - (1270) - (1280)</td>
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<tr>
<td>11</td>
<td>Inhaled Anticholinergic (Atrovent, Combivent, Spiriva)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td></td>
<td>(1290) - (1300) - (1310) - (1320)</td>
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<tr>
<td>12</td>
<td>Anti-allergic Inhaled Medications (Intal, Tilade and others)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
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<td>(1330) - (1340) - (1350) - (1360)</td>
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<td>13</td>
<td>Anti-allergic Nasal Medications (Nasalacrom, Astelin and others)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
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<tr>
<td>14</td>
<td>Anti-allergic Oral Medications (Allegra, Claritin, Zyrtec, Chlor-Trimeton and others)</td>
<td>1</td>
<td>0</td>
<td>8</td>
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<td>(1410) - (1420) - (1430) - (1440)</td>
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<tr>
<td>15</td>
<td>Leukotriene Antagonist / 5LO Inhibitors (Accolate, Zyflo, Singulair)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
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<tr>
<td></td>
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<td></td>
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<tr>
<td>16</td>
<td>IgE Blocker (Xolair)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
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<td>(1490) - (1500) - (1510) - (1520)</td>
</tr>
<tr>
<td>17</td>
<td>Topical Steroids - Prescription (Synalar, Lidex, Dermacin, Fluocinonide and others)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
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<td>(1530) - (1540) - (1550) - (1560)</td>
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<tr>
<td>18</td>
<td>Topical Steroids - OTC (Hydrocortisone - multiple strengths and products)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
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<tr>
<td></td>
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<td>(1570) - (1580) - (1590) - (1600)</td>
</tr>
<tr>
<td>19</td>
<td>Nasal Steroids (Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Rhinocort, Nasonex and others)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
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<td>(1610) - (1620) - (1630) - (1640)</td>
</tr>
<tr>
<td>20</td>
<td>Oral Steroids (Prednisone, Medrol and others)</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>Unknown</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>(1650) - (1660) - (1670) - (1680)</td>
</tr>
</tbody>
</table>
21. **Inhaled Steroids**

(Azmacort, Beclovent, Vanceril, AeroBid, QVAR, Flovent, Pulmicort, Advair Diskus and others)

- **If NO or unknown, skip to Question #22.**
- **If YES, complete Questions #21a - 21c.**

21a. Indicate most recent type of inhaled steroid taken

- **Yes**
- **No**
- **Unknown**

If YES, indicate date medication was last taken:

- **month / day / year**

- **beclomethasone MDI (1 puff = 42 μg)**
  - (e.g., Beclovent, Vanceril)
- **beclomethasone MDI (1 puff = 84 μg)**
  - (e.g., Vanceril-DS)
- **beclomethasone HFA (1 puff = 40 μg)**
  - (e.g., QVAR)
- **beclomethasone HFA (1 puff = 80 μg)**
  - (e.g., QVAR)
- **budesonide DPI (1 puff = 80 μg)**
  - (e.g., Symbicort Turbuhaler)
- **budesonide DPI (1 puff = 160 μg)**
  - (e.g., Symbicort Turbuhaler)
- **budesonide DPI (1 puff = 200 μg)**
  - (e.g., Pulmicort Turbuhaler)
- **budesonide DPI (1 puff = 320 μg)**
  - (e.g., Symbicort Turbuhaler)
- **flunisolide MDI (1 puff = 250 μg)**
  - (e.g., Aerobid, Aerobid - M)
- **fluticasone MDI (1 puff = 44 μg)**
  - (e.g., Flovent)
- **fluticasone MDI (1 puff = 110 μg)**
  - (e.g., Flovent)
- **fluticasone MDI (1 puff = 220 μg)**
  - (e.g., Flovent)
- **fluticasone DPI (1 puff = 50 μg)**
  - (e.g., Flovent Rotadisk)
- **fluticasone DPI (1 puff = 100 μg)**
  - (e.g., Advair Diskus)
- **fluticasone DPI (1 puff = 250 μg)**
  - (e.g., Advair Diskus)
- **fluticasone DPI (1 puff = 500 μg)**
  - (e.g., Advair Diskus)
- **mometasone DPI (1 puff = 220 μg)**
  - (e.g., Asmanex Thwisthaler)
- **triamcinolone acetonide MDI (1 puff = 100 μg)**
  - (e.g., Azmacort)
- **other __________________________**
  - (1730)
MEDICAL HISTORY

Subject ID: 1  6 - ___ - ___
Visit Number: 1

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.

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

22. Statin medications

☐ 1 Yes  ☐ 0 No  ☐ 8 Unknown

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 rosvastatin (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)
MEDICAL HISTORY

27. Breasts

28. Endocrine Systems

29. Lung - other than asthma

29a. Have you ever had pneumonia?

29b. Have you ever had bronchitis?

30. Heart and Blood Vessels

31. Liver or Pancreas

32. Kidneys or Urinary Tract System

33. Reproductive System

34. Stomach or Intestines

34a. Do you have gastroesophageal reflux disease (GERD)?

35. Muscles or Bones

36. Nervous System

37. Psychiatric

38. Other

39. Drug Allergies

40. Food Allergies

SUBJECT’S WEIGHT

(Clinic Coordinator completed)

41. Weight (without shoes or heavy clothing)

___ ___ . ___ kg (2000)

Subject Source Documentation
Subject’s Initials: ___ ___ (2010)
Date: ___ / ___ / ___ ___ (2020)
Please reference the Drug Classifications list for a complete list of examples for the questions below. If any medications other than 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?
   Examples: Pepsi, Coke, Coffee, Mountain Dew, Tea, Rootbeer, Red Bull
   [ ] Yes [ ] No (1000)

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

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

4. Have you consumed any food containing alcohol or beverages containing alcohol in the past 6 hours?
   [ ] Yes [ ] No (1030)

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

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

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

8. Have you used any nasal decongestants in the past 6 hours?
   Examples: oxymetazoline (Afrin)
   [ ] Yes [ ] No (1060)

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

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

11. Have you used any nasal steroids in the past 48 hours?
    Examples: Flonase, Rhinocort, Nasonex
    [ ] Yes [ ] No (1090)
12. Have you used any smokeless tobacco products today?  
   Examples: chewing tobacco, snuff  
   □ 1 Yes  □ 0 No (1095)

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

14. Is there any other reason you should not proceed with spirometry testing?  
   If YES, explain ____________________________
   ____________________________
   □ 1 Yes  □ 0 No (1110)

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

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

Complete for all subjects at Visit 1.
If subject is less than 21 years old, complete Question #16 at each visit.
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

   ➤ *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:

________________________________________________________________________
________________________________________________________________________

⇒ *Skip to the SIGNATURES section.*
3. Did clinical staff terminate the subject due to ...

3a. pregnancy? (Check N/A if the subject is male.)
[ ] Yes [ ] No [ ] N/A

3b. loss to follow-up? *
[ ] Yes [ ] No (1040)

3c. an asthma-related adverse event? *
[ ] Yes [ ] No (1050)

3d. a medication-related adverse event? *
[ ] Yes [ ] No (1060)

3e. an adverse event not related to asthma or medications? *
[ ] Yes [ ] No (1070)

3f. non-compliance with QVAR dosing? *
[ ] Yes [ ] No (1080)

3g. non-compliance with diary completion? *
[ ] Yes [ ] No (1090)

3h. non-compliance with visit attendance? *
[ ] Yes [ ] No (1100)

3i. non-compliance with peak flow monitoring? *
[ ] Yes [ ] No (1110)

3j. significant asthma exacerbation?
[ ] Yes [ ] No (1120)

3k. ineligibility during the BASALT/TALC common runin period for reasons other than compliance or exacerbation? *
[ ] Yes [ ] No (1130)

3l. subject allocated to TALC prior to study start date
[ ] Yes [ ] No (1132)

3m. subject allocated to TALC after recruitment closed
[ ] Yes [ ] No (1134)

3n. subject allocated to BASALT after recruitment closed
[ ] Yes [ ] No (1136)

3o. other reason? *
[ ] Yes [ ] No (1140)

* Additional explanation required:

________________________________________________________________________
________________________________________________________________________

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.

<table>
<thead>
<tr>
<th>Clinic Coordinator Signature</th>
<th>1170</th>
<th>1180</th>
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<th>1200</th>
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<tbody>
<tr>
<td></td>
<td>month</td>
<td>day</td>
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</tbody>
</table>

Subject ID: 6
Visit Number: ___
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.

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

   - [ ] I am certain the capsules contained placebo.  (1020)
   - [ ] I think the capsules probably contained placebo.
   - [ ] I have no idea what was in the subject’s capsules, but my best guess would be:
     - [ ] Placebo
     - [ ] Active Tiotropium (1030)
   - [ ] I think the capsules probably contained active tiotropium.
   - [ ] 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**.

- [ ] I am certain the subject was on low dose QVAR.
- [ ] I think the subject probably was on low dose QVAR.
- [ ] I have no idea what dose of QVAR the subject received, but my best guess would be:
  - [ ] Low Dose
  - [ ] High Dose
- [ ] I think the subject was probably on high dose QVAR.
- [ ] 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)
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

2. QVAR MDI

   ➔ If Unchanged, proceed to Question #3.

   2a. Date change began
     ___________________/_______/_______ (1020)

   2b. Date change ended
     ___________________/_______/_______ (1030)

   2c. Ongoing at current visit
     □ 1 (1040)

3. Scheduled Diskus®

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

   3a. Date change began
     ___________________/_______/_______ (1060)

   3b. Date change ended
     ___________________/_______/_______ (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

4b. Date change ended

4c. Ongoing at current visit

☐ 1 (1120)
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

   ➔ Value obtained from Question #1 on P18_COMPLY_WKS

1b. Total number of puffs in DOSER™ history

   ➔ Value obtained from Question #2 on P18_COMPLY_WKS

1c. Percent compliance = \( \frac{\text{Question #1b}}{\text{Question #1a}} \times 100 \)

   ➔ 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

   ➔ Value obtained from Question #4 on P18_COMPLY_WKS

1e. Total number of compliant days

   ➔ Value obtained from Question #5 on P18_COMPLY_WKS

1f. Percent compliance = \( \frac{\text{Question #1e}}{\text{Question #1d}} \times 100 \)

   ➔ 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 = \( \frac{\text{Question } #2c}{\text{Question } #2a} \times 100 \) ___ ___ ___ . ___ % (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 = \( \frac{\text{Question } #3b}{\text{Question } #3a} \times 100 \) ___ ___ ___ . ___ % (1120)

→ *If the subject took less than 75% of the scheduled doses, re-emphasize the importance of maintaining the daily dosing schedule.*
To the subject: If your peak flow is below ___ 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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
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<td>Month</td>
<td>Day</td>
<td>Month</td>
<td>Day</td>
<td>Month</td>
<td>Day</td>
</tr>
</tbody>
</table>

**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 **(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 **(1120)**
    - __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

**Symptoms ++ since you woke**

13. Shortness of Breath **(1130)**
    - __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

    - __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

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.**

<table>
<thead>
<tr>
<th>Symptom Severity Rating Scale</th>
<th>0 = Absent</th>
<th>1 = Mild</th>
<th>2 = Moderate</th>
<th>3 = Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>No symptom</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom was minimally troublesome, i.e. not sufficient to interfere with normal daily activity or sleep.</td>
<td>1 = Mild</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom was sufficiently troublesome to interfere with normal daily activity or sleep.</td>
<td>2 = Moderate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom was so severe as to prevent normal activity and/or sleep.</td>
<td>3 = Severe</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**To the subject:** If your peak flow is below ___ ___ ___ 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.**

|-------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|

**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 puffs (s) from QVAR Inhaler (AM) (1040)
5. Total number of puffs (s) from Scheduled Diskus® (AM) (1043)
6. Total number of capsules (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 puffs (s) from QVAR Inhaler (PM) (1120)
15. Total number of puffs (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)

**++ 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.
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)?

   ![Yes/No](1) Yes  ![No](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)?

   ![Yes/No](1) Yes  ![No](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)?

   ![Yes/No](1) Yes  ![No](0) No (1020)

4. Is there any other reason why this subject should not be randomized in the TALC study?

   If YES, describe: ____________________________

   ![Yes/No](1) Yes  ![No](0) No (1030)

5. Is the subject eligible to proceed?

   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.

   ![Yes/No](1) Yes  ![No](0) No (1040)
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?
   - ECG
   - 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?
   - Yes
   - No (1060)
   
   ➔ If YES, please complete the Clinical and Laboratory Adverse Events (AECLIN) form.
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 other than 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? □ Yes □ No (1000)
   Examples: Pepsi, Coke, Coffee, Mountain Dew, Tea, Rootbeer, Red Bull

2. Have you used medications with caffeine in the past 6 hours? □ Yes □ 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? □ Yes □ 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? □ Yes □ No (1030)

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

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

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

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

9. Have you used any cough medicines, anti-tussives, or expectorants in the past 48 hours? □ Yes □ 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? □ Yes □ No (1080)
    Example: albuterol (Ventolin or Proventil), study RESCUE

11. Have you used any nasal steroids in the past 48 hours? □ Yes □ No (1090)
    Examples: Flonase, Rhinocort, Nasonex
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Have you used any smokeless tobacco products today?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Examples: chewing tobacco, snuff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Have you used your scheduled Diskus in the past 12 hours?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>(Do not complete for Visits 6A-6H, 7, 10A-10H, 11 and 15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Have you used your scheduled HandiHaler in the past 24 hours?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>(Do not complete for Visits 6A-6H, 7, 10A-10H, 11 and 15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. At this time, is your asthma worse because of recent exposure to triggers?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Examples: cold air, smoke, allergens, recent exercise, a recent respiratory tract infection, or other pulmonary infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Is there any other reason you should not proceed with spirometry testing?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>If YES, explain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Is the subject eligible to proceed with the spirometry testing?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>If any of the shaded boxes are filled in, the subject is ineligible for spirometry and exhaled nitric oxide testing.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>➤ If YES, proceed to Question #18 or the next form/procedure listed on the visit procedure checklist.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Height (without shoes)</td>
<td>cm</td>
<td></td>
</tr>
<tr>
<td>If subject is less than 21 years old, complete Question #18 at each visit.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-----</td>
<td>----</td>
</tr>
<tr>
<td>1. Did the subject experience an increase in cough, phlegm/mucus,</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>2. Did the subject require an increase in asthma medications (oral,</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>medications) as a result of rescue intervention or by the opinion of</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>the treating physician?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>➔ If YES, please complete the CMED form.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Did the subject experience a significant asthma exacerbation?</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>experienced a significant asthma exacerbation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>➔ If NO, STOP HERE. DO NOT SUBMIT THIS FORM TO THE DCC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Date significant asthma exacerbation occurred</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Did the subject seek care for the asthma exacerbation?</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>6. What type of care was sought?</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>6a. Study Investigator?</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>6b. Primary Care or Other Physician?</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>☑</td>
<td>☐</td>
</tr>
</tbody>
</table>

(Part of the document image is missing or not visible.)
6c. Emergency Room visit?

   If YES, name of hospital: ________________________________

7. Was the subject hospitalized?

   ➔ 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? □ Yes □ 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) □ Yes □ No (1130)

8b. Nebulized beta-agonist
   ➔ If YES, please complete the CMED form.

8c. Inhaled corticosteroids
   ➔ If YES, please complete the CMED form.

8d. Oral corticosteroids
   ➔ If YES, please complete the CMED form.

8e. Intravenous corticosteroids
   ➔ If YES, please complete the CMED form.

9. Was the asthma exacerbation treated as outlined in the protocol?
   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)
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 not 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 (1000) placebo
   - [ ] 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 TALT 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
- □ 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
- □ 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)*

________________________________________
________________________________________
________________________________________
________________________________________
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**.

- [ ] I am certain the inhalers contained low dose QVAR
- [ ] I think the inhalers probably contained low dose QVAR
- [ ] I have no idea which type of QVAR inhalers I received, but my best guess would be:
  - [ ] Low Dose
  - [ ] High Dose
- [ ] I think the inhalers probably contained high dose QVAR
- [ ] 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.).

- [ ] I have no comments
- [ ] I observed the following *(Describe below)*

_________________________________________________________________________________

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

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

2. Who initiated termination of the subject?  
   - 0 Clinical Staff (1010)  
   - 1 Subject. 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:  
   ____________________________________________________________  
   ____________________________________________________________

   ➤ Skip to the SIGNATURES section. (1030)
TERMINATION OF STUDY PARTICIPATION

Subject ID: __ __ __ __ __ __ __ __ __ __ __
Visit Number: __ __ __ __

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

4a. pregnancy?  
(Check N/A if the subject is male.)

☐ 1 Yes  ☐ 0 No  ☐ 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.

Clinic Coordinator Signature  __ __ / __ __ / ____ ____ (1180)

ACRN Investigator Signature  __ __ / __ __ / ____ ____ (1200)
1. Has the subject experienced a significant asthma exacerbation during the TALC trial?
   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

   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

2. Has the subject taken prednisone (for any reason) during the TALC trial?
   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

   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

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)?
   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

   3b. If YES, was the subject’s last dose of open-label ICS taken prior to today’s date?
      □ 1 Yes  □ 0 No

   3bi. If NO, will the subject discontinue use of these medications today?
      □ 1 Yes  □ 0 No

4. Is the subject prepared to schedule Visit 7 or 11 at this time?
   □ 1 Yes  □ 0 No

   *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.
1. Has the subject experienced a significant asthma exacerbation during the TALC trial?
   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:

   [ ] Yes [ ] No (1000) 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?

   [ ] Yes [ ] No (1020)

2. Has the subject taken prednisone (for any reason) during the TALC trial?
   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:

   [ ] Yes [ ] No (1030) 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?

   [ ] Yes [ ] 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)?
   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:

   [ ] Yes [ ] No (1060) month / day / year (1070)

   3b. If YES, was the subject’s last dose of open-label ICS taken prior to today’s date?

   [ ] Yes [ ] No (1080)

   3bi. If NO, will the subject discontinue use of these medications today?

   [ ] Yes [ ] No (1085)

4. Has a study investigator assessed the subject at this visit?
   4a. If YES, does the study investigator allow the subject to schedule Visit 7 or 11 at this time?

   [ ] Yes [ ] No (1090)

5. Is the subject prepared to schedule Visit 7 or 11 at this time?
   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.
(Clinic Coordinator completed)

1. Has the subject experienced a significant asthma exacerbation during the TALC trial?
   - 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)
   - If YES, did the subject experience his/her last significant asthma exacerbation at least 4 weeks prior to today’s date?
     - Yes 0 No (1020)

2. Has the subject taken prednisone (for any reason) during the TALC trial?
   - 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)
   - If YES, was the subject’s last dose of prednisone taken at least 4 weeks prior to today’s date?
     - 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)?
   - 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)
   - If YES, was the subject’s last dose of open-label ICS taken at least 2 weeks prior to today’s date?
     - Yes 0 No (1080)

4. Is the subject prepared to complete Visit 7 or 11 at this time?
   - 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.
POST-ALBUTEROL
(4 puffs)
SPIROMETRY TESTING

Subject Initials: __ __ __
Visit Number: __ ____
Visit Date: ___ / ___ / ___
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 FEV₁ and FVC is maximized.

3. Results of best effort post-albuterol:
   3a. FVC ____ . ____ ____ L (1020)
   3b. FEV₁ ____ . ____ ____ L (1030)
   3c. FEV₁ (% predicted) ____ ____ ____ % predicted (1040)
   3d. PEFR ____ . ____ ____ L/S (1050)
   3e. FEF₂₅-₇₅ ____ . ____ ____ L/S (1060)

4. In your judgment, was the subject’s spirometry technique acceptable? ___ Yes ___ No (1070)
   4a. If NO, why was it unacceptable?
      Inadequate inspiratory effort ___ Yes ___ No (1080)
      Inadequate expiratory effort ___ Yes ___ No (1090)
      Inadequate duration of expiration ___ Yes ___ No (1100)
      Cough during procedures ___ Yes ___ No (1110)
      Other (specify) ____________________ ___ Yes ___ No (1120)
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 FEV₁ and FVC is maximized.

3. Results of best effort post-ipratropium:
   3a. FVC _______ _______ _______ L (1020)
   3b. FEV₁ _______ _______ _______ L (1030)
   3c. FEV₁ (% predicted) _______ _______ % predicted (1040)
   3d. PEFR _______ _______ _______ L/S (1050)
   3e. FEF₂₅₋₇₅ _______ _______ _______ 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?
   □ 1 Yes □ 0 No (1080)
   Inadequate inspiratory effort
   □ 1 Yes □ 0 No (1090)
   Inadequate expiratory effort
   □ 1 Yes □ 0 No (1100)
   Inadequate duration of expiration
   □ 1 Yes □ 0 No (1110)
   Cough during procedures
   □ 1 Yes □ 0 No (1120)
   Other (specify) ________________________________

(Please complete)
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  
   
   ➔ 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.

   ☐ 1  Positive  ☐ 2  Negative (1030)

Subject Source Documentation
Subject’s Initials:  __ __ __ (1040)
Date:  __ __ / __ __ / __ __ __ (1050)
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?
   - Yes [ ]
   - No [ ]

   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
   (Ask the subject his/her date of birth.)

   ___ ___ / ___ ___ / _________ ___ (1020)

   Month    Day    Year

3. Subject’s gender
   - Male [ ]
   - Female [ ]

4. Subject’s Race and Ethnicity
   4a. Subject’s ethnic background
       (Ask the subject to identify his/her ethnic background.)

       - Hispanic or Latino [ ]
       - Not Hispanic or Latino [ ]

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

       American Indian or Alaskan Native
       - Yes [ ]
       - No [ ]

       Asian
       - Yes [ ]
       - No [ ]

       Black or African American
       - Yes [ ]
       - No [ ]

       White
       - Yes [ ]
       - No [ ]

       Native Hawaiian or Other Pacific Islander
       - Yes [ ]
       - No [ ]

       Other (specify) ____________________________

       - Yes [ ]
       - No [ ]
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 ___________________________ (110)

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.
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.

1. I am told I snore loudly and bother others.
   - Never
   - Rarely
   - Sometimes
   - Usually
   - Always

2. I am told I stop breathing ("hold my breath") in sleep.
   - Never
   - Rarely
   - Sometimes
   - Usually
   - Always

3. I awake suddenly gasping for breath, unable to breathe.
   ➔ 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.
     - Yes
     - No

   3b. It happens when I have chest tightness, wheezing, or cough and takes more than a couple of breaths to fully recover.
     - Yes
     - No

4. I sweat a great deal at night.
   - Never
   - Rarely
   - Sometimes
   - Usually
   - Always

5. I have high blood pressure (or once had it).
   - Never
   - Rarely
   - Sometimes
   - Usually
   - Always

6. I have a problem with my nose blocking up when I am trying to sleep.
   - Never
   - Rarely
   - Sometimes
   - Usually
   - Always

7. My snoring or my breathing problem is much worse if I sleep on my back.
   - Never
   - Rarely
   - Sometimes
   - Usually
   - Always

8. My snoring or my breathing problem is much worse if I fall asleep right after drinking alcohol.
   - Never
   - Rarely
   - Sometimes
   - Usually
   - Always
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.

<table>
<thead>
<tr>
<th>Likelihood of Dozing</th>
<th>Never</th>
<th>Slight</th>
<th>Moderate</th>
<th>High</th>
</tr>
</thead>
</table>

10. Sitting and reading  

11. Watching TV  

12. Sitting, inactive in a public place (for example, a theater or a meeting)  

13. As a passenger in a car for an hour without a break  

14. Lying down to rest in the afternoon when circumstances permit  

15. Sitting and talking to someone  

16. Sitting quietly after a lunch without alcohol  

17. In a car, while stopped for a few minutes in traffic  

18. During the past 2 months, on average, how many hours of \textit{actual sleep} (including daytime naps) did you get in a 24-hour period? This may be different than the number of hours you spent in bed.  

CURRENT WEIGHT

19. What is your current weight in pounds?  

Subject Source Documentation  
Subject’s Initials:  
Date:  

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

2. Description of Adverse Event (ICD9 Code)
   Describe: ________________________________

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

4. Unit of time for above interval
   - 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

   5b. Life-threatening event
   - 1 Yes
   - 0 No

   5c. Inpatient hospitalization required
   - If NO, skip to Question #5d.

   Admission date
   - Month / Day / Year

   Discharge date
   - Month / Day / Year

   5d. Hospitalization prolonged
   - 1 Yes
   - 0 No

   5e. Disabling or incapacitating
   - 1 Yes
   - 0 No

   5f. Overdose
   - 1 Yes
   - 0 No

   5g. Cancer
   - 1 Yes
   - 0 No

   5h. Congenital anomaly
   - 1 Yes
   - 0 No

   5i. Serious laboratory abnormality with clinical symptoms
   - 1 Yes
   - 0 No

   5j. Other (specify) ________________________________
   - 1 Yes
   - 0 No

(Clinic Coordinator completed)
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  
If YES, describe ______________________

6d. Concurrent disorder  
If YES, describe ______________________

6e. Other event  
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: ___ / ___ / ___ ___
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

   ___ ___ / ___ ___ / ___ ___ ___ ___ (1010)

   month day year

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)
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.

<table>
<thead>
<tr>
<th></th>
<th>Largest Wheal</th>
<th>Perpendicular Wheal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Positive Control</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1120)</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1130)</td>
</tr>
<tr>
<td>2. Negative Control</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1140)</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1150)</td>
</tr>
<tr>
<td>3. Mite Mix</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1160)</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1170)</td>
</tr>
<tr>
<td>4. Cockroach Mix</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1180)</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1190)</td>
</tr>
<tr>
<td>5. Mouse</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1200)</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1210)</td>
</tr>
<tr>
<td>6. Rat</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1220)</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1230)</td>
</tr>
<tr>
<td>7. Penicillium</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1240)</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1250)</td>
</tr>
<tr>
<td>8. Alternaria</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1260)</td>
<td>Diameter: ___ ___ mm&lt;br&gt;(1270)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Largest Wheal</td>
</tr>
<tr>
<td>---</td>
<td>----------------</td>
<td>---------------</td>
</tr>
<tr>
<td>9</td>
<td>Aspergillus</td>
<td>Diameter: ___ ___ mm (1270)</td>
</tr>
<tr>
<td>10</td>
<td>Cladosporium</td>
<td>Diameter: ___ ___ mm (1290)</td>
</tr>
<tr>
<td>11</td>
<td>Cat</td>
<td>Diameter: ___ ___ mm (1310)</td>
</tr>
<tr>
<td>12</td>
<td>Dog</td>
<td>Diameter: ___ ___ mm (1330)</td>
</tr>
</tbody>
</table>

13. Is the mean diameter for the ‘Negative Control’ < 3 mm?  
   - 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?  
   - 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’?  
   - If **YES**, go to Question #15.

15. Was this test acceptable?  
   - If **YES**, go to Question #15.
   - If **NO**, go to Question #15. The subject has dermatographia and therefore, do not repeat skin testing on this subject.

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.
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 FEV₁ and FVC is maximized.

2. Results of best effort:
   2a. FVC ___ . ___ ___ L (1010)
   2b. FEV₁ ___ . ___ ___ L (1020)
   2c. FEV₁ (% predicted) ___ ___ ___ % predicted (1030)
   2d. PEFR ___ . ___ ___ L/S (1040)
   2e. FEF₂₅₋₇₅ ___ . ___ ___ 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)
(Technician completed)

Processing Sample

1. Technician ID
   
2. Processing Date
   
3. Time processing started (based on 24-hour clock)
   
4. Total Cell Count
   
Differential Cell Counts

5. Technician ID

6. Read Date

7. Squamous Cells

8. Did the subject’s sputum sample reveal ≥ 80% squamous cells?  
   
   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
   
10. Epithelial Cells
   
11. Macrophages
   
12. Neutrophils
   
13. Eosinophils
   
14. Lymphocytes
1. Date of Over-Read

2. Is the slide quality acceptable?
   - 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)
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? 

   **Duration of sputum induction at current visit should not exceed this.**

   ___ ___ . ___ minutes (1000)

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? □ ✔ Yes □ ☐ No (1040)

5. Volume of sputum sample at this visit ___ ___ ___ . ___ ml (1050)

   5a. Is the volume of the sample ≥ 1 ml? □ ✔ Yes □ ☐ No (1060)

6. Is the sample adequate for laboratory analysis? □ ✔ Yes □ ☐ 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 FEV₁ immediately after completion of sputum induction

7a. FEV₁ 

7b. FEV₁ (% predicted)

7c. Time of FEV₁ in Question #7a (based on 24-hour clock)

7d. Percent difference in FEV₁ \( \frac{\text{Reference} - \text{Question #7a}}{\text{Reference}} \times 100 \)

**Reference = FEV₁ used for assessment of eligibility for SI.**

7e. Did the subject’s FEV₁ drop > 10% (from post-albuterol baseline) as indicated in Question #7d?

☐ 1 Yes ☐ 0 No

⇒ If NO, STOP HERE and continue with remaining visit procedures.
⇒ If YES, proceed to the Additional Treatment for Sputum Induction (SPUTUM_ADD_TRT) form.
AdditionaL Treatment Post Sputum Induction

(technician completed)

complete this form only if the subject has experienced > 10% fall in FEV₁ from post-albuterol baseline immediately after completion of sputum induction.

Clinic Use Only
Sputum Induction Reversal Reference Value: Reference x 0.90 = __ __ L
Reference = FEV₁ used for assessment of eligibility for Sputum Induction.

→ Administer 2 puffs of albuterol and wait 15 minutes, then perform spirometry.

1. Subject’s FEV₁ after initial 2 puffs of albuterol
   1a. FEV₁ __ __ __ L (1000)
   1b. FEV₁ (% predicted) __ __ __ % predicted (1010)
   1c. Time of FEV₁ from Question #1a (based on 24-hour clock) __ __ __ (1020)
   1d. Was the FEV₁ 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 FEV₁ after 2 additional puffs of albuterol
   2a. FEV₁ __ __ __ L (1040)
   2b. FEV₁ (% predicted) __ __ __ % predicted (1050)
   2c. Time of FEV₁ from Question #2a (based on 24-hour clock) __ __ __ (1060)
   2d. Was the FEV₁ 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)
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 FEV₁ 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 FEV₁ used for assessment of eligibility for sputum induction
   ____ . ____ L (1040)

4. Subject’s FEV₁ (% predicted) used for assessment of eligibility for sputum induction
   ____ ____ % predicted (1050)

5. Was the subject’s FEV₁ (% 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?
   If YES, explain ____________________________
   □ 1 Yes □ 0 No (1070)

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.