Asthma Clinical Research Network
NIH/NHLBI

CLINICAL AND LABORATORY ADVERSE EVENTS

(Clinic Coordinator completed)

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

Subject Initials: ___ ___ ___

Visit Number: ___ ___ ___

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

❑0 None

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

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

** Please complete the appropriate Change in Medications form.

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

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

Asthma Clinical Research Network
NIH/NHLBI

AM1® QUALITY CONTROL

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

(Technician completed)

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

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

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

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

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

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

Clinic Use Only

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

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

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

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

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

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

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

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

Asthma Clinical Research Network
NIH/NHLBI

ASTHMA HISTORY

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

(Subject Interview completed)

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

2. Think back to when a doctor first diagnosed you with asthma.

   2a. Approximately how old were you? ____ ____ years **(1010)**

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

3. How do you categorize your asthma symptoms throughout the course of the year?
   - ☐ 1 Relatively the same all year
   - ☐ 2 Vary by season(s) **(1040)**

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

   3a. Winter? ☐ 1 Yes ☐ 0 No **(1050)**
   3b. Spring? ☐ 1 Yes ☐ 0 No **(1060)**
   3c. Summer? ☐ 1 Yes ☐ 0 No **(1070)**
   3d. Fall? ☐ 1 Yes ☐ 0 No **(1080)**

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? ____ ____ **(1090)**

   4b. Hospitalizations have you had due to asthma? ____ ____ **(1100)**

   4c. Courses of oral corticosteroid therapy (eg., prednisone) for asthma have you taken? ____ ____ **(1110)**

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 **(1120)**

   ➔ If ***YES***, record your best estimate of the number of days missed. ____ ____ ____ **(1130)**

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 **(1140)**

   6b. Father ❑1 Yes ❑0 No ❑8 Don't Know **(1150)**

   6c. Brothers or Sisters ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A **(1160)**

   6d. Child(ren) ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A **(1170)**

Subject Source Documentation

Subject's Initials: __ __ __ **(1180)**

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

Asthma Clinical Research Network
NIH/NHLBI

CONCOMITANT MEDICATIONS FOR ASTHMA/ALLERGY AND ADVERSE EVENTS

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

Subject Initials: ___ ___ ___

Visit Number: ___ ___ ___

(Coordinator completed)

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

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

❑0 None

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

UNITS and FREQUENCY CODES FOR CONCOMITANT MEDICATIONS

Asthma Clinical Research Network
NIH/NHLBI

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

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

Asthma Clinical Research Network
NIH/NHLBI

eDEM™ MONITOR QUALITY CONTROL

Subject ID: ___ ___ - ___ ___ - ___ ___ ___
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 ___ ___ / ___ ___ / ___ ___ ___ ___
month *day* *year* **(1010)**

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

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

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

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

- ☐1 First issuing
- ☐2 "Old" device was recalled
- ☐3 "Old" device experiencing low voltage (< 2.90 volts)
- ☐4 "Old" device had downloading problems
- ☐5 "Old" device experienced AC adaptor failure
- ☐6 "Old" device experienced battery failure
- ☐7 "Old" device was lost
- ☐8 "Old" device validity expired
- ☐9 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

EXHALED NITRIC OXIDE

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

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

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

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

   ➔ ***If YES, proceed to Question #2 on the next page.***

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

❑1 Equipment failure, please specify

_____

_____

_____

❑2 Equipment not calibrated

❑3 Subject refusal

❑4 Clinic oversight

❑5 Other _____

(1010)

For each maneuver, record the time and FE_{NO} value. If the maneuver was not accepted by the NIOX machine, record the time and select the 'Maneuver Not Acceptable' check box. When TWO reproducible measurements are achieved, select the 'Reproducible Measurements' check box for both maneuvers. The two measurements are considered reproducible when they are within 5% of their mean or 1.25 ppb of their mean.

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

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

If ***NO***, explain _____

_____

_____

_____

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MAXIMUM REVERSIBILITY TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

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

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

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

2. Subject's FEV_1 after 4 puffs of albuterol

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

   2b. FEV_1 ___ . ___ ___ L **(1020)**

   2c. FEV_1 (% predicted) ___ ___ ___ % predicted **(1030)**

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

3. Time albuterol administered *(based on 24-hour clock)* ___ ___ ___ ___ **(1040)**

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

   4a. Time spirometry started (*based on 24-hour clock*) ___ ___ ___ ___ **(1050)**

   4b. FEV_1 ___ . ___ ___ L **(1060)**

   4c. FEV_1 (% predicted) ___ ___ ___ % predicted **(1070)**

   4d. Percent difference in FEV_1

   $$\frac{(\textit{Question \#4b - Question \#2b})}{\textit{Question \#2b}} \times 100$$ ___ ___ . ___ % **(1080)**

   4e. Is the percent difference from Question #4d ≤ 5.0%? ☐ 1 Yes ☐ 0 No **(1090)**

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

   ➔ ***If NO, administer 2 puffs of albuterol and wait 15 minutes, then perform spirometry.***

5. Time albuterol administered *(based on 24-hour clock)* ___ ___ ___ ___ **(1100)**

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

   6a. Time spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ **(1110)**

   6b. FEV_1 ___ . ___ ___ L **(1120)**

   6c. FEV_1 (% predicted) ___ ___ ___ % predicted **(1130)**

Asthma Clinical Research Network
NIH/NHLBI

METHACHOLINE CHALLENGE TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

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

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

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

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

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

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

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

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

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

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

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

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

Asthma Clinical Research Network
NIH/NHLBI

ADDITIONAL TREATMENT POST METHACHOLINE CHALLENGE TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

➔ ***If NO, skip to Question #4.***

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

➔ ***If NO, skip to Question #3b.***

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

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

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

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

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

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

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

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

4. Subject's final FEV_1 after methacholine challenge.

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

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

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

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

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

Physician Source Documentation

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

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

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

Asthma Clinical Research Network
NIH/NHLBI

METHACHOLINE CHALLENGE TESTING CHECKLIST

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

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

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

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

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

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

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

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

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

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

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

   _____ **(1055)**

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

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

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

Asthma Clinical Research Network
NIH/NHLBI

MIA
ACTH STIMULATION TESTS

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. In the past, has the subject had an ACTH stimulation test performed? ❑1 Yes ❑0 No **(1000)**

   1a. If ***YES***, has the subject had a reaction to the test? ❑1 Yes ❑0 No **(1010)**

   ➔ ***If YES, the ACTH test cannot be performed and the subject cannot continue in the study. Complete the MIA Termination of Study Participation (P15_TERM) form and follow study termination procedures.***

2. Is the subject currently pregnant? (If subject is male, check N/A) ❑1 Yes ❑0 No ❑9 N/A **(1020)**

   ➔ ***If YES, the subject must be terminated from the study. Complete the MIA Termination of Study Participation (P15_TERM) form and follow study termination procedures.***

3. Time blood was drawn for "Baseline Cortisol" tube *(based on 24-hour clock)* ___ ___ ___ ___ **(1030)**

4. Record subject's baseline cortisol level ___ ___ . ___ ___ mcg/dL **(1040)**

5. Time blood was drawn for "30 Minute Post ACTH Cortisol" tube *(based on 24-hour clock)* ___ ___ ___ ___ **(1050)**

6. Record subject's 30 minute post-ACTH cortisol level ___ ___ . ___ ___ mcg/dL **(1060)**

7. Time blood was drawn for "60 Minute Post ACTH Cortisol" tube *(based on 24-hour clock)* ___ ___ ___ ___ **(1070)**

8. Record subject's 60 minute post-ACTH cortisol level ___ ___ . ___ ___ mcg/dL **(1080)**

9. Is the value in Question #6 or Question #8 ≥ 20 mcg/dL? ❑1 Yes ❑0 No **(1090)**

   ➔ ***If NO, the subject cannot continue in the study. Complete the MIA Termination of Study Participation (P15_TERM) form and follow study termination procedures.***

Physician Source Documentation
Physician Signature: _____ **(1100)**
Date: __ __ / __ __ / __ __ __ __ **(1110)**

MIA
BRONCHOSCOPY

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 4
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Time Obtained *(based on 24-hour clock)* ___ ___ ___ ___ **(1000)**

Biopsy Sample Ranking	**Location**
1	❑1 RML ❑2 RLL ❑3 RUL ❑4 LLL ❑5 LUL ❑6 LINGULA ❑7 Not Collected **(1010)**
2	❑1 RML ❑2 RLL ❑3 RUL ❑4 LLL ❑5 LUL ❑6 LINGULA ❑7 Not Collected **(1020)**
3	❑1 RML ❑2 RLL ❑3 RUL ❑4 LLL ❑5 LUL ❑6 LINGULA ❑7 Not Collected **(1030)**
4	❑1 RML ❑2 RLL ❑3 RUL ❑4 LLL ❑5 LUL ❑6 LINGULA ❑7 Not Collected **(1040)**
5	❑1 RML ❑2 RLL ❑3 RUL ❑4 LLL ❑5 LUL ❑6 LINGULA ❑7 Not Collected **(1050)**
6	❑1 RML ❑2 RLL ❑3 RUL ❑4 LLL ❑5 LUL ❑6 LINGULA ❑7 Not Collected **(1060)**
7	❑1 RML ❑2 RLL ❑3 RUL ❑4 LLL ❑5 LUL ❑6 LINGULA ❑7 Not Collected **(1070)**
8	❑1 RML ❑2 RLL ❑3 RUL ❑4 LLL ❑5 LUL ❑6 LINGULA ❑7 Not Collected **(1080)**

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MIA BRONCHOSCOPY BIOPSY RESULTS

Date Completed: ___ ___ / ___ ___ / ___ ___
Month / Day / Year

(Technician completed)

Instructions: Fax to Rosanne Pogash at the ACRN DCC at (717) 531-5779. Under Bronchoscopy PCR Assignment, Not Adequate should only be assigned if it is the final result.

Subject ID	Bronchoscopy PCR Assignment		
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$
___ ___ - ___ ___ - ___ ___ ___	$Positive_A$	$Negative_B$	$Not\ Adequate_C$

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MIA BRONCHOSCOPY CHECKLIST

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 4
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

The Bronchoscopy procedure and its related risks must be reviewed again at this visit. The subject must initial and date the appropriate consent to confirm that the bronchoscopy procedure has been reviewed one more time and that he/she is willing to undergo the procedure.

1.	Is the subject's postbronchodilator $FEV_1 \geq 60\%$ predicted after 4 puffs of albuterol?	☐ 1 Yes	☐ 0 No	**(1000)**
2.	Are any of the coagulation parameters out of range and preventing the subject to be eligible for bronchoscopy?	☐ 1 Yes	☐ 0 No	**(1010)**
3.	Within the last **6 months**, has the subject had intubation for asthma?	☐ 1 Yes	☐ 0 No	**(1020)**
4.	Within the last **6 months**, has the subject had more than 12 asthma exacerbations?	☐ 1 Yes	☐ 0 No	**(1030)**
5.	Within the last **6 weeks**, has the subject been hospitalized for asthma?	☐ 1 Yes	☐ 0 No	**(1040)**
6.	Within the last **6 weeks**, has the subject had a respiratory tract infection?	☐ 1 Yes	☐ 0 No	**(1050)**
7.	Within the last **48 hours**, did the subject experience an increase in cough, phlegm/mucus, chest tightness, wheezing, or shortness of breath along with an increase in rescue inhaler use of ≥ 8 puffs per 24 hours over baseline use?	☐ 1 Yes	☐ 0 No	**(1060)**
8.	Within the last **48 hours**, did the subject use an average of ≥ 16 puffs per 24 hours from his/her rescue inhaler?	☐ 1 Yes	☐ 0 No	**(1070)**
9.	Is the subject's pulse oximetry demonstrating oxygen saturation of < 90% on room air?	☐ 1 Yes	☐ 0 No	**(1080)**

10.	Is the subject eligible to proceed with the bronchoscopy procedure? ***If any of the shaded boxes are completed, the subject is ineligible for the bronchoscopy procedure.***	☐ 1 Yes	☐ 0 No	**(1090)**

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

➔ ***If NO, and the subject is not eligible due to Question #1 or #9 only, STOP HERE. DO NOT send this form to the DCC and reschedule Visit 4. If the subject is ineligible for any other reason, complete the MIA Termination of Study Participation (P15_TERM) form.***

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MIA CLINIC COORDINATOR STUDY TREATMENT QUESTIONNAIRE (Visits 5-9)

Subject ID: 1 5 - __ __ - __ __ __
Subject Initials: __ __ __
Visit Number: __ __
Visit Date: __ __ / __ __ / __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __ __

(Clinic Coordinator completed)

This questionnaire is to be completed at Visit 9 by the ACRN study coordinator who was primarily responsible for the subject's MIA visits during the preceding 16 weeks. If a randomized subject terminates prior to Visit 9, this form should be completed at the time of the termination visit.

1. Blinded Scheduled Pills

Subjects in the MIA study were randomized to receive either active clarithromycin pills or placebo pills. 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 (Visit 5 through Visit 9)**.

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

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

_____

_____

_____

_____

Clinic Coordinator Source Documentation

Coordinator's Initials: __ __ __ **(1020)**

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

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MIA
CHANGE IN MEDICATIONS

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

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

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

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

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

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

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

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

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

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

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

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

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

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MIA CLARITHROMYCIN BLOOD DRAW

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Did the subject take the study pill on the morning of the visit? ❑ 1 Yes ❑ 0 No **(1000)**

2. Record the date the subject last took the study pill ___ ___ / ___ ___ / ___ ___ ___ ___ **(1010)** (month / day / year)

3. Record the time the subject last took the study pill *(based on 24-hour clock)* ____ ____ ____ ____ **(1020)**

4. Record the date the blood for Clarithromycin concentration was drawn ___ ___ / ___ ___ / ___ ___ ___ ___ **(1030)** (month / day / year)

5. Record the time the blood for Clarithromycin concentration was drawn *(based on 24-hour clock)* ____ ____ ____ ____ **(1040)**

Asthma Clinical Research Network
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MIA COMPLIANCE CHECKLIST

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Check the following compliance criteria at all scheduled Visits 2 - 9.

1. **Pill Count**

1a. Number of pills dispensed in eDEM™ vial ___ ___ ___ pills **(1000)**

➔ Value obtained from vial label

1b. Number of pills returned in eDEM™ vial ___ ___ ___ pills **(1010)**

1c. Actual number of pills taken (Question #1a - Question #1b) ___ ___ ___ pills **(1020)**

1d. Number of prescribed doses ___ ___ ___ doses **(1030)**

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

➔ ***If the percent compliance for the Pill Count is less than 75%, re-emphasize the importance of maintaining the daily dosing schedule.***

2. **eDEM™ Monitor**

At all visits, the information for Questions #2a - #2d is obtained from the eDEM™ Monitor Report.

2a. Number of monitored days ___ ___ ___ days **(1050)**

2b. Number of doses taken ___ ___ ___ doses **(1060)**

2c. % Prescribed number of doses taken ___ ___ ___ . ___ % **(1070)**

2d. Doses in time window/prescribed doses (Percent compliance) ___ ___ ___ . ___ % **(1080)**

➔ ***If the percent compliance for the eDEM™ is less than 75%, re-emphasize the importance of maintaining the daily dosing schedule.***

Check the following compliance criteria at all scheduled Visits 2 - 11.

3. **Doser™ Compliance for Flovent® MDI**

If the interval between visits exceeds 30 days, complete Questions #3a - #3c using data for the 30 days prior to the visit.

3a. Total number of full days since the last visit ___ ___ days **(1090)**

➔ Value obtained from Question #4 on P15_COMPLY_WKS

3b. Total number of compliant days ___ ___ days **(1100)**

➔ Value obtained from Question #5 on P15_COMPLY_WKS

3c. Percent compliance = $\frac{\textit{Question \#3b}}{\textit{Question \#3a}} \times 100$ ___ ___ ___ . ___ % **(1110)**

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

3d. Total number of scheduled puffs since the last visit ___ ___ ___ puffs **(1120)**

➔ Value obtained from Question #1 on P15_COMPLY_WKS

3e. Total number of puffs in Doser™ history ___ ___ ___ puffs **(1130)**

➔ Value obtained from Question #2 on P15_COMPLY_WKS

3f. Percent compliance = $\frac{\textit{Question \#3e}}{\textit{Question \#3d}} \times 100$ ___ ___ ___ . ___ % **(1140)**

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

4. **Diary Card Compliance**

4a. Total number of full days since the last visit ___ ___ ___ days **(1150)**

4b. Total number of days where all 3 measurements (AM PEFR, PM PEFR, and complete symptom score) have been recorded ___ ___ ___ days **(1160)**

4c. Percent compliance = $\frac{\textit{Question \#4b}}{\textit{Question \#4a}}$ *x 100* ___ ___ ___ . ___ % **(1170)**

4d. Total number of days where the subject measured both AM PEFR and PM PEFR on schedule and transcribed the measurements accurately on his/her diary cards ___ ___ ___ days **(1180)**

4e. Percent compliance on schedule = $\frac{\textit{Question \#4d}}{\textit{Question \#4a}}$ *x 100* ___ ___ ___ . ___ % **(1190)**

➔ ***If the percent compliance for either Question #4c or #4e is less than 75%, re-emphasize the importance of accurately and regularly completing diary cards.***

Asthma Clinical Research Network
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MIA DIARY CARD

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

Subject ID: 15-___-_____
Subject Initials: ___
Return Visit Number: ___
Return Visit Date: ___/___/___ (Month / Day / Year)

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

Please use black ink to complete.	Day 1: ____	Day 2: ____	Day 3: ____	Day 4: ____	Day 5: ____	Day 6: ____	Day 7: ____
Date (ddate)	___/___ month day	___/___ month day	___/___ month day	___/___ month day	___/___ month day	___/___ month day	___/___ month day
MORNING EVALUATION (Between 5 AM and 10 AM)							
1. Number of times you woke up last night due to asthma (1010)	___	___	___	___	___	___	___
2. Time of AM Peak Flow (within 15 minutes of awakening) (1020)	__:__	__:__	__:__	__:__	__:__	__:__	__:__
3. AM Peak Flow (liters/min)** (1030)/(1035)	___	___	___	___	___	___	___
4. Total number of puff(s) from Flovent® Inhaler **(AM)** (1040)	___	___	___	___	___	___	___
5. Number of pill(s) taken **(AM)** (1050)	___	___	___	___	___	___	___
Symptoms++ during the night — 6. Shortness of Breath (1060)							
7. Chest Tightness (1070)							
8. Wheezing (1080)							
9. Cough (1090)							
10. Phlegm/Mucus (1100)							
NIGHT-TIME EVALUATION (Between 8 PM and 1 AM)							
11. Time of PM Peak Flow (between 8 PM and 1 AM) (1110)	__:__	__:__	__:__	__:__	__:__	__:__	__:__
12. PM Peak Flow (liters/min)** (1120)/(1125)	___	___	___	___	___	___	___
13. Total number of puff(s) from Flovent® Inhaler **(PM)** (1130)	___	___	___	___	___	___	___
14. Number of pill(s) taken **(PM)** (1140)	___	___	___	___	___	___	___
Symptoms++ since you woke — 15. Shortness of Breath (1150)							
16. Chest Tightness (1160)							
17. Wheezing (1170)							
18. Cough (1180)							
19. Phlegm/Mucus (1190)							
24 HOUR EVALUATION							
20. Total number of puffs from albuterol (RESCUE) inhaler during past 24 hours. *(Do not record preventive use.)* (1200)	___	___	___	___	___	___	___

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

++ Symptom Severity Rating Scale

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

Asthma Clinical Research Network
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MIA DIARY CARD

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

Subject ID: 1 5 - ___ - ___
Subject Initials: ___
Return Visit Number: ___
Return Visit Date: ___ / ___ / ___ (Month / Day / Year)

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

Please use black ink to complete.	Day 1: ____	Day 2: ____	Day 3: ____	Day 4: ____	Day 5: ____	Day 6: ____	Day 7: ____
Date (ddate)	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day
MORNING EVALUATION (Between 5 AM and 10 AM)							
1. Number of times you woke up last night due to asthma (1010)	___	___	___	___	___	___	___
2. Time of AM Peak Flow (within 15 minutes of awakening) (1020)	__ : __	__ : __	__ : __	__ : __	__ : __	__ : __	__ : __
3. AM Peak Flow (liters/min)** (1030) / (1035)	___	___	___	___	___	___	___
4. Total number of puff(s) from Flovent® Inhaler **(AM)** (1040)	___	___	___	___	___	___	___
Symptoms++ during the night — 5. Shortness of Breath (1060)							
6. Chest Tightness (1070)							
7. Wheezing (1080)							
8. Cough (1090)							
9. Phlegm/Mucus (1100)							
NIGHT-TIME EVALUATION (Between 8 PM and 1 AM)							
10. Time of PM Peak Flow (between 8 PM and 1 AM) (1110)	__ : __	__ : __	__ : __	__ : __	__ : __	__ : __	__ : __
11. PM Peak Flow (liters/min)** (1120) / (1125)	___	___	___	___	___	___	___
12. Total number of puff(s) from Flovent® Inhaler **(PM)** (1130)	___	___	___	___	___	___	___
Symptoms++ since you woke — 13. Shortness of Breath (1150)							
14. Chest Tightness (1160)							
15. Wheezing (1170)							
16. Cough (1180)							
17. Phlegm/Mucus (1190)							
24 HOUR EVALUATION							
18. Total number of puffs from albuterol (RESCUE) inhaler during past 24 hours. *(Do not record preventive use.)* (1200)	___	___	___	___	___	___	___

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

++ Symptom Severity Rating Scale

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

Asthma Clinical Research Network
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MIA EXHALED BREATH CONDENSATE COLLECTION

Supervisor ID: ___ ___ ___ ___ ___ ___

Subject ID: 1 5 - ___ ___ - ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: ___ ___

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

Technician ID: ___ ___ ___ ___ ___ ___

(Technician Completed)

1. Was EBC collection attempted at this visit? ❑1 Yes ❑0 No **(1000)**

   ➔ ***If NO, complete Question #1a and STOP.***
   ➔ ***If YES, proceed to Question #2.***

   1a. Check the primary reason EBC collection was not attempted.
   ❑1 Subject Refusal
   ❑2 Equipment Unavailable
   ❑3 Clinic Oversight
   ❑4 Other_____ **(1010)**

2. Time EBC collection started (based on 24-hour clock). ___ ___ ___ ___ **(1020)**

3. Time EBC collection stopped (based on 24-hour clock). ___ ___ ___ ___ **(1030)**

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

_____

_____

_____

_____

_____

4. Was at least one tube collected at this visit? ❑1 Yes ❑0 No **(1040)**

   ➔ ***If NO, STOP HERE.***

   4a. If ***YES***, record the number of tubes aliquoted. ___ tubes **(1050)**

5. Were the tubes stored immediately at -70° Celsius or colder? ❑1 Yes ❑0 No **(1060)**

   ➔ ***If YES, STOP HERE.***

   5a. At what temperature were the tubes stored? ___ ___ ___ ° C **(1070)**

Asthma Clinical Research Network
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MIA ELECTROCARDIOGRAM (ECG)

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Record subject's QTc measurement ___ ___ ___ msec **(1000)**

   1a. If FEMALE, is Question #1 ≥ 450 msec? ☐ 1 Yes ☐ 0 No **(1010)**

   1b. If MALE, is Question #1 ≥ 430 msec? ☐ 1 Yes ☐ 0 No **(1020)**

2. Did the physician observe any other ECG result that would prevent the subject from taking clarithromycin for 16 weeks and/or having a bronchoscopy? ☐ 1 Yes ☐ 0 No **(1030)**

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

   _____

   _____

   _____

3. Are any of the shaded boxes completed? ☐ 1 Yes ☐ 0 No **(1040)**

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

   ➔ ***If NO, complete the MIA Termination of Study Participation (P15_TERM) form and follow study termination procedures.***

Physician Source Documentation

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

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

Asthma Clinical Research Network
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MIA ELIGIBILITY CHECKLIST 1

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___ ___

(Subject Interview completed)

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

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

2. Is the subject willing to undergo fiberoptic bronchoscopy with endobronchial biopsy for the PCR status determination? ☐1 Yes ☐0 No **(1020)**

3. Is the subject willing to give blood for safety variable measurements? ☐1 Yes ☐0 No **(1030)**

4. Is the subject between 18 and 60 years of age, inclusive? ☐1 Yes ☐0 No **(1040)**

5. Is the subject planning to move away from this clinical center in the next 9 months such that his/her ability to complete the study will be jeopardized? ☐1 Yes ☐0 No **(1050)**

6. Does the subject have current evidence of any of the conditions listed on the Exclusionary Medical Conditions reference card (P15_EXCLMED)? ☐1 Yes ☐0 No **(1060)**

   If ***YES***, describe _____

7. Has the subject taken any medications listed on the Exclusionary Drugs reference card (P15_EXCLDRUG) within the specified time periods? ☐1 Yes ☐0 No **(1070)**

   If ***YES***, describe _____

8. Is the subject currently taking any medications listed on the Clarithromycin Exclusionary Drugs reference card (P15_CLAR_EXCLD)? ☐1 Yes ☐0 No **(1080)**

   If ***YES***, describe _____

9. Is the subject currently taking prescription or over-the-counter medication(s) other than those listed on the Allowed Medications reference card (P15_MEDALLOW)? ☐1 Yes ☐0 No **(1090)**

   If ***YES***, describe _____

   ➔ ***If YES and the drug is not listed on an exclusionary reference card (P15_EXCLDRUG, P15_CLAR_EXCLD), please contact the scientific coordinator to determine if the medication will be allowed.***

10. Has the subject used systemic corticosteroids during the past 6 weeks? ☐1 Yes ☐0 No **(1100)**

11.	Has the subject had a change in the dose of controller therapy or therapies during the past 6 weeks?	☐ 1 Yes	☐ 0 No **(1110)**
12.	Is the subject currently receiving hyposensitization therapy (e.g., allergy shots) other than an established maintenance regimen implemented continuously for a minimum of 3 months?	☐ 1 Yes	☐ 0 No **(1120)**
13.	Has the subject used any smokeless tobacco products (e.g., chew, snuff) in the past year?	☐ 1 Yes	☐ 0 No **(1130)**
14.	Has the subject smoked a pipe, cigar, marijuana, or any other substance in the past year?	☐ 1 Yes	☐ 0 No **(1140)**
15.	Record smoking history in pack-years. (Enter '00.0' if none)	___ ___ . ___ **(1150)**	
	15a. Is Question #15 ≥ 10?	☐ 1 Yes	☐ 0 No **(1160)**
16.	Has the subject had a respiratory tract infection in the past 6 weeks?	☐ 1 Yes	☐ 0 No **(1170)**
17.	Has the subject experienced a significant asthma attack in the past 6 weeks?	☐ 1 Yes	☐ 0 No **(1180)**
18.	Has the subject been hospitalized for asthma in the past 6 weeks?	☐ 1 Yes	☐ 0 No **(1190)**
19.	Has the subject had more than 12 asthma exacerbations in the past 6 months?	☐ 1 Yes	☐ 0 No **(1200)**
20.	Has the subject experienced a life-threatening asthma attack requiring intubation or mechanical ventilation in the past 10 years?	☐ 1 Yes	☐ 0 No **(1210)**
21.	Does the subject work night shift or have an altered day/night cycle for other reasons?	☐ 1 Yes	☐ 0 No **(1220)**
22.	Does the subject regularly consume grapefruit or grapefruit juice?	☐ 1 Yes	☐ 0 No **(1230)**
	22a. If ***YES***, is the subject willing to withhold consumption of grapefruit or grapefruit juice throughout the MIA study?	☐ 1 Yes	☐ 0 No **(1240)**

23. Is the subject eligible to proceed? ☐ 1 Yes ☐ 0 No **(1250)**

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

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

Subject Source Documentation

Subject Initials: __ __ __ **(1260)**

Date: __ __ / __ __ / __ __ __ __ **(1270)**

Asthma Clinical Research Network
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MIA ELIGIBILITY CHECKLIST 2

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Record the subject's Average Score from the ACQ_JUN_SCORE form — ___ . ___ ___ **(1000)**

   1a. Prior to Visit 1, was the subject on the controller therapy of ICS only or ICS/LABA? — ☐ 1 Yes ☐ 0 No **(1003)**

   ➔ ***If NO, skip to Question #1b.***

   1ai. Is Question #1 ≥ 1.25 OR in the opinion of the local investigator/clinic coordinator does the subject have a reasonable chance to have an ACQ score ≥ 1.25 at Visit 3? — ☐ 1 Yes ☐ 0 No **(1006)**

   ➔ ***Skip to Question #2.***

   1b. Is Question #1 ≥ 1.50? — ☐ 1 Yes ☐ 0 No **(1010)**

2. Is the subject's postbronchodilator $FEV_1 \geq 60\%$ predicted after two puffs of albuterol? — ☐ 1 Yes ☐ 0 No **(1020)**

3. According to the ECG results, is the subject eligible to enroll in the MIA study? — ☐ 1 Yes ☐ 0 No **(1030)**

   ➔ Use Question #3 from the P15_ECG form to answer this question

4. Is the subject potentially able to bear children? (If subject is male, check N/A and go to Question #5.) — ☐ 1 Yes ☐ 0 No ☐ 9 N/A **(1040)**

   4a. If ***YES***, is the subject currently pregnant or lactating? — ☐ 1 Yes ☐ 0 No **(1050)**

   4b. If ***YES***, is the subject using an approved birth control method indicated on the Birth Control (BIRCTRL) reference card? — ☐ 1 Yes ☐ 0 No **(1060)**

   ➔ The subject must use one non-barrier method with single barrier method <u>OR</u> double barrier method.

5. Is the subject able to use a metered dose inhaler (MDI) properly, as evidenced by achieving a score of 6 on two consecutive, separate inhalations using the MDI Inhalation Technique Checklists (SCORE, TECH_MDI)? — ☐ 1 Yes ☐ 0 No **(1070)**

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

7. Is there any other reason why this subject should not be included in the study? ☐ 1 Yes ☐ 0 No **(1090)**

   ➔ If ***YES***, describe: _____

8. Is the subject eligible to proceed? ☐ 1 Yes ☐ 0 No **(1100)**
   If any of the shaded boxes are completed, the subject is ineligible.

   ➔ ***If NO, STOP HERE.***

9. Did the subject's FEV_1 improve $\geq$ 12% in response to two puffs of albuterol? ☐ 1 Yes ☐ 0 No **(1110)**

   ➔ ***If NO, the subject will have to meet methacholine criteria at Visit 2 to complete eligibility for the study. Proceed with Visit 1 according to the checklist.***

Asthma Clinical Research Network
NIH/NHLBI

MIA ELIGIBILITY CHECKLIST 3

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 2
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Since Visit 1, did the subject experience a significant asthma exacerbation? ☐ 1 Yes ☐ 0 No **(1000)**

2. Since Visit 1, has the subject had a respiratory tract infection? ☐ 1 Yes ☐ 0 No **(1010)**

3. At Visit 1, did the subject's FEV_1 improve $\geq$ 12% in response to two puffs of albuterol? (Question #9 on P15_ELIG2) ☐ 1 Yes ☐ 0 No **(1020)**

   ➔ If ***YES***, proceed to Question #5.

4. Does the subject have a methacholine PC20 $\leq$ 16 mg/ml? ☐ 1 Yes ☐ 0 No **(1030)**

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

   ➔ ***If NO, complete the MIA Termination of Study Participation (P15_TERM) form.***
   ➔ ***If YES, continue with remaining visit procedures.***

Asthma Clinical Research Network
NIH/NHLBI

MIA ELIGIBILITY CHECKLIST 4

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 3
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Since Visit 1, has the subject received treatment with any excluded medications (P15_EXCLDRUG, P15_CLAR_EXCLD)? ☐ 1 Yes ☐ 0 No **(1000)**

2. Since Visit 2, did the subject experience a significant asthma exacerbation? ☐ 1 Yes ☐ 0 No **(1010)**

3. Since Visit 2, has the subject had a respiratory tract infection? ☐ 1 Yes ☐ 0 No **(1020)**

4. Record the subject's Average Score from the ACQ_JUN_SCORE form ___ . ___ ___ **(1030)**

   4a. Is Question #4 ≥ 1.25? ☐ 1 Yes ☐ 0 No **(1040)**

5. Using the pill count, did the subject take at least 75% of the required pills from his or her pill vial during the interval between Visits 2 and 3? ☐ 1 Yes ☐ 0 No **(1050)**

   ➔ Use Question #1e from P15_COMPLY to answer this question

6. Using the eDEM™ Monitor, did the subject take at least 75% of the required pills at the correct time-window during the interval between Visits 2 and 3? ☐ 1 Yes ☐ 0 No **(1060)**

   ➔ Use Question #2d from P15_COMPLY to answer this question

7. Using the history stored in the Doser™, did the subject take 4 puffs per day (correct daily dose) on at least 75% of the days during the interval between Visits 2 and 3? ☐ 1 Yes ☐ 0 No **(1070)**

   ➔ Use Question #3c from P15_COMPLY to answer this question

8. Using the history stored in the Doser™, did the subject take at least 75% of the required puffs from his or her Flovent® inhaler during the interval between Visits 2 and 3? ☐ 1 Yes ☐ 0 No **(1080)**

   ➔ Use Question #3f P15_COMPLY to answer this question

9. Did the subject record both AM and PM peak flow measurements and symptoms on his or her Diary Cards (P15_DIARY) on at least 75% of the days during the interval between Visits 2 and 3? ☐ 1 Yes ☐ 0 No **(1090)**

   ➔ Use Question #4c from P15_COMPLY to answer this question

10. Did the subject measure his or her AM and PM peak flow on schedule and accurately transcribe the measurements on his or her Diary Cards (P15_DIARY) on at least 75% of the days during the interval between Visits 2 and 3? ☐ 1 Yes ☐ 0 No **(1100)**

    ➔ Use Question #4e from P15_COMPLY to answer this question

11. Is the subject's postbronchodilator $FEV_1 \geq 60\%$ of predicted after four puffs of albuterol? ☐ 1 Yes ☐ 0 No **(1110)**

12. Is the subject able to use a metered dose inhaler (MDI) properly, as evidenced by achieving a score of 6 on two consecutive, separate inhalations using the MDI Inhalation Technique Checklist (SCORE, TECH_MDI)? ☐ 1 Yes ☐ 0 No **(1120)**

13. Is the subject able to use the AM1® device correctly, as evidenced by achieving a satisfactory rating on the AM1® Performance Checklist (PERF_AM1)? ☐ 1 Yes ☐ 0 No **(1130)**

14. Does the subject wish to withdraw consent from the study? ☐ 1 Yes ☐ 0 No **(1140)**

15. Is there any new information that makes the subject ineligible according to the eligibility criteria? ☐ 1 Yes ☐ 0 No **(1150)**
    If ***YES,*** describe: _____

16. Is there any other reason why this subject should not be included in the study? ☐ 1 Yes ☐ 0 No **(1160)**
    If ***YES,*** describe: _____

17. Is the subject eligible? ☐ 1 Yes ☐ 0 No **(1170)**
    If any of the shaded boxes are completed, the subject is ineligible.

    ➔ ***If NO, complete the MIA Termination of Study Participation (P15_TERM) form.***
    ➔ ***If YES, proceed with remaining Visit 3 procedures.***

Asthma Clinical Research Network
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MIA ELIGIBILITY CHECKLIST 5

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 5
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Since Visit 4, has the subject had a respiratory tract infection? ❑1 Yes ❑0 No **(1000)**

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

   1a. If ***YES***, has the subject been free of infection-related symptoms for at least **6** weeks prior to Visit 5? ❑1 Yes ❑0 No **(1010)**

   ➔ If ***NO,*** STOP HERE. DO NOT send this form to the DCC and reschedule Visit 5.

2. Since Visit 4, has the subject experienced a significant asthma exacerbation as defined in the protocol? ❑1 Yes ❑0 No **(1020)**

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

   2a. Has the subject received prednisone therapy? ❑1 Yes ❑0 No **(1030)**

   ➔ If ***NO*** and the subject has NOT recovered, prednisone therapy should be prescribed and Visit 5 should be rescheduled **6** weeks after the last dose of prednisone.

   ➔ If ***NO,*** and the subject has recovered, skip to Question #3.

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

   2aii. Was the last dose taken at least 6 weeks prior to today's date? ❑1 Yes ❑0 No **(1050)**

   ➔ If ***NO***, STOP HERE. DO NOT send this form to the DCC and reschedule Visit 5 as above.

3. Record the subject's Average Score from the ACQ_JUN_SCORE form ___ . ___ ___ **(1060)**

   3a. In the opinion of the ACRN investigator, has the subject's clinical status and ACQ returned to the level similar to that observed during Visits 1 through 3? ❑1 Yes ❑0 No **(1070)**

   3ai. Obtain the signature of the ACRN investigator who evaluated the subject. _____ **(1075)**

4. Is the subject's FEV_1 < 80% of the baseline? ❑1 Yes ❑0 No **(1080)**

   ➔ Baseline is defined as the pre-bronchodilator FEV_1 value obtained at Visit 2.

5. Since Visit 4, has the subject received treatment with any excluded medications (P15_EXCLDRUG, P15_CLAR_EXCLD)? ☐ 1 Yes ☐ 0 No **(1090)**

6. Since Visit 4, has the subject experienced > 2 significant asthma exacerbations? ☐ 1 Yes ☐ 0 No **(1100)**

7. Since Visit 4, has the subject had > 2 respiratory tract infections? ☐ 1 Yes ☐ 0 No **(1110)**

8. Did the clinic receive confirmation via the Subject Status report that the subject is eligible for randomization? ☐ 1 Yes ☐ 0 No **(1120)**

   ➔ If ***NO,*** reschedule Visit 5.

9. Is there any new information that makes the subject ineligible according to the eligibility criteria? ☐ 1 Yes ☐ 0 No **(1130)**

   ➔ If ***YES***, describe: _____

10. Is there any other reason why this subject should not be included in the study? ☐ 1 Yes ☐ 0 No **(1140)**

    ➔ If ***YES***, describe: _____

11. Is the subject eligible? ☐ 1 Yes ☐ 0 No **(1150)**
    If any of the shaded boxes are completed, the subject is ineligible.

    ➔ ***If the subject is eligible and will participate in MIA, randomize the subject. Otherwise, please complete the MIA Termination of Study Participation (P15_TERM) form.***

12. Drug Packet Number **(record on P15_LOG)**

    1 5 - ___ - ___
    (1160) (1170) (1180)

Asthma Clinical Research Network
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MIA
FLUID PHASE MEASUREMENTS

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Completed Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___ ___

(Technician completed)

		Non-detectable limit	Quantity not sufficient to dilute
Tryptase	___ ___ ___ . ___ mcg/L **(1000)**	❑ **(1010)**	❑ **(1020)**

Complete at Visit 3 Only

IL-10	___ ___ ___ . ___ pg/ml **(1030)**	❑ **(1040)**	❑ **(1050)**

Asthma Clinical Research Network
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MIA LABORATORY SAFETY CHECKLIST

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

(Visits 1, 3, 6-9 only)

		Lab Value Out of Range
1. CBC with differential cell count		
1a. Eosinophils (absolute count)	___ ___ ___ ___ /mm^3 **(1000)**	☐$_1$ **(1010)**
1b. WBC	___ ___ ___ . ___ K/uL **(1020)**	☐$_1$ **(1030)**
1c. HCT	___ ___ . ___ % **(1040)**	☐$_1$ **(1050)**
1d. HGB	___ ___ . ___ g/dL **(1060)**	☐$_1$ **(1070)**
1e. Platelet Count	___ ___ ___ K/uL **(1080)**	☐$_1$ **(1090)**
1f. Differential		
1fi. Lymphocytes	___ ___ . ___ % **(1100)**	☐$_1$ **(1110)**
1fii. Monocytes	___ ___ . ___ % **(1120)**	☐$_1$ **(1130)**
1fiii. Basophils	___ ___ . ___ % **(1140)**	☐$_1$ **(1150)**
1fiv. Neutrophils	___ ___ . ___ % **(1160)**	☐$_1$ **(1170)**
1fv. Eosinophils	___ ___ . ___ % **(1180)**	☐$_1$ **(1190)**

(Visits 1, 6-9 only)

2. Liver Function Test (LFT)		
2a. AST	___ ___ ___ U/L **(1200)**	☐$_1$ **(1210)**
2b. ALT	___ ___ ___U/L **(1220)**	☐$_1$ **(1230)**
2c. Total Bilirubin	___ ___ . ___ mg/dL **(1240)**	☐$_1$ **(1250)**
2d. Total Alkaline Phosphatase	___ ___ ___ ___ U/L **(1260)**	☐$_1$ **(1270)**
3. Mg^{++}	___ ___ . ___ mg/dL **(1280)**	☐$_1$ **(1290)**
4. K^{+}	___ ___ . ___ mmol/L **(1300)**	☐$_1$ **(1310)**
5. BUN + Creatinine		
5a. BUN	___ ___ ___ mg/dL **(1320)**	☐$_1$ **(1330)**
5b. Creatinine	___ ___ . ___ mg/dL **(1340)**	☐$_1$ **(1350)**

6. Are any lab values out of range? ☐ 1 Yes ☐ 0 No **(1360)**

   ➔ ***If NO, STOP HERE.***

   ➔ ***If YES, the supervising physician must evaluate the results immediately.***

   6a. If YES, does the subject need to be evaluated? ☐ 1 Yes ☐ 0 No **(1370)**

   ➔ ***If YES, the subject must be evaluated by the supervising physician within 24 hours.***

(Physician completed)

7. Is the subject allowed to continue in the study? ☐ 1 Yes ☐ 0 No **(1380)**

   ➔ ***If NO, the subject cannot continue in the study. Complete the MIA Termination of Study Participation (P15_TERM) form and follow study termination procedures.***

Physician Source Documentation

Physician Signature: _____ **(1390)**

Date: __ __ / __ __ / __ __ __ __ **(1400)**

Asthma Clinical Research Network
NIH/NHLBI

MIA SCHEDULED MEDICATIONS (Visits 5 - 8)

Subject ID: 1 5 - __ __ - __ __ __
Subject Initials: __ __ __
Visit Number: __ __
Visit Date: __ __ / __ __ / __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __ __

(Clinic Coordinator completed)

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

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

2. Number of Flovent® MDIs dispensed
   - ❑ 0 None
   - ❑ 1 One
   - ❑ 2 Two **(1010)**

3. Number of Scheduled Pill Vials dispensed
   - ❑ 0 None
   - ❑ 1 One **(1020)**

Affix the drug log label below:

Copy the drug label number below:

1 5 - __ __ - __ __
(1030) (1040) (1050)

Coordinator's Signature: _____ **(1060)**
Date: __ __ / __ __ / __ __ __ __ **(1070)**

By signing in the source documentation box you are:

1) confirming that the label on the medications matches the number on the outside of the packet and the outside of the kit.
2) confirming that the subject name and ID number written on the outside of the kit correspond to the person receiving the medications.
3) confirming that the correct medications were distributed at this visit.

Asthma Clinical Research Network
NIH/NHLBI

MIA
MEDICAL HISTORY

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Subject Interview completed)

1. When your first asthma symptoms began, was it immediately after or as a result of a respiratory infection such as a cold or pneumonia? ❑1 Yes ❑0 No ❑8 Don't Know **(1000)**

2. Have you ever had pneumonia? ❑1 Yes ❑0 No ❑8 Don't Know **(1010)**

   If ***YES***,

   2a. How many times in your life has this occurred? ___ ___ **(1020)**

   2b. How many of these episodes were treated with antibiotics? ___ ___ **(1030)**

   2c. Approximately how old were you when you had your first pneumonia? ___ ___ years **(1040)**

   2d. Approximately how old were you when you had your most recent pneumonia? ___ ___ years **(1050)**

3. On average, how many respiratory infections do you experience per year? ___ ___ **(1060)**

4. Do respiratory infections make your asthma worse? ❑1 Yes ❑0 No **(1070)**

5. Do you have allergies (for example to pollen, grasses, trees or animals)? ❑1 Yes ❑0 No ❑8 Don't Know **(1080)**

   If ***YES***,

   5a. How would you categorize your allergies? ❑1 Relatively the same all year ❑2 Vary by season(s) **(1090)**

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

   5ai. Winter? ❑1 Yes ❑0 No **(1100)**

   5aii. Spring? ❑1 Yes ❑0 No **(1110)**

   5aiii. Summer? ❑1 Yes ❑0 No **(1120)**

   5aiv. Fall? ❑1 Yes ❑0 No **(1130)**

6. Do you have food or drug allergies? ❑1 Yes ❑0 No **(1140)**

   If ***YES***, please specify _____
   _____
   _____

PRIOR ASTHMA TREATMENT

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

			If Yes, indicate date medication was last taken month / day / year
7.	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 **(1150)**	__ __ / __ __ / __ __ __ __ **(1160) (1170) (1180)**
	7a. If ***YES***, indicate average daily puffs in the past month. (Enter '00' if none used.)	___ ___ puffs **(1190)**	
8.	Long-acting Inhaled Beta-Agonists (**Serevent, Foradil, Advair Diskus**)	❑1 Yes ❑0 No ❑8 Unknown **(1200)**	__ __ / __ __ / __ __ __ __ **(1210) (1220) (1230)**
9.	Asthma medication via a Nebulizer Machine	❑1 Yes ❑0 No ❑8 Unknown **(1240)**	__ __ / __ __ / __ __ __ __ **(1250) (1260) (1270)**
10.	Oral Beta-Agonists (**Alupent, Brethine, Bricanyl, Metaprel, Proventil, Ventolin, Repetabs, Volmax and others**)	❑1 Yes ❑0 No ❑8 Unknown **(1280)**	__ __ / __ __ / __ __ __ __ **(1290) (1300) (1310)**
11.	Short-acting Oral Theophylline (**Aminophylline, Slo-Phyllin and others**)	❑1 Yes ❑0 No ❑8 Unknown **(1320)**	__ __ / __ __ / __ __ __ __ **(1330) (1340) (1350)**
12.	Sustained release Oral Theophylline (**Slo-bid, Theo-Dur, Uniphyl and others**)	❑1 Yes ❑0 No ❑8 Unknown **(1360)**	__ __ / __ __ / __ __ __ __ **(1370) (1380) (1390)**
13.	Inhaled Anticholinergic (**Atrovent, Combivent, Spiriva**)	❑1 Yes ❑0 No ❑8 Unknown **(1400)**	__ __ / __ __ / __ __ __ __ **(1410) (1420) (1430)**
14.	Anti-allergic Inhaled Medications (**Intal, Tilade and others**)	❑1 Yes ❑0 No ❑8 Unknown **(1440)**	__ __ / __ __ / __ __ __ __ **(1450) (1460) (1470)**
15.	Anti-allergic Nasal Medications (**Nasalcrom, Astelin and others**)	❑1 Yes ❑0 No ❑8 Unknown **(1480)**	__ __ / __ __ / __ __ __ __ **(1490) (1500) (1510)**

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

16. Anti-allergic Oral Medications (**Allegra, Claritin, Zyrtec, Chlor-Trimeton and others**) ❑1 Yes ❑0 No ❑8 Unknown **(1520)** __ __ / __ __ / __ __ __ __ **(1530) (1540) (1550)**

17. Leukotriene Antagonist / 5LO Inhibitors (**Accolate, Zyflo, Singulair**) ❑1 Yes ❑0 No ❑8 Unknown **(1560)** __ __ / __ __ / __ __ __ __ **(1570) (1580) (1590)**

18. IgE Blocker (**Xolair**) ❑1 Yes ❑0 No ❑8 Unknown **(1600)** __ __ / __ __ / __ __ __ __ **(1610) (1620) (1630)**

19. Topical Steroids - Prescription (**Synalar, Lidex, Dermacin, Fluocinonide and others**) ❑1 Yes ❑0 No ❑8 Unknown **(1640)** __ __ / __ __ / __ __ __ __ **(1650) (1660) (1670)**

20. Topical Steroids - OTC (**Hydrocortisone - multiple strengths and products)** ❑1 Yes ❑0 No ❑8 Unknown **(1680)** __ __ / __ __ / __ __ __ __ **(1690) (1700) (1710)**

21. Nasal Steroids (**Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Rhinocort, Nasonex and others)** ❑1 Yes ❑0 No ❑8 Unknown **(1720)** __ __ / __ __ / __ __ __ __ **(1730) (1740) (1750)**

22. Oral Steroids (**Prednisone, Medrol and others**) ❑1 Yes ❑0 No ❑8 Unknown **(1760)** __ __ / __ __ / __ __ __ __ **(1770) (1780) (1790)**

Next, I will read a list of inhaled steroid medications. Please indicate if you had used any of these medications prior to being screened for the MIA study. If you did, please indicate, to the best of your knowledge, the date last taken.

23. Inhaled Steroids (prior to MIA study) (**Azmacort, Beclovent, Vanceril, AeroBid, QVAR, Flovent, Pulmicort, Advair Diskus and others**) ❑$_1$ Yes ❑$_0$ No ❑$_8$ Unknown **(1800)** __ __ / __ __ / __ __ __ __ **(1810) (1820) (1830)**

➔ ***If NO or unknown, skip to Question #24.***

➔ ***If YES, complete Questions #23a - 23c.***

23a. Indicate most recent type of inhaled steroid taken prior to screening for MIA

- ❑$_1$ beclomethasone MDI (1 puff = 42 µg) (**e.g., Beclovent, Vanceril**)
- ❑$_2$ beclomethasone MDI (1 puff = 84 µg) (**e.g., Vanceril-DS**)
- ❑$_3$ beclomethasone HFA (1 puff = 40 µg) (**e.g., QVAR**)
- ❑$_4$ beclomethasone HFA (1 puff = 80 µg) (**e.g., QVAR**)
- ❑$_5$ budesonide DPI (1 puff = 200 µg) (**e.g., Pulmicort Turbuhaler**)
- ❑$_6$ flunisolide MDI (1 puff = 250 µg) (**e.g., Aerobid, Aerobid - M**)
- ❑$_7$ fluticasone MDI (1 puff = 44 µg) (**e.g., Flovent**)
- ❑$_8$ fluticasone MDI (1 puff = 110 µg) (**e.g., Flovent**)
- ❑$_9$ fluticasone MDI (1 puff = 220 µg) (**e.g., Flovent**)
- ❑$_{10}$ fluticasone DPI (1 puff = 50 µg) (**e.g., Flovent Rotadisk**)
- ❑$_{11}$ fluticasone DPI (1 puff = 100 µg) (**e.g., Advair Diskus**)
- ❑$_{12}$ fluticasone DPI (1 puff = 250 µg) (**e.g., Advair Diskus**)
- ❑$_{13}$ fluticasone DPI (1 puff = 500 µg) (**e.g., Advair Diskus**)
- ❑$_{14}$ triamcinolone acetonide MDI (1 puff = 100 µg) (**e.g., Azmacort**)
- ❑$_{15}$ other _____ **(1840)**

23b. Indicate number of daily inhaled steroid puffs used prior to screening for MIA

___ ___ puffs **(1850)**

23c. Indicate how long you had used the inhaled steroid prior to screening for MIA

- ❑$_1$ less than 1 month
- ❑$_2$ 1 - 6 months
- ❑$_3$ greater than 6 months **(1860)**

PRIOR DISEASES, ILLNESSES AND SURGERIES

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

				If Yes, Comment
24.	Skin	❑1 Yes	❑0 No	_____ **(1870)**
25.	Blood, Lymph, or Immune Systems	❑1 Yes	❑0 No	_____ **(1880)**
26.	Eyes	❑1 Yes	❑0 No	_____ **(1890)**
27.	Ears, Nose, or Throat	❑1 Yes	❑0 No	_____ **(1900)**
28.	Breasts	❑1 Yes	❑0 No	_____ **(1910)**
29.	Endocrine Systems	❑1 Yes	❑0 No	_____ **(1920)**
30.	Lung - other than asthma	❑1 Yes	❑0 No	_____ **(1930)**
31.	Heart and Blood Vessels	❑1 Yes	❑0 No	_____ **(1940)**
32.	Liver or Pancreas	❑1 Yes	❑0 No	_____ **(1950)**
33.	Kidneys or Urinary Tract System	❑1 Yes	❑0 No	_____ **(1960)**
34.	Reproductive System	❑1 Yes	❑0 No	_____ **(1970)**
35.	Stomach or Intestines	❑1 Yes	❑0 No	_____ **(1980)**
36.	Muscles or Bones	❑1 Yes	❑0 No	_____ **(1990)**
37.	Nervous System	❑1 Yes	❑0 No	_____ **(2000)**
38.	Psychiatric	❑1 Yes	❑0 No	_____ **(2010)**
39.	Other _____	❑1 Yes	❑0 No	_____ **(2020)**

SUBJECT'S WEIGHT

(Clinic Coordinator completed)

40. Weight (*without shoes or heavy clothing*) ___ ___ ___ . ___ kg **(2030)**

Subject Source Documentation

Subject's Initials: __ __ __ **(2040)**

Date: __ __ / __ __ / __ __ __ __ **(2050)**

Asthma Clinical Research Network
NIH/NHLBI

MIA PULMONARY PROCEDURE CHECKLIST

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Subject Interview completed)

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

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

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

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

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

5. Have you used chlorpheniramine, diphenhydramine, fexofenadine, desloratadine, or loratadine in the past **48 hours**? ☐ 1 Yes ☐ 0 No **(1040)**
   ***Examples**: Chlor-Trimeton, Benadryl, Allegra, Clarinex, Claritin, Tylenol PM*

6. Have you used any antihistamines **other than** chlorpheniramine (Chlor-Trimeton and others), diphenhydramine (Benadryl), fexofenadine (Allegra), desloratadine (Clarinex), or loratadine (Claritin) in the past **72 hours**? ☐ 1 Yes ☐ 0 No **(1050)**

7. Have you used any decongestants or cold remedies in the past **48** hours? ☐ 1 Yes ☐ 0 No **(1060)**
   ***Examples**: pseudoephedrine (Sudafed), oxymetazoline (Afrin), Tylenol Allergy*

8. Have you used a rescue intermediate-acting inhaled beta-agonist in the past **6** hours? ☐ 1 Yes ☐ 0 No **(1070)**
   ***Example**: albuterol (Ventolin or Proventil)*

9. Have you used a long-acting inhaled beta-agonist in the past **24** hours? ☐ 1 Yes ☐ 0 No **(1080)**
   ***Examples**: Serevent, Foradil, Advair*

10. Have you used any oral corticosteroids in the past **4** weeks? ☐ 1 Yes ☐ 0 No **(1090)**
    ***Example**: Prednisone*

11. Have you used any nasal steroids in the past **48** hours? ☐ 1 Yes ☐ 0 No **(1100)**
***Examples**: Flonase, Rhinocort, Nasonex*

12. Have you used any cough medicines, anti-tussives, or expectorants in the past **24** hours? ☐ 1 Yes ☐ 0 No **(1110)**
***Examples**: guaifenesin, dextromethorphan, Duratuss, Benylin, Triaminic expectorant, Dayquil Anti-Cough*

13. Have you used any other asthma controller medication in the past **6** weeks? ☐ 1 Yes ☐ 0 No **(1120)**
***Examples**: Singulair, Accolate*

14. At this time, is your asthma worse because of recent exposure to triggers? ☐ 1 Yes ☐ 0 No **(1130)**
***Examples**: cold air, smoke, allergens, recent exercise, a recent respiratory tract infection, or other pulmonary infection*

15. **(Complete at Visits 5-11 only)**
Since the last visit, have you experienced or been treated for a bacterial infection? ☐ 1 Yes ☐ 0 No **(1140)**
***Examples**: pneumonia, bronchitis, sinusitis, UTI, skin, ear*

If ***YES***, please indicate the type of infection(s):

_____
_____
_____

16. Is there any other reason you should not proceed with spirometry testing? ☐ 1 Yes ☐ 0 No **(1150)**

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

17. Is the subject eligible to proceed with the spirometry testing? ☐ 1 Yes ☐ 0 No **(1160)**

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

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

➔ ***If NO, reschedule the visit. If the new visit falls outside the visit window, contact the MIA scientific coordinator.***

Complete for all subjects at Visit 1. If subject is less than 21 years old, complete Question #18 at each visit.

18. Height (*without shoes*) ___ ___ ___ cm **(1170)**

Asthma Clinical Research Network
NIH/NHLBI

MIA
POST-RANDOMIZATION
A.M. CORTISOL

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete at Visits 7, 9 and 11 only

1. Record subject's a.m. cortisol value ___ ___ . ___ ___ mcg/dL **(1000)**

   1a. Is Question #1 < 40% of the value obtained at Visit 3? ❑1 Yes ❑0 No **(1010)**

   ➔ ***If NO, STOP HERE.***
   ➔ ***If YES, bring the subject in, prior to the next shipment, and obtain blood for new a.m. cortisol analysis.***

   1b. Record subject's new a.m. cortisol value ___ ___ . ___ ___ mcg/dL **(1020)**

   1bi. Is Question #1b < 40% of the value obtained at Visit 3? ❑1 Yes ❑0 No **(1030)**

   ➔ ***If YES, bring the subject in and perform ACTH stimulation tests. Complete the MIA ACTH Stimulation tests (P15_ACTH) form.***

Asthma Clinical Research Network
NIH/NHLBI

MIA
PRE-RANDOMIZATION
A.M. CORTISOL

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete at Visit 1 only

1. Record subject's a.m. cortisol value ___ ___ . ___ ___ mcg/dL **(1000)**

   1a. Was the subject taking steroids at the time of Visit 1? ☐ 1 Yes ☐ 0 No **(1010)**

   ➔ ***If YES, STOP HERE.***

   1b. Is Question #1 < 5 mcg/dL? ☐ 1 Yes ☐ 0 No **(1020)**

   ➔ ***If NO, STOP HERE.***
   ➔ ***If YES, bring the subject in, prior to the next shipment, and obtain blood for new a.m. cortisol analysis.***

   1c. Record subject's new a.m. cortisol value ___ ___ . ___ ___ mcg/dL **(1030)**

   1ci. Is Question #1c < 5 mcg/dL? ☐ 1 Yes ☐ 0 No **(1040)**

   ➔ ***If YES, bring the subject in and perform ACTH stimulation tests. Complete the MIA ACTH Stimulation tests (P15_ACTH) form.***

Complete at Visit 3 only

2. Record subject's a.m. cortisol value ___ ___ . ___ ___ mcg/dL **(1050)**

   2a. Is Question #2 < 5 mcg/dL? ☐ 1 Yes ☐ 0 No **(1060)**

   ➔ ***If NO, STOP HERE.***
   ➔ ***If YES, bring the subject in, prior to the next shipment, and obtain blood for new a.m. cortisol analysis.***

   2b. Record subject's new a.m. cortisol value ___ ___ . ___ ___ mcg/dL **(1070)**

   2bi. Is Question #2b < 5 mcg/dL? ☐ 1 Yes ☐ 0 No **(1080)**

   ➔ ***If YES, bring the subject in and perform ACTH stimulation tests. Complete the MIA ACTH Stimulation tests (P15_ACTH) form.***

Asthma Clinical Research Network
NIH/NHLBI

MIA
SIGNIFICANT ASTHMA EXACERBATION

Subject ID: 1 5 - ___ - ___ ___ ___
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 on 2 of 3 consecutive scheduled morning or evening measurements? ☐1 Yes ☐0 No **(1020)**

   1d. A fall in prebronchodilator FEV_1 to < 80% of baseline? ☐1 Yes ☐0 No ☐9 N/A **(1030)**

   1e. A fall in postbronchodilator FEV_1 to < 60% predicted? ☐1 Yes ☐0 No ☐9 N/A **(1040)**

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 **(1050)**

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

3. Did the subject experience a significant asthma exacerbation? ☐1 Yes ☐0 No **(1060)**
   If any of the shaded boxes are completed, the subject experienced a significant asthma exacerbation.

   ➔ ***If NO, STOP HERE. DO NOT SUBMIT THIS FORM TO THE DCC.***
   ➔ ***If YES, but the subject did not undergo bronchoscopy, complete this form, then STOP. The subject is ineligible for the study. Please complete the MIA Termination of Study Participation (P15_TERM) form.***

4. Date significant asthma exacerbation occurred ___ ___ / ___ ___ / ___ ___ ___ ___
month day year **(1070)**

5. Did the subject seek care for the asthma exacerbation? ❑ 1 Yes ❑ 0 No **(1080)**

➔ ***If NO, skip to Question #8.***

6. What type of care was sought?

6a. Study Investigator? ❑ 1 Yes ❑ 0 No **(1090)**

If ***YES***, indicate type of contact.
❑ 1 Scheduled clinic visit
❑ 2 Unscheduled clinic visit
❑ 3 Phone contact **(1100)**

6b. Primary Care or Other Physician? ❑ 1 Yes ❑ 0 No **(1110)**

Name of physician: _____

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

6c. Emergency Room visit? ❑ 1 Yes ❑ 0 No **(1130)**

Name of hospital: _____

7. Was the subject hospitalized? ❑ 1 Yes ❑ 0 No **(1140)**

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

If ***YES***,

7a. Name of hospital: _____

7b. Duration of hospital stay? ___ ___ . ___ days **(1150)**

7c. Was intubation or ventilation assistance required? ❑ 1 Yes ❑ 0 No **(1160)**

8. Did the subject receive treatment with inhaled, oral, or intravenous corticosteroids? ❑ 1 Yes ❑ 0 No **(1170)**

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

9. Was the asthma exacerbation resolved solely by increasing PRN use of the rescue inhaler? ❑ 1 Yes ❑ 0 No **(1180)**

10. Was the asthma exacerbation treated as outlined in the protocol? ❑ 1 Yes ❑ 0 No **(1190)**

    If ***NO***, describe_____
    _____
    _____

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

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

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 **(1210)**

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 **(1220)**

14. Was the significant asthma exacerbation related to the collection of exhaled breath condensate? *(Check one box only)*

    ❑ 1 Definitely related
    ❑ 2 Probably related
    ❑ 3 Relationship undetermined
    ❑ 4 Probably not related
    ❑ 5 Definitely not related **(1230)**

Asthma Clinical Research Network
NIH/NHLBI

MIA SUBJECT STUDY TREATMENT QUESTIONNAIRE (Visits 5-9)

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Subject completed)

This questionnaire is to be completed by the MIA subject at the end of Visit 9. If a randomized subject terminates prior to Visit 9, please ask him or her to complete this form during the termination visit.

1. **Scheduled Pills**

As a MIA study participant you were randomized to receive either a real (i.e., active) clarithromycin pill or a look-alike placebo (i.e., inactive) pill. Please check the box that most closely represents your feelings about the **scheduled pills** you took **over the past 16 weeks.**

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

2. Please comment with respect to the **taste** of the medication you received from your **scheduled pills over the past 16 weeks.**

- ☐ 1 Tasted good **(1020)**
  (*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 pills over the past 16 weeks.**

- ☐ 1 Smelled good **(1030)**
  (*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 pills over the past 16 weeks.**

☐ 1 Pleasant sensations **(1040)**

(*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 pills**.

☐ 1 I have no further comments **(1050)**

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

_____

_____

_____

_____

Subject Source Documentation

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

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

Asthma Clinical Research Network
NIH/NHLBI

MIA
TERMINATION OF STUDY PARTICIPATION

Subject ID: 1 5 - ___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete this form only for those subjects who have successfully completed Visit 1 and have been terminated or deemed ineligible.

1. Has the subject completed the study through Visit 11? ❑1 Yes ❑0 No **(1000)**
   ➔ ***If YES, skip to the SIGNATURES section.***

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

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

*** Additional explanation required:**

_____

_____

_____

➔ ***Skip to the SIGNATURES section.*** **(1030)**

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

4a.	pregnancy? *(Check N/A if the subject is male.)*	☐ 1 Yes	☐ 0 No	☐ 9 N/A	**(1040)**
4b.	ineligibility during the run-in period (Visits 1-4) *	☐ 1 Yes	☐ 0 No		**(1050)**
4c.	ineligibility during the stratification period (after bronchoscopy and prior to randomization) *	☐ 1 Yes	☐ 0 No		**(1060)**
4d.	loss to follow-up? *	☐ 1 Yes	☐ 0 No		**(1070)**
4e.	a respiratory tract infection	☐ 1 Yes	☐ 0 No		**(1080)**
4f.	an asthma-related adverse event? *	☐ 1 Yes	☐ 0 No		**(1090)**
4g.	a medication-related adverse event? *	☐ 1 Yes	☐ 0 No		**(1100)**
4h.	an adverse event not related to asthma or medications? *	☐ 1 Yes	☐ 0 No		**(1110)**
4i.	non-compliance with Flovent® dosing? *	☐ 1 Yes	☐ 0 No		**(1120)**
4j.	non-compliance with taking scheduled pills? *	☐ 1 Yes	☐ 0 No		**(1130)**
4k.	non-compliance with diary completion? *	☐ 1 Yes	☐ 0 No		**(1140)**
4l.	non-compliance with visit attendance? *	☐ 1 Yes	☐ 0 No		**(1150)**
4m.	non-compliance with peak flow monitoring? *	☐ 1 Yes	☐ 0 No		**(1160)**
4n.	subject experienced > 2 asthma exacerbations during stratification phase (after bronchoscopy and prior to randomization)	☐ 1 Yes	☐ 0 No		**(1170)**
4o.	subject experienced > 2 respiratory tract infections during stratifcation phase (after bronchoscopy and prior to randomization)	☐ 1 Yes	☐ 0 No		**(1180)**
4p.	other reason? *	☐ 1 Yes	☐ 0 No		**(1190)**

*** If Yes, additional explanation required:**

_____

_____

_____

(1200)

4q. Indicate the letter corresponding to the primary reason the subject was terminated. ____ **(1210)**

SIGNATURES

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

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

_____ **(1220)** ___ ___ /___ ___ /___ ___ ___ ___ **(1230)**

Clinic Coordinator Signature — month day year

_____ **(1240)** ___ ___ /___ ___ /___ ___ ___ ___ **(1250)**

Principal Investigator Signature — month day year

Asthma Clinical Research Network
NIH/NHLBI

POST-ALBUTEROL (2 puffs) SPIROMETRY TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

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

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

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

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

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

3. Results of best effort post-albuterol:

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

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

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

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

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

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

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

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

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

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

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

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

Asthma Clinical Research Network
NIH/NHLBI

POST-ALBUTEROL (4 puffs) SPIROMETRY TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

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

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

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

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

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

3. Results of best effort post-albuterol:

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

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

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

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

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

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

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

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

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

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

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

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

Asthma Clinical Research Network
NIH/NHLBI

URINE PREGNANCY TEST

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

(Clinic Coordinator Completed)

Complete this form for female subjects only.

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

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

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

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

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

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

"Attach Registry Form Label Here"

ACRN REGISTRY

Subject's Last Name: _____

Subject's First Name: _____

Subject's Initials: ___ ___ ___

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

Coordinator ID: ___ ___ ___ ___ ___ ___

(Clinic Coordinator/Subject Interview Completed)

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

ADMINISTRATIVE

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

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

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

DEMOGRAPHICS

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

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

4. Subject's Race and Ethnicity

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

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

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

   Asian ☐1 Yes ☐0 No **(1060)**

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

   White ☐1 Yes ☐0 No **(1080)**

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

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

* R E G I S T R Y *

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

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

Subject Source Documentation

Subject's Initials: __ __ __

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

Administrative Use Only

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

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

Registry Form Storage Instructions:

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

REGISTRY FORMS SHOULD NOT BE SENT TO THE DCC.

Asthma Clinical Research Network
NIH/NHLBI

SERIOUS ADVERSE EVENT REPORTING FORM

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

(Clinic Coordinator completed)

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

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

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

   Describe: _____

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

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

5. Why was the event serious?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

REPORTING INVESTIGATOR:

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

Name: _____

Signature: _____

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

Asthma Clinical Research Network
NIH/NHLBI

ALLERGY SKIN TEST RESULTS

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

(Clinic Coordinator completed)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

_____ **(1076)**

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

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

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

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

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

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

ALLERGY SKIN TEST RESULTS

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

Visit Number: ___ ___ ___

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

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

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

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

➔ If ***YES***, go to Question #14.

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

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

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

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

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

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

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

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

If any of the gray shaded boxes are checked, this test was not acceptable.

➔ ***Allergy Skin testing may be rescheduled for the next visit if the subject's test was unacceptable due to the use of exclusionary medications.***

Asthma Clinical Research Network
NIH/NHLBI

SPIROMETRY TESTING

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

Complete this form only if the subject is eligible according to the appropriate Pulmonary Procedure Checklist form.

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

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

2. Results of best effort:

   2a. FVC ___ . ___ ___ L **(1010)**

   2b. FEV_1 ___ . ___ ___ L **(1020)**

   2c. FEV_1 (% predicted) ___ ___ ___ % predicted **(1030)**

   2d. PEFR ___ ___ . ___ ___ L/S **(1040)**

   2e. FEF_{25-75} ___ . ___ ___ L/S **(1050)**

3. In your judgment, was the subject's spirometry technique acceptable? ❑1 Yes ❑0 No **(1060)**

   3a. If **NO**, why was it unacceptable?

   Inadequate inspiratory effort ❑1 Yes ❑0 No **(1070)**

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

   Inadequate duration of expiration ❑1 Yes ❑0 No **(1090)**

   Cough during procedures ❑1 Yes ❑0 No **(1100)**

   Other *(specify)* _____ ❑1 Yes ❑0 No **(1110)**

Asthma Clinical Research Network
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SPUTUM INDUCTION LAB VALUES

Subject ID: ___ ___ -___ ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Slide #: ___

(Technician completed)

Processing Sample

1. Technician ID ___ ___ ___ ___ ___ ___ **(1000)**

2. Processing Date ___ ___ / ___ ___ / ___ ___ ___ ___ **(1010)**
month day year

3. Time processing started *(based on 24-hour clock)* ___ ___ ___ ___ **(1020)**

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

Differential Cell Counts

5. Technician ID ___ ___ ___ ___ ___ ___ **(1040)**

6. Read Date ___ ___ / ___ ___ / ___ ___ ___ ___ **(1050)**
month day year

7. Squamous Cells ___ ___ . ___ % **(1060)**

8. Did the subject's sputum sample reveal ≥ 80% squamous cells? ☐ 1 Yes ☐ 0 No **(1070)**

➔ ***If NO, please complete Question #9 through Question #14 and send the sputum sample for overreading***.

➔ ***If YES, STOP HERE and mark the samples as excluded from shipment to San Francisco in the Sample Tracking Module***.

The parameters below are calculated following exclusion of squamous cells.

9. Total Cell Count ___ ___ ___ ___ . ___ x 10^4 cells/ml **(1080)**

10. Epithelial Cells ___ ___ . ___ % **(1090)**

11. Macrophages ___ ___ . ___ % **(1100)**

12. Neutrophils ___ ___ . ___ % **(1110)**

13. Eosinophils ___ ___ . ___ % **(1120)**

14. Lymphocytes ___ ___ . ___ % **(1130)**

Asthma Clinical Research Network
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SPUTUM INDUCTION UCSF OVER-READ

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

(Technician completed)

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

2. Is the slide quality acceptable? ❑ 1 Yes ❑ 0 No **(1010)**
   ➔ If ***NO***, please comment below. If a back-up slide is required, update the Sample Tracking Module.

_____
_____
_____
_____
_____

Differential Cell Counts

3. Squamous Cells ___ ___ . ___ % **(1020)**

The parameters below are calculated following exclusion of squamous cells.

4. Epithelial Cells ___ ___ . ___ % **(1030)**
5. Macrophages ___ ___ . ___ % **(1040)**
6. Neutrophils ___ ___ . ___ % **(1050)**
7. Eosinophils ___ ___ . ___ % **(1060)**
8. Lymphocytes ___ ___ . ___ % **(1070)**

Asthma Clinical Research Network
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SPUTUM INDUCTION

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

Complete this form only if the subject is eligible according to the Sputum Induction Checklist (SPUTUMCHK) form.

1. ***(If attempting sputum induction for the first time in this protocol or subject has not had an adequate sample at prior attempts, do not complete Question #1.)***

   What was the duration of sputum induction the first time the subject's sample was processed and had < 80% squamous cells for this protocol? ___ ___ . ___ minutes **(1000)**

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

2. Sputum induction start time *(based on 24-hour clock)* ___ ___ ___ ___ **(1010)**

3. Sputum induction stop time *(based on 24-hour clock)* ___ ___ ___ ___ **(1020)**

4. Duration of sputum induction collection phase at this visit ___ ___ . ___ minutes **(1030)**

   4a. Was the duration ≥ 4 minutes? ☐ 1 Yes ☐ 0 No **(1040)**

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

   5a. Is the volume of the sample ≥ 1 ml? ☐ 1 Yes ☐ 0 No **(1060)**

6. Is the sample adequate for laboratory analysis? ☐ 1 Yes ☐ 0 No **(1070)**
   If either shaded box in Question #4a or #5a are completed, the sputum sample is not adequate and should not be sent for analysis of squamous cell counts.

   ➔ ***If YES, the technician reading the slide should complete the Sputum Induction Lab Values (SPUTLAB) form.***

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

7a. FEV_1 ___ . ___ ___ L **(1080)**

7b. FEV_1 (% predicted) ___ ___ ___ % predicted **(1090)**

7c. Time of FEV_1 in Question #7a (*based on 24-hour clock*) ___ ___ ___ ___ **(1100)**

7d. Percent difference in FEV_1 $\frac{(Reference - Question\ \#7a)}{Reference}$ x 100 ___ ___ . ___ % **(1110)**

Reference = FEV_1 used for assessment of eligibility for SI.

7e. Did the subject's FEV_1 drop > 10% (from post-albuterol baseline) as indicated in Question #7d? ❑ 1 Yes ❑ 0 No **(1120)**

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

➔ ***If YES, proceed to the Additional Treatment for Sputum Induction (SPUTUM_ADD_TRT) form.***

Asthma Clinical Research Network
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ADDITIONAL TREATMENT POST SPUTUM INDUCTION

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

Complete this form only if the subject has experienced > 10% fall in FEV_1 from post-albuterol baseline immediately after completion of sputum induction.

Clinic Use Only

Sputum Induction Reversal Reference Value: *Reference x 0.90 =* ___ . ___ ___ *L*

Reference = FEV_1 used for assessment of eligibility for Sputum Induction.

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

1. Subject's FEV_1 after initial 2 puffs of albuterol

   1a. FEV_1 ___ . ___ ___ L **(1000)**

   1b. FEV_1 (% predicted) ___ ___ ___ % predicted **(1010)**

   1c. Time of FEV_1 from Question #1a (*based on 24-hour clock*) ___ ___ ___ ___ **(1020)**

   1d. Was the FEV_1 from Question #1a ≥ the sputum induction reversal reference value in the gray box above? ❑1 Yes ❑0 No **(1030)**

   ➔ ***If YES, stop here and continue with remaining visit procedures.***
   ➔ ***If NO, administer 2 puffs of albuterol and wait 15 minutes, then perform spirometry. Proceed to Question #2.***

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

   2a. FEV_1 ___ . ___ ___ L **(1040)**

   2b. FEV_1 (% predicted) ___ ___ ___ % predicted **(1050)**

   2c. Time of FEV_1 from Question #2a (*based on 24-hour clock*) ___ ___ ___ ___ **(1060)**

   2d. Was the FEV_1 from Question #2a ≥ the sputum induction reversal reference value in the gray box above? ❑1 Yes ❑0 No **(1070)**

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

Physician Source Documentation

Physician signature: _____ **(1080)**

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

Time: __ __ __ __ *(based on 24-hour clock)* **(1100)**

Asthma Clinical Research Network
NIH/NHLBI

SPUTUM INDUCTION CHECKLIST

Supervisor ID: ___ ___ ___ ___ ___ ___

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

(Technician completed)

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

1. ***(If attempting Sputum Induction for the first time in this protocol, do not complete Question #1)***
   Was the subject's sputum sample processed and had < 80% squamous cells the first time a sputum induction was attempted for this protocol? ☐ 1 Yes ☐ 0 No **(1000)**

2. ***(Only for subjects who completed a methacholine challenge at this visit.)***
   Was the subject's FEV_1 after reversal from the methacholine challenge ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form? ☐ 1 Yes ☐ 0 No **(1010)**

   2a. If ***NO***, has the subject received permission from the supervising physician to proceed with sputum induction testing? ☐ 1 Yes ☐ 0 No **(1020)**
   Physician's Signature: _____ **(1030)**

3. Subject's FEV_1 used for assessment of eligibility for sputum induction ___ . ___ ___ L **(1040)**

4. Subject's FEV_1 (% predicted) used for assessment of eligibility for sputum induction ___ ___ ___ % predicted **(1050)**

5. Was the subject's FEV_1 (% predicted) from Question #4 ≥ 60% predicted? ☐ 1 Yes ☐ 0 No **(1060)**

6. Is there any other reason the subject should not proceed with sputum induction? ☐ 1 Yes ☐ 0 No **(1070)**
   If ***YES***, explain _____

7. Is the subject eligible for sputum induction? ☐ 1 Yes ☐ 0 No **(1080)**
   If any of the shaded boxes are completed, the subject is NOT eligible for sputum induction.
   ➔ ***If YES, proceed to the Sputum Induction (SPUTUM) form.***