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Asthma Clinical Research Network
NIH/NHLBI

PRICE
CLINICAL ADVERSE EVENTS

Subject ID: 1 2 - ___ - ___ ___ ___
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) / 3. DATE STOPPED (1030) (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 (P12_SERIOUS) form.

** Please complete the appropriate Concomitant Medications (P12_CMED_AS, P12_CMED_NON) form, if applicable.

Asthma Clinical Research Network
NIH/NHLBI

PRICE AM1® QUALITY CONTROL

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

(Technician completed)

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

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

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

4. Is a new AM1® device being tested? ❑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

PRICE
CLINIC COORDINATOR STUDY TREATMENT QUESTIONNAIRE

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

(Coordinator completed)

This questionnaire is to be completed at Visit 10 by the ACRN study coordinator who was primarily responsible for the subject's PRICE visits during the preceding 24 weeks. If a randomized subject terminates prior to Visit 10, this form should be completed at the time of the termination visit.

1. **Blinded Scheduled MDI**
Subjects in the PRICE 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 during the randomized treatment period (i.e., Week 8 until termination).

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

Coordinator's Initials: __ __ __ (1020)

Date: __ __/__ __/__ __ __ __ (1030)

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

Asthma Clinical Research Network
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PRICE
CONCOMITANT MEDICATIONS for ASTHMA and ALLERGIES

Subject ID: 1 2 - ___ - ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: ___ ___

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

(Clinic Coordinator completed)

At Visit 1: 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, code, dose/units, frequency, route, and start date. Refer to the PRICE 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 PRICE 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

PRICE COMPLIANCE CHECKLIST

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

(Clinic Coordinator completed)

Complete Question #1 at Visit 3 Only.

1. **Doser™ Compliance for Study Inhaler**

The information for Question #1a - #1c is obtained from the last 14 full days prior to Visit 3.

1a. Total number of scheduled puffs ___ ___ ___ puffs (1000)

➜Value obtained from Question #4 on the P12_COMPLY_WKS

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

➜Value obtained from Question #5 on the P12_COMPLY_WKS

1c. Percent compliance ___ ___ ___ . ___ % (1020)

➜ Value obtained from Question #6 on the P12_COMPLY_WKS

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

Complete Question #2 at Visits 5, 7, 8, 9, 10 and 99.

2. **Doser™ Compliance for Study Inhaler**

At Visits 5, 7, 8, 9, 10 and 99 if the interval between visits exceeds 30 days, complete Questions #2a - 2c using data for the 30 days prior to the visit.

2a. Total number of scheduled puffs since the last visit ___ ___ ___ puffs (1030)

➜ Value obtained from Question #1 on the P12_COMPLY_WKS

2b. Total number of puffs in Doser™ history ___ ___ ___ puffs (1040)

➜ Value obtained from Question #2 on the P12_COMPLY_WKS

2c. Percent compliance ___ ___ ___ . ___ % (1050)

➜ Value obtained from Question #3 on the P12_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

PRICE DIARY CARD

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

Subject ID: 1 2 - ___ - ___ ___ ___
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 60-90 minutes 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, 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)/(1030)		___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
4. Total number of puff(s) from Study 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)/(1120)		___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
12. Total number of puff(s) from Study Inhaler **(PM)** (1130)		___	___	___	___	___	___	___
Symptoms++ since you woke.	13. Shortness of Breath (1140)							
	14. Chest Tightness (1150)							
	15. Wheezing (1160)							
	16. Cough (1170)							
	17. Phlegm/Mucus (1180)							
24 HOUR EVALUATION								
18. Total number of **puffs** from albuterol **(RESCUE)** inhaler over a 24 hour period. *(Do not record preventive use.)* (1190)		___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___

****** 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
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PRICE
ELIGIBILITY CHECKLIST 1

Subject ID: 1 2 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

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

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

2. Is the subject between 18 and 55 years of age, inclusive? ☐ 1 Yes ☐ 0 No (1020)

3. Are you planning to move away from this clinical center in the next 6 months such that your ability to complete the study will be jeopardized? ☐ 1 Yes ☐ 0 No (1030)

4. Have you used any smokeless tobacco products (chew, snuff) in the past year? ☐ 1 Yes ☐ 0 No (1040)

5. Have you smoked a pipe, cigar, marijuana, or any other substance in the past year? ☐ 1 Yes ☐ 0 No (1050)

6. Do you have a smoking history less than 10 pack-years? ☐ 1 Yes ☐ 0 No (1060)

   Record history in pack-years. (Enter '00.0' if none) ___ ___ . ___ (1070)

7. Have you had a respiratory tract infection in the past 6 weeks? ☐ 1 Yes ☐ 0 No (1080)

8. Have you experienced a significant asthma attack in the past 6 weeks? ☐ 1 Yes ☐ 0 No (1090)

9. Have you experienced a life-threatening asthma attack requiring treatment with intubation and mechanical ventilation in the past 10 years? ☐ 1 Yes ☐ 0 No (1100)

10. Do you work night shift or have an altered day/night cycle for other reasons? ☐ 1 Yes ☐ 0 No (1110)

11. Were you a randomized subject in the ACRN MICE study? ☐ 1 Yes ☐ 0 No (1120)

12. Are you potentially able to bear children? (If subject is male, check N/A and go to Question #13.) ❑ 1 Yes ❑ 0 No ❑ 9 N/A (1130)

12a. If ***YES,*** are you currently pregnant or lactating? ❑ 1 Yes ❑ 0 No (1140)

12b. 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 (1150)

12c. If ***YES***, record results of pregnancy test. ❑ 1 Positive ❑ 2 Negative (1160)

13. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ❑ 1 Yes ❑ 0 No (1170)

➜ ***If NO, please complete the Termination of Study Participation (P12_TERM) form.***

Subject's Initials: ___ (1180)

Date: __ __ / __ __ / __ __ __ __ (1190)

Asthma Clinical Research Network
NIH/NHLBI

PRICE
ELIGIBILITY CHECKLIST 2

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

(Clinic Coordinator completed)

1. Does the subject have current evidence of any of the conditions listed on the Exclusionary Medical Conditions reference card (P12_EXCLMED)?
   If ***YES***, describe _____
   ☐ 1 Yes ☐ 0 No (1000)

2. Has the subject taken any medications listed on the Exclusionary Drugs reference card (P12_EXCLDRUG) within the specified time periods?
   If ***YES***, describe _____
   ☐ 1 Yes ☐ 0 No (1010)

3. Is the subject currently taking prescription or over-the-counter medication(s) other than those listed on the Allowed Medications reference card (P12_MEDALLOW)?
   If ***YES***, describe _____
   ☐ 1 Yes ☐ 0 No (1020)

4. Is the subject currently receiving hyposensitization therapy other than an established maintenance regimen?
   ☐ 1 Yes ☐ 0 No (1030)

5. Has the subject used orally inhaled or systemic corticosteroids during the past 4 weeks?
   ☐ 1 Yes ☐ 0 No (1040)

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

   ➜ ***If NO, please complete the Termination of Study Participation (P12_TERM) form.***

Subject's Initials: ___ ___ ___ (1060)
Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (1070)

PRICE
ELIGIBILITY CHECKLIST 3

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

(Clinic Coordinator completed)

1. Is the subject's prebronchodilator FEV_1 between 55% and 85% of predicted (inclusive)? ☐ 1 Yes ☐ 0 No (1000)

2. Was the subject's methacholine PC_{20} obtained during Visit 1 ≤ 12 mg/ml? ☐ 1 Yes ☐ 0 No (1010)

3. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ☐ 1 Yes ☐ 0 No (1020)

   ➜ ***If NO, please complete the Termination of Study Participation (P12_TERM) form.***

Asthma Clinical Research Network
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PRICE
ELIGIBILITY CHECKLIST 4

Subject ID: 1 2 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 3
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

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

2. Since Visit 1, has the subject received treatment with any excluded medications (P12_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 run-in inhaler during the last two weeks of the run-in period? ☐ 1 Yes ☐ 0 No (1020)

4. 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 Cards (P12_DIARY) an average of at least six days per week? ☐ 1 Yes ☐ 0 No (1030)

5. 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 (1040)

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

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

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

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

   ➜ ***If NO, please complete the Termination of Study Participation (P12_TERM) form.***

Asthma Clinical Research Network
NIH/NHLBI

PRICE
ELIGIBILITY CHECKLIST 5

Subject ID: 1 2 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 4
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

(Complete form at Visit 4. For each question, refer to data collected at this visit or the previous visit. That is, reference Visit 3 and Visit 4.)

1. Did the subject have sputum eosinophil differential count available from the local lab (i.e., is Question #8 on the P12_SPUTLAB form completed)? ❑ 1 Yes ❑ 0 No (1000)

2. Did the subject have exhaled Nitric Oxide data available (i.e., was the balloon read)? ❑ 1 Yes ❑ 0 No (1010)

3. Did the subject have maximum reversibility data available from the postbronchodilator pulmonary function test (i.e., is Question #12b, #14b, or #16b on the P12_MAXREV form completed)? ❑ 1 Yes ❑ 0 No (1020)

(Complete Question #4 at Denver, Madison, and San Francisco Only.)

4. Did the subject have PV Curve flow data available (i.e., all the Questions on P12_PV form were completed)? ❑ 1 Yes ❑ 0 No (1030)

5. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ❑ 1 Yes ❑ 0 No (1040)

➜ ***If NO, please complete the Termination of Study Participation (P12_TERM) form.***

PRICE LABORATORY MEASUREMENTS

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

(Clinic Coordinator completed)

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

(Complete Questions #2 - #5 at Visit 1 Only.)

2. WBC ___ ___ ___ . ___ K/uL (1010)

3. HCT ___ ___ . ___ % (1020)

4. HGB ___ ___ . ___ g/dL (1030)

5. Differential

   5a. Lymphocytes ___ ___ . ___ % (1040)

   5b. Monocytes ___ ___ . ___ % (1050)

   5c. Basophils ___ ___ . ___ % (1060)

   5d. Neutrophils ___ ___ . ___ % (1070)

(Clinic Coordinator completed)

PHYSICAL EXAMINATION

1. Height *(without shoes)* ___ ___ . ___ inches (1000)

2. Weight *(without shoes or heavy clothing)* ___ ___ ___ . ___ pounds (1010)

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.

3. Resting blood pressure ___ ___ ___ / ___ ___ ___ mm Hg
systolic (1020) diastolic (1030)

4. Pulse ___ ___ ___ beats/min (1040)

5. Respiratory rate ___ ___ breaths/min (1050)

6. Body temperature ___ ___ ___ . ___ ° F (1060)

LONG PHYSICAL EXAM

(Physician completed)

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

		Not Done	Normal	Abnormal	
7.	Hair and Skin	❑2	❑1	❑0	_____ (1070)
8.	Lymph nodes	❑2	❑1	❑0	_____ (1080)
9.	Eyes (excluding corrective lenses)	❑2	❑1	❑0	_____ (1090)
10.	Ears, Nose, and Throat	❑2	❑1	❑0	_____ (1100)
11.	Respiratory (excluding asthma)	❑2	❑1	❑0	_____ (1110)
12.	Cardiovascular	❑2	❑1	❑0	_____ (1120)
13.	Gastrointestinal	❑2	❑1	❑0	_____ (1130)
14.	Musculoskeletal	❑2	❑1	❑0	_____ (1140)
15.	Neurological	❑2	❑1	❑0	_____ (1150)
16.	Mental Status	❑2	❑1	❑0	_____ (1160)
17.	Other _____ (check Not Done if non-applicable)	❑2	❑1	❑0	_____ (1170)

PULMONARY AUSCULTATION

18. 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 (1180)

Physician/Clinician signature: _____ (1190)

Date: __ __ / __ __ / __ __ __ __ (1200)

Time: __ __ __ __ *(based on 24-hour clock)* (1210)

Asthma Clinical Research Network
NIH/NHLBI

PRICE
MAXIMUM REVERSIBILITY TESTING

Supervisor ID: ___ ___ ___ ___ ___

Subject ID: 1 2 - ___ - ___ ___ ___
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 [e.g., Allegra or Chlor-Trimeton] in the past 48 hours? ☐ 1 Yes ☐ 0 No (1030)

4b. Have you used any oral decongestants or cold remedies [e.g., pseudoephedrine (Sudafed) or oxymetazoline (Afrin)] 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 P12_EXCLDRUG reference card) to treat your asthma or allergies in the past 6 weeks? ☐ 1 Yes ☐ 0 No (1070)
   ➜ ***If YES, complete the Concomitant Medications for Asthma and Allergies (P12_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 (1080)

6. Is there any other reason you should not proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1090)
   ➜ ***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 (1100)

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.***

PREBRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

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

Height *(without shoes)* ___ ___ . ___ inches (1110)

9. Time spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ (1120)

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

10. Results of best effort:

10a. FVC ___ . ___ ___ L (1130)

10b. FEV_1 ___ . ___ ___ L (1140)

10c. FEV_1 (% predicted) ___ ___ ___ % predicted (1150)

10d. PEFR ___ ___ . ___ ___ L/S (1160)

10e. FEF_{25-75} ___ . ___ ___ L/S (1170)

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

11. Time albuterol administered *(based on 24-hour clock)* ___ ___ ___ ___ (1180)

12. Subject's FEV_1 after 4 puffs of albuterol

12a. Time spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ (1190)

12b. FEV_1 ___ . ___ ___ L (1200)

12c. FEV_1 (% predicted) ___ ___ ___ % predicted (1210)

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

13. Time albuterol administered *(based on 24-hour clock)* ___ ___ ___ ___ (1220)

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

    14a. Time spirometry started (*based on 24-hour clock*) ___ ___ ___ ___ (1230)

    14b. FEV_1 ___ . ___ ___ L (1240)

    14c. FEV_1 (% predicted) ___ ___ ___ % predicted (1250)

    14d. Percent difference in FEV_1 $\frac{(\textit{Question \#14b - Question \#12b})}{\textit{Question \#12b}}$ x 100 ___ ___ . ___ % (1260)

    14e. Is the percent difference from Question #14d ≤ 5.0%? ❑1 Yes ❑0 No (1270)

➜ ***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)* ___ ___ ___ ___ (1280)

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

    16a. Time spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ (1290)

    16b. FEV_1 ___ . ___ ___ L (1300)

    16c. FEV_1 (% predicted) ___ ___ ___ % predicted (1310)

PRICE
MEDICAL HISTORY

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

(Subject Interview completed)

DEMOGRAPHICS

1. What is your date of birth? ___ ___ / ___ ___ / ___ ___ ___ ___ (1000)
month day year

2. Subject's gender
❑1 Male
❑2 Female (1010)

3. Subject's Race and Ethnicity

3a. Subject's ethnic background
❑1 Hispanic or Latino
❑2 Not Hispanic or Latino (1020)

3b. Subject's racial background *(Ask the subject to identify all that apply.)*

3bi.	American Indian or Alaskan Native	❑1 Yes	❑0 No (1030)
3bii.	Asian	❑1 Yes	❑0 No (1040)
3biii.	Black or African American	❑1 Yes	❑0 No (1050)
3biv.	White	❑1 Yes	❑0 No (1060)
3bv.	Native Hawaiian or Other Pacific Islander	❑1 Yes	❑0 No (1070)
3bvi.	Other _____	❑1 Yes	❑0 No (1080)

4. Subject's primary racial identification
(This identification will be used in pulmonary function testing. Ask the subject which category best describes him or her and 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 _____
(1090)

ASTHMA HISTORY

5. 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 (1100)

6. 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 (1110)

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

- ❑1 Winter
- ❑2 Spring
- ❑3 Summer
- ❑4 Fall
- ❑5 Same all year (1120)

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

8a. Asthma episodes have you had that required emergency care or an unscheduled office visit? ____ ____ (1130)

8b. Hospitalizations have you had due to asthma? ____ ____ (1140)

8c. Courses of oral corticosteroid therapy for asthma (such as prednisone or Medrol) have you taken? ____ ____ (1150)

9. Have you missed any days of work or school due to asthma in the last 12 months? ❑1 Yes ❑0 No ❑9 N/A (1160)

If ***YES***, record your best estimate of the number of days missed. ____ ____ (1170)

10. 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.*)

10a. Mother	❑1 Yes	❑0 No	❑8 Don't Know (1180)	
10b. Father	❑1 Yes	❑0 No	❑8 Don't Know (1190)	
10c. Brothers or Sisters	❑1 Yes	❑0 No	❑8 Don't Know	❑9 N/A (1200)
10d. Child(ren)	❑1 Yes	❑0 No	❑8 Don't Know	❑9 N/A (1210)

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
11.	Non-long-acting Inhaled Beta-Agonists **(Bronkaid Mist, Duo-Medihaler, Medihaler-Epi, Primatene Mist, Alupent, Brethaire, Brethine, Bronkometer, Maxair, Metaprel, Proventil, Tornalate, Ventolin, Xopenex and others)**	❑1 Yes	❑0 No	❑8 Unknown (1220)	__ __/__ __/__ __ __ __ (1230) (1240) (1250)
12.	Long-acting Inhaled Beta-Agonists (MDI) **(Serevent, Foradil, Advair Diskus)**	❑1 Yes	❑0 No	❑8 Unknown (1260)	__ __/__ __/__ __ __ __ (1270) (1280) (1290)
13.	Asthma medication via a Nebulizer Machine	❑1 Yes	❑0 No	❑8 Unknown (1300)	__ __/__ __/__ __ __ __ (1310) (1320) (1330)
14.	Oral Beta-Agonists **(Alupent, Brethine, Bricanyl, Metaprel, Proventil, Ventolin, Repetabs, Volmax and others)**	❑1 Yes	❑0 No	❑8 Unknown (1340)	__ __/__ __/__ __ __ __ (1350) (1360) (1370)
15.	Short-acting Oral Theophylline **(Aminophylline, Slo-Phyllin and others)**	❑1 Yes	❑0 No	❑8 Unknown (1380)	__ __/__ __/__ __ __ __ (1390) (1400) (1410)

					If Yes, indicate date medication was last taken month / day / year
16.	Sustained release Oral Theophylline **(Slo-bid, Theo-Dur, Uniphyl and others)**	❑1 Yes	❑0 No	❑8 Unknown (1420)	__ __/__ __/__ __ __ __ (1430) (1440) (1450)
17.	Inhaled Anticholinergic **(Atrovent, Combivent)**	❑1 Yes	❑0 No	❑8 Unknown (1460)	__ __/__ __/__ __ __ __ (1470) (1480) (1490)
18.	Anti-allergic Inhaled Medications **(Intal, Tilade and others)**	❑1 Yes	❑0 No	❑8 Unknown (1500)	__ __/__ __/__ __ __ __ (1510) (1520) (1530)
19.	Anti-allergic Nasal Medications **(Nasalcrom, Astelin and others)**	❑1 Yes	❑0 No	❑8 Unknown (1540)	__ __/__ __/__ __ __ __ (1550) (1560) (1570)
20.	Anti-allergic Oral Medications **(Allegra, Claritin, Zyrtec, Chlor-Trimeton and others)**	❑1 Yes	❑0 No	❑8 Unknown (1580)	__ __/__ __/__ __ __ __ (1590) (1600) (1610)
21.	Oral Steroids **(Prednisone, Medrol and others)**	❑1 Yes	❑0 No	❑8 Unknown (1620)	__ __/__ __/__ __ __ __ (1630) (1640) (1650)
22.	Inhaled Steroids **(Azmacort, Beclovent, Vanceril, AeroBid, Flovent, Pulmicort, Advair Diskus and others)**	❑1 Yes	❑0 No	❑8 Unknown (1660)	__ __/__ __/__ __ __ __ (1670) (1680) (1690)
23.	Nasal Steroids **(Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Rhinocort, Nasonex and others)**	❑1 Yes	❑0 No	❑8 Unknown (1700)	__ __/__ __/__ __ __ __ (1710) (1720) (1730)
24.	Topical Steroids - Prescription **(Synalar, Lidex, Dermacin, Fluocinonide and others)**	❑1 Yes	❑0 No	❑8 Unknown (1740)	__ __/__ __/__ __ __ __ (1750) (1760) (1770)
25.	Topical Steroids - OTC **(Hydrocortisone - multiple strengths and products)**	❑1 Yes	❑0 No	❑8 Unknown (1780)	__ __/__ __/__ __ __ __ (1790) (1800) (1810)
26.	Leukotriene Antagonist / 5L0 Inhibitors **(Accolate, Zyflo, Singulair)**	❑1 Yes	❑0 No	❑8 Unknown (1820)	__ __/__ __/__ __ __ __ (1830) (1840) (1850)

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

				If Yes, Comment
27.	Skin	❑1 Yes	❑0 No	_____ (1860)
28.	Blood, Lymph, or Immune Systems	❑1 Yes	❑0 No	_____ (1870)
29.	Eyes	❑1 Yes	❑0 No	_____ (1880)
30.	Ears, Nose, or Throat	❑1 Yes	❑0 No	_____ (1890)
31.	Breasts	❑1 Yes	❑0 No	_____ (1900)
32.	Endocrine Systems	❑1 Yes	❑0 No	_____ (1910)
33.	Lung - other than asthma	❑1 Yes	❑0 No	_____ (1920)
34.	Heart and Blood Vessels	❑1 Yes	❑0 No	_____ (1930)
35.	Liver or Pancreas	❑1 Yes	❑0 No	_____ (1940)
36.	Kidneys or Urinary Tract System	❑1 Yes	❑0 No	_____ (1950)
37.	Reproductive System	❑1 Yes	❑0 No	_____ (1960)
38.	Stomach or Intestines	❑1 Yes	❑0 No	_____ (1970)
39.	Muscles or Bones	❑1 Yes	❑0 No	_____ (1980)
40.	Nervous System	❑1 Yes	❑0 No	_____ (1990)
41.	Psychiatric	❑1 Yes	❑0 No	_____ (2000)
42.	Other _____	❑1 Yes	❑0 No	_____ (2010)

Subject's Initials: __ __ __ (2020)

Date: __ __ / __ __ / __ __ __ __ (2030)

Asthma Clinical Research Network
NIH/NHLBI

PRICE
METHACHOLINE CHALLENGE TESTING

Supervisor ID: ___ ___ ___ ___ ___

Subject ID: 1 2 - ___ - ___ ___ ___
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 (P12_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 P12_SPIRO form as the baseline reference.

3. Does the subject have a history of urinary retention? ☐ 1 Yes ☐ 0 No (1025)
   ➜ ***If YES, please complete the Termination of Study Participation (P12_TERM) form.***

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 P12_SPIRO form as the baseline reference.

Baseline FEV_1 prior to methacholine challenge

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

B. 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 #7a (*based on 24-hour clock*) ___ ___ ___ ___ (1090)

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

8. Was additional treatment used in the first hour? ❑1 Yes ❑0 No (1110)
➜ ***If NO, skip to Question #10.***
➜ ***If YES, please complete the Concomitant Medications for Asthma and Allergies (P12_CMED_AS) form.***

8a. Additional albuterol by MDI ❑1 Yes ❑0 No (1120)
➜ ***If NO, skip to Question #8b.***
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 #9a (*based on 24-hour clock*) ___ ___ ___ ___ (1200)

9d. Was the FEV_1 from Question #9a ≥ the methacholine reversal reference value (B) 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 #11.***

➜ ***If YES, please complete the appropriate Concomitant Medications for Asthma and Allergies (P12_CMED_AS) form.***

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

➜ ***If NO, skip to Question #10b.***

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 (P12_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 #11a (*based on 24-hour clock*) ___ ___ ___ ___ (1330)

11d. Was the FEV_1 from Question #11a ≥ the methacholine reversal reference value (B) 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)

Asthma Clinical Research Network
NIH/NHLBI

PRICE NITRIC OXIDE COLLECTION

Subject ID: 1 2 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Collector ID: ___ ___ ___ ___ ___

(Technician completed)

Nitric oxide measurements should be taken after successfully completing the Spirometry Testing (P12_SPIRO) form and prior to performing baseline spirometry.

Individuals participating in Nitric Oxide balloon collection and/or reading must be certified in the applicable procedure(s).

ANORA number: ____ ____ ____ (1000)

(Collector completed) ***(Reader completed)***

Balloon Id	Time Collected *(based on 24-hour clock)*	Time Read *(based on 24-hour clock)*	Measurement (ppb)
____ ____ ____ ____ (1010)	____ ____ ____ ____ (1020)	____ ____ ____ ____ (1030)	____ ____ ____ . ____ (1040)
____ ____ ____ ____ (1050)	____ ____ ____ ____ (1060)	____ ____ ____ ____ (1070)	____ ____ ____ . ____ (1080)
____ ____ ____ ____ (1090)	____ ____ ____ ____ (1100)	____ ____ ____ ____ (1110)	____ ____ ____ . ____ (1120)

Date balloons were read: ___ ___ / ___ ___ / ___ ___ ___ ___ (1130)
month / day / year

Reader ID: ___ ___ ___ ___ ___ (1140)

Comments:

Asthma Clinical Research Network
NIH/NHLBI

PRICE
PV CURVE

Supervisor ID: ___ ___ ___ ___ ___

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

(Clinic Coordinator completed)

1. Placement of esophageal balloon
   ❑1 Right nare
   ❑2 Left nare (1000)

2. Balloon depth from external nares ___ ___ cm (1010)

3. Time PV Curve started (*based on 24-hour clock*) ___ ___ ___ ___ (1015)

4. Total lung capacity (TLC) ___ ___ . ___ ___ L (1020)

5. Percent predicted TLC ___ ___ ___ % (1030)

6. Thoracic gas volume (TGV) ___ . ___ ___ L (1035)

7. FVC ___ . ___ ___ L (1040)

8. Percent predicted FVC ___ ___ ___ % (1050)

9. P_{tp} at TLC ($P_{el}100$ at TLC) ___ ___ . ___ cm H_2O (1060)

10. Coefficient of elastic retraction ___ ___ . ___ ___ cm H_2O/L (1070)

11. Upstream Resistance (R_{us}) ___ ___ . ___ ___ cm H_2O/L/sec (1080)

12. Coefficients A, B, K

    12a. A ___ ___ . ___ ___ L (1090)

    12b. A - B ___ ___ . ___ ___ L (1100)

    12c. K ___ ___ . ___ ___ ___ (1110)

Asthma Clinical Research Network
NIH/NHLBI

PRICE
FEV_1 RESPONSE

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

(Clinic Coordinator completed)

1. Since Visit 5, has the subject experienced a significant asthma exacerbation as defined in the protocol?
   ☐ 1 Yes ☐ 0 No (1000)

2. What was the subject's FEV_1 value recorded during the prebronchodilator pulmonary function test at Visit 4 (i.e., Question #10b on the Visit 4 Maximum Reversibility Testing (P12_MAXREV) form)?
   ___ . ___ ___ L (1010)

3. What was the subject's FEV_1 value recorded during the prebronchodilator pulmonary function test at Visit 6 (i.e., Question #10b on the Visit 6 Maximum Reversibility Testing (P12_MAXREV) form)?
   ___ . ___ ___ L (1020)

4. FEV_1 Response

   4a. Improvement in FEV_1
   Question #3 - Question #2
   ___ . ___ ___ L (1030)

   4b. Percent improvement $\frac{\text{Question \#4a}}{\text{Question \#2}}$ X 100 %
   ___ ___ . ___ % (1040)

   4c. Categorize the subject's FEV_1 Response
   ☐ 1 ≤ 5.0%
   ☐ 2 5.1 - 14.9%, inclusive
   ☐ 3 ≥ 15.0% (1050)

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

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

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

8. 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 PRICE, randomize the subject. Otherwise, please complete the Termination of Study Participation (P12_TERM) form.***

9. Drug Packet Number **(record on P12_LOG)** 1 2 - ___ - ___ ___

(1100) (1110) (1120)

Asthma Clinical Research Network
NIH/NHLBI

PRICE SERIOUS ADVERSE EVENT REPORTING FORM

Subject ID: 1 2 - ___ - ___ ___ ___
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 (P12_AECLIN) form, the Concomitant Medications for Asthma and Allergies (P12_CMED_AS) form, and any relevant source documents.

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

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 ___ ___ / ___ ___ / ___ ___ ___ ___ (1070) (month / day / year)

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

   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

PRICE
SHORT PHYSICAL EXAM

Subject ID: 1 2 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 5
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)

Physician/CC signature: _____ (1040)
Date: __ __ / __ __ / __ __ __ __ (1050)
Time: __ __ __ __ *(based on a 24-hour clock)* (1060)

URINE PREGNANCY TEST

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

❑ 1 Positive
❑ 2 Negative
❑ 9 N/A (1070)

➜ ***If pregnancy test results are positive, subject must be terminated from study participation. Complete a P12_TERM form and follow study termination procedures.***

Pregnancy Test Source Documentation

Subject's Initials: __ __ __ (1080)

Date: __ __ / __ __ / __ __ __ __ (1090)

Asthma Clinical Research Network
NIH/NHLBI

PRICE
SIGNIFICANT ASTHMA EXACERBATION

Subject ID: 1 2 - ___ - ___ ___ ___
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.

➜ ***(Complete Question # 1 for randomized subjects ONLY.)***

1. Is this significant exacerbation visit replacing a regular visit? ☐ 1 Yes ☐ 0 No (1000)

   1a. If ***YES***, indicate visit number of scheduled visit ___ ___ (1010)

   1b. If ***NO***, indicate last regular visit completed ___ ___ (1020)

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

   2a. 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 (1030)

   2b. Use of rescue inhaler ≥ 16 total puffs per 24 hours? ☐ 1 Yes ☐ 0 No (1040)

   2c. A fall in prebronchodilator PEFR to ≤ 65% of baseline on 2 of 3 consecutive measurements? ☐ 1 Yes ☐ 0 No (1050)

   2d. A fall in prebronchodilator FEV_1 to ≤ 80% of baseline? ☐ 1 Yes ☐ 0 No (1060)

   2e. A fall in FEV_1 to < 40% of predicted? ☐ 1 Yes ☐ 0 No (1065)

3. 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 (1070)

4. Did the subject experience a significant asthma exacerbation? ☐ 1 Yes ☐ 0 No (1080)
   If any of the shaded boxes are filled in, the subject experienced a significant asthma exacerbation.

   ➜ ***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 (P12_TERM) form. If the subject has experienced a significant asthma exacerbation and has been randomized, please complete this form and continue with the significant exacerbation packet.***

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

5. Date of significant asthma exacerbation ___ ___ / ___ ___ / ___ ___ ___ ___ (1090)
month *day* *year*

6. Did the subject seek care for the asthma exacerbation? ☐ 1 Yes ☐ 0 No (1100)

➜ ***If NO, skip to Question #9.***

7. What type of care was sought?

7a. Study Investigator? ☐ 1 Yes ☐ 0 No (1110)

If ***YES***, indicate type of contact.
☐ 1 Scheduled clinic visit
☐ 2 Unscheduled clinic visit
☐ 3 Phone contact (1120)

7b. Primary Care or Other Physician? ☐ 1 Yes ☐ 0 No (1130)

Name of physician: _____

If ***YES***, indicate type of contact.
☐ 1 Scheduled clinic visit
☐ 2 Unscheduled clinic visit
☐ 3 Phone contact (1140)

7c. Emergency Room visit? ☐ 1 Yes ☐ 0 No (1150)

Name of hospital: _____

8. Was the subject hospitalized? ☐ 1 Yes ☐ 0 No (1160)

➜ ***If YES, please complete the Serious Adverse Event (P12_SERIOUS) form .***

If ***YES***,

8a. Name of hospital: _____

8b. Duration of hospital stay? ___ ___ days (1170)

8c. Was intubation or ventilation assistance required? ☐ 1 Yes ☐ 0 No (1180)

9. Did the asthma exacerbation require treatment with inhaled, oral, or intravenous glucocorticoids? ☐ 1 Yes ☐ 0 No (1190)

➜ ***If YES, please complete the Concomitant Medications for Asthma and Allergies (P12_CMED_AS) form.***

10. Was the asthma exacerbation resolved solely by increasing PRN use of the rescue inhaler?

☐ 1 Yes ☐ 0 No (1200)

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

☐ 1 Yes ☐ 0 No (1210)

If ***NO***, describe _____

_____

_____

12. 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 (1220)

13. 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 (1230)

14. 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 (1240)

Complete Question #15 at Denver, Madison and San Francisco Only.

15. Was the significant asthma exacerbation related to the PV curve procedure? *(Check one box only)*

☐ 1 Definitely related
☐ 2 Probably related
☐ 3 Relationship undetermined
☐ 4 Probably not related
☐ 5 Definitely not related
☐ 9 N/A, PV Curve not done (1250)

Asthma Clinical Research Network
NIH/NHLBI

PRICE
ALLERGY SKIN TEST RESULTS

Subject ID: 1 2 - ___ - ___ ___ ___
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

PRICE
SPIROMETRY TESTING

Supervisor ID: ___ ___ ___ ___ ___

Subject ID: 1 2 - ___ - ___ ___ ___
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 [e.g., Allegra or Chlor-Trimeton] in the past 48 hours? ☐ 1 Yes ☐ 0 No (1030)

4b. Have you used any oral decongestants or cold remedies [e.g., pseudoephedrine (Sudafed) or oxymetazoline (Afrin)] 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 P12_EXCLDRUG reference card) to treat your asthma or allergies in the past 6 weeks? ☐ 1 Yes ☐ 0 No (1070)

   ➜ ***If YES, complete the Concomitant Medications for Asthma and Allergies (P12_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 (1080)

6. Have you had a respiratory tract infection or any other pulmonary infection since the last visit? ☐ 1 Yes ☐ 0 No (1090)

7. Is there any other reason you should not proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1100)

If ***YES***, explain _____

_____

(Clinic Coordinator completed)

8. Does the subject have evidence of oral candidiasis? ☐ 1 Yes ☐ 0 No (1110)

➜ ***If YES, complete the Clinical Adverse Events (P12_AECLIN) form and contact study investigator.***

9. Is the subject eligible to proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1120)
If any of the shaded boxes are filled in, the subject is ineligible for pulmonary function testing.

➜ ***If NO, do NOT complete the rest of this form. Testing should be rescheduled within the visit window.***

PREBRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

10. ***(If subject is > 21 years old, do not complete Question #10.)***

Height (*without shoes*) ___ ___ . ___ inches (1130)

11. Time spirometry started (*based on 24-hour clock*) ___ ___ ___ ___ (1140)

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

12. Results of best effort:

12a. FVC ___ . ___ ___ L (1150)

12b. FEV_1 ___ . ___ ___ L (1160)

12c. FEV_1 (% predicted) ___ ___ ___ % predicted (1170)

12d. PEFR ___ ___ . ___ ___ L/S (1180)

12e. FEF_{25-75} ___ . ___ ___ L/S (1190)

(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)

PRICE
SPUTUM INDUCTION
UCSF OVER-READ

Subject ID: 1 2 - ___ - ___ ___ ___
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)
➜ If ***NO***, please comment below.

_____
_____
_____
_____
_____

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)

PRICE
SPUTUM INDUCTION

Supervisor ID: ___ ___ ___ ___ ___

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

(Technician completed)

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

   ➜ ***If YES, complete Question #2.***
   ➜ ***If NO, skip to Question #3.***

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

   2a. Subject's FEV_1 after reversal from methacholine challenge ___ . ___ ___ L (1020)

   2b. Subject's FEV_1 (% predicted) after reversal from methacholine challenge ___ ___ ___ % predicted (1030)

   2c. Was the subject's FEV_1 from Question #2a ≥ the methacholine reversal reference value on page 2 of the Methacholine Challenge Testing (P12_METHA) form? ☐ 1 Yes ☐ 0 No (1040)

   ➜ ***Skip to Question #4.***

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

   3a. Subject's FEV_1 15 minutes after 4 puffs of albuterol or post maximum reversibility testing ___ . ___ ___ L (1050)

   3b. Subject's FEV_1 15 minutes after 4 puffs of albuterol or post maximum reversibility testing (% predicted) ___ ___ ___ % predicted (1060)

4. Was the subject's FEV_1 (% predicted) from Question #2b or Question #3b ≥ 60% predicted? ☐ 1 Yes ☐ 0 No (1070)

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

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

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

7. ***(If Visit 0, 3, or 4, do not complete Question #7.)***

What was the duration of sputum induction at Visit 3 (or at Visit 4, if not obtained at Visit 3)? ___ ___ . ___ minutes (1100)

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

8a. FEV_1 ___ . ___ ___ L (1110)

8b. FEV_1 (% predicted) ___ ___ ___ % predicted (1120)

8c. Time of FEV_1 in Question #8a (*based on 24-hour clock*) ___ ___ ___ ___ (1130)

8d. Percent difference in FEV_1 $\frac{(\textit{Question \#2a or \#3a - Question \#8a})}{\textit{Question \#2a or \#3a}} \times 100$ ___ ___ . ___ % (1140)

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

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

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

12. Is the sample adequate for laboratory analysis? ☐ 1 Yes ☐ 0 No (1180)

If the shaded box in Question #11 is filled in, the sputum sample is inadequate and should not be sent to the laboratory for analysis. Sputum induction should be attempted at the next scheduled visit. Continue with the rest of this form.

13. Did the subject's FEV_1 immediately after completion of sputum induction drop > 20% (from post-albuterol baseline) as indicated in Question #8d? ☐ 1 Yes ☐ 0 No (1190)

➜ ***If YES, proceed with Question #14 on the next page.***

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

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

Clinic Use Only

Sputum Induction Reversal Reference Value (Question #2a or Question #3a) x 0.90 = __ . __ __ L

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

14a. FEV_1 ___ . ___ ___ L (1200)

14b. FEV_1 (% predicted) ___ ___ ___ % predicted (1210)

14c. Time of FEV_1 from Question #14a (*based on 24-hour clock*) ___ ___ ___ ___ (1220)

14d. Was the FEV_1 from Question #14a ≥ 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 #15.***

15. Subject's final FEV_1 after sputum induction

15a. FEV_1 ___ . ___ ___ L (1240)

15b. FEV_1 (% predicted) ___ ___ ___ % predicted (1250)

15c. Time of FEV_1 from Question #15a (*based on 24-hour clock*) ___ ___ ___ ___ (1260)

15d. Was the FEV_1 from Question #15a ≥ 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 signature: _____ (1280)

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

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

Asthma Clinical Research Network
NIH/NHLBI

PRICE SUBJECT STUDY TREATMENT QUESTIONNAIRE

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

(Subject completed)

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

1. **Scheduled Inhaler**
As a PRICE 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**.

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

Subject's Initials: ___ ___ ___ (1020)

Date: ___ ___/___ ___/___ ___ ___ ___ (1030)

2. Please comment with respect to the taste of the medication you received from your **scheduled inhaler**.

☐ 1 Tasted good (1040)

(*Describe*) _____

☐ 2 No noticeable taste

☐ 3 Tasted bad

(*Describe*) _____

3. Please comment with respect to the smell of the medication you received from your **scheduled inhaler**.

☐ 1 Smelled good (1050)

(*Describe*) _____

☐ 2 No noticeable smell

☐ 3 Smelled bad

(*Describe*) _____

4. Please comment with respect to any physical sensations produced by the medication you you received from your **scheduled inhaler**.

☐ 1 Pleasant sensations (1060)

(*Describe*) _____

☐ 2 No noticeable sensations

☐ 3 Unpleasant sensations

(*Describe*) _____

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

☐ 1 I have no further comments (1070)

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

_____

_____

_____

_____

Asthma Clinical Research Network
NIH/NHLBI

PRICE
TERMINATION OF STUDY PARTICIPATION

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

(Clinic Coordinator completed)

Please indicate the reason(s) for termination of study participation.

1. ***(Visits 10 or 99 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: ___ ___ ___ (1010)
   Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (1020)

2. ***(Visits 10 or 99 Only)***
   Has the subject completed the study?
   ➜ ***If YES, skip to the SIGNATURES section on page 2.***

   ❑1 Yes ❑0 No (1030)

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 (1040)

4. ***(Non-randomized subjects only, i.e., Visits 1 - 6)***
   During the initial run-in period, has the subject experienced a significant asthma exacerbation as defined in the protocol?

   ❑1 Yes ❑0 No (1050)

5. ***(Non-randomized subjects only, i.e., Visits 1 - 6)***
   Has the subject been deemed ineligible according to any eligibility criteria **other than** a significant asthma exacerbation?

   ❑1 Yes ❑0 No (1060)

6. Has the subject withdrawn consent? ❑1 Yes ❑0 No (1070)

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 no longer willing to undergo PV curve procedure
- ❑11 other _____ (1080)

7. Has the subject been lost to follow-up? ❑1 Yes ❑0 No (1090)

8. Has the subject experienced a serious adverse event (e.g., an adverse event resulting in death or hospitalization, etc.)? ❑1 Yes ❑0 No (1100)

➜ ***If YES, complete the Serious Adverse Event Reporting (P12_SERIOUS) form.***

(Visits 6 - 10 or 99 Only)

9. Has the subject been terminated due to a significant exacerbation during the randomized treatment phase (i.e., after Visit 6)? ❑1 Yes ❑0 No (1110)

SIGNATURES

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

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

_____ (1120) ___ ___ /___ ___ /___ ___ ___ ___ (1130)

Clinic Coordinator Signature — month day year

_____ (1140) ___ ___ /___ ___ /___ ___ ___ ___ (1150)

Principal Investigator Signature — month day year

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