Asthma Clinical Research Network
NIH/NHLBI

SMOG
CLINICAL ADVERSE EVENTS

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year

(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 if the subject has not experienced any clinical adverse events since the last visit. If "None", sign and date this page.

❑0 None

CC's Signature: _____
Date: __ __ / __ __ / __ __ __ __

(1000) DESCRIPTION OF ADVERSE EVENT	(1010) 1. ICD9 CODE	(1020) 2. DATE STARTED (Top Line) / (1030) 3. DATE STOPPED (Bottom Line) MONTH / DAY / YEAR	(1040) 4. ONGOING at current visit	(1050) 5. DURATION Complete ONLY if duration is less than 24 hours. HOUR(S)	(1060) 6. TYPE 1 - INTERMITTENT 2 - CONTINUOUS	(1070) 7. SEVERITY 1 - MILD 2 - MODERATE 3 - SEVERE	(1080) 8. SERIOUS 1 - YES * 0 - NO	(1090) 9. LIKELIHOOD OF RELATIONSHIP TO STUDY DRUG 1 - NONE 2 - UNLIKELY (REMOTE) 3 - POSSIBLE 4 - PROBABLE 5 - HIGHLY PROBABLE	(1100) 10. CHANGE IN STUDY MEDICATIONS 1 - DISCONTINUED 2 - REDUCED 3 - INTERRUPTED, BUT RESUMED AT CURRENT DOSE 4 - UNCHANGED 5 - INCREASED	(1110) 11. OUTCOME *(Skip if #3 is missing.)* 1 - COMPLETELY RECOVERED 2 - RECOVERED, BUT WITH LASTING EFFECTS 3 - DEATH *	(1120) 12. TREATMENT REQUIRED 1 - NONE 2 - MEDICATION ** 3 - HOSPITALIZATION * 4 - OTHER
__ __	___.__	__/__/____ / __/__/____	❑1	__ __							
__ __	___.__	__/__/____ / __/__/____	❑1	__ __							
__ __	___.__	__/__/____ / __/__/____	❑1	__ __							
__ __	___.__	__/__/____ / __/__/____	❑1	__ __							
__ __	___.__	__/__/____ / __/__/____	❑1	__ __							

* Please complete a Serious Adverse Event Reporting Form (P10_SERIOUS).

** Please complete the Concomitant Medications for Asthma and Allergies (P10_CMED_AS) form.

Asthma Clinical Research Network
NIH/NHLBI

SMOG
AM1®
QUALITY CONTROL

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Technician completed)

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

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

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

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

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

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

Clinic Use Only

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

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

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

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

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

10. Did the AM1® pass? ❑1 Yes ❑0 No (1160)

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

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

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

Asthma Clinical Research Network
NIH/NHLBI

SMOG
CLINIC COORDINATOR
POST-STUDY
QUESTIONNAIRE

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Coordinator completed)

This questionnaire is to be completed at Visit 6 and 10 by the ACRN study coordinator who was primarily responsible for the subject's SMOG visits during the preceeding 8 weeks. If a randomized subject terminates prior to Visit 10, this form should be completed at the time of the termination visit.

1. Subjects in the SMOG study were randomized to receive either an active inhaled steroid inhaler or a placebo inhaler. 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 8 weeks.

- ☐ 1 I am certain it was placebo. (1000)
- ☐ 2 I think it was probably placebo.
- ☐ 3 I have no idea which treatment the subject received, but my best guess would be:
  - ☐ 1 Placebo
  - ☐ 2 Active Drug (1010)
- ☐ 4 I think it was probably active drug.
- ☐ 5 I am certain it was active drug.

2. Subjects in the SMOG study were randomized to receive either an active tablet or a placebo tablet. 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 8 weeks.

- ☐ 1 I am certain it was placebo. (1020)
- ☐ 2 I think it was probably placebo.
- ☐ 3 I have no idea which treatment the subject received, but my best guess would be:
  - ☐ 1 Placebo
  - ☐ 2 Active Drug (1030)
- ☐ 4 I think it was probably active drug.
- ☐ 5 I am certain it was active drug.

Coordinator's Initials: __ __ __ (1040)

Date: __ __/__ __/__ __ __ __ (1050)

3. Please comment with respect to any observations you made that helped you to make your choice in Question #1 or #2.

_____

_____

_____

_____

Asthma Clinical Research Network
NIH/NHLBI

SMOG
CONCOMITANT MEDICATIONS for ASTHMA and ALLERGIES

Subject ID: 1 0 - ___ - ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: ___ ___

Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year

(Clinic Coordinator completed)

At Visit 0: Please list all concomitant medications used to treat **asthma** and **allergies** that the subject has taken since signing the informed consent. Indicate the name of the medication, dose, units, frequency, route, and start date. Refer to the SMOG Drug Codes module for applicable codes. Check the "None" box if the subject has not taken any **asthma** or **allergy** concomitant medications since signing the informed consent. **Do not list study drugs or RESCUE medications.**

Subsequent visits: Please list all concomitant medications, used to treat asthma and allergies, that the subject has started taking since the last visit. Indicate the name of the medication, code, dose/units, frequency, route, start date, and stop date, if applicable. Refer to the SMOG Drug Codes module for applicable codes. Check the "None" box if the subject has not started taking any **asthma** or **allergy** concomitant medications since the last visit. If the subject is still taking the medication at the end of the current visit, please check the "ongoing" box and leave the stop date column blank. **Do not list study drugs or RESCUE medications.**

❑$_0$ None

NAME OF MEDICATION (1000)	CODE (1010)	DOSE	UNITS	FREQUENCY (1020)	ROUTE	START DATE (MM/DD/YYYY) (1030) (1040) (1050)	STOP DATE (MM/DD/YYYY) (1060)	ONGOING AT CURRENT VISIT (1070)
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$
__ __						___ / ___ / _____	___ / ___ / _____	❑$_1$

Asthma Clinical Research Network
NIH/NHLBI

SMOG COMPLIANCE CHECKLIST

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Check the following compliance criteria at Visits 3 through 10.

1. **Tablet count**

1a. Total number of tablets dispensed in eDEM™ vial ___ ___ pills (1000)

1b. Total number of tablets returned in eDEM™ vial ___ ___ pills (1010)

1c. Total number of prescribed doses ___ ___ doses (1020)

1d. Actual number of tablets taken (Question #1a - Question #1b) ___ ___ pills (1030)

1e. Percent compliance = $\frac{\textit{Question \#1d}}{\textit{Question \#1c}}$ x *100* ___ ___ ___ . ___ % (1040)

➜ If the percent compliance for the Tablet count is less than 85%, re-emphasize the importance of maintaining the daily dosing schedule.

2. **eDEM™ Monitor (Visit 4 ONLY)**

The information for Question #2a - Question #2d is obtained from the 14 day eDEM™ Monitor Report.

2a. Number of monitored days ___ ___ days (1120)

2b. Number of doses taken ___ ___ doses (1130)

2c. % Prescribed number of doses taken ___ ___ ___ . ___ % (1140)

2d. Doses in time window/prescribed doses (Percent compliance) ___ ___ ___ . ___ % (1150)

➜ If the percent compliance for the eDEM™ is less than 85%, the subject is ineligible for study participation.

3. **eDEM™ Monitor**

At All Visits, the information for Question #3a-3d is obtained from the eDEM™ Monitor Report.

3a. Number of monitored days ___ ___ days (1050)

3b. Number of doses taken ___ ___ doses (1060)

3c. % Prescribed number of doses taken ___ ___ ___ . ___ % (1070)

3d. Doses in the time window/prescribed doses (Percent compliance) ___ ___ ___ . ___ % (1080)

➜ If the percent compliance for the eDEM™ is less than 85%, re-emphasize the importance of maintaining the daily dosing schedule.

4. **Doser™ Compliance for Scheduled Inhaler (Visit 4 ONLY)**

The information for Question #4a - #4c is obtained from the last 14 full days prior to Visit 4.

4a. Total number of scheduled puffs. ___ ___ ___ puffs (1160)

➜Value obtained from Question 4 on the P10_COMPLY_WKS

4b. Total number of puffs in Doser™ history ___ ___ ___ puffs (1170)

➜Value obtained from Question 5 on the P10_COMPLY_WKS

4c. Percent compliance ___ ___ ___ . ___ % (1180)

➜ Value obtained from Question 6 on the P10_COMPLY_WKS

➜ If the percent compliance for the Doser™ is less than 85%, the subject is ineligible for study participation.

5. **Doser™ Compliance for Scheduled Inhaler**

At Visits 3-10, if the interval between visits exceeds 30 days, complete Questions #5a-5c using data for the 30 days prior to the visit.

5a. Total number of scheduled puffs since the last visit ___ ___ ___ puffs (1090)

➜ Value obtained from Question 1 on the P10_COMPLY_WKS

5b. Total number of puffs in Doser™ history ___ ___ ___ puffs (1100)

➜ Value obtained from Question 2 on the P10_COMPLY_WKS

5c. Percent compliance ___ ___ ___ . ___ % (1110)

➜ Value obtained from Question 3 on the P10_COMPLY_WKS

➜ If the percent compliance for the Doser™ is less than 85%, re-emphasize the importance of maintaining the daily dosing schedule.

Asthma Clinical Research Network
NIH/NHLBI

SMOG DIARY CARD

Subject's Initials: _ _ _
Date: _ _ / _ _ / _ _ _ _

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Return Visit Number: ___ ___
Return Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year

To the subject:
If your peak flow is below _____ liters/minute, use your RESCUE 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 two hours of RESCUE use, or if you are experiencing extreme symptoms.
If you have taken more than _____ puffs/24 hours for the past 48 hours from your RESCUE inhaler (combined, total puffs), contact study personnel.

Please use black ink to complete.		Day 1: _____	Day 2: _____	Day 3: _____	Day 4: _____	Day 5: _____	Day 6: _____	Day 7: _____
Date (dmonth/dday)		___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day
MORNING EVALUATION (Between 5 AM and 10 AM)								
1. Number of times that you woke up last night due to asthma (1000)		___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
2. Time of AM Peak Flow (within 15 minutes of awakening) (1010)		__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
3. AM Peak Flow (liters/min)** (1020)/(1025)		___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
4. Total number of puff(s) from scheduled 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 scheduled inhaler **(PM)** (1130)		___	___	___	___	___	___	___
13. Number of pill(s) taken **(PM)** (1140)		___	___	___	___	___	___	___
Symptoms++ since you woke.	14. Shortness of Breath (1150)							
	15. Chest Tightness (1160)							
	16. Wheezing (1170)							
	17. Cough (1180)							
	18. Phlegm/Mucus (1190)							
24 HOUR EVALUATION								
19. Total number of **puffs** from albuterol **(RESCUE)** inhaler over a 24 hour period. *(Do not record preventive use.)* (1200)		___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___

** Record the best of three attempts. Circle the value if you have taken any albuterol (RESCUE) inhaler medication in the last two hours.

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

Asthma Clinical Research Network
NIH/NHLBI

SMOG
SCREEN DROPOUT

(Prior to Visit 1)

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete this form only for those subjects who have successfully completed the screening visit and have been terminated or deemed ineligible prior to Visit 1. After the form is completed, fax it immediately to the SMOG Primary Data Manager at the DCC at (717) 531-4359.

1. Has the subject withdrawn consent? ❑1 Yes ❑0 No (1000)

   If ***YES***, indicate the **primary** reason.
   - ❑1 no longer interested in participating
   - ❑2 access to clinic is difficult (location, transportation, parking)
   - ❑3 moving out of the area
   - ❑4 unable to continue in study due to personal constraints
   - ❑5 unable to continue due to medical condition unrelated to asthma
   - ❑6 other _____ (1010)

2. Is the subject being withdrawn from the study due to a match not being found? ❑1 Yes ❑0 No (1020)

3. Has the subject been lost to follow-up? ❑1 Yes ❑0 No (1030)

4. Is the subject withdrawing from the study due to pregnancy? ❑1 Yes ❑0 No ❑9 N/A (1040)
   (Check N/A if the subject is male.)

5. Is the subject being withdrawn for other reasons? ❑1 Yes ❑0 No (1070)
   If ***YES***, describe _____

SIGNATURES

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

I verify that all information collected on the ACRN SMOG 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 ACRN SMOG Protocol.

_____ (1080)
Clinic Coordinator Signature

___ ___ / ___ ___ / ___ ___ ___ ___ (1090)
month day year

Asthma Clinical Research Network
NIH/NHLBI

SMOG
eDEM™ MONITOR
QUALITY CONTROL

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Technician completed)

1. Serial Number of eDEM™ monitor being tested ___ ___ ___ ___ ___ (1000)

2. Test date ___ ___ / ___ ___ / ___ ___ ___ ___ (1010)
month / day / year

3. Record monitor's validity ___ ___ . ___ ___ ___ ___
month (1020) *year* (1030)

4. Record battery voltage ___ ___ . ___ ___ volts (1040)

5. Is this a new eDEM™ monitor being tested? ❑1 Yes ❑0 No (1050)

If ***YES***, indicate the primary reason.

- ❑1 "Old" device was recalled
- ❑2 "Old" device experiencing low voltage (< 2.90 volts)
- ❑3 "Old" device had downloading problems
- ❑4 "Old" device experienced AC adaptor failure
- ❑5 "Old" device experienced battery failure
- ❑6 "Old" device was lost
- ❑7 Other (1060)

6. Did the eDEM™ monitor pass? ❑1 Yes ❑0 No (1070)

➜ *If **NO**, issue a new eDEM™ monitor and complete another eDEM™ Monitor Quality Control form.*

Asthma Clinical Research Network
NIH/NHLBI

SMOG
ELIGIBILITY CHECKLIST 1

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

1. Are you planning to move away from this clinical center in the next 12 months such that your ability to complete the study will be jeopardized? ☐ 1 Yes ☐ 0 No (1000)

2. Have you used any smokeless tobacco products (chew, snuff) in the past year? ☐ 1 Yes ☐ 0 No (1010)

3. Have you smoked a pipe, cigar, or marijuana in the past year? ☐ 1 Yes ☐ 0 No (1020)

4. Have you had a respiratory tract infection in the past 6 weeks? ☐ 1 Yes ☐ 0 No (1030)

5. Do you work night shift or have an altered day/night cycle for other reasons? ☐ 1 Yes ☐ 0 No (1040)

6. Are you potentially able to bear children? (If subject is male, check N/A and go to Question #7.) ☐ 1 Yes ☐ 0 No ☐ 9 N/A (1050)

   6a. If ***YES,*** are you currently pregnant or lactating? ☐ 1 Yes ☐ 0 No (1060)

   6b. If ***YES,*** are you using one of the approved birth control methods indicated on this reference card? *(Show subject the Birth Control Methods reference card.)* ☐ 1 Yes ☐ 0 No (1070)

   6c. If ***YES***, record results of pregnancy test. ☐ 1 Positive ☐ 2 Negative (1075)

7. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ☐ 1 Yes ☐ 0 No (1080)

   ➜ ***If NO, please complete the Termination of Study Participation (P10_TERM) form.***

Subject's Initials: __ __ __ (1090)
Date: __ __ / __ __ / __ __ __ __ (1100)

Asthma Clinical Research Network
NIH/NHLBI

SMOG
ELIGIBILITY CHECKLIST 2

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 4
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

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

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

3. Using the history stored in the Doser™, did the subject take at least 85% of the required puffs from his or her scheduled inhaler during the last two weeks of the run-in period? ☐ 1 Yes ☐ 0 No (1020)

4. Using the eDEM™ Monitor, did the subject take at least 85% of the required pills from his or her eDEM™ Monitor during the last two weeks of the run-in period? ☐ 1 Yes ☐ 0 No (1030)

5. During the last two weeks of the run-in period, did the subject record both AM and PM peak flow measurements and symptoms on his or her Diary Card (P10_DIARY) an average of at least six days per week? ☐ 1 Yes ☐ 0 No (1040)

6. During the last two weeks of the run-in period, did the subject use an average of less than 56 puffs per week from his or her rescue inhaler (albuterol)? ☐ 1 Yes ☐ 0 No (1050)

7. Does the subject wish to withdraw consent from the study? ☐ 1 Yes ☐ 0 No (1060)

8. Is there any new information that makes the subject ineligible according to the eligibility criteria? ☐ 1 Yes ☐ 0 No (1070)
   If ***YES,*** describe: _____

9. Is there any other reason why this subject should not be included in the study? ☐ 1 Yes ☐ 0 No (1080)
   If ***YES,*** describe: _____

10. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ☐ 1 Yes ☐ 0 No (1090)

➜ ***If the subject is eligible and will participate in SMOG, randomize the subject. Otherwise, please complete the Termination of Study Participation (P10_TERM) form.***

11. Drug Packet Number **(record on LOG)** 1 0 - ___ - ___ ___ (1100) (1110) (1120)

(Clinic Coordinator completed)

VITAL SIGNS

The subject should sit quietly for five minutes before blood pressure measurements are recorded and maintain this position while all vital signs are taken.

1. Resting blood pressure ___ ___ ___ / ___ ___ ___ mm Hg
   systolic (1000) diastolic (1010)

2. Pulse ___ ___ ___ beats/min (1020)

3. Respiratory rate ___ ___ breaths/min (1030)

4. Body temperature ___ ___ ___ . ___ ° F (1040)

(Physician completed)

Please indicate current physical findings by checking the appropriate boxes below. If ABNORMAL, please describe concisely.

		Not Done	Normal	Abnormal	
6.	Hair and Skin	❑2	❑1	❑0	_____ (1080)
7.	Lymph nodes	❑2	❑1	❑0	_____ (1090)
8.	Eyes (excluding corrective lenses)	❑2	❑1	❑0	_____ (1100)
9.	Ears, Nose, and Throat	❑2	❑1	❑0	_____ (1110)
10.	Respiratory (excluding asthma)	❑2	❑1	❑0	_____ (1120)
11.	Cardiovascular	❑2	❑1	❑0	_____ (1130)
12.	Gastrointestinal	❑2	❑1	❑0	_____ (1140)
13.	Musculoskeletal	❑2	❑1	❑0	_____ (1150)
14.	Neurological	❑2	❑1	❑0	_____ (1160)
15.	Mental Status	❑2	❑1	❑0	_____ (1170)
16.	Other _____ (check Not Done if non-applicable)	❑2	❑1	❑0	_____ (1180)

PULMONARY AUSCULTATION

17. Indicate subject's condition. *(Check one box only)*

If applicable, describe sounds:

_____

_____

_____

❑1 No wheezing

❑2 Wheeze on inspiration or expiration

❑3 Adventitious sounds other than wheezing (1190)

Physician/Clinician signature: _____ (1200)

Date: __ __ / __ __ / __ __ __ __ (1210)

Time: __ __ __ __ *(based on 24-hour clock)* (1220)

SMOG
MAXIMUM REVERSIBILITY TESTING

Supervisor ID: ___ ___ ___ ___ ___

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 2
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___

(Subject Interview completed)

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

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

3. Have you consumed any food containing alcohol or beverages containing alcohol in the past 6 hours? ☐ 1 Yes ☐ 0 No (1020)

4a. Have you used any antihistamines in the past 48 hours? ☐ 1 Yes ☐ 0 No (1030)

4b. Have you used any oral decongestants or cold remedies in the past 48 hours? ☐ 1 Yes ☐ 0 No (1040)

4c. Have you used any nasal steroids in the past 48 hours? ☐ 1 Yes ☐ 0 No (1050)

4d. Have you used a rescue intermediate-acting inhaled beta-agonist [e.g. albuterol (Ventolin or Proventil)] in the past 6 hours? ☐ 1 Yes ☐ 0 No (1060)

4e. Have you taken any other medications (see the EXCLDRUG reference card) to treat your asthma or allergies in the past 6 weeks? ☐ 1 Yes ☐ 0 No (1100)
   ➜ ***If YES, complete the Concomitant Medications for Asthma and Allergies (P10_CMED_AS) form.***

5. At this time, is your asthma worse because of recent exposure to triggers (e.g. cold air, smoke, allergens, or recent exercise)? ☐ 1 Yes ☐ 0 No (1110)

6. Is there any other reason you should not proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1120)
   ➜ ***See MOP for washout periods pertaining to other medications.***

   If ***YES***, explain _____

   _____

7. Is the subject eligible to proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1130)
   If any of the shaded boxes are filled in, the subject is NOT eligible for pulmonary function testing.

   ➜ ***If NO, do NOT complete page 2 or 3. Testing should be rescheduled within the visit window.***

8. ***(If subject is > 21 years old, do not complete Question #8.)***

Height *(without shoes)* ___ ___ . ___ inches (1140)

PREBRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

9. Time spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ (1150)

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

10. Results of best effort:

10a. FVC ___ . ___ ___ L (1160)

10b. FEV_1 ___ . ___ ___ L (1170)

10c. FEV_1 (% predicted) ___ ___ ___ % predicted (1180)

10d. PEFR ___ ___ . ___ ___ L/S (1190)

10e. FEF_{25-75} ___ . ___ ___ L/S (1200)

➜ ***Administer 4 puffs of albuterol and wait 15 minutes.***

11. Time albuterol administered *(based on 24-hour clock)* ___ ___ ___ ___ (1210)

12. Subject's FEV_1 after 4 puffs of albuterol

12a. Time spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ (1220)

12b. FEV_1 ___ . ___ ___ L (1230)

12c. FEV_1 (% predicted) ___ ___ ___ % predicted (1240)

➜ ***Administer 2 puffs of albuterol and wait 15 minutes.***

13. Time albuterol administered *(based on 24-hour clock)* ___ ___ ___ ___ (1250)

14. Subject's FEV_1 after additional 2 puffs of albuterol

14a. Time spirometry started (*based on 24-hour clock*) ____ ____ ____ ____ (1260)

14b. FEV_1 ____ . ____ ____ L (1270)

14c. FEV_1 (% predicted) ____ ____ ____ % predicted (1280)

14d. Percent difference in FEV_1 $\frac{\textit{(Question \#14b - Question \#12b)}}{\textit{Question \#12b}}$ x 100 ____ ____ . ____ % (1290)

14e. Is the percent difference from Question #14d $\leq$ 5.0%? ❑ 1 Yes ❑ 0 No (1300)

➜ ***If YES, STOP HERE and continue with remaining visit procedures.***
➜ ***If NO, administer 2 puffs of albuterol and wait 15 minutes.***

15. Time albuterol administered *(based on 24-hour clock)* ____ ____ ____ ____ (1310)

16. Subject's FEV_1 after last 2 puffs of albuterol

16a. Time spirometry started *(based on 24-hour clock)* ____ ____ ____ ____ (1320)

16b. FEV_1 ____ . ____ ____ L (1330)

16c. FEV_1 (% predicted) ____ ____ ____ % predicted (1340)

(Subject Interview completed)

ASTHMA HISTORY

1. Approximately how old were you when your asthma first appeared? (*Check one box only*)

- ❑1 less than 10 years old
- ❑2 10-19 years old
- ❑3 20-29 years old
- ❑4 30-39 years old
- ❑5 40-49 years old
- ❑6 50 years or more
- ❑8 unknown (1000)

2. How many years have you had asthma? (*Check one box only*)

- ❑1 less than 1 year
- ❑2 1-4 years
- ❑3 5-9 years
- ❑4 10-14 years
- ❑5 15 years or more
- ❑8 unknown (1010)

3. What season is your asthma the worst? (*Check one box only*)

- ❑1 Winter
- ❑2 Spring
- ❑3 Summer
- ❑4 Fall
- ❑5 Same all year (1020)

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

4a. Asthma episodes have you had that required emergency care or an unscheduled office visit? ____ ____ (1030)

4b. Hospitalizations have you had due to asthma? ____ ____ (1040)

4c. Courses of oral corticosteroid therapy for asthma (such as prednisone or Medrol) have you taken? ____ ____ (1050)

5. Have you missed any days of work or school due to asthma in the last 12 months? ❑1 Yes ❑0 No ❑9 N/A (1060)

If ***YES***, record your best estimate of the number of days missed. ____ ____ (1070)

6. 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 siblings or children.*)

6a.	Mother	❑1 Yes	❑0 No	❑8 Don't Know (1080)	
6b.	Father	❑1 Yes	❑0 No	❑8 Don't Know (1090)	
6c.	Brothers or Sisters	❑1 Yes	❑0 No	❑8 Don't Know	❑9 N/A (1100)
6d.	Child(ren)	❑1 Yes	❑0 No	❑8 Don't Know	❑9 N/A (1110)

PRIOR ASTHMA TREATMENT

Next, I will read a list of medications. Indicate if you have ever used the 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
7.	Short-acting Inhaled Beta-Agonists (MDI) (**Bronkaid Mist, Duo-Medihaler, Medihaler-Epi, Primatene Mist and others**)	❑1 Yes (1120)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1130) (1140) (1150)
8.	Intermediate-acting Inhaled Beta-Agonists (MDI) (**Alupent, Brethaire, Brethine, Bronkometer, Maxair, Metaprel, Proventil, Tornalate, Ventolin, Xopenex and others)**	❑1 Yes (1160)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1170) (1180) (1190)
9.	Long-acting Inhaled Beta-Agonists (MDI) (**Serevent, Foradil, Advair Diskus**)	❑1 Yes (1200)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1210) (1220) (1230)
10.	Asthma medication via a Nebulizer Machine	❑1 Yes (1240)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1250) (1260) (1270)
11.	Intermediate-acting Oral Beta-Agonists (**Alupent, Brethine, Bricanyl, Metaprel, Proventil, Ventolin and others**)	❑1 Yes (1280)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1290) (1300) (1310)
12.	Long-acting Oral Beta-Agonists (**Repetabs, Volmax**)	❑1 Yes (1320)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1330) (1340) (1350)

					If Yes, indicate date medication was last taken month / day / year
13.	Short-acting Oral Theophylline (**Aminophylline, Slo-Phyllin and others**)	❑1 Yes (1360)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1370) (1380) (1390)
14.	Sustained release Oral Theophylline (**Slo-bid, Theo-Dur, Uniphyl and others**)	❑1 Yes (1400)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1410) (1420) (1430)
15.	Inhaled Anticholinergic (**Atrovent, Combivent**)	❑1 Yes (1440)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1450) (1460) (1470)
16.	Anti-allergic Inhaled Medications (**Intal, Tilade and others**)	❑1 Yes (1480)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1490) (1500) (1510)
17.	Anti-allergic Nasal Medications (**Nasalcrom, Astelin and others**)	❑1 Yes (1520)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1530) (1540) (1550)
18.	Anti-allergic Oral Medications (**Allegra, Claritin, Zyrtec, Chlor-Trimeton and others**)	❑1 Yes (1560)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1570) (1580) (1590)
19.	Oral Steroids (**Prednisone, Medrol and others**)	❑1 Yes (1600)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1610) (1620) (1630)
20.	Inhaled Steroids (**Azmacort, Beclovent, Vanceril, AeroBid, Flovent, Pulmicort, Advair Diskus and others**)	❑1 Yes (1640)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1650) (1660) (1670)
21.	Nasal Steroids (**Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Rhinocort, Nasonex and others)**	❑1 Yes (1680)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1690) (1700) (1710)
22.	Topical Steroids - Prescription (**Synalar, Lidex, Dermacin, Fluocinonide and others**)	❑1 Yes (1720)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1730) (1740) (1750)
23.	Topical Steroids - OTC (**Hydrocortisone - multiple strengths and products)**	❑1 Yes (1760)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1770) (1780) (1790)
24.	Leukotriene Antagonist / 5L0 Inhibitors (**Accolate, Zyflo, Singulair**)	❑1 Yes (1800)	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __ (1810) (1820) (1830)

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

				If Yes, Comment
25.	Skin	❑1 Yes	❑0 No	_____ (1840)
26.	Blood, Lymph, or Immune Systems	❑1 Yes	❑0 No	_____ (1850)
27.	Eyes	❑1 Yes	❑0 No	_____ (1860)
28.	Ears, Nose, or Throat	❑1 Yes	❑0 No	_____ (1870)
29.	Breasts	❑1 Yes	❑0 No	_____ (1880)
30.	Endocrine Systems	❑1 Yes	❑0 No	_____ (1890)
31.	Lung - other than asthma	❑1 Yes	❑0 No	_____ (1900)
32.	Heart and Blood Vessels	❑1 Yes	❑0 No	_____ (1910)
33.	Liver or Pancreas	❑1 Yes	❑0 No	_____ (1920)
34.	Kidneys or Urinary Tract System	❑1 Yes	❑0 No	_____ (1930)
35.	Reproductive System	❑1 Yes	❑0 No	_____ (1940)
36.	Stomach or Intestines	❑1 Yes	❑0 No	_____ (1950)
37.	Muscles or Bones	❑1 Yes	❑0 No	_____ (1960)
38.	Nervous System	❑1 Yes	❑0 No	_____ (1970)
39.	Psychiatric	❑1 Yes	❑0 No	_____ (1980)
40.	Other _____	❑1 Yes	❑0 No	_____ (1990)

Subject's Initials: __ __ __ (2000)

Date: __ __ / __ __ / __ __ __ __ (2010)

Asthma Clinical Research Network
NIH/NHLBI

SMOG METHACHOLINE CHALLENGE TESTING

Supervisor ID: ___ ___ ___ ___ ___

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete this form only if the subject has successfully completed the Spirometry Testing (P10_SPIRO) form.

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

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

2. Does the subject have a baseline (pre-diluent) FEV_1 less than 55% of predicted? ☐ 1 Yes ☐ 0 No (1020)
   Use the prebronchodilator FEV_1 value from the P10_SPIRO form as the baseline reference.

3. Does the subject have a history of urinary retention? ☐ 1 Yes ☐ 0 No (1025)
   If YES, the subject may not proceed with the methacholine challenge testing without written medical clearance from the study physician.
   If YES, and the subject is not randomized, the subject is ineligible to participate in the study and a Termination of Study Participation (P10_TERM) form should be completed.

4. Is there any other reason the subject should not proceed with the methacholine challenge testing? ☐ 1 Yes ☐ 0 No (1030)
   If ***YES,*** explain _____

5. Is the subject eligible to proceed with the diluent (solution #0) pulmonary function testing for the methacholine challenge? ☐ 1 Yes ☐ 0 No (1040)
   If any of the shaded boxes are filled in, the subject is NOT eligible for the methacholine challenge.

   ➜ ***If NO, do NOT complete the rest of this form.***
   If possible, the baseline pulmonary function testing and the methacholine challenge should be rescheduled within the visit window.

METHACHOLINE CHALLENGE TEST *(Technician completed)*

Clinic Use Only

Use the prebronchodilator FEV_1 value from the P10_SPIRO form as the baseline reference.

Baseline FEV_1 prior to methacholine challenge

A. FEV_1 ___ . ___ ___ ***L***

B. FEV_1 (% predicted) ___ ___ ___ ***% predicted***

Methacholine Reversal Reference Value ***Question A x 0.90 =*** ___ . ___ ___ ***L***

6. PC_{20} ___ ___ ___ . ___ ___ ___ ___ mg/ml (1050)

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

7. Subject's FEV_1 after standard reversal from methacholine challenge

   If subject is continuing with sputum induction, standard reversal = 4 puffs albuterol.
   If subject is not continuing with sputum induction, standard reversal = 2 puffs albuterol.

   7a. FEV_1 ___ . ___ ___ L (1070)

   7b. FEV_1 (% predicted) ___ ___ ___ % predicted (1080)

   7c. Time of FEV_1 in Question #6a (*based on 24-hour clock*) ___ ___ ___ ___ (1090)

   7d. Was the FEV_1 from Question #6a ≥ the methacholine reversal reference value in the gray box above? ❑1 Yes ❑0 No (1100)
   ➜ ***If YES, STOP HERE and continue with remaining visit procedures.***

8. Was additional treatment used in the first hour? ❑1 Yes ❑0 No (1110)

   ➜ ***If NO, skip to Question #9.***
   ➜ ***If YES, please complete the Concomitant Medications for Asthma and Allergies (P10_CMED_AS) form.***

   8a. Additional albuterol by MDI ❑1 Yes ❑0 No (1120)

   ➜ ***If NO, skip to Question #7b.***

   8ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four (1130)

   8b. Nebulized Beta-agonist ❑1 Yes ❑0 No (1140)

   8c. Subcutaneous epinephrine ❑1 Yes ❑0 No (1150)

   8d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No (1160)

   8e. Other _____ ❑1 Yes ❑0 No (1170)

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

9a. FEV_1 ___ . ___ ___ L (1180)

9b. FEV_1 (% predicted) ___ ___ ___ % predicted (1190)

9c. Time of FEV_1 in Question #8a (*based on 24-hour clock*) ___ ___ ___ ___ (1200)

9d. Was the FEV_1 from Question #8a ≥ the methacholine reversal reference value in the gray box on page 2 of this form? ❑1 Yes ❑0 No (1210)

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

10. Was additional treatment used after one hour? ❑1 Yes ❑0 No (1220)

➜ ***If NO, skip to Question #10.***

➜ ***If YES, please complete the appropriate Concomitant Medications for Asthma and Allegies (P10_CMED_AS) form.***

10a. Additional albuterol by MDI ❑1 Yes ❑0 No (1230)

➜ ***If NO, skip to Question #9b.***

10ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four (1240)

10b. Nebulized Beta-agonist ❑1 Yes ❑0 No (1250)

10c. Subcutaneous epinephrine ❑1 Yes ❑0 No (1260)

10d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No (1270)

10e. Treatment in the emergency room ❑1 Yes ❑0 No (1280)

10f. Overnight hospitalization ❑1 Yes ❑0 No (1290)

➜ ***If YES, please complete the Serious Adverse Event (P10_SERIOUS) form.***

10g. Other _____ ❑1 Yes ❑0 No (1300)

11. Subject's final FEV_1 after methacholine challenge.

11a. FEV_1 ___ . ___ ___ L (1310)

11b. FEV_1(% predicted) ___ ___ ___ % predicted (1320)

11c. Time of FEV_1 from Question #10a (*based on 24-hour clock*) ___ ___ ___ ___ (1330)

11d. Was the FEV_1 from Question #10a ≥ the methacholine reversal reference value in the gray box on page 2 of this form? ❑1 Yes ❑0 No (1340)

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

Physician signature: _____ (1350)

Date: __ __ / __ __ / __ __ __ __ (1360)

Time: __ __ __ __ *(based on 24-hour clock)* (1370)

SMOG SCREENING FORM

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

ADMINISTRATIVE

1. ***Did the subject sign the Informed Consent?*** ☐ 1 Yes ☐ 0 No (1000)

1a. If ***YES***, record the date the form was signed. ___ ___ / ___ ___ / ___ ___ ___ ___ (1010) *month / day / year*

➜ ***Consent should be reviewed and signed on the day Visit 0 is performed.***

DEMOGRAPHICS

2. Record subject's date of birth. ___ ___ / ___ ___ / ___ ___ ___ ___ (1020) *month / day / year*

2a. Is the subject between 18 and 50, inclusive? ☐ 1 Yes ☐ 0 No (1030)

3. Subject's gender
☐ 1 Male
☐ 2 Female (1040)

4. Subject's Race and Ethnicity *(Ask the subject which category best describes him or her.)*

4a. Subject's ethnic background *(Check one box only.)*
☐ 1 Hispanic or Latino
☐ 2 Not Hispanic or Latino (1042)

4b. Subject's racial background

4bi. American Indian or Alaskan Native ☐ 1 Yes ☐ 0 No (1046)

4bii. Asian ☐ 1 Yes ☐ 0 No (1047)

4biii. Black or African American ☐ 1 Yes ☐ 0 No (1048)

4biv. White ☐ 1 Yes ☐ 0 No (1049)

4bv. Native Hawaiian or Other Pacific Islander ☐ 1 Yes ☐ 0 No (1050)

4bvi. Other _____ ☐ 1 Yes ☐ 0 No (1051)

MEDICAL HISTORY

5. Does the subject have current evidence of any of the conditions listed on the Exclusionary Medical Conditions reference card (EXCLMED)? ☐ 1 Yes ☐ 0 No (1060)
If ***YES***, describe _____

6. Has the subject taken any medications listed on the Exclusionary Drugs reference card (EXCLDRUG) within the specified time periods? If ***YES***, describe _____ ☐ 1 Yes ☐ 0 No (1070)

7. Is the subject currently taking prescription or over-the-counter medication(s) other than those listed on the Allowed Medications reference card (MEDALLOW)? If ***YES***, describe _____ ☐ 1 Yes ☐ 0 No (1080)

8. Is the subject currently receiving hyposensitization therapy other than an established maintenance regimen implemented continuously for a minimum of three months? ☐ 1 Yes ☐ 0 No (1090)

9. Has the subject experienced a significant asthma attack in the past six weeks? ☐ 1 Yes ☐ 0 No (1100)

10. Has the subject experienced a life-threatening asthma attack requiring treatment with intubation and mechanical ventilation in the past ten years? ☐ 1 Yes ☐ 0 No (1110)

11. Average number of puffs of "as-needed" inhaled β_2-agonists (e.g. Ventolin, Proventil, etc.) used by the subject on a weekly basis. *(Do not include preventive puffs.)* ___ ___ ___ puffs (1120)

11a. Is the value recorded in Question #11 less than 56 puffs? ☐ 1 Yes ☐ 0 No (1130)

12. Is the subject routinely exposed to second hand smoke? ☐ 1 Yes ☐ 0 No (1140)

13. Has the subject smoked cigarettes in the past year? ☐ 1 Yes ☐ 0 No (1150)

For Non-Smokers:

13a. If ***NO***, does the subject have a smoking history of less than 5 pack-years? ☐ 1 Yes ☐ 0 No (1160)

Record history in pack-years. *(Enter '00.0' if none.)* ___ ___ . ___ (1170)

For Smokers:

13b. If ***YES***, does the subject have a smoking history between 2 and 15 pack-years (inclusively)? ☐ 1 Yes ☐ 0 No (1180)

Record history in pack-years. ___ ___ . ___ (1190)

13bi. Is the subject currently smoking between 10 and 40 cigarettes (1/2 - 2 packs) per day (inclusively)? ☐ 1 Yes ☐ 0 No (1200)

PHYSICAL EXAMINATION

14. Subject's height *(without shoes)* ___ ___ . ___ inches (1210)

15. Subject's weight *(without shoes or heavy clothing)* ___ ___ ___ . ___ pounds (1220)

16. Is the subject potentially able to bear children? ❑ 1 Yes ❑ 0 No ❑ 9 N/A (1222)
(Check N/A if the subject is male.)

16a. If ***YES***, is the subject using one of the approved methods indicated on the Birth Control reference card (BIRCTRL)? ❑ 1 Yes ❑ 0 No (1223)

16b. If ***YES***, record results of pregnancy test.
❑ 1 Positive
❑ 2 Negative (1224)

Pregnancy Test Source Documentation
Subject's Initials: __ __ __ (1225)
Date: __ __ / __ __ / __ __ __ __ (1226)

➜ ***If pregnancy test results are positive, the subject is ineligible for study participation. STOP HERE.***

SPIROMETRY

17. Subject's primary racial identification
(Check one box only.)
❑ 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 _____ (1228)

18. Has the subject consumed caffeine in the past 6 hours? ❑ 1 Yes ❑ 0 No (1230)
Examples*: Caffeinated colas (Pepsi, Coke), Coffee, Mello-Yello, Mountain Dew, Tea, Barq's Rootbeer, Red Bull*

19. Has the subject used medication with caffeine in the past 6 hours? ❑ 1 Yes ❑ 0 No (1240)
Examples*: Anacin, Darvon compound, Esgic, Excedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*

20. Has the subject consumed any food containing alcohol or beverages containing alcohol in the past 6 hours? ❑ 1 Yes ❑ 0 No (1250)

21. Have you used any antihistamines in the past 48 hours? ☐ 1 Yes ☐ 0 No (1252)

22. Have you used any oral decongestants or cold remedies in the past 48 hours? ☐ 1 Yes ☐ 0 No (1253)

23. Have you used any nasal steroids in the past 48 hours? ☐ 1 Yes ☐ 0 No (1254)

24. Have you used a rescue intermediate-acting inhaled beta-agonist [e.g. albuterol (Ventolin or Proventil)] in the past 6 hours? ☐ 1 Yes ☐ 0 No (1256)

25. At this time, is your asthma worse because of recent exposure to triggers (e.g. cold air, smoke, allergens, or recent exercise)? ☐ 1 Yes ☐ 0 No (1257)

26. Is there any other reason you should not proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1258)

➜ ***See MOP for washout periods pertaining to other medications.***

If ***YES***, explain _____

_____

Perform spirometry and record the results from the best effort.
The best effort reflects the trial where the sum of FEV_1 and FVC is maximized.

27. Supervisor ID ___ ___ ___ ___ ___ (1260)

28. Technician ID ___ ___ ___ ___ ___ (1270)

29. Time spirometry started *(based on a 24-hour clock)* ___ ___ ___ ___ (1275)

30. Spirometry results:

30a. FVC ___ . ___ ___ L (1280)

30b. FEV_1 ___ . ___ ___ L (1290)

30c. FEV_1 (% predicted) ___ ___ ___ % predicted (1300)

30d. Is the subject's $FEV_1 \geq 70\%$ and $\leq 90\%$ of predicted? ☐ 1 Yes ☐ 0 No (1310)

DIFFUSING CAPACITY FOR CARBON MONOXIDE TEST

31. D_LCO ___ ___ ___ . ___ % predicted (1320)

32. Does the subject have a $D_LCO \geq$ 80% predicted? ☐ 1 Yes ☐ 0 No (1330)

To qualify for the SMOG study, the subject will need EITHER a ≥ 12 % increase in FEV_1 in response to aerosolized albuterol during reversibility testing, or a methacholine PC_{20} value ≤ 8 mg/ml.

SOURCE DOCUMENTATION

33. Does the subject have source documentation of a ≥ 12 % increase in FEV_1 in response to aerosolized albuterol (any spirometry system) within the past 6 months? ❑ 1 Yes ❑ 0 No (1340)

➜ ***If YES, record values below and proceed to Question #39:***

Prebronchodilator FEV_1 ___ . ___ ___ L (1350)

Postbronchodilator FEV_1 ___ . ___ ___ L (1360)

Date of source documentation ___ ___ / ___ ___ / ___ ___ ___ ___ (1370)
month *day* *year*

➜ ***If NO, go to Question #34.***

34. Does the subject have source documentation of a methacholine PC_{20} ≤ 8 mg/ml (ACRN system only) within the past 6 months? ❑ 1 Yes ❑ 0 No (1380)

➜ ***If YES, record values below and proceed to Question #39:***

PC_{20} ___ . ___ ___ ___ ___ mg/ml (1390)

Date of source documentation ___ ___ / ___ ___ / ___ ___ ___ ___ (1400)
month *day* *year*

If the subject does not have source documentation of reversibility or methacholine PC_{20} perform EITHER a Methacholine Challenge or Reversibility Testing.

METHACHOLINE at Visit 0:

35. Supervisor ID ___ ___ ___ ___ ___ (1410)

36. Technician ID ___ ___ ___ ___ ___ (1420)

37. Methacholine results:

37a. PC_{20} ___ ___ ___ . ___ ___ ___ ___ mg/ml (1430)

37b. Time methacholine challenge was completed (based on a 24-hour clock) ___ ___ ___ ___ (1440)

37c. Is the subject's PC_{20} value ≤ 8 mg/ml? ❑ 1 Yes ❑ 0 No (1450)

REVERSIBILITY TESTING at Visit 0:

38. Did the subject demonstrate a ≥ 12 % increase in response to aerosolized albuterol during reversibility testing at Visit 0? ☐ 1 Yes ☐ 0 No (1460)

39. Is the subject eligible for the SMOG study? ☐ 1 Yes ☐ 0 No (1470)

If any of the shaded boxes are filled in, or the subject does not have either a ≥ 12 % increase in FEV_1 in response to aerosolized albuterol during reversibility testing, or a methacholine PC_{20} value ≤ 8 mg/ml, the subject is ineligible.

➜ ***If YES, proceed with the P10_GAMATCH form and blood sampling procedures.***

Screening Source Documentation

Subject's Initials: __ __ __ (1480)

Date: __ __ / __ __ / __ __ __ __ (1490)

Asthma Clinical Research Network
NIH/NHLBI

SMOG SERIOUS ADVERSE EVENT REPORTING FORM

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form must be faxed to the DCC at (717) 531-4359 and the Project Scientist at NHLBI within 72 hours of notification of a serious event. Also fax the Clinical Adverse Events form (P10_AECLIN), the Concomitant Medications for Asthma and Allergies (P10_CMED_AS) form, and any relevant source documents.

1. Date of Adverse Event ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) (1000)

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

   Describe: _____

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

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

5. Why was the event serious?

   5a. Fatal Event? ❑ 1 Yes ❑ 0 No (1040)

   5b. Life-threatening event? ❑ 1 Yes ❑ 0 No (1050)

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

   5c1. Admission date ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) (1070)

   5c2. Discharge date ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) (1080)

   5d. Hospitalization prolonged? ❑ 1 Yes ❑ 0 No (1090)

   5e. Disabling or incapacitating? ❑ 1 Yes ❑ 0 No (1100)

   5f. Overdose? ❑ 1 Yes ❑ 0 No (1110)

   5g. Cancer? ❑ 1 Yes ❑ 0 No (1120)

   5h. Congenital anomaly? ❑ 1 Yes ❑ 0 No (1130)

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

   5j. Other _____ ❑ 1 Yes ❑ 0 No (1150)

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

6a. Toxicity of study drug(s)? ❑1 Yes ❑0 No (1160)

6b. Withdrawal of study drug(s)? ❑1 Yes ❑0 No (1170)

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

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

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

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

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

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

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

REPORTING INVESTIGATOR:

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

_____
_____
_____
_____
_____

Name: _____

Address: _____
_____
_____

Signature: _____

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

Asthma Clinical Research Network
NIH/NHLBI

SMOG
SHORT PHYSICAL EXAM

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

VITAL SIGNS

The subject should sit quietly for five minutes before blood pressure measurements are recorded and maintain this position while all vital signs are taken.

1. Resting blood pressure ___ ___ ___ / ___ ___ ___ mm Hg
   systolic (1000) diastolic (1010)

2. Pulse ___ ___ ___ beats/min (1020)

PULMONARY AUSCULTATION

3. Indicate subject's condition. *(Check one box only)*
   If applicable, describe sounds:
   _____
   _____

   ❑ 1 No wheezing
   ❑ 2 Wheeze on inspiration or expiration
   ❑ 3 Adventitious sounds other than wheezing (1030)

4. Does the subject have evidence of oral candidiasis? ❑ 1 Yes ❑ 0 No (1040)
   If YES, please complete the Clinical Adverse Events (P10_AECLIN) form.

Physician/CC signature: _____ (1050)
Date: __ __ / __ __ / __ __ __ __ (1060)
Time: __ __ __ __ *(based on a 24-hour clock)* (1070)

URINE PREGNANCY TEST

5. (Complete Question #5 for Visits 4, 6, 8 Only.)

Pregnancy test results
(Check N/A if subject is male or unable to bear children.)

❑ 1 Positive
❑ 2 Negative
❑ 9 N/A (1080)

➜ ***If pregnancy test results are positive, subject must be terminated from study participation. Complete a P10_TERM form and follow study termination procedures.***

Pregnancy Test Source Documentation

Subject's Initials: __ __ __ (1090)

Date: __ __ / __ __ / __ __ __ __ (1100)

SMOG
SIGNIFICANT ASTHMA EXACERBATION

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

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

1. Did the subject experience an increase in cough, phlegm/mucus, chest tightness, wheezing, or shortness of breath along with any of the following conditions?

   1a. An increase in rescue inhaler use of ≥ 8 puffs per 24 hours over baseline rescue inhaler use for a period of 48 hours? ☐ 1 Yes ☐ 0 No (1000)

   1b. Use of rescue inhaler ≥ 16 total puffs per 24 hours for a period of 48 hours? ☐ 1 Yes ☐ 0 No (1010)

   1c. A fall in prebronchodilator PEFR to ≤ 65% of baseline? ☐ 1 Yes ☐ 0 No (1020)

   1d. Symptoms persisting after 60 minutes of rescue treatment? ☐ 1 Yes ☐ 0 No (1030)

2. Were oral or parenteral corticosteroids given to the subject for his/her asthma exacerbation as a result of rescue intervention or by the opinion of the treating physician? ☐ 1 Yes ☐ 0 No (1040)

3. Did the subject experience a significant asthma exacerbation? ☐ 1 Yes ☐ 0 No (1050)
   If any of the shaded boxes are filled in, the subject experienced a SIGEX.

   ➜ ***If YES, but the subject has not yet been randomized, complete this form, then STOP. The subject is ineligible for the study; please complete the Termination of Study Participation (P10_TERM) form. If the subject has experienced a significant asthma exacerbation and has been randomized, please complete this form and continue with the treatment failure packet.***

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

4. Date of significant asthma exacerbation ___ ___ / ___ ___ / ___ ___ ___ ___ (1060)
month *day* *year*

5. Did the subject seek care for the asthma exacerbation? ☐ 1 Yes ☐ 0 No (1070)

➜ ***If NO, skip to Question #8.***

6. What type of care was sought?

6a. Study Investigator? ☐ 1 Yes ☐ 0 No (1080)

If ***YES***, indicate type of contact.
☐ 1 Scheduled clinic visit
☐ 2 Unscheduled clinic visit
☐ 3 Phone contact (1090)

6b. Primary Care or Other Physician? ☐ 1 Yes ☐ 0 No (1100)

Name of physician: _____

If ***YES***, indicate type of contact.
☐ 1 Scheduled clinic visit
☐ 2 Unscheduled clinic visit
☐ 3 Phone contact (1110)

6c. Emergency Room visit? ☐ 1 Yes ☐ 0 No (1120)
Name of hospital: _____

7. Was the subject hospitalized? ☐ 1 Yes ☐ 0 No (1130)

➜ ***If YES, please complete the Serious Adverse Event (P10_SERIOUS) form .***

If ***YES***,

7a. Name of hospital: _____

7b. Duration of hospital stay? ___ ___ days (1140)

7c. Was intubation or ventilation assistance required? ☐ 1 Yes ☐ 0 No (1150)

8. Did the asthma exacerbation require treatment with inhaled, oral, or intravenous glucocorticoids? ☐ 1 Yes ☐ 0 No (1160)

➜ ***If YES, please complete the Concomitant Medications for Asthma and Allergies (P10_CMED_AS) form.***

9. Was the asthma exacerbation resolved solely by increasing PRN use of the rescue inhaler? ☐ 1 Yes ☐ 0 No (1170)

10. Was the asthma exacerbation treated as outlined in the protocol?

☐ 1 Yes ☐ 0 No (1180)

If ***NO***, describe _____

_____

_____

11. Was the significant asthma exacerbation related to the routine pulmonary function testing? *(Check one box only)*

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

12. Was the significant asthma exacerbation related to the methacholine challenge testing? *(Check one box only)*

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

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

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

Asthma Clinical Research Network
NIH/NHLBI

SMOG
ALLERGY SKIN TEST RESULTS

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

A. Has the subject had a previous skin test using ACRN procedures within three years of the visit date? ❑ 1 Yes ❑ 0 No (1000)

If ***YES***,

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

ID of coordinator who performed the skin test ___ ___ ___ ___ ___ (1020)

If the subject had a previous ACRN skin test within three years of the visit date, attach a photocopy of the previous skin test form to this form.

At the time of data entry, enter section A from this form and then enter the data recorded on the photocopy.

If any of the medications listed in the skin test section of the ACRN Manual of Operations were taken within the exclusionary periods, reschedule the skin testing procedure.

B. Skin test site
❑ 1 back
❑ 2 forearm (1030)

Method
❑ 1 prick
❑ 2 puncture (1040)

Time test sites pricked/punctured (based on 24-hour clock) ___ ___ ___ ___ (1050)

Time test sites evaluated (based on 24-hour clock) ___ ___ ___ ___ (1060)

A reaction is defined as a wheal of at least 3 mm in diameter and an erythema at least 10 mm in diameter. For each allergen, indicate whether there was a reaction. If yes, transfer the tracing of each wheal and record the longest diameter and the diameter at the perpendicular midpoint in mm.

1. Diluting Fluid	Was there a reaction? ❑0 No ❑1 Yes (1070) Largest Wheal (1080) Diameter ___ ___ ___ mm Perpendicular Wheal (1090) Diameter ___ ___ ___ mm	8. Alternaria	Was there a reaction? ❑0 No ❑1 Yes (1280) Largest Wheal (1290) Diameter ___ ___ ___ mm Perpendicular Wheal (1300) Diameter ___ ___ ___ mm
2. Tree Mix	Was there a reaction? ❑0 No ❑1 Yes (1100) Largest Wheal (1110) Diameter ___ ___ ___ mm Perpendicular Wheal (1120) Diameter ___ ___ ___ mm	9. Cladosporium	Was there a reaction? ❑0 No ❑1 Yes (1310) Largest Wheal (1320) Diameter ___ ___ ___ mm Perpendicular Wheal (1330) Diameter ___ ___ ___ mm
3. Grass Mix	Was there a reaction? ❑0 No ❑1 Yes (1130) Largest Wheal (1140) Diameter ___ ___ ___ mm Perpendicular Wheal (1150) Diameter ___ ___ ___ mm	10. Aspergillus	Was there a reaction? ❑0 No ❑1 Yes (1340) Largest Wheal (1350) Diameter ___ ___ ___ mm Perpendicular Wheal (1360) Diameter ___ ___ ___ mm
4. Ragweed	Was there a reaction? ❑0 No ❑1 Yes (1160) Largest Wheal (1170) Diameter ___ ___ ___ mm Perpendicular Wheal (1180) Diameter ___ ___ ___ mm	11. D. Farinae	Was there a reaction? ❑0 No ❑1 Yes (1370) Largest Wheal (1380) Diameter ___ ___ ___ mm Perpendicular Wheal (1390) Diameter ___ ___ ___ mm

5. Weed Mix	Was there a reaction? ❑0 No ❑1 Yes (1190) Largest Wheal (1200) Diameter ___ ___ ___ mm Perpendicular Wheal (1210) Diameter ___ ___ ___ mm	12. D. Pteryn	Was there a reaction? ❑0 No ❑1 Yes (1400) Largest Wheal (1410) Diameter ___ ___ ___ mm Perpendicular Wheal (1420) Diameter ___ ___ ___ mm
6. Dogs	Was there a reaction? ❑0 No ❑1 Yes (1220) Largest Wheal (1230) Diameter ___ ___ ___ mm Perpendicular Wheal (1240) Diameter ___ ___ ___ mm	13. Cockroach	Was there a reaction? ❑0 No ❑1 Yes (1430) Largest Wheal (1440) Diameter ___ ___ ___ mm Perpendicular Wheal (1450) Diameter ___ ___ ___ mm
7. Cats	Was there a reaction? ❑0 No ❑1 Yes (1250) Largest Wheal (1260) Diameter ___ ___ ___ mm Perpendicular Wheal (1270) Diameter ___ ___ ___ mm	14. Histamine	Was there a reaction? ❑0 No ❑1 Yes (1460) Largest Wheal (1470) Diameter ___ ___ ___ mm Perpendicular Wheal (1480) Diameter ___ ___ ___ mm

Asthma Clinical Research Network
NIH/NHLBI

SMOG
SPIROMETRY TESTING

Supervisor ID: ___ ___ ___ ___ ___

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Subject Interview completed)

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

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

3. Have you consumed any food containing alcohol or beverages containing alcohol in the past 6 hours? ☐ 1 Yes ☐ 0 No (1020)

4a. Have you used any antihistamines in the past 48 hours? ☐ 1 Yes ☐ 0 No (1030)

4b. Have you used any oral decongestants or cold remedies in the past 48 hours? ☐ 1 Yes ☐ 0 No (1040)

4c. Have you used any nasal steroids in the past 48 hours? ☐ 1 Yes ☐ 0 No (1050)

4d. Have you used a rescue intermediate-acting inhaled beta-agonist [e.g. albuterol (Ventolin or Proventil)] in the past 6 hours? ☐ 1 Yes ☐ 0 No (1060)

4e. Have you taken any other medications (see the EXCLDRUG reference card) to treat your asthma or allergies in the past 6 weeks? ☐ 1 Yes ☐ 0 No (1100)
   ➜ ***If YES, complete the Concomitant Medications for Asthma and Allergies (P10_CMED_AS) form.***

5. At this time, is your asthma worse because of recent exposure to triggers (e.g. cold air, smoke, allergens, or recent exercise)? ☐ 1 Yes ☐ 0 No (1110)

6. Is there any other reason you should not proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1120)

   ➜ ***See MOP for washout periods pertaining to other medications.***

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

7. Is the subject eligible to proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1130)
   If any of the shaded boxes are filled in, the subject is NOT eligible for pulmonary function testing.

   ➜ ***If NO, do NOT complete page 2. Testing should be rescheduled within the visit window.***

8. ***(If subject is > 21 years old, do not complete Question #8.)***

Height (*without shoes*) ___ ___ . ___ inches (1140)

PREBRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

9. Time spirometry started (*based on 24-hour clock*) ___ ___ ___ ___ (1150)

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

10. Results of best effort:

10a. FVC ___ . ___ ___ L (1160)

10b. FEV_1 ___ . ___ ___ L (1170)

10c. FEV_1 (% predicted) ___ ___ ___ % predicted (1180)

10d. PEFR ___ ___ . ___ ___ L/S (1190)

10e. FEF_{25-75} ___ . ___ ___ L/S (1200)

SMOG
SPUTUM INDUCTION
LAB VALUES

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Read Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___

(Technician completed)

Total and Differential Cell Counts

1. Total Cell Count ___ ___ . ___ ___ x 10^5/ml (1000)

2. Squamous Cells ___ ___ ___ . ___ % (1010)

3. Did the subject's sputum sample reveal ≥ 80% squamous cells? ☐ 1 Yes ☐ 0 No (1020)

➜ ***If NO, please complete Question #4 through Question #9 and send the sputum sample for overreading***.

➜ ***If YES, STOP HERE and do not send the sputum sample for overreading***.

The parameters below are calculated following exclusion of squamous cells.

4. Total Cell Count ___ ___ . ___ ___ x 10^5/ml (1030)

5. Epithelial Cells ___ ___ ___ . ___ % (1040)

6. Macrophages ___ ___ ___ . ___ % (1050)

7. Neutrophils ___ ___ ___ . ___ % (1060)

8. Eosinophils ___ ___ ___ . ___ % (1070)

9. Lymphocytes ___ ___ ___ . ___ % (1080)

SMOG
SPUTUM INDUCTION
UCSF OVER-READ

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___

(Technician completed)

1. Date of Over-Read ___ ___ / ___ ___ / ___ ___ ___ ___
month day year (1000)

2. Is the slide quality acceptable? ❑ 1 Yes ❑ 0 No (1010)

_____
_____
_____
_____
_____

Total and 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)

(Technician completed)

1. ***(If Visit 4, do not complete Question #1)***
   At Visit 4, was the subject able to continue sputum induction for more than 4 minutes and able to produce a satisfactory induced sputum sample (< 80% squamous cells)
   ☐ 1 Yes ☐ 0 No (1000)

2. Did the subject complete the methacholine challenge?
   ☐ 1 Yes ☐ 0 No (1010)

   ➜ ***If YES, complete Question #3.***
   ➜ ***If NO, skip to Question #4.***

3. ***(For subjects who completed the methacholine challenge)***

   3a. Subject's FEV_1 after reversal from methacholine challenge ___ . ___ ___ L (1020)

   3b. Subject's FEV_1 (% predicted) after reversal from methacholine challenge ___ ___ ___ % predicted (1030)

   3c. Was the subject's FEV_1 from Question #3a ≥ the methacholine reversal reference value on page 2 of the P10_METHA form?
   ☐ 1 Yes ☐ 0 No (1040)

   ➜ ***Skip to Question #5.***

4. ***(For subjects who did NOT complete the methacholine challenge)***

   4a. Subject's FEV_1 15 minutes after 4 puffs of albuterol ___ . ___ ___ L (1050)

   4b. Subject's FEV_1 15 minutes after 4 puffs of albuterol (% predicted) ___ ___ ___ % predicted (1060)

5. Was the subject's FEV_1 (% predicted) from Question #3b or Question #4b ≥ 60% predicted?
   ☐ 1 Yes ☐ 0 No (1070)

6. Is there any other reason the subject should not proceed with sputum induction?
   ☐ 1 Yes ☐ 0 No (1080)
   If ***YES***, explain _____

7. Is the subject eligible for sputum induction? ☐ 1 Yes ☐ 0 No (1090)

If any of the shaded boxes are filled in, the subject is NOT eligible for sputum induction.

➜ ***If NO, do NOT complete the rest of this form.***

8. ***(If Visit 4, do not complete Question #8.)***

What was the duration of sputum induction the first time it exceeded 4 minutes, not including current visit? ___ ___ . ___ minutes (1100)

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

9. Subject's FEV_1 immediately after completion of sputum induction

9a. FEV_1 ___ . ___ ___ L (1110)

9b. FEV_1 (% predicted) ___ ___ ___ % predicted (1120)

9c. Time of FEV_1 in Question #9a (*based on 24-hour clock*) ___ ___ ___ ___ (1130)

9d. Percent difference in FEV_1 $\frac{(\textit{Question \#3a or \#4a - Question \#9a})}{\textit{Question \#3a or \#4a}} \times 100$ ___ ___ . ___ % (1140)

10. Duration of sputum induction at this visit ___ ___ . ___ minutes (1150)

11. Volume of sputum sample at this visit ___ ___ ___ . ___ ml (1160)

12. Did the subject tolerate sputum induction for > 4 minutes at this visit? ☐ 1 Yes ☐ 0 No (1170)

13. Is the sample adequate for analysis of squamous cells? ☐ 1 Yes ☐ 0 No (1180)

If the shaded box in Question #12 is filled in, the sputum sample is not adequate and should not be sent for analysis of squamous cell counts.

14. Did the subject's FEV_1 immediately after completion of sputum induction drop > 20% (from post-albuterol baseline) as indicated in Question #9d? ☐ 1 Yes ☐ 0 No (1190)

➜ ***If YES, proceed with Question #15 on the next page.***

➜ ***If NO, STOP HERE and continue with remaining visit procedures.***

Complete page 3 only if the subject has a fall in FEV_1 (from post-albuterol baseline) of > 20% during or immediately after sputum induction.

Clinic Use Only

Sputum Induction Reversal Reference Value (Question #3a or Question #4a) x 0.90 = __ . __ __ L

15. Subject's FEV_1 after initial 2 puffs of albuterol following sputum induction

15a. FEV_1 ___ . ___ ___ L (1200)

15b. FEV_1 (% predicted) ___ ___ ___ % predicted (1210)

15c. Time of FEV_1 from Question #15a (*based on 24-hour clock*) ___ ___ ___ ___ (1220)

15d. Was the FEV_1 from Question #15a ≥ the sputum induction reversal reference value in the gray box above? ❑ 1 Yes ❑ 0 No (1230)

➜ ***If YES, stop here and continue with remaining visit procedures.***

➜ ***If NO, proceed with additional procedures as instructed in the MOP and complete Question #16.***

16. Subject's final FEV_1 after sputum induction

16a. FEV_1 ___ . ___ ___ L (1240)

16b. FEV_1 (% predicted) ___ ___ ___ % predicted (1250)

16c. Time of FEV_1 from Question #16a (*based on 24-hour clock*) ___ ___ ___ ___ (1260)

16d. Was the FEV_1 from Question #16a ≥ the sputum induction reversal reference value in the gray box on page 3 of this form? ❑ 1 Yes ❑ 0 No (1270)

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

Physician/CC signature: _____ (1280)

Date: __ __ / __ __ / __ __ __ __ (1290)

Time: __ __ __ __ *(based on a 24-hour clock)* (1300)

Asthma Clinical Research Network
NIH/NHLBI

SMOG SUBJECT POST-STUDY QUESTIONNAIRE

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Subject completed)

This questionnaire is to be completed by the SMOG subject at the end of Visit 6 and 10. If a randomized subject terminates prior to Visit 10, please ask him or her to complete this form during the termination visit.

1. As a SMOG study participant you were randomized to receive either an active (i.e. real) inhaled steroid inhaler or a look-alike placebo (i.e. inactive) inhaler. Please check the box that most closely represents your feelings about the **scheduled inhaler** you received, over the past 8 weeks.

☐ 1 I am certain it was placebo. (1000)

☐ 2 I think it was probably placebo.

☐ 3 I have no idea which treatment I received, but my best guess would be:

- ☐ 1 Placebo (1010)
- ☐ 2 Active Drug

☐ 4 I think it was probably active drug.

☐ 5 I am certain it was active drug.

2. As a SMOG study participant you were randomized to receive either an active (i.e. real) tablet or a look-alike placebo (i.e. inactive) tablet. Please check the box that most closely represents your feelings about the **tablets** you received, over the past 8 weeks.

☐ 1 I am certain it was placebo. (1020)

☐ 2 I think it was probably placebo.

☐ 3 I have no idea which treatment I received, but my best guess would be:

- ☐ 1 Placebo (1030)
- ☐ 2 Active Drug

☐ 4 I think it was probably active drug.

☐ 5 I am certain it was active drug.

Subject's Initials: __ __ __ (1040)

Date: __ __/__ __/__ __ __ __ (1050)

3. Please comment with respect to the taste of the **scheduled inhaler** you received, over the past 8 weeks.

☐ 1 Tasted good (1060)

(*Describe*) _____

☐ 2 No noticeable taste

☐ 3 Tasted bad

(*Describe*) _____

4. Please comment with respect to the smell of the **scheduled inhaler** you received, over the past 8 weeks.

☐ 1 Smelled good (1070)

(*Describe*) _____

☐ 2 No noticeable smell

☐ 3 Smelled bad

(*Describe*) _____

5. Please comment with respect to any physical sensations produced by the **scheduled inhaler** you received, over the past 8 weeks.

☐ 1 Pleasant sensations (1080)

(*Describe*) _____

☐ 2 No noticeable sensations

☐ 3 Unpleasant sensations

(*Describe*) _____

6. Please comment with respect to any other observations you may have made regarding your **scheduled inhaler**.

☐ 1 I have no further comments (1090)

☐ 2 I observed the following: (*Describe below*)

_____

_____

_____

_____

7. Please comment with respect to the taste of the **tablets** you received, over the past 8 weeks.

☐ 1 Tasted good (1100)

(*Describe*) _____

☐ 2 No noticeable taste

☐ 3 Tasted bad

(*Describe*) _____

8. Please comment with respect to the smell of the **tablets** you received, over the past 8 weeks.

☐ 1 Smelled good (1110)

(*Describe*) _____

☐ 2 No noticeable smell

☐ 3 Smelled bad

(*Describe*) _____

9. Please comment with respect to any physical sensations produced by the **tablets** you received, over the past 8 weeks.

☐ 1 Pleasant sensations (1120)

(*Describe*) _____

☐ 2 No noticeable sensations

☐ 3 Unpleasant sensations

(*Describe*) _____

10. Please comment with respect to any other observations you may have made regarding the **tablets** you received.

☐ 1 I have no further comments (1130)

☐ 2 I observed the following: (*Describe below*)

_____

_____

_____

_____

Asthma Clinical Research Network
NIH/NHLBI

SMOG
TERMINATION OF STUDY PARTICIPATION

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Please indicate the reason for termination of study participation.

1. ***(Visit 10 Only)***
Pregnancy test results
(Check N/A if the subject is male or unable to bear children.)

❑1 Positive
❑2 Negative
❑9 N/A (1000)

Pregnancy Test Source Documentation
Subject's Initials: __ __ __ (1030)
Date: __ __ / __ __ / __ __ __ __ (1040)

2. (Visit 10 Only)
Has the subject completed the study?
➜ ***If YES, skip to the SIGNATURES section on page 2.***

❑1 Yes ❑0 No (1010)

3. Is the subject withdrawing from the study due to pregnancy?
(Check N/A if the subject is male.)

❑1 Yes ❑0 No ❑9 N/A (1020)

4. ***(Visit 1 - Visit 4 non-randomized subjects Only***)
During the run-in period, has the subject experienced a significant asthma exacerbation as defined in the protocol?

❑1 Yes ❑0 No (1050)

5. ***(Visit 3 - Visit 4 non-randomized subjects Only***)
During the first two weeks of the run-in period, has the subject failed to comply with regular use of study drugs (missed >15%) as reflected on the Diary Cards?

❑1 Yes ❑0 No (1060)

6. ***(Visit 3 - Visit 4 non-randomized subjects Only***)
During the run-in period, has the subject failed to record his or her peak flow measurements and symptoms on the Diary Cards on average >15% of the required time?

❑1 Yes ❑0 No (1070)

7. ***(Visit 1 - Visit 4 non-randomized subjects Only***)
Has the subject been deemed ineligible according to any eligibility criteria **other than** a significant asthma exacerbation?
If ***YES***, explain _____

❑1 Yes ❑0 No (1080)

8. Has the subject withdrawn consent? ❑1 Yes ❑0 No (1090)

If ***YES***, indicate the **primary** reason.

- ❑1 no longer interested in participating
- ❑2 no longer willing to follow protocol
- ❑3 access to clinic is difficult (location, transportation, parking)
- ❑4 unable to make visits during clinic hours
- ❑5 moving out of the area
- ❑6 unable to continue in study due to personal constraints
- ❑7 dissatisfied with asthma control
- ❑8 unable to continue due to medical condition unrelated to asthma
- ❑9 side effects of study medications
- ❑10 treatment failure
- ❑11 other _____ (1100)

9. Has the subject been lost to follow-up? ❑1 Yes ❑0 No (1110)

10. Has the subject experienced a serious adverse event (e.g., an adverse event resulting in death or hospitalization, etc.)? ❑1 Yes ❑0 No (1120)

➜ ***If YES, complete the Serious Adverse Event Reporting (P10_SERIOUS) form.***

SIGNATURES

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

I verify that all information collected on the ACRN SMOG 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 ACRN SMOG Protocol.

_____ (1130) ___ ___ /___ ___ /___ ___ ___ ___ (1140)

Clinic Coordinator Signature — month day year

_____ (1150) ___ ___ /___ ___ /___ ___ ___ ___ (1160)

Principal Investigator Signature — month day year

Asthma Clinical Research Network
NIH/NHLBI

SMOG
TREATMENT FAILURE

Subject ID: 1 0 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Were corticosteroids (oral, inhaled, or parenteral) given to the subject for treatment of asthma deterioration? ☐ 1 Yes ☐ 0 No (1000)

   ➜ ***If YES, please complete the Concomitant Medications for Asthma and Allergies (P10_CMED_AS) form.***

2. Did the subject have a pre-bronchodilator FEV_1 < 80% of established at Visit 4? ☐ 1 Yes ☐ 0 No (1010)

3. Has the subject required > 1 Emergency Department or Urgent Care visit for an asthma exacerbation? ☐ 1 Yes ☐ 0 No (1020)

4. Has the subject been hospitalized for treatment of an asthma exacerbation? ☐ 1 Yes ☐ 0 No (1030)

5. Based on clinical judgement, did the physician deem the subject a treatment failure due to safety reasons? ☐ 1 Yes ☐ 0 No (1040)

6. Is the subject a treatment failure? ☐ 1 Yes ☐ 0 No (1050)
   If any of the shaded boxes are filled in, the subject is a treatment failure.

   ➜ ***If YES, please continue with the Treatment Failure (P10_TXFAIL) form.***

7. Date treatment failure occurred ___ ___ / ___ ___ / ___ ___ ___ ___ (1060)
   month day year

8. Was the subject taken off study drugs as a result of the treatment failure? ☐ 1 Yes ☐ 0 No (1070)

9. Was the subject started on additional open label therapy as a result of the treatment failure? ☐ 1 Yes ☐ 0 No (1080)

   ➜ ***If YES, please complete the Concomitant Medications for Asthma and Allergies (P10_CMED_AS) form.***

Asthma Clinical Research Network
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FLUID PHASE MEASUREMENTS

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

(Technician completed)

		Non-detectable limit	Quantity not sufficient to dilute
ECP	___ ___ ___ ___ ___ mcg/L (Q1000)	❑ (Q1010)	❑ (Q1020)
Tryptase	___ ___ ___ . ___ mcg/L (Q1030)	❑ (Q1040)	❑ (Q1050)

ACRN ICD9 Adverse Event Codes

Asthma Clinical Research Network
NIH/NHLBI

Cardiac	
Ankle edema	782.3X
Chest pain	786.5X
Hypertension	796.2X
Hypotension	796.3X
Palpitations	785.1X
Substernal Tightness	786.59
Tachycardia	785.0X
Dermatological	
Bruising	929.9X
Eczema	692.9X
Flushing	782.62
Hematoma	923.9X
Lacerations	
Complicated	879.8X
Uncomplicated	879.9X
Photosensitivity	
Sun	692.72
Other - not sun	692.82
Poison Ivy/Oak	692.6X
Skin rash	782.1X
Sunburn	692.71
Urticaria (Hives)	708.XX
EENT	
Allergic Rhinitis	477.XX
Coughing	786.2X
Dry mouth	527.7X
Earache	388.70
Hoarseness/Dysphonia	784.49
Laryngitis	464.0X
Nasal Congestion	478.1X
Nosebleed	784.7X
Oral candidiasis	112.0X
Otitis/Ear infection	382.9X
Sinus Congestion	478.1X
Sinusitis	473.9X
Sore throat/Pharyngitis	462.XX
Tinnitus	388.30
Toothache	525.9X

Gastrointestinal	
Abdominal pain	789.0X
Bloating/Flatulence	787.3X
Constipation	564.0X
Diarrhea	558.9X
Heartburn	787.1X
Hemorrhoids	455.6X
Loss of Appetite	783.0X
Nausea	787.02
Nausea and Vomiting	787.01
Reflux symptoms	530.11
Stomach upset/distress	536.8X
Vomiting	787.03
Weight gain	783.1X
Weight loss	783.2X
Infections	
Appendicitis	541.XX
Bronchitis	490.XX
Cellulitis	682.9X
Chickenpox	052.9X
Chills	780.9X
Cold	460.XX
Fever/Fever with chills	780.6X
Hepatitis	573.3X
Herpes infection	054.9X
Infectious mononucleosis	075.XX
Influenza virus infection	487.1X
Lower Respiratory Infection	519.8X
Measles	055.9X
Mumps	072.9X
Pneumonia	486.XX
Sinus infection/Sinusitis	473.9X
Tonsillitis	463.XX
Tuberculosis	011.9X
Upper Respiratory Infection (URI)	465.9X
Urinary Tract Infection	599.0X
Vaginitis	616.10

Neurologic/Psychiatric	
Anxiety	300.00
Depression	311.XX
Dizziness	780.4X
Drowsiness	780.09
Fatigue/Weakness	780.7X
Headache	784.0X
Impotence	302.72
Insomnia	780.52
Nervousness	799.2X
Tremor	781.0X
Ophthalmological	
Blurred vision	368.8X
Conjunctivitis	372.30
Increased intraocular pressure	365.00
Significant Asthma Exacerbation	493.9X
Skeletal/Muscle/Rheumatologic	
Backache	724.5X
Fracture	829.0X
Joint pain	719.4X
Muscle aches/pains/ myalgias	729.1X
Sprained ankle	845.00
Tendonitis	726.90
Urologic/Gynecologic	
Difficulty urinating (retention of urine)	788.20
Dysmenorrhea/Menstrual cramps	625.3X
Hematuria	599.7X
Increased urinary frequency	788.41