Asthma Clinical Research Network
NIH/NHLBI

CLINICAL ADVERSE EVENTS

Enter this form when the subject's last visit is completed.

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 1
Visit 1 Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)

(Clinic Coordinator completed)

If the subject experienced any clinical adverse events (including intercurrent events), complete this log. If no clinical adverse events occurred throughout the entire study, check none, and sign and date this page.

❑0 None

Signature:
Date:

DESCRIPTION OF ADVERSE EVENT	1. ICD9 CODE	2. DATE STARTED (Top Line) / 3. DATE STOPPED (Bottom Line) MONTH / DAY / YEAR	4. ONGOING at final visit	5. DURATION Complete ONLY if duration is less than 24 hours. HOUR(S)	6. TYPE 1 - INTERMITTENT 2 - CONTINUOUS	7. SEVERITY 1 - MILD 2 - MODERATE 3 - SEVERE	8. SERIOUS * 1 - YES 0 - NO	9. LIKELIHOOD OF RELATIONSHIP TO TEST DRUG 1 - NONE 2 - UNLIKELY (REMOTE) 3 - POSSIBLE 4 - PROBABLE 5 - HIGHLY PROBABLE	10. CHANGE IN STUDY MEDICATIONS 1 - DISCONTINUED 2 - REDUCED 3 - INTERRUPTED, BUT RESUMED AT CURRENT DOSE 4 - UNCHANGED 5 - INCREASED	11. OUTCOME *(Skip if #4 is checked.)* 1 - COMPLETELY RECOVERED 2 - RECOVERED, BUT WITH LASTING EFFECTS 3 - DEATH *	12. TREATMENT REQUIRED 1 - NONE 2 - MEDICATION ** 3 - HOSPITALIZATION * 4 - OTHER
1. EVENT	CAE_01 ___.__	CAE_02 __/__/__ / CAE_03 __/__/__	❑1 CAE_04	CAE_05 __	CAE_06	CAE_07	CAE_08	CAE_09	CAE_10	CAE_11	CAE_12
2.	___.__	__/__/__ / __/__/__	❑1	__							
3.	___.__	__/__/__ / __/__/__	❑1	__							
4.	___.__	__/__/__ / __/__/__	❑1	__							
5.	___.__	__/__/__ / __/__/__	❑1	__							

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

** Please complete the appropriate Concomitant Medications Log (CMED).

Asthma Clinical Research Network
NIH/NHLBI

AIRWATCH™ QUALITY CONTROL

Subject ID: __ __ __ __ __
Subject Initials: __ __ __
Visit Number: __ __
Current Date: __ __ / __ __ / __ __ (month / day / year)
Interviewer ID: __ __ __ __ __

(Technician completed)

AIR_01 1. Serial Number of AirWatch™ being tested __ __ __ __ - __ __ __ __

AIR_02 2. Serial Number of mouthpiece being tested __ __ __ __

AIR_03 3. Test date __ __ / __ __ / __ __ (*month / day / year*)

AIR_04 4. Is this a new AirWatch™ device being tested? ❑1 Yes ❑0 No

AIR_04a If ***YES***, indicate reason.
- ❑1 "Old" device was recalled
- ❑2 "Old" device failed QC testing
- ❑3 "Old" device had display problems
- ❑4 "Old" device experienced battery failure
- ❑5 "Old" device was lost
- ❑6 Other

	AirWatch™ (L/Min)	Jones FVC (L/Min)	Clinic Use Only: Relative Bias (AirWatch™ - Jones FVC) / Jones FVC * 100 %	Clinic Use Only: Rank (smallest to largest)
5. Trial 1	AIR_05a	AIR_05b	__ __ __ . __ %	__
6. Trial 2	AIR_06a	AIR_06b	__ __ __ . __ %	__
7. Trial 3	AIR_07a	AIR_07b	__ __ __ . __ %	__
8. Trial 4	AIR_08a	AIR_08b	__ __ __ . __ %	__
9. Trial 5	AIR_09a	AIR_09b	__ __ __ . __ %	__

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 AirWatch™ or mouthpiece 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 AirWatch™:** (i) subtract the original median relative bias (the median relative bias when the AirWatch™ or mouthpiece was first dispensed) from the current median relative bias, and (ii) subtract the original inter-quartile range (the inter-quartile range when the AirWatch™ or mouthpiece 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 AirWatch™ to be reissued to the subject.*

AIR_10 10. Did the AirWatch™ pass? ❑1 Yes ❑0 No

AIR_11 11. If ***NO***, is this the third mouthpiece tested with this AirWatch™ at this visit? ❑1 Yes ❑0 No

- ☞ *If **NO**, issue a new mouthpiece and complete another AirWatch™ Quality Control form.*
- ☞ *If **YES**, issue a new AirWatch™ and mouthpiece and complete another AirWatch™ Quality Control form.*

Asthma Clinical Research Network
NIH/NHLBI

BIOLOGICAL QUALITY CONTROL

Subject ID: __ __ __ __ __
Subject Initials: __ __ __
Visit Number: 0 1
Current Date: __ __ / __ __ / __ __ (month / day / year)
Interviewer ID: __ __ __ __ __

(Technician completed)

BIO_01 1. Serial Number of AirWatch™ being tested __ __ __ __ - __ __ __ __

BIO_02 2. Serial Number of mouthpiece being tested __ __ __ __

		Clinic Use Only			Highest Value
BIO_03	3. Spirometer (L/Min)	__ __ __	__ __ __	__ __ __	__ __ __
BIO_04	4. AirWatch™ (L/Min)	__ __ __	__ __ __	__ __ __	__ __ __

Biological Relative Bias

$$\frac{(\text{AirWatch}^{TM} - \text{Spirometer})}{\text{Spirometer}} * 100\% \quad \_\_\_ \_\_\_ \_\_\_ . \_\_\_ \%$$

The Biological Relative Bias must be between –25% and 25%.

BIO_05 5. Did the subject pass the Biological Quality Control testing? ❑1 Yes ❑0 No

- ☞ ***If YES, please continue with Visit 1. Do not complete the rest of this form.***
- ☞ ***If NO, please check the AirWatch™, reinstruct the subject, and retest. The subject should perform 3 additional AirWatch™ blows which should be compared to the highest spirometry value recorded above (in Question #3).***

		Clinic Use Only			Highest Value
BIO_06	6. AirWatch™ (L/Min)	__ __ __	__ __ __	__ __ __	__ __ __

Biological Relative Bias $\frac{(\text{AirWatch}^{TM} - \text{Spirometer})}{\text{Spirometer}} * 100\%$ __ __ __ . __ %

BIO_07 7. Did the subject pass the Biological Quality Control testing? ❑1 Yes ❑0 No

- ☞ ***If YES, please continue with Visit 1.***
- ☞ ***If NO, and you feel the subject could improve with additional instruction, please complete another BIOQC form. Subjects must pass BIOQC before proceeding with the study.***

If the subject cannot pass BIOQC at this visit, please complete the Termination of Study Participation form (TERM).

Asthma Clinical Research Network

CONCOMITANT MEDICATIONS for ASTHMA-RELATED DRUGS

Subject ID: __ __ __ __ __

Subject Initials: __ __ __

Visit Number: 0 1

Visit 1 Date: __ __ / __ __ / __ __ (month / day / year)

(Clinic Coordinator completed)

At Visit 1: Please list all concomitant medications the subject is taking that are asthma related in the table below. Indicate the name of the medication, dose, units, frequency, route, and start date. Refer to the Concomitant Medications list (MED) for the codes.

Subsequent visits: Please update the table below at each visit. Indicate any new asthma related medications started and any medications that were stopped since the last visit. If the subject is still taking the medication at the end of the study, please check the "ongoing" box. Check the "None" box if the subject has not taken any asthma related concomitant medications during the entire study.

❑0 None

CODE	NAME OF MEDICATION	DOSE	UNITS	FREQUENCY	ROUTE	START DATE (MM/DD/YY)	STOP DATE (MM/DD/YY)	ONGOING AT END OF STUDY
CMED_01	1. CMEDNO	CMED_02		CMED_04		CMED_06	CMED_07	CMED_08
	2.		CMED_03		CMED_05	___/___/___	___/___/___	❑1
	3.					___/___/___	___/___/___	❑1
	4.					___/___/___	___/___/___	❑1
	5.					___/___/___	___/___/___	❑1
	6.					___/___/___	___/___/___	❑1
	7.					___/___/___	___/___/___	❑1
	8.					___/___/___	___/___/___	❑1
	9.					___/___/___	___/___/___	❑1
	10.					___/___/___	___/___/___	❑1
	11.					___/___/___	___/___/___	❑1
	12.					___/___/___	___/___/___	❑1
	13.					___/___/___	___/___/___	❑1
	14.					___/___/___	___/___/___	❑1
	15.					___/___/___	___/___/___	❑1

Asthma Clinical Research Network
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SLIC DIARY CARD

Initials:
Date:

Subject ID: 5 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Return Visit Number: ___ ___
Return Visit Date: ___ ___ / ___ ___ / ___ ___
month day year

Please use black ink to complete.

To the subject:

If your peak flow is below _____ liters/minute, use your Ventolin®(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 one hour of Rescue use.

If you have used your Ventolin®(RESCUE) inhaler more than _____ puffs/24 hours for the past 48 hours, contact study personnel.

	Day 1: _____	Day 2: _____	Day 3: _____	Day 4: _____	Day 5: _____	Day 6: _____	Day 7: _____
Date	dmonth / dday ___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day
MORNING EVALUATION							
1. Number of times that you woke up last night due to asthma	DRY_01 ___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
2. Time of AM Peak Flow	DRY_02 ___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___
3. AM Peak Flow (liters/min)** recorded first thing in the morning	DRY_03 DRY_03W DRY_03R ___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
4. Total number of puffs of Ventolin® (**RESCUE**) **during the night** *(Do not record preventive puffs.)*	DRY_04 ___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
Symptoms++ during the night. 5. Shortness of Breath	DRY_05						
6. Chest Tightness	DRY_06						
7. Wheezing	DRY_07						
8. Cough	DRY_08						
9. Phlegm/Mucus	DRY_09						
NIGHT-TIME EVALUATION							
10. Time of PM Peak Flow	DRY_10 ___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___	___ ___ : ___ ___
11. PM Peak Flow (liters/min)** recorded at bedtime	DRY_11 DRY_11W DRY_11R ___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
12. Total number of puffs of Ventolin® (**RESCUE**) **since you woke** *(Do not record preventive puffs.)*	DRY_12 ___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
Symptoms++ since you woke. 13. Shortness of Breath	DRY_13						
14. Chest Tightness	DRY_14						
15. Wheezing	DRY_15						
16. Cough	DRY_16						
17. Phlegm/Mucus	DRY_17						
SCHEDULED MEDICATIONS							
18. Total number of ***Inhaler 1 A*** puffs **since you woke**	DRY_18 ___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
19. Total number of ***Inhaler 1 B*** puffs **since you woke**	DRY_19 ___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
20. Total number of ***Inhaler 2*** puffs **since you woke**	DRY_20 ___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___

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

++ Symptom Severity Rating Scale

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

Asthma Clinical Research Network
NIH/NHLBI

RUN-IN DIARY CARD

Initials:
Date:

Subject ID: 3 __ __ __ __
Subject Initials: __ __ __
Return Visit Number: __ __
Return Visit Date: __ __ / __ __ / __ __
month day year

Please use black ink to complete.

To the subject:

If your peak flow is below _____ liters/minute, use your Ventolin®(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 one hour of Rescue use.

If you have used your Ventolin®(RESCUE) inhaler more than _____ puffs/24 hours for the past 48 hours, contact study personnel.

		Day 1: ____	Day 2: ____	Day 3: ____	Day 4: ____	Day 5: ____	Day 6: ____	Day 7: ____
Date		dmonth / dday	__ / __	__ / __	__ / __	__ / __	__ / __	__ / __
		month day	month day	month day	month day	month day	month day	month day
MORNING EVALUATION								
1. Number of times that you woke up last night due to asthma		DRY_01	__ __	__ __	__ __	__ __	__ __	__ __
2. Time of AM Peak Flow		DRY_02	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
3. AM Peak Flow (liters/min)** recorded first thing in the morning		DRY_03 DRY_03R	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __
4. Total number of puffs of Ventolin® (**RESCUE**) **during the night** *(Do not record preventive puffs.)*		DRY_04	__ __	__ __	__ __	__ __	__ __	__ __
Symptoms++ during the night.	5. Shortness of Breath	DRY_05						
	6. Chest Tightness	DRY_06						
	7. Wheezing	DRY_07						
	8. Cough	DRY_08						
	9. Phlegm/Mucus	DRY_09						
NIGHT-TIME EVALUATION								
10. Time of PM Peak Flow		DRY_10	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
11. PM Peak Flow (liters/min)** recorded at bedtime		DRY_11 DRY_11R	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __
12. Total number of puffs of Ventolin® (**RESCUE**) **since you woke** *(Do not record preventive puffs.)*		DRY_12	__ __	__ __	__ __	__ __	__ __	__ __
Symptoms++ since you woke.	13. Shortness of Breath	DRY_13						
	14. Chest Tightness	DRY_14						
	15. Wheezing	DRY_15						
	16. Cough	DRY_16						
	17. Phlegm/Mucus	DRY_17						
SCHEDULED MEDICATIONS								
18. Total number of Azmacort® puffs **since you woke**		DRY_18	__ __	__ __	__ __	__ __	__ __	__ __

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

++ Symptom Severity Rating Scale

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

Asthma Clinical Research Network
NIH/NHLBI

ELECTROCARDIOGRAM REPORT

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

ECG_01 1. Ventricular heart rate ____ ____ beats/min

2. Cardiac cycle measurements

ECG_02A 2a. P - R Interval ____ ____ seconds

ECG_02B 2b. QRS Duration ____ ____ seconds

ECG_02C 2c. Q - T Interval ____ ____ seconds

ECG_03 ***3. (If Visit 1, do not complete Question # 3.)***

Have there been any clinically important changes from Visit 1? ❑1 Yes ❑0 No

➜ ***If YES, please complete the Clinical Adverse Event form (AECLIN).***

Asthma Clinical Research Network
NIH/NHLBI

ELIGIBILITY CHECKLIST 1

Subject ID: 3 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

E1_01	1.	***Did the subject sign the Informed Consent form?***	☐ 1 Yes ☐ 0 No
E1_01A		*If **YES**, record the date the form was signed.*	___ ___ / ___ ___ / ___ ___ (month / day / year)
E1_02	2.	Are you between the ages of 12 and 65 years inclusive?	☐ 1 Yes ☐ 0 No
E1_03	3.	Do you plan to move more than 75 miles away from this clinic in the next year?	☐ 1 Yes ☐ 0 No
E1_04	4.	Have you used any smokeless tobacco products (chew, snuff) in the past year?	☐ 1 Yes ☐ 0 No
E1_05	5.	Have you smoked cigarettes, a pipe, cigars, or any other substance in the past year?	☐ 1 Yes ☐ 0 No
E1_06	6.	Do you have a smoking history greater than 10 pack-years?	☐ 1 Yes ☐ 0 No
E1_06A		Record history in pack-years. (Enter '00' if none)	___ ___
E1_07	7.	Have you had a respiratory tract infection in the past 6 weeks?	☐ 1 Yes ☐ 0 No
E1_08	8.	Have you experienced a significant asthma attack in the past 6 weeks?	☐ 1 Yes ☐ 0 No
E1_09	9.	Have you experienced a life-threatening asthma attack requiring treatment with intubation and mechanical ventilation in the past 10 years?	☐ 1 Yes ☐ 0 No
E1_10	10.	Are you potentially able to bear children?	☐ 1 Yes ☐ 0 No ☐ 9 N/A
E1_10A		If ***YES***, are you using a birth control method indicated on this reference card? (*Show subject the Birth Control Methods reference card.*)	☐ 1 Yes ☐ 0 No

➜ ***Please complete the appropriate Concomitant Medications form, if needed.***

Initials:
Date:

E1_11	11.	Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is NOT eligible.***	☐ 1 Yes ☐ 0 No

☞ If YES, please continue with Visit 1.
☞ If NO, please complete the Termination of Study Participation form (TERM).

Asthma Clinical Research Network
NIH/NHLBI

ELIGIBILITY CHECKLIST 2

Subject ID: 3 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

E2_01 1. Does the subject have current evidence of any of the conditions listed on the Medical Conditions reference card (EXCLMED)? ☐1 Yes ☐0 No
If ***YES***, describe _____

E2_02 2. Has the subject taken any medications listed on the Exclusionary Drugs reference card (EXCLDRUG) within the specified time periods? ☐1 Yes ☐0 No
If ***YES***, describe _____

E2_03 3. Is the subject currently taking prescription or over-the-counter medication(s) other than those listed on the Allowed Medications reference card (MEDALLOW)? ☐1 Yes ☐0 No
If ***YES***, describe _____

E2_04 4. Is the subject currently receiving hyposensitization therapy other than an established maintenance regimen? ☐1 Yes ☐0 No

E2_05 5. Is the subject currently using intranasal steroids, or does the subject anticipate using intranasal steroids during their participation in the study? ☐1 Yes ☐0 No

E2_05A If ***YES***, please choose one of the following:

- ☐0 The subject agrees to stop use of all intranasal steroids for the duration of the study.
- ☐1 The subject agrees to adhere to a course of beclomethasone dipropionate at a dose not to exceed 100 µg in each nostril BID throughout the duration of the study.
  ➜ ***Please complete the appropriate Concomitant Medications form.***
- ☐2 The subject does not agree to adhere to the criteria regarding intranasal steroid use as outlined in the Manual of Operations.

E2_06 6. Does the subject have an abnormal screening electrocardiogram [ischemic heart disease or arrhythmia; not excluded for occasional (≤ 3/min) atrial or ventricular premature contractions, or clinically insignificant sinus bradycardia]? ☐1 Yes ☐0 No

E2_07 7. Does the subject have a positive pregnancy test? ☐1 Yes ☐0 No ☐9 N/A

Initials:
Date:

E2_08 8. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is NOT eligible.*** ☐1 Yes ☐0 No

- ☞ If YES, please continue with Visit 1.
- ☞ If NO, please complete the Termination of Study Participation form (TERM).

Asthma Clinical Research Network
NIH/NHLBI

ELIGIBILITY CHECKLIST 3

Subject ID: 3 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

E3_01 1. Is the subject able to use a metered dose inhaler properly? ❑ 1 Yes ■ 0 No

E3_02 2. Did the subject pass Biological Quality Control (BIOQC) testing at this visit? ❑ 1 Yes ■ 0 No

E3_03 3. Is the subject eligible? If either of the shaded boxes is filled in, the subject is NOT eligible. ❑ 1 Yes ■ 0 No

- ☞ If YES, please continue with this form.
- ☞ If NO, please complete the Termination of Study Participation form (TERM).

E3_04 4. Is the subject currently taking inhaled corticosteroids? ❑ 1 Yes ❑ 0 No

➜ ***If NO, complete Section 1.***

➜ ***If YES, complete Section 2 on the next page.***

Section 1 - Complete for subjects <u>not</u> currently taking inhaled corticosteroids

E3_05 5. Does the subject have a prebronchodilator $FEV_1 \leq 80\%$ of predicted? ❑ 1 Yes ■ 0 No

E3_06 6. Does the subject have source documentation of $\geq$ 12% increase in FEV_1 in response to aerosolized albuterol (any spirometry system) in the past 6 months? ❑ 1 Yes ■ 0 No

E3_07 7. Is the subject eligible? ***If either of the shaded boxes in Section 1 is filled in, the subject is NOT eligible.*** ❑ 1 Yes ■ 0 No

- ☞ If YES, please continue with Visit 1. Do not complete page 2 of this form.
- ☞ If NO, please complete the Termination of Study Participation form (TERM).

Section 2 - Complete for subjects currently taking inhaled corticosteroids

E3_08 8. Does the subject have a prebronchodilator $FEV_1 \geq 40\%$ of predicted? ❑ 1 Yes ■ 0 No

➜ ***If NO, go to Question #10.***

E3_09 9. Does the subject have a prebronchodilator $FEV_1 > 80\%$ of predicted? ❑ 1 Yes ❑ 0 No

E3_09A If ***YES***, does the subject have source documentation of PC_{20} for methacholine ≤ 8 mg/ml (ACRN spirometry system and methodology only) in the past 6 months? ❑ 1 Yes ■ 0 No

(Note: If the subject's PC_{20} for methacholine challenge at this visit ≤ 8 mg/ml, this question should be marked 'Yes.')

E3_09B If ***NO***, does the subject have source documentation of ≥ 12% increase in FEV_1 in response to aerosolized albuterol (any spirometry system) ***or*** of PC_{20} for methacholine ≤ 8 mg/ml (ACRN spirometry system and methodology only) in the past 6 months? ❑ 1 Yes ■ 0 No

(Note: If the subject's PC_{20} for methacholine challenge at this visit ≤ 8 mg/ml, this question should be marked 'Yes.')

E3_10 10. Is the subject eligible? ***If any of the shaded boxes in Section 2 are* filled in, *the subject is NOT eligible.*** ❑ 1 Yes ■ 0 No

- ☞ If YES, please continue with Visit 1.
- ☞ If NO, please complete the Termination of Study Participation form (TERM).

Asthma Clinical Research Network
NIH/NHLBI

ELIGIBILITY CHECKLIST 4

Subject ID: 3 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 4
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

E4_01	1.	Is the subject's pre-bronchodilator FEV_1 obtained during Visit 4 spirometry less than 55% of predicted?	■ 1 Yes	❑ 0 No
E4_02	2.	Has the subject experienced a significant asthma exacerbation as defined in the Manual of Operations since the first study visit?	■ 1 Yes	❑ 0 No
E4_03	3.	Has the subject used the Azmacort® inhaler less than twice a day on more than 12 days during the run-in period?	■ 1 Yes	❑ 0 No
E4_04	4.	On average during the run-in period, has the subject recorded peak flow measurements and symptoms on the symptom diary card fewer than 5 days per week?	■ 1 Yes	❑ 0 No
E4_05	5.	Has the subject used the "as-needed" β-agonist an average of ≥ 16 puffs per 24 hours during the last week of the run-in period (week 6)?	■ 1 Yes	❑ 0 No
E4_06	6.	Is there any new information that makes the subject ineligible according to the eligibility criteria? If ***YES***, describe _____	■ 1 Yes	❑ 0 No
E4_07	7.	Does the subject wish to withdraw consent from the study?	■ 1 Yes	❑ 0 No
E4_08	8.	Is there any other reason for which this subject should not be included in the study? If ***YES***, describe _____	■ 1 Yes	❑ 0 No

E4_09	9.	Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is NOT eligible.***	❑ 1 Yes	■ 0 No

☞ If YES, please continue with the randomization process (*next page*).
☞ If NO, please complete the Termination of Study Participation form (TERM).

E4_10

10. Is the subject's pre-bronchodilator FEV_1 obtained during Visit 4 spirometry greater than 80% of predicted? ❑$_1$ Yes ❑$_0$ No

➜ ***If NO, skip to Question #12. The subject should be assigned to the SLIC study.***
➜ ***If YES, run the PEF calculator.***

E4_11

11. Is the subject's average PEF variability $\leq$ 20% during the last two weeks of run-in period (weeks 5 and 6)? ❑$_1$ Yes ❑$_0$ No

➜ ***If YES, the subject should be assigned to the SOCS study.***
➜ ***If NO, the subject should be assigned to the SLIC study.***

If the subject is eligible to participate in SOCS or SLIC, run the randomization program.
If an electronic connection is impossible, call the DCC at (717) 531 - 4262, 8:00 AM - 5:00 PM E.S.T.
During the hours 5:00 PM - 9:00 PM E.S.T. call the beeper number and leave a phone number at which you can be contacted.

E4_12

12. In which study is the subject participating? ❑$_1$ SOCS ❑$_2$ SLIC

Clinic Use Only (SOCS only)
Information needed for subject randomization:
Age: _____
Sex: _____
Race: _____
PC_{20} at visit 4: __ __ . __ __ __

E4_13

13. Study drug packet number. __ __ __ __ __

Asthma Clinical Research Network
NIH/NHLBI

SPUTUM FLUID PHASE MEASUREMENTS

Subject ID: __ __ __ __ __
Subject Initials: __ __ __
Visit Number: __ __
Visit Date: __ __ / __ __ / __ __ (month / day / year)
Technician ID: __ __ __ __ __

(Technician completed)

					Non-detectable limit	Quantity not sufficient to dilute
1.	ECP	ECP	____ ____ ____ ____ ____	mcg/L	ECP_NON ❑	ECP_SUFF ❑
2.	Tryptase	TRYPTASE	____ ____ ____ . ____	mcg/L	TRY_NON ❑	TRY_SUFF ❑

Asthma Clinical Research Network
NIH/NHLBI

SCHEDULED INHALERS

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form must be completed every time scheduled inhalers are distributed.

INH_01 1. What type of visit is this?

- ❑1 Scheduled visit
- ❑2 Drug swap visit
- ❑3 Unscheduled visit

2. Were the following inhalers distributed?

INH_02A1 SOCS Subjects Only: Inhaler 1 ❑1 Yes ❑0 No

INH_02A2 Inhaler 2 ❑1 Yes ❑0 No

INH_02B1 SLIC Subjects Only: Inhaler 1A ❑1 Yes ❑0 No

INH_02B2 Inhaler 1B ❑1 Yes ❑0 No

INH_02B3 Inhaler 2 ❑1 Yes ❑0 No

SCHEDULED INHALER ***(Visit 4 through Visit 12 for SOCS - Visit 4 through Visit 10 for SLIC)***

Affix and sign the new drug label below:

By signing the label here you are confirming that you have:

1) checked the label on the inhaler(s) with the drug packet number on the outside of the packet.
2) confirmed that the drug is being given to the subject with the name and ID number written on the outside of the packet.
3) confirmed that this is the correct medication to be distributed at this visit.

(Clinic Coordinator completed)

URINE TEST RESULTS

Run-in: Visit 1 and Visit 4
SOCS: Visit 10 and Visit 13
SLIC: Visit 11

LAB_01 1. Pregnancy test results

Initials:
Date:

- ❑1 Positive
- ❑2 Negative
- ❑9 N/A

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

BLOOD TEST RESULTS

Electrolyte Analysis

Run-in: Visit 1
SOCS: Visit 10
SLIC: Visit 11

LAB_02 2. Potassium ___ ___ ___ mmol/L

LAB_03 3. Sodium ___ ___ ___ mmol/L

LAB_04 4. Chloride ___ ___ ___ mmol/L

LAB_05 5. Carbon Dioxide ___ ___ ___ mmol/L

(Clinic Coordinator completed)

VITAL SIGNS

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

LX_01A
LX_01B

1. Resting blood pressure ___ ___ ___ / ___ ___ ___ mm Hg
systolic diastolic

LX_02

2. Pulse ___ ___ ___ beats/min

LX_03

3. Respiration ___ ___ breaths/min

LX_04

4. Body Temperature ___ ___ ___ . ___ ° F

PULMONARY AUSCULTATION

LX_05

5. Indicate condition of subject. (*Check one box only*)

If applicable, describe sounds:

_____
_____
_____

- ❑1 No wheezing
- ❑2 Wheeze on inspiration or expiration
- ❑3 Adventitious sounds other than wheezing

PHYSICAL EXAMINATION

LX_06

6. Does the subject have evidence of oral candidiasis? ❑1 Yes ❑0 No

If YES, please complete the Clinical Adverse Events form (AECLIN).

Please indicate current physical findings by checking the appropriate boxes below, and if ABNORMAL, please describe concisely:

			Not Done	Normal	Abnormal	
LX_07	7.	Hair and Skin	❑2	❑1	❑0	_____
LX_08	8.	Lymph nodes	❑2	❑1	❑0	_____
LX_09	9.	Eyes (excluding corrective lenses)	❑2	❑1	❑0	_____
LX_10	10.	Ears, Nose, and Throat	❑2	❑1	❑0	_____
LX_11	11.	Respiratory (excluding asthma)	❑2	❑1	❑0	_____
LX_12	12.	Cardiovascular	❑2	❑1	❑0	_____
LX_13	13.	Gastrointestinal	❑2	❑1	❑0	_____
LX_14	14.	Musculoskeletal	❑2	❑1	❑0	_____
LX_15	15.	Neurological	❑2	❑1	❑0	_____
LX_16	16.	Mental Status	❑2	❑1	❑0	_____
LX_17	17.	Other _____	❑2	❑1	❑0	_____

Physician signature: _____

Date: __ __ / __ __ / __ __

Time: __ __ : __ __

ADVERSE EVENTS (*If Visit 1, do NOT complete Question #18.)*

LX_18 18. ***Ask the subject:*** Have you experienced any new medical conditions since the last clinic visit? ❑1 Yes ❑0 No

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

If any of the Clinical Adverse Events warrants a laboratory test, report any adverse results on a Laboratory Adverse Events form (AELAB).

(Subject Interview completed)

DEMOGRAPHY

MHX_01 1. What is your date of birth? ____ ____ / ____ ____ / ____ ____
month day year

MHX_02 2. What is your ethnic background?

- ❑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_____

MHX_03 3. What is your sex?

- ❑1 Male
- ❑2 Female

ASTHMA HISTORY

MHX_04 4. Approximately how old were you when your asthma first appeared? (*Check one box only*)

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

Initials:
Date:

MHX_05 5. How many years have you had asthma? (*Check one box only*)

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

MHX_06 6. In what season is your asthma the worst? (*Check one box only*)

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

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

MHX_07A 7a. Asthma episodes have you had that required emergency care or an unscheduled office visit? ___ ___

MHX_07B 7b. Hospitalizations have you had due to asthma? ___ ___

MHX_07C 7c. Courses of oral corticosteroid therapy for asthma (such as prednisone or Medrol) have you taken? ___ ___

MHX_08 8. Have you missed any days of work or school due to asthma in the last 12 months? ❑1 Yes ❑0 No ❑9 N/A

MHX_08A If ***YES***, record your best estimate of the number of days missed. ___ ___

9. 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.*)

MHX_09A	9a. Mother	❑1 Yes	❑0 No	❑8 Don't Know	
MHX_09B	9b. Father	❑1 Yes	❑0 No	❑8 Don't Know	
MHX_09C	9c. Brothers or Sisters	❑1 Yes	❑0 No	❑8 Don't Know	❑9 N/A
MHX_09D	9d. Child(ren)	❑1 Yes	❑0 No	❑8 Don't Know	❑9 N/A

PRIOR ASTHMA TREATMENT

Next, I will read a list of asthma medications. Indicate if you have used the medication. If you have, please indicate to the best of your knowledge, the date last taken.

					If Yes, indicate date medication was last taken month / day / year
MHX_10 MHX_10X	10.	Short acting Inhaled Beta-Agonists (MDI) (**Bronkaid Mist, Duo-Medihaler, Medihaler-Epi, Primatene Mist and others**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __
MHX_11 MHX_11X	11.	Intermediate acting Inhaled Beta-Agonists (MDI) (**Alupent, Brethaire, Brethine, Bronkometer, Maxair, Metaprel, Proventil, Tornalate, Ventolin and others)**	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __
MHX_12 MHX_12X	12.	Long acting Inhaled Beta-Agonists (MDI) (**Serevent**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __
MHX_13 MHX_13X	13.	Asthma medication via a Nebulizer Machine	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __
MHX_14 MHX_14X	14.	Intermediate acting Oral Beta-Agonists (**Alupent, Brethine, Bricanyl, Metaprel, Proventil, Ventolin and others**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __
MHX_15 MHX_15X	15.	Long acting Oral Beta-Agonists (**Repetabs, Volmax**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __
MHX_16 MHX_16X	16.	Short acting Oral Theophylline (**Aminophylline and others)**	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __
MHX_17 MHX_17X	17.	Sustained release Oral Theophylline (**Slo-bid, Theo-Dur, Uniphyl and others**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __
MHX_18 MHX_18X	18.	Inhaled Anticholinergic (**Atrovent**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __
MHX_19 MHX_19X	19.	Anti-allergic Medications (**Intal, Nasalcrom, Tilade and others**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __
MHX_20 MHX_20X	20.	Oral Steroids (**Prednisone, Medrol and others**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __

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

MHX_21 / **MHX_21X**

21. Inhaled Steroids (**Azmacort, Beclovent, Vanceril, AeroBid, Flovent and others**)

❑1 Yes ❑0 No ❑8 Unknown __ __/__ __/__ __

If ***YES***,

MHX_21A

21a. Indicate most recent type.

- ❑1 beclomethasone diproprionate (1 puff = 42μg) (e.g., Beclovent, Vanceril)
- ❑2 triamcinolone acetonide (1 puff = 100μg) (e.g., Azmacort)
- ❑3 flunisolide (1 puff = 250μg) (e.g., AeroBid)
- ❑4 fluticasone (1 puff = 44, 110, or 220μg) (e.g., Flovent)

MHX_21B

21b. Indicate most recent daily puffs. ___ ___ puffs

MHX_21C

21c. Indicate most recent daily use. ___ ___ ___ ___ μg

MHX_21D

21d. Indicate most recent duration.

- ❑1 less than 1 month
- ❑2 1 - 6 months
- ❑3 greater than 6 months

MHX_22 / **MHX_22X**

22. Leukotriene Antagonist / 5L0 Inhibitors (**Zafirlukast (Accolate), Zileuton)**

❑1 Yes ❑0 No ❑8 Unknown __ __/__ __/__ __

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

					If Yes, Comment
MHX_23	23.	Skin	❑1 Yes	❑0 No	_____
MHX_24	24.	Blood, Lymph, or Immune Systems	❑1 Yes	❑0 No	_____
MHX_25	25.	Eyes	❑1 Yes	❑0 No	_____
MHX_26	26.	Ears, Nose, or Throat	❑1 Yes	❑0 No	_____
MHX_27	27.	Breasts	❑1 Yes	❑0 No	_____
MHX_28	28.	Endocrine	❑1 Yes	❑0 No	_____
MHX_29	29.	Lung	❑1 Yes	❑0 No	_____
MHX_30	30.	Heart and Blood Vessels	❑1 Yes	❑0 No	_____
MHX_31	31.	Liver or Pancreas	❑1 Yes	❑0 No	_____
MHX_32	32.	Kidneys or Urinary Tract System	❑1 Yes	❑0 No	_____
MHX_33	33.	Reproductive System	❑1 Yes	❑0 No	_____
MHX_34	34.	Stomach or Intestines	❑1 Yes	❑0 No	_____
MHX_35	35.	Muscles or Bones	❑1 Yes	❑0 No	_____
MHX_36	36.	Nervous System	❑1 Yes	❑0 No	_____
MHX_37	37.	Psychiatric	❑1 Yes	❑0 No	_____
MHX_38	38.	Other _____	❑1 Yes	❑0 No	_____

METHACHOLINE CHALLENGE TESTING

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

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

METH_01 1. Has the subject had an acute asthma attack requiring oral steroids (prednisone or a similar drug) in the past 4 weeks? ☐ 1 Yes ☐ 0 No

METH_02 2. Has the subject had any other severe acute illness in the past 4 weeks? ☐ 1 Yes ☐ 0 No

METH_02a If ***Yes***, has the subject received permission from the supervising physician to proceed with the methacholine challenge testing? ☐ 1 Yes ☐ 0 No

Name of physician: _____

METH_03 3. Does the subject have a baseline (pre-diluent) FEV_1 less than 55% of predicted FEV_1? ☐ 1 Yes ☐ 0 No

At visit 1 use the prebronchodilator FEV_1 value from the SPIRO form as the baseline reference.

For visit 4 through final visit:

For SLIC, use the 1 hour post-salmeterol FEV_1 from the SPIRO form as the baseline reference.
For SOCS, use the prebronchodilator FEV_1 value from the SPIRO form as the baseline reference.

METH_04 4. Is there any other reason the subject should not proceed with the methacholine challenge testing? ☐ 1 Yes ☐ 0 No

If ***Yes***, explain _____

METH_05 5. Is the subject eligible to proceed with the diluent (solution #0) pulmonary function testing for the methacholine challenge? ☐ 1 Yes ☐ 0 No

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

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

METHACHOLINE CHALLENGE TEST *(Technician completed)*

Clinic Use Only

At visit 1 use the prebronchodilator FEV_1 value from the SPIRO form as the baseline reference.

For visit 4 through final visit:

For SLIC, use the 1 hour post-salmeterol FEV_1 from the SPIRO form as the baseline reference.

For SOCS, use the prebronchodilator FEV_1 value from the SPIRO form as the baseline reference.

Baseline FEV_1 prior to methacholine challenge

A. FEV_1 ____ . ____ ____ ***L***

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

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

METH_06 6. PC_{20} ____ ____ . ____ ____ ____ mg/ml

METH_06a 6a. Time methacholine challenge was completed. (*based on 24-hour clock*) ____ ____ ____ ____

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.

METH_07a 7a. FEV_1 ____ . ____ ____ L

METH_07b 7b. FEV_1 (% predicted) ____ ____ ____ % predicted

METH_07c 7c. Time of FEV_1 in Question #7a (*based on 24-hour clock*) ____ ____ ____ ____

METH_07d 7d. Was the FEV_1 from Question #7a ≥ the methacholine reversal reference value in the gray box above? ❑1 Yes ❑0 No

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

METH_08 8. Was additional treatment used in the first hour? ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #10.***

➜ ***If YES, please complete the appropriate Concomitant Medications form, if needed.***

METH_08a 8a. Additional albuterol by MDI ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #8b.***

METH08a1 8ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four

METH_08b 8b. Nebulized Beta-agonist ❑1 Yes ❑0 No

METH_08c 8c. Subcutaneous epinephrine ❑1 Yes ❑0 No

METH_08d 8d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

METH_08e 8e. Other _____ ❑1 Yes ❑0 No

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

METH_09a 9a. FEV_1 ___ . ___ ___ L

METH_09b 9b. FEV_1 (% predicted) ___ ___ ___ % predicted

METH_09c 9c. Time of FEV_1 in Question #9a (*based on 24-hour clock*) ___ ___ ___ ___

METH_09d 9d. Was the FEV_1 from Question #9a $\geq$ the methacholine reversal reference value in the gray box on page 2 of this form? ❑1 Yes ❑0 No

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

METH_10 10. Was additional treatment used after one hour? ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #11.***

➜ ***If YES, please complete the appropriate Concomitant Medications form, if needed.***

METH_10a 10a. Additional albuterol by MDI ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #10b.***

METH10a1 10ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four

METH_10b 10b. Nebulized Beta-agonist ❑1 Yes ❑0 No

METH_10c 10c. Subcutaneous epinephrine ❑1 Yes ❑0 No

METH_10d 10d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

METH_10e 10e. Treatment in the emergency room ❑1 Yes ❑0 No

METH_10f 10f. Overnight hospitalization ❑1 Yes ❑0 No

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

METH_10g 10g. Other _____ ❑1 Yes ❑0 No

11. Subject's final FEV_1 after methacholine challenge.

METH_11a 11a. FEV_1 ___ . ___ ___ L

METH_11b 11b. FEV_1 (% predicted) ___ ___ ___ % predicted

METH_11c 11c. Time of FEV_1 from Question #11a (*based on 24-hour clock*) ___ ___ ___ ___

METH_11d 11d. Was the FEV_1 from Question #11a ≥ the methacholine reversal reference value in the gray box on page 2 of this form? ❑ 1 Yes ❑ 0 No

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

Physician signature: _____

Date: __ __ / __ __ / __ __

Time: __ __ : __ __

Asthma Clinical Research Network
NIH/NHLBI

NITRIC OXIDE MEASUREMENTS

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Collector ID: ___ ___ ___ ___ ___

Nitric Oxide measurements should be taken after completing the spirometry checklist and prior to performing baseline spirometry.

NO_ANORA ANORA number: ___ ___

	(Collector completed)		***(Reader completed)***
Balloon Id	**Time Collected** *(based on 24-hour clock)*	**Time Read** *(based on 24-hour clock)*	**Measurement (ppb)**
NO_BAL1a ___ ___ ___	NO_BAL1b ___ ___.___ ___	NO_BAL1c ___ ___.___ ___	NO_BAL1d ___ ___ ___.___
NO_BAL2a ___ ___ ___	NO_BAL2b ___ ___.___ ___	NO_BAL2c ___ ___.___ ___	NO_BAL2d ___ ___ ___.___
NO_BAL3a ___ ___ ___	NO_BAL3b ___ ___.___ ___	NO_BAL3c ___ ___.___ ___	NO_BAL3d ___ ___ ___.___

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

NO_READ Reader ID: ___ ___ ___ ___ ___

Comments:

Asthma Clinical Research Network
NIH/NHLBI

QUALITY OF LIFE QUESTIONNAIRE

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject completed)

Please tell us how much you have been limited by your asthma during the last 2 weeks in each of your 5 most important activities. Refer to the Quality of Life Activities form (QOLACT) for your list of activities. If you have not done the activity in the last 2 weeks, leave the question blank.

HOW LIMITED HAVE YOU BEEN DURING THE LAST 2 WEEKS IN THESE ACTIVITIES?

		Not at all Limited	A Little Limitation	Some Limitation	Moderate Limitation	Very Limited	Extremely Limited	Totally Limited
QOL_01	1. Activity 1	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_02	2. Activity 2	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_03	3. Activity 3	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_04	4. Activity 4	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_05	5. Activity 5	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

		None	Very Little	Some	Moderate Amount	A Good Deal	A Great Deal	A Very Great Deal
QOL_06	6. How much discomfort or distress have you felt over the last 2 weeks as a result of CHEST TIGHTNESS?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

Initials:
Date:

IN GENERAL, HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS DID Y0U:

		None of the Time	Hardly Any of the Time	A Little of the Time	Some of the Time	A Good Bit of the Time	Most of the Time	All of the Time
QOL_07	7. Feel CONCERNED ABOUT HAVING ASTHMA?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_08	8. Feel SHORT OF BREATH as a result of your asthma?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_09	9. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO CIGARETTE SMOKE?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_10	10. Experience a WHEEZE in your chest?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_11	11. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF CIGARETTE SMOKE?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

		None	Very Little	Some	Moderate Amount	A Good Deal	A Great Deal	A Very Great Deal
QOL_12	12. How much discomfort or distress have you felt over the last 2 weeks as a result of COUGHING?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

IN GENERAL, HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS DID YOU:

		None of the Time	Hardly Any of the Time	A Little of the Time	Some of the Time	A Good Bit of the Time	Most of the Time	All of the Time
QOL_13	13. Feel FRUSTRATED as a result of your asthma?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_14	14. Experience a feeling of CHEST HEAVINESS?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_15	15. Feel CONCERNED ABOUT THE NEED TO USE MEDICATION for your asthma?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_16	16. Feel the need to CLEAR YOUR THROAT?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_17	17. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO DUST?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_18	18. Experience DIFFICULTY BREATHING OUT as a result of your asthma?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_19	19. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF DUST?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_20	20. WAKE UP IN THE MORNING WITH ASTHMA SYMPTOMS?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_21	21. Feel AFRAID OF NOT HAVING YOUR ASTHMA MEDICATION AVAILABLE?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_22	22. Feel bothered by HEAVY BREATHING?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_23	23. Experience asthma symptoms as a RESULT OF THE WEATHER OR AIR POLLUTION?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_24	24. Were you WOKEN AT NIGHT by your asthma?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_25	25. AVOID OR LIMIT GOING OUTSIDE BECAUSE OF THE WEATHER OR AIR POLLUTION?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

IN GENERAL, HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS DID YOU:

		None of the Time	Hardly Any of the Time	A Little of the Time	Some of the Time	A Good Bit of the Time	Most of the Time	All of the Time
QOL_26	26. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO STRONG SMELLS OR PERFUME?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_27	27. Feel AFRAID OF GETTING OUT OF BREATH?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_28	28. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF STRONG SMELLS OR PERFUME?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_29	29. Has your asthma INTERFERED WITH GETTING A GOOD NIGHT'S SLEEP?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
QOL_30	30. Have a feeling of FIGHTING FOR AIR?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

		No Limitation		Very Few Not Done		Several Not Done		Most Not Done
QOL_31	31. Think of the OVERALL RANGE OF ACTIVITIES that you would have liked to have done during the last 2 weeks. How much has your range of activities been limited by your asthma? .	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

		Not at all Limited	A Little Limitation	Some Limitation	Moderate Limitation	Very Limited	Extremely Limited	Totally Limited
QOL_32	32. Overall, among ALL THE ACTIVITIES that you have done during the last 2 weeks, how limited have you been by your asthma?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

Asthma Clinical Research Network
NIH/NHLBI

SERIOUS ADVERSE EVENT REPORTING FORM

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form must be faxed to the DCC at (717) 531-4359 within 72 hours of notification of a serious event. Also fax the Clinical Adverse Events Log (AECLIN), the Concomitant Medications Log (CMED_AS), and any relevant source documents.

SER_01 1. Description of Adverse Event (ICD9 Code) ___ ___ ___ . ___ ___

Describe: _____

SER_02 2. Time interval between taking the study drug (last dose before symptoms) and subsequent onset of symptoms? ___ ___

SER_03 3. Unit of time for above interval

- ☐ 1 second(s)
- ☐ 2 minute(s)
- ☐ 3 hour(s)
- ☐ 4 day(s)

4. Why was the event serious?

SER_04a	4a.	Fatal Event?	☐ 1 Yes	☐ 0 No
SER_04b	4b.	Life-threatening event?	☐ 1 Yes	☐ 0 No
SER_04c	4c.	Inpatient hospitalization required?	☐ 1 Yes	☐ 0 No
SER_04d	4d.	Hospitalization prolonged?	☐ 1 Yes	☐ 0 No
SER_04e	4e.	Disabling or incapacitating?	☐ 1 Yes	☐ 0 No
SER_04f	4f.	Overdose?	☐ 1 Yes	☐ 0 No
SER_04g	4g.	Cancer?	☐ 1 Yes	☐ 0 No
SER_04h	4h.	Congenital anomaly?	☐ 1 Yes	☐ 0 No
SER_04i	4i.	Serious laboratory abnormality with clinical symptoms?	☐ 1 Yes	☐ 0 No
SER_04j	4j.	Other _____	☐ 1 Yes	☐ 0 No

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

SER_05a	5a.	Toxicity of study drug?	☐ 1 Yes	☐ 0 No
SER_05b	5b.	Withdrawal of study drugs?	☐ 1 Yes	☐ 0 No

SER_05c 5c. Concurrent medication? ❑ 1 Yes ❑ 0 No

If ***YES***, describe _____

SER_05d 5d. Concurrent disorder? ❑ 1 Yes ❑ 0 No

If ***YES***, describe _____

SER_05e 5e. Other event? ❑ 1 Yes ❑ 0 No

If ***YES***, describe _____

DO NOT ENTER QUESTIONS # 6 - 7: FOR REPORTING PURPOSES ONLY.

6. If subject died, cause of death: _____

_____

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

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

Reporting Investigator:

Name: _____

Address: _____

_____

Signature: _____

Date: __ __ / __ __ / __ __

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

_____

_____

_____

_____

_____

Asthma Clinical Research Network
NIH/NHLBI

SHORT PHYSICAL EXAM

Subject ID: __ __ __ __ __
Subject Initials: __ __ __
Visit Number: __ __
Visit Date: __ __ / __ __ / __ __ (month / day / year)
Interviewer ID: __ __ __ __ __

(Clinic Coordinator completed)

VITAL SIGNS

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

SX_01a / **SX_01b**

1. Resting blood pressure ___ ___ ___ / ___ ___ ___mm Hg (systolic / diastolic)

SX_02

2. Pulse ___ ___ ___ beats/min

PULMONARY AUSCULTATION

SX_03

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

_____

_____

- ❑ 1 No wheezing
- ❑ 2 Wheeze on inspiration or expiration
- ❑ 3 Adventitious sounds other than wheezing

SX_04

4. Does the subject have evidence of oral candidiasis? ❑ 1 Yes ❑ 0 No

If YES, please complete the Clinical Adverse Events form (AECLIN).

Physician/Nurse signature: _____
Date: __ __ / __ __ / __ __
Time: __ __ : __ __

ADVERSE EVENTS

SX_05

5. ***Ask the subject:*** Have you experienced any new medical conditions since the last clinic visit? ❑ 1 Yes ❑ 0 No

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

If any of the Clinical Adverse Events warrants a laboratory test, report any adverse results of such tests on a Laboratory Adverse Events form (AELAB)

.

Asthma Clinical Research Network
NIH/NHLBI

HEALTH STATUS QUESTIONNAIRE SF-36

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject completed)

Below are questions about your health in general and questions about your health as it relates specifically to asthma. Please read and answer the questions carefully. If you are not sure about how to answer a question, please give the best answer you can.

SF36_01

1. In general, would you say your health is:

- ❑ 1 Excellent
- ❑ 2 Very Good
- ❑ 3 Good
- ❑ 4 Fair
- ❑ 5 Poor

SF36_02

2. Compared to ONE YEAR AGO, how would you rate your health in general NOW?

- ❑ 1 Much better now than one year ago
- ❑ 2 Somewhat better now than one year ago
- ❑ 3 About the same
- ❑ 4 Somewhat worse now than one year ago
- ❑ 5 Much worse now than one year ago

Initials:
Date:

The following questions are about activities you might do during a typical day. Does YOUR HEALTH now limit you in these activities? If so, how much?

			Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
SF36_03a	3a.	VIGOROUS ACTIVITIES, such as running, lifting heavy objects, participating in strenuous sports	❑1	❑2	❑3
SF36_03b	3b.	MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	❑1	❑2	❑3
SF36_03c	3c.	Lifting or carrying groceries	❑1	❑2	❑3
SF36_03d	3d.	Climbing SEVERAL flights of stairs	❑1	❑2	❑3
SF36_03e	3e.	Climbing ONE flight of stairs	❑1	❑2	❑3
SF36_03f	3f.	Bending, kneeling, or stooping	❑1	❑2	❑3
SF36_03g	3g.	Walking MORE THAN A MILE	❑1	❑2	❑3
SF36_03h	3h.	Walking SEVERAL BLOCKS	❑1	❑2	❑3
SF36_03i	3i.	Walking ONE BLOCK	❑1	❑2	❑3
SF36_03j	3j.	Bathing or dressing yourself	❑1	❑2	❑3

DURING THE PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities AS A RESULT OF YOUR PHYSICAL HEALTH?

SF36_04a	4a.	Cut down on the AMOUNT OF TIME you spent on work or other activities	❑1 Yes	❑0 No
SF36_04b	4b.	ACCOMPLISHED LESS than you would like	❑1 Yes	❑0 No
SF36_04c	4c.	Were limited in the KIND of work or other activities	❑1 Yes	❑0 No
SF36_04d	4d.	Had DIFFICULTY performing the work or other activities *(for example, it took extra effort)*	❑1 Yes	❑0 No

DURING THE PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities AS A RESULT OF ANY EMOTIONAL PROBLEMS *(such as feeling depressed or anxious)*?

SF36_05a	5a.	Cut down on the AMOUNT OF TIME you spent on work or other activities	❑1 Yes	❑0 No
SF36_05b	5b.	ACCOMPLISHED LESS than you would like	❑1 Yes	❑0 No
SF36_05c	5c.	Didn't do work or other activities as CAREFULLY as usual	❑1 Yes	❑0 No

SF36_06 6. DURING THE PAST 4 WEEKS, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- ❑1 Not at all
- ❑2 Slightly
- ❑3 Moderately
- ❑4 Quite a bit
- ❑5 Extremely

SF36_07 7. How much shortness of breath have you had during the PAST 4 WEEKS?

- ❑1 None
- ❑2 Very mild
- ❑3 Mild
- ❑4 Moderate
- ❑5 Severe
- ❑6 Very severe

SF36_08 8. DURING THE PAST 4 WEEKS, how much did pain interfere with your normal work *(including both work outside the home and housework)*?

- ❑1 Not at all
- ❑2 A little bit
- ❑3 Moderately
- ❑4 Quite a bit
- ❑5 Extremely

These questions are about how you feel and how things have been with you during the PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the PAST 4 WEEKS...

			All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
SF36_09a	9a.	Did you feel full of pep?	❑1	❑2	❑3	❑4	❑5	❑6
SF36_09b	9b.	Have you been a very nervous person?	❑1	❑2	❑3	❑4	❑5	❑6
SF36_09c	9c.	Have you felt so down in the dumps that nothing could cheer you up?	❑1	❑2	❑3	❑4	❑5	❑6
SF36_09d	9d.	Have you felt calm and peaceful?	❑1	❑2	❑3	❑4	❑5	❑6
SF36_09e	9e.	Did you have a lot of energy?	❑1	❑2	❑3	❑4	❑5	❑6
SF36_09f	9f.	Have you felt downhearted and blue?	❑1	❑2	❑3	❑4	❑5	❑6
SF36_09g	9g.	Did you feel worn out?	❑1	❑2	❑3	❑4	❑5	❑6
SF36_09h	9h.	Have you been a happy person?	❑1	❑2	❑3	❑4	❑5	❑6
SF36_09i	9i.	Did you feel tired?	❑1	❑2	❑3	❑4	❑5	❑6

SF36_10

10. DURING THE PAST 4 WEEKS, how much of the time has your physical health or emotional problems interfered with your social activities *(like visiting with friends, relatives, etc.)?*

- ❑1 All of the time
- ❑2 Most of the time
- ❑3 Some of the time
- ❑4 A little of the time
- ❑5 None of the time

How TRUE or FALSE is each of the following statements for you?

		Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
SF36_11a	11a. I seem to get sick a little easier than other people.	❑1	❑2	❑3	❑4	❑5
SF36_11b	11b. I am as healthy as anybody I know.	❑1	❑2	❑3	❑4	❑5
SF36_11c	11c. I expect my health to get worse.	❑1	❑2	❑3	❑4	❑5
SF36_11d	11d. My health is excellent.	❑1	❑2	❑3	❑4	❑5

Asthma Clinical Research Network
NIH/NHLBI

SIGNIFICANT ASTHMA EXACERBATION

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer 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?

SAE_01a	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
SAE_01b	1b.	Use of rescue inhaler ≥ 16 total puffs per 24 hours for a period of 48 hours?	■ 1 Yes ❑ 0 No
SAE_01c	1c.	PEF which did not increase to 65% of reference levels after 60 minutes of rescue beta agonist use?	■ 1 Yes ❑ 0 No
SAE_01d	1d.	Symptoms which persisted after 60 minutes of rescue beta-agonist use?	■ 1 Yes ❑ 0 No
SAE_02	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

If any of the shaded boxes are filled in, the subject experienced a significant asthma exacerbation.
If SLIC subject ➜ Please complete this form and continue with the treatment failure packet.
If SOCS subject and the shaded box in Question #2 is checked ➜ Please complete this form and continue with the treatment failure packet.

If the subject does not meet the above criteria as defined in the Manual of Operations,DO NOT COMPLETE THIS FORM.

If the subject has experienced a significant asthma exacerbation but has not yet completed the RUN-IN period, STOP. The subject is ineligible for the study. ➜ Please complete the Termination of Study Participation form (TERM).

SAE_03 3. Date of significant asthma exacerbation ___ ___ / ___ ___ / ___ ___ (month / day / year)

SAE_04 4. Did the subject seek care for the asthma exacerbation? ☐1 Yes ☐0 No

➜ ***If NO, skip to Question #6.***

5. What type of care was sought?

SAE_05a 5a. Study Investigator? ☐1 Yes ☐0 No

SAE_05a1 If ***YES***, indicate type of contact.

☐1 Scheduled clinic visit
☐2 Unscheduled clinic visit
☐3 Phone contact

SAE_05b 5b. Primary Care or Other Physician? ☐1 Yes ☐0 No

Name of physician: _____

SAE_05b1 If ***YES***, indicate type of contact.

☐1 Scheduled clinic visit
☐2 Unscheduled clinic visit
☐3 Phone contact

SAE_05c 5c. Emergency Room visit? ☐1 Yes ☐0 No

Name of hospital: _____

SAE_06 6. Was the subject hospitalized? ☐1 Yes ☐0 No

Name of hospital: _____

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

If ***YES***,

SAE_06a 6a. Duration of hospital stay? ___ ___ days

SAE_06b 6b. Was intubation or ventilation assistance required? ☐1 Yes ☐0 No

SAE_07 7. Did the asthma exacerbation require treatment with inhaled, oral, or intravenous glucocorticoids? ☐1 Yes ☐0 No

➜ ***If YES, please complete the appropriate Concomitant Medications form, if needed.***

.

SAE_08 8. Was the asthma exacerbation treated as outlined in the Manual of Operations?

☐ 1 Yes ☐ 0 No

If ***NO***, describe_____

_____

_____

SAE_09 9. Was the significant asthma exacerbation related to the routine pulmonary function testing? *(Check one box only)*

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

SAE_10 10. 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

SAE_11 11. Was the significant asthma exacerbation related to the Sputum Induction? *(Check one box only)*

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

SAE_12 12. Was the significant asthma exacerbation related to the Bronchoscopy? *(Check one box only)*

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

(*Subject Interview completed*)

SAE_13 13. Interval of time since last exacerbation

- ❑ 1 < 1 month
- ❑ 2 1 -2 months
- ❑ 3 3 - 6 months
- ❑ 4 7 - 12 months
- ❑ 5 > 1 year

SAE_14 14. Over what time period did the subject's asthma symptoms worsen prior to being diagnosed as having a significant asthma exacerbation?

- ❑ 1 0 - 6 hours
- ❑ 2 7 - 12 hours
- ❑ 3 13 - 24 hours
- ❑ 4 25 - 48 hours
- ❑ 5 > 48 hours

SAE_15 15. Was the asthma exacerbation resolved solely by increasing PRN use of the rescue inhaler?

❑ 1 Yes ❑ 0 No

In the table below, rate each of the following triggering factors with respect to their relationship to the current exacerbation.

1 = Definitely related
2 = Probably related
3 = Relationship undetermined
4 = Probably not related
5 = Definitely not related

	Triggering factors	Relationship to current asthma exacerbation*
SAE_16	16. Allergen exposure (cat, dog, pollen)	
SAE_17	17. Viral respiratory tract infection (common cold)	
SAE_18	18. Sinus infection	
SAE_19	19. Exercise	
SAE_20	20. Weather conditions	
SAE_21	21. Irritant exposure (smoke, pollution, perfume)	
SAE_22	22. Occupational exposure	
SAE_23	23. Emotional stress	
SAE_24	24. Failure to understand protocol directions	
SAE_25	25. Poor compliance	
SAE_26	26. Health care access problem	
SAE_27	27. Other - Specify:	

* based upon information obtained from the patient and discussed by the clinic coordinator and physician

SAE_28 28. Did allergen exposure occur? ❑1 Yes ❑0 No

➜ ***If NO, skip to question 29.***

SAE_28a 28a. Based upon the subject's allergy skin test, does the time of year of the current exacerbation correlate with these results in your geographic area? (e.g. for the midwest: trees/grass and spring, ragweed and fall, mold and summer/fall, etc.) ❑1 Yes ❑0 No

28b. Based upon the subject's allergy skin test, did the subject have a clinically relevant exposure to any of the following within a 24 hour period prior to the exacerbation?

SAE_28b1	28bi.	Dog	❑1 Yes	❑0 No
SAE_28b2	28bii.	Cat	❑1 Yes	❑0 No
SAE_28b3	28biii.	Pollen	❑1 Yes	❑0 No
SAE_28b4	28biv.	Mold	❑1 Yes	❑0 No
SAE_28b5	28bv.	Dust mites	❑1 Yes	❑0 No

SAE_29 29. Did the subject experience any allergic rhinitis symptoms during the week prior to his/her exacerbation? ❑1 Yes ❑0 No

➜ ***If NO, skip to question 30.***

29a. Which of the following symptoms did the subject experience?

			Not Present	Mild	Moderate	Severe
SAE_29a1	29ai.	Watery rhinorrhea	❑0	❑1	❑2	❑3
SAE_29a2	29aii.	Purulent rhinorrhea	❑0	❑1	❑2	❑3
SAE_29a3	29aiii.	Post nasal drainage	❑0	❑1	❑2	❑3
SAE_29a4	29aiv.	Nasal itching	❑0	❑1	❑2	❑3
SAE_29a5	29av.	Palatal itching	❑0	❑1	❑2	❑3
SAE_29a6	29avi.	Sneezing	❑0	❑1	❑2	❑3
SAE_29a7	29avii.	Cough	❑0	❑1	❑2	❑3
SAE_29a8	29aviii.	Headache	❑0	❑1	❑2	❑3
SAE_29a9	29aix.	Anosmia	❑0	❑1	❑2	❑3
SAE_29a0	29ax.	Malaise	❑0	❑1	❑2	❑3

SAE_30 30. Did the subject experience any "cold" symptoms during the week prior to their exacerbation? ❑1 Yes ❑0 No

➜ ***If NO, skip to question 31.***

30a. Which of the following "cold' symptoms did the subject experience?

			Not Present	Mild	Moderate	Severe
SAE_30a1	30ai.	Watery rhinorrhea	☐ 0	☐ 1	☐ 2	☐ 3
SAE_30a2	30aii.	Purulent rhinorrhea	☐ 0	☐ 1	☐ 2	☐ 3
SAE_30a3	30aiii.	Post nasal drainage	☐ 0	☐ 1	☐ 2	☐ 3
SAE_30a4	30aiv.	Headache	☐ 0	☐ 1	☐ 2	☐ 3
SAE_30a5	30av.	Sore throat	☐ 0	☐ 1	☐ 2	☐ 3
SAE_30a6	30avi.	Fever	☐ 0	☐ 1	☐ 2	☐ 3
SAE_30a7	30avii.	Cough	☐ 0	☐ 1	☐ 2	☐ 3
SAE_30a8	30aviii.	Malaise	☐ 0	☐ 1	☐ 2	☐ 3
SAE_30a9	30aix.	Muscle aches	☐ 0	☐ 1	☐ 2	☐ 3

SAE_31 — 31. Did sinusitis occur within the last week? ☐ 1 Yes ☐ 0 No

➜ ***If NO, skip to question 32.***

31a. If sinusitis occurred within the last week, how was it diagnosed?

SAE_31a1	31ai.	History and exam	☐ 1 Yes	☐ 0 No
SAE_31a2	31aii.	Sinus radiographs	☐ 1 Yes	☐ 0 No
SAE_31a3	31aiii.	CT scan of sinuses	☐ 1 Yes	☐ 0 No

SAE_31b — 31b. Which statement best describes the subject's clinical experience with sinus disease?

- ☐ 0 NOT a problem
- ☐ 1 Acute
- ☐ 2 Subacute
- ☐ 3 Chronic

SAE_32 — 32. Did exercise contribute to the current exacerbation? ☐ 1 Yes ☐ 0 No

Name of activity: _____

SAE_33 — 33. Did weather conditions contribute to the current exacerbation? ☐ 1 Yes ☐ 0 No

➜ ***If NO, skip to question 34.***

33a. What weather conditions were felt to be contributory?

SAE_33a1	33ai.	Weather too hot?	☐ 1 Yes	☐ 0 No
SAE_33a2	33aii.	Weather too cold?	☐ 1 Yes	☐ 0 No
SAE_33a3	33aiii.	Weather too dry?	☐ 1 Yes	☐ 0 No
SAE_33a4	33aiv.	Weather too humid?	☐ 1 Yes	☐ 0 No
SAE_33a5	33av.	Change in weather?	☐ 1 Yes	☐ 0 No

Describe change: _____

SAE_34 — 34. Did irritant exposure contribute to the current exacerbation? ☐ 1 Yes ☐ 0 No

➜ ***If NO, skip to question 35.***

34a. Did the subject have relevant exposure to the following irritants?

SAE_34a1	34ai.	Cigarette smoke	☐ 1 Yes	☐ 0 No
SAE_34a2	34aii.	Indoor air pollution	☐ 1 Yes	☐ 0 No

Please specify type of indoor air pollution: _____

SAE_34a3	34aiii.	Outdoor air pollution	☐ 1 Yes	☐ 0 No

Please specify type of outdoor air pollution: _____

SAE_34a4	34aiv.	Perfume/cologne	☐ 1 Yes	☐ 0 No
SAE_34a5	34av.	Aerosols	☐ 1 Yes	☐ 0 No
SAE_34a6	34avi.	Other	☐ 1 Yes	☐ 0 No

Please specify other: _____

SAE_35 — 35. Did occupational exposure contribute to the current exacerbation? ☐ 1 Yes ☐ 0 No

➜ ***If NO, skip to question 36.***

Please specify substance involved: _____

SAE_35a	35a.	Was this the first exposure to the above substance?	☐ 1 Yes	☐ 0 No
SAE_35b	35b.	Did multiple exposures occur to this substance?	☐ 1 Yes	☐ 0 No

SAE_36 — 36. Did emotional stress contribute to the current exacerbation? ☐ 1 Yes ☐ 0 No

➜ ***If NO, skip to question 37.***

Please describe the stressful situation: _____

SAE_36a	36a.	Was this the first time the stressful situation occurred?	☐ 1 Yes	☐ 0 No
SAE_36b	36b.	Does this stressful situation occur often?	☐ 1 Yes	☐ 0 No

SAE_37 37. Did failure to understand the protocol directions contribute to the current exacerbation? ❑1 Yes ❑0 No

➜ ***If NO, skip to question 38.***

➜ ***If YES, please describe the failure.***

_____

_____

_____

SAE_38 38. Did poor compliance contribute to the current exacerbation? ❑1 Yes ❑0 No

➜ ***If NO, skip to question 39.***

➜ ***If YES, please describe the problem with compliance.***

_____

_____

_____

SAE_39 39. Did a problem with access to health care contribute to the current exacerbation? ❑1 Yes ❑0 No

➜ ***If NO, skip to question 40.***

➜ ***If YES, please describe the problem.***

_____

_____

_____

SAE_40 40. Are there any other important factors that contributed to the current exacerbation? ❑1 Yes ❑0 No

➜ ***If YES, please describe.***

_____

_____

_____

Asthma Clinical Research Network
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ALLERGY SKIN TEST RESULTS

Subject ID: 3 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

SKIN_PST A. Has the subject had a previous skin test using ACRN procedures? ❑1 Yes ❑0 No

SKIN_PTD If ***YES***, date of previous skin test ___ ___ / ___ ___ / ___ ___ (month / day / year)

If the subject had a previous ACRN skin test within three years of the visit date, attach a photocopy of the previous skin test form to this form.
At the time of data entry, enter section A from this form and then enter the data recorded on the photocopy.

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

SKIN_TS B. Skin test site
❑1 back
❑2 forearm

SKIN_TT Time subject skin **tested** (based on 24-hour clock) ___ ___ ___ ___

SKIN_TE Time skin tests **evaluated** (based on 24-hour clock) ___ ___ ___ ___

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

	SKIN_01	Was there a reaction? ❑0 No ❑1 Yes		**SKIN_08**	Was there a reaction? ❑0 No ❑1 Yes
		Largest Wheal			Largest Wheal
	SKIN_01a	Diameter ___ ___ ___ mm		**SKIN_08a**	Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
1. Diluting Fluid	**SKIN_01b**	Diameter ___ ___ ___ mm	8. Alternaria	**SKIN_08b**	Diameter ___ ___ ___ mm
	SKIN_02	Was there a reaction? ❑0 No ❑1 Yes		**SKIN_09**	Was there a reaction? ❑0 No ❑1 Yes
		Largest Wheal			Largest Wheal
	SKIN_02a	Diameter ___ ___ ___ mm		**SKIN_09a**	Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
2. Tree Fluid	**SKIN_02b**	Diameter ___ ___ ___ mm	9. Cladosporium	**SKIN_09b**	Diameter ___ ___ ___ mm
	SKIN_03	Was there a reaction? ❑0 No ❑1 Yes		**SKIN_10**	Was there a reaction? ❑0 No ❑1 Yes
		Largest Wheal			Largest Wheal
	SKIN_03a	Diameter ___ ___ ___ mm		**SKIN_10a**	Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
3. Grass Mix	**SKIN_03b**	Diameter ___ ___ ___ mm	10. Aspergillus	**SKIN_10b**	Diameter ___ ___ ___ mm
	SKIN_04	Was there a reaction? ❑0 No ❑1 Yes		**SKIN_11**	Was there a reaction? ❑0 No ❑1 Yes
		Largest Wheal			Largest Wheal
	SKIN_04a	Diameter ___ ___ ___ mm		**SKIN_11a**	Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
4. Ragweed	**SKIN_04b**	Diameter ___ ___ ___ mm	11. D. Farinae	**SKIN_11b**	Diameter ___ ___ ___ mm

	SKIN_05	Was there a reaction? ❑0 No ❑1 Yes		**SKIN_12**	Was there a reaction? ❑0 No ❑1 Yes
		Largest Wheal			Largest Wheal
	SKIN_05a	Diameter ___ ___ ___ mm		**SKIN_12a**	Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
5. Weed Mix	**SKIN_05b**	Diameter ___ ___ ___ mm	12. D. Pteryn	**SKIN_12b**	Diameter ___ ___ ___ mm
	SKIN_06	Was there a reaction? ❑0 No ❑1 Yes		**SKIN_13**	Was there a reaction? ❑0 No ❑1 Yes
		Largest Wheal			Largest Wheal
	SKIN_06a	Diameter ___ ___ ___ mm		**SKIN_13a**	Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
6. Dogs	**SKIN_06b**	Diameter ___ ___ ___ mm	13. Cockroach	**SKIN_13b**	Diameter ___ ___ ___ mm
	SKIN_07	Was there a reaction? ❑0 No ❑1 Yes		**SKIN_14**	Was there a reaction? ❑0 No ❑1 Yes
		Largest Wheal			Largest Wheal
	SKIN_07a	Diameter ___ ___ ___ mm		**SKIN_14a**	Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
7. Cats	**SKIN_07b**	Diameter ___ ___ ___ mm	14. Histamine	**SKIN_14b**	Diameter ___ ___ ___ mm

(Subject Interview completed)

RTRY_01 1. Height (*without shoes*) ___ ___ ___ . ___ cm

Height should be measured at every visit if subject is ≤ 21 years old and only at Visit 1 if subject is > 21 years old.

BASELINE PULMONARY FUNCTION TESTING *(Technician completed)*

RTRY_02 2. Time spirometry started (*based on 24-hour clock*) ___ ___ ___ ___

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

RTRY_03a	3. Results of best effort	FVC	___ . ___ ___ L
RTRY_03b		FEV_1	___ . ___ ___ L
RTRY_03c		FEV_1	___ ___ ___ % predicted
RTRY_03d		PEFR	___ ___ . ___ ___ L/S
RTRY_03e		FEF_{25-75}	___ . ___ ___ L/S

If the subject's prebronchodilator FEV_1 in Question #3 ≤ 80% of the prebronchodilator value obtained at Visit 4, the subject is a treatment failure. Please complete this form and continue with the SLIC treatment failure packet. Otherwise, continue with this form and the remaining visit procedures.

RTRY_04	4.	Have you used your Ventolin® (**RESCUE**) inhaler in the past 6 hours? ***If the time is less than 6 hours, pulmonary function testing must be rescheduled.***	■ 1 Yes	❑ 0 No
RTRY_05	5.	Have you used ***Inhaler 2*** in the past 12 hours?	■ 1 Yes	❑ 0 No
RTRY_06	6.	Have you consumed caffeine in the past 8 hours? ***Examples****: Caffeinated colas (Pepsi, Coke), Coffee, Mello-Yello, Mountain Dew, Tea*	■ 1 Yes	❑ 0 No
RTRY_07	7.	Have you used medications with caffeine in the past 8 hours? ***Examples****: Anacin, Darvon compound, Esgic, Excederin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*	■ 1 Yes	❑ 0 No
RTRY_08	8.	Have you consumed any food containing alcohol or beverages containing alcohol in the past 8 hours?	■ 1 Yes	❑ 0 No
RTRY_09a	9a.	Have you used fexofenadine (e.g. Allegra) or chlorpheniramine (e.g. Chlor-Trimeton) in the past 48 hours?	■ 1 Yes	❑ 0 No
RTRY_09b	9b.	Have you used pseudoephedrine (e.g. Sudafed) or oxymetazoline (e.g. Afrin) in the past 48 hours?	■ 1 Yes	❑ 0 No
RTRY_10	10.	Have you had a respiratory tract infection or any other pulmonary infection since the last visit?	❑ 1 Yes	❑ 0 No
RTRY_11	11.	At this time, is your asthma worse because of recent exposure to triggers (for example: cold air, smoke, allergens, or recent exercise)?	❑ 1 Yes	❑ 0 No
RTRY_12	12.	Is there any other reason you should not proceed with the pulmonary function testing? If ***YES***, explain _____ _____	■ 1 Yes	❑ 0 No
RTRY_13	13.	Is the subject eligible to proceed? ***If any of the shaded boxes are filled in, the subject is NOT eligible to proceed.***	❑ 1 Yes	■ 0 No

If NO, and if

(i) this is SLIC treatment failure visit, complete page 3 and the SLIC treatment failure packet.

(ii) this is not a SLIC treatment failure visit, do not complete page 3 of this form. Complete remaining visit procedures with the exception of post-salmeterol testing and methacholine challenge.

RTRY_14a	14. Results of best effort post-salmeterol	FVC	____ . ____ ____ L
RTRY_14b		FEV_1	____ . ____ ____ L
RTRY_14c		FEV_1	____ ____ ____ % predicted
RTRY_14d		PEFR	____ ____ . ____ ____ L/S
RTRY_14e		FEF_{25-75}	____ . ____ ____ L/S

If the subject's post-salmeterol FEV_1 in Question #14 $\leq$ 80% of the post-salmeterol value obtained at Visit 4, the subject is a treatment failure. Please continue with the SLIC treatment failure packet.

If the subject is not a treatment failure by any criterion, continue with the remaining visit procedures.

Asthma Clinical Research Network
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SPIROMETRY TESTING

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

SPIR_01 1. ***(If Visit 1, do not complete Question #1.)***
Have you used your Ventolin® (**RESCUE**) inhaler in the past 6 hours? ☐ 1 Yes ☐ 0 No
If the time is less than 6 hours, pulmonary function testing must be rescheduled.

SPIR_02 2. ***(Visit 5 through Last Visit Only)***
(SOCS subjects) Have you used ***Inhaler 2*** in the past 48 hours? ☐ 1 Yes ☐ 0 No
(SLIC subjects) Have you used ***Inhaler 2*** in the past 12 hours?

SPIR_03 3. Have you consumed caffeine in the past 8 hours? ☐ 1 Yes ☐ 0 No
Examples*: Caffeinated colas (Pepsi, Coke), Coffee, Mello-Yello, Mountain Dew, Tea*

SPIR_04 4. Have you used medications with caffeine in the past 8 hours? ☐ 1 Yes ☐ 0 No
Examples*: Anacin, Darvon compound, Esgic, Excederin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*

SPIR_05 5. Have you consumed any food containing alcohol or beverages containing alcohol in the past 8 hours? ☐ 1 Yes ☐ 0 No

SPIR_06a 6a. Have you used fexofenadine (e.g. Allegra) or chlorpheniramine (e.g. Chlor-Trimeton) in the past 48 hours? ☐ 1 Yes ☐ 0 No

SPIR_06b 6b. Have you used pseudoephedrine (e.g. Sudafed) or oxymetazoline (e.g. Afrin) in the past 48 hours? ☐ 1 Yes ☐ 0 No

SPIR_07 7. ***(For Sputum Induction only)*** Have you used any cough or cold preparations (e.g. expectorants, decongestants, or antitussives) in the past 48 hours? ☐ 1 Yes ☐ 0 No
➔ ***If Yes, reschedule visit within visit window.***

SPIR_08 8. Have you had a respiratory tract infection or any other pulmonary infection since the last visit? ☐ 1 Yes ☐ 0 No

SPIR_09 9. At this time, is your asthma worse because of recent exposure to triggers (for example: cold air, smoke, allergens, or recent exercise)? ☐ 1 Yes ☐ 0 No

SPIR_10 10. Is there any other reason you should not proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No
If ***YES***, explain _____

SPIR_11

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

☞ ***If YES, please continue.***

☞ ***If NO, do NOT complete page 2 or 3 unless this is a SOCS or SLIC treatment failure visit.***
If this is a regular protocol visit, the pulmonary function testing should be rescheduled within the visit window.

SPIR_12

12. Height (*without shoes*) ___ ___ ___ . ___ cm

Height should be measured at every visit if subject is ≤ 21 years old and only at Visit 1 if subject is > 21 years old.

BASELINE PULMONARY FUNCTION TESTING *(Technician completed)*

SPIR_13

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

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

SPIR_14a

14. Results of best effort — FVC ___ . ___ ___ L

SPIR_14b — FEV_1 ___ . ___ ___ L

SPIR_14c — FEV_1 ___ ___ ___ % predicted

SPIR_14d — PEFR ___ ___ . ___ ___ L/S

SPIR_14e — FEF_{25-75} ___ . ___ ___ L/S

THIS PAGE IS FOR SLIC VISITS 4 THROUGH 11 AND SLIC TREATMENT FAILURE VISITS ONLY

Visits 5 through 11:
Compare the subject's prebronchodilator FEV_1 in Question #14 to the prebronchodilator value obtained at Visit 4 for possible treatment failure status. See SOCS/SLIC Manual of Operations for details.

SPIR_15a	15. Results of best effort post-salmeterol	FVC	___ . ___ ___ L
SPIR_15b		FEV_1	___ . ___ ___ L
SPIR_15c		FEV_1	___ ___ ___ % predicted
SPIR_15d		PEFR	___ ___ . ___ ___ L/S
SPIR_15e		FEF_{25-75}	___ . ___ ___ L/S

Visits 5 through 11:
Compare the subject's post-salmeterol FEV_1 in Question #15 to the post-salmeterol value obtained at Visit 4 for possible treatment failure status. See SOCS/SLIC Manual of Operations for details.

If the subject did not complete salmeterol reversibility testing please provide an explanation below.

_____

_____

_____

SPUTUM INDUCTION LAB VALUES

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID ___ ___ ___ ___ ___

(Technician completed)

Total and Differential Cell Counts

SLAB_01	1.	Total Cell Count	___ ___ . ___ ___ x 10^5/ml
SLAB_02	2.	Squamous Cells	___ ___ ___ . ___ %

The parameters below are calculated following exclusion of squamous cells.

SLAB_03	3.	Total Cell Count	___ ___ . ___ ___ x 10^5/ml
SLAB_04	4.	Epithelial Cells	___ ___ ___ . ___ %
SLAB_05	5.	Macrophages	___ ___ ___ . ___ %
SLAB_06	6.	Neutrophils	___ ___ ___ . ___ %
SLAB_07	7.	Eosinophils	___ ___ ___ . ___ %
SLAB_08	8.	Lymphocytes	___ ___ ___ . ___ %

SLAB_09 9. Did the subject's sputum sample reveal ≥ 80% squamous cells? ■ 1 Yes ☐ 0 No

If the shaded box in Question #9 is filled in, the sputum sample should not be sent for overreading.

SPUTUM INDUCTION

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Technician completed)

SPUT_01 1. ***(Visit 5 through Last Visit Only)*** ☐ 1 Yes ☐ 0 No

At visit 4, was the subject able to continue sputum induction for more than 4 minutes and able to produce a satisfactory induced sputum sample (≥ 1 ml and < 80% squamous cells)?

➜ ***If NO, stop here. DO NOT proceed with sputum induction.***
➜ ***If YES, please continue with this form.***

SPUT_02 2. Did the subject complete the methacholine challenge? ☐ 1 Yes ☐ 0 No

➜ ***If NO, skip to Question #3.***

SPUT_02a 2a. Subject's FEV_1 after all reversal from methacholine challenge ___ . ___ ___ L

SPUT_02b 2b. Subject's FEV_1 (% predicted) after all reversal from methacholine challenge ___ ___ ___ % predicted

SPUT_02c 2c. Was the subject's FEV_1 from Question #2a ≥ the methacholine reversal reference value on page 2 of the METHA form? ☐ 1 Yes ■ 0 No

SPUT_02d 2d. Is the FEV_1 from Question #2b ≥ 60% predicted? ☐ 1 Yes ■ 0 No

If either of the shaded boxes is filled in, STOP here. DO NOT proceed with sputum induction.
If neither of the shaded boxes is filled in, Skip to Question #6 on the next page.

(For subjects who did not complete methacholine challenge)

SPUT_03 3. Subject's FEV_1 15 minutes after 4 puffs of albuterol ___ . ___ ___ L

SPUT_04 4. Subject's FEV_1 15 minutes after 4 puffs of albuterol (% predicted) ___ ___ ___ % predicted

SPUT_05 5. Is the subject's post-albuterol FEV_1 ≥ 60% predicted? ☐ 1 Yes ■ 0 No

If the shaded box in Question #5 is filled in, STOP here. DO NOT proceed with sputum induction.

SPUT_06 ***6. (If Visit 1, do not complete Question #6.)***

What was the duration of sputum induction the first time it exceeded 4 minutes, not including current visit?
(Duration of sputum induction at current visit should not exceed this.) ___ ___ . ___ minutes

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

SPUT_07a 7a. FEV_1 ___ . ___ ___ L

SPUT_07b 7b. FEV_1 (% predicted) ___ ___ ___ % predicted

SPUT_07c 7c. Time of FEV_1 from Question #7a (*based on 24-hour clock*) ___ ___ ___ ___

Clinic Use Only

% change in FEV_1 after sputum induction $\frac{\textit{(Question \#2a or 3 - Question \#7a)}}{\textit{Question \#2a or 3}} \times 100$: ___ ___ . ___ %

SPUT_08 8. Duration of sputum induction at this visit ___ ___ . ___ minutes

SPUT_09 9. Volume of sputum sample at this visit ___ ___ ___ . ___ ml

SPUT_10 10. Was the subject's sputum sample volume ≥ 1 ml at this visit? ☐ 1 Yes ☐ 0 No

SPUT_11 11. Did the subject tolerate sputum induction for > 4 minutes at this visit? ☐ 1 Yes ☐ 0 No

SPUT_12 12. Is the sample adequate for analysis of squamous cells? ☐ 1 Yes ☐ 0 No

If either of the shaded boxes is filled in, the sputum sample should not be sent for analysis of squamous cell counts.

Complete pages 3 and 4 only if the subject has a fall in FEV_1 (from post-albuterol baseline) of > 20% during or immediately after sputum induction.

Clinic Use Only

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

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

SPUT_13a 13a. FEV_1 ___ . ___ ___ L

SPUT_13b 13b. FEV_1 (% predicted) ___ ___ ___ % predicted

SPUT_13c 13c. Time of FEV_1 from Question #13a (*based on 24-hour clock*) ___ ___ ___ ___

SPUT_13d 13d. Was the FEV_1 from Question #13a ≥ the sputum induction reversal reference value in the gray box above? ❑1 Yes ❑0 No

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

SPUT_14 14. Was additional treatment used in the first hour? ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #16.***

➜ ***If YES, please complete the appropriate Concomitant Medications form, if needed.***

SPUT_14a 14a. Additional albuterol by MDI ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #14b.***

SPUT14a1 14ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four

SPUT_14b 14b. Nebulized Beta-agonist ❑1 Yes ❑0 No

SPUT_14c 14c. Subcutaneous epinephrine ❑1 Yes ❑0 No

SPUT_14d 14d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

SPUT_14e 14e. Other _____ ❑1 Yes ❑0 No

15. Subject's FEV_1 after additional treatment within the first hour

SPUT_15a 15a. FEV_1 ___ . ___ ___ L

SPUT_15b 15b. FEV_1 (% predicted) ___ ___ ___ % predicted

SPUT_15c 15c. Time of FEV_1 from Question #15a (*based on 24-hour clock*) ___ ___ ___ ___

SPUT_15d 15d. Was the FEV_1 from Question #15a ≥ the sputum induction reversal reference value in the gray box on page 3 of this form? ❑1 Yes ❑0 No

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

SPUT_16 16. Was additional treatment used after one hour? ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #17.***

➜ ***If YES, please complete the appropriate Concomitant Medications form, if needed.***

SPUT_16a 16a. Additional albuterol by MDI ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #16b.***

SPUT16a1 16ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four

SPUT_16b 16b. Nebulized Beta-agonist ❑1 Yes ❑0 No

SPUT_16c 16c. Subcutaneous epinephrine ❑1 Yes ❑0 No

SPUT_16d 16d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

SPUT_16e 16e. Treatment in the emergency room ❑1 Yes ❑0 No

SPUT_16f 16f. Overnight hospitalization ❑1 Yes ❑0 No

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

SPUT_16g 16g. Other _____ ❑1 Yes ❑0 No

17. Subject's final FEV_1 after sputum induction

SPUT_17a 17a. FEV_1 ___ . ___ ___ L

SPUT_17b 17b. FEV_1 (% predicted) ___ ___ ___ % predicted

SPUT_17c 17c. Time of FEV_1 from Question #17a (*based on 24-hour clock*) ___ ___ ___ ___

SPUT_17d 17d. Was the FEV_1 from Question #17a ≥ the sputum induction reversal reference value in the gray box on page 3 of this form? ❑1 Yes ❑0 No

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

Physician signature: _____

Date: __ __ / __ __ / __ __

Time: __ __ : __ __

Asthma Clinical Research Network
NIH/NHLBI

SLIC SUBGROUP DETERMINATION

Subject ID: 5 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 5
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

SGR_01 1. Is the subject's pre-bronchodilator FEV_1 greater than 80% of predicted? ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #3. The subject should be included in SUBGROUP II***
➜ ***If YES, run the PEF calculator.***

SGR_02 2. Is the subject's average PEF variability ≤ 20% during the past two weeks? ❑1 Yes ❑0 No

➜ ***If YES, the subject should be included in SUBGROUP I.***
➜ ***If NO, the subject should be included in SUBGROUP II.***

Run the randomization program.
If an electronic connection is impossible, call the DCC at (717) 531 - 4262, 8:00 AM - 5:00 PM E.S.T.
During the hours 5:00 PM - 9:00 PM E.S.T. call the beeper number and leave a phone number at which you can be contacted.

SGR_03 3. To which subgroup is the subject allocated?
❑1 SUBGROUP I
❑2 SUBGROUP II

Clinic Use Only
Information needed for subject randomization:
Age: _____
Sex: _____
Race: _____

SGR_04 4. Visit 5 study drug packet number. ___ ___ ___ ___ ___

TERMINATION OF STUDY PARTICIPATION

Subject ID: ___ ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Please indicate the reason for termination of study participation.

TERM_01 ***1. (SOCS Visit 13 and SLIC Visit 11 Only)***

Has the subject completed the study? ❑1 Yes ❑0 No

➜ ***If YES, skip to the SIGNATURES section on page 2.***

TERM_02 2. Is the subject withdrawing from the study due to pregnancy? ❑1 Yes ❑0 No

Initials:
Date:

TERM_03 3. ***(Visit 1 through Visit 4 Only)***

During the run-in period, has the subject experienced a significant asthma exacerbation as defined in the Manual of Operations? ❑1 Yes ❑0 No

TERM_04 4. ***(Visit 1 through Visit 4 Only)***

Has the subject been deemed ineligible according to any eligibility criteria **other than** a significant exacerbation? ❑1 Yes ❑0 No

TERM_05 5. Has the subject withdrawn consent? ❑1 Yes ❑0 No

TERM_05A If ***YES***, indicate the **primary** reason.

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

TERM_06 6. Has the subject been lost to follow-up? ☐1 Yes ☐0 No

TERM_07 7. Did a physician initiate subject termination? ☐1 Yes ☐0 No

TERM_08 8. Has the subject experienced a serious adverse event (e.g., hospitalization, death, etc.)? ☐1 Yes ☐0 No

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

TERM_09 ***9. (SOCS Visits 10 - 13 Only)***

Has the subject been assigned drop-out status during the single blind run-out period? ☐1 Yes ☐0 No

SIGNATURES

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

I verify that all information collected on the ACRN SOCS or SLIC 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 SOCS or SLIC Protocol and Manual of Operations.

TERM_S1

Clinic Coordinator Signature

TERM_DT1

___ ___ ___ ___ ___ ___

month day year

TERM_S2

Principal Investigator Signature

TERM_DT2

___ ___ ___ ___ ___ ___

month day year

Asthma Clinical Research Network
NIH/NHLBI

SLIC TREATMENT FAILURE

Subject ID: 5 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 9 9
Current Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

TXF2_01 1. Is this treatment failure visit replacing a regular visit? ☐ 1 Yes ☐ 0 No

TXF2_01A If ***YES***, indicate visit number of scheduled visit ___ ___

TXF2_01B If ***NO***, indicate last regular visit completed ___ ___

TXF2_02 2. Did the subject experience a **post**-salmeterol FEV_1 value ≤ 80% of the post-salmeterol baseline value recorded at Visit 4? ☐ 1 Yes ☐ 0 No

TXF2_03 3. Did the subject experience **pre**bronchodilator FEV_1 values ≤ 80% of the prebronchodilator value recorded at Visit 4 on two consecutive sets of spirometric determinations? ☐ 1 Yes ☐ 0 No
(See the Manual of Operations for more detail.)

TXF2_04 4. Did the subject experience a fall in **post**bronchodilator AM PEFR to ≤ 80% of baseline (baseline defined as the average AM pre-bronchodilator PEFR recorded during the two weeks prior to visit 4)? ☐ 1 Yes ☐ 0 No
(Subjects may take 2-4 puffs of Rescue every 20 minutes up to 1 hour.)

TXF2_04A 4a. If YES, please record the **post**bronchodilator AM PEFR value that qualified the subject as a treatment failure. ___ ___ ___ L/min

TXF2_05 5. Did the subject experience a fall in **pre**bronchodilator PEFR to ≤ 65% of baseline (baseline defined as the average AM pre-bronchodilator PEFR recorded during the two weeks prior to visit 4) on two out of three consecutive scheduled measurements? ☐ 1 Yes ☐ 0 No

6. Did the subject experience one of the following conditions?

TXF2_06A 6a. An increase in rescue inhaler use of ≥ 8 puffs per 24 hours over baseline rescue inhaler use (baseline defined as the average daily use during the two weeks prior to visit 4) for a period of 48 hours? ☐ 1 Yes ☐ 0 No

TXF2_06B 6b. Use of rescue inhaler ≥ 16 total puffs per 24 hours for a period of 48 hours? ☐ 1 Yes ☐ 0 No

TXF2_07 7. Did the subject require emergency treatment (at a medical facility) that was related to, or complicated by, his/her asthma and which resulted in corticosteroid treatment or hospitalization for an acute asthma exacerbation? ☐ 1 Yes ☐ 0 No

➜ ***If YES, please complete the Serious Adverse Event Reporting Form (SERIOUS) if hospitalized and the appropriate Concomitant Medications Form if needed.***

TXF2_08 8. Did the subject require treatment with oral or parenteral corticosteroids for an asthma related condition? ☐ 1 Yes ☐ 0 No

➜ ***If YES, please complete the Concomitant Medications Form (CMED_AS).***

TXF2_09 9. Did the subject experience a significant asthma exacerbation? ☐ 1 Yes ☐ 0 No

TXF2_10 10. Based on clinical safety judgement, did the physician deem this subject a treatment failure? ☐ 1 Yes ☐ 0 No

TXF2_11 11. Is the subject a treatment failure? ***If any of the shaded boxes in #2 - 10 are filled in, the subject is a treatment failure.*** ☐ 1 Yes ☐ 0 No

☞ If YES, please complete this form and continue with the Treatment Failure packet.

12. Has the subject taken any of the following medications since the treatment failure conditions started?

TXF2_12A 12a. Inhaled or Oral Steroids ☐ 1 Yes ☐ 0 No

TXF2_12B 12b. Theophylline ☐ 1 Yes ☐ 0 No

TXF2_12C 12c. Beta-Agonist via nebulizer ☐ 1 Yes ☐ 0 No

TXF2_12D 12d. Cromolyn ☐ 1 Yes ☐ 0 No

TXF2_12E 12e. Nedocromil ☐ 1 Yes ☐ 0 No

TXF2_12F 12f. Ipratropium bromide ☐ 1 Yes ☐ 0 No

TXF2_12G 12g. Zafirlukast ☐ 1 Yes ☐ 0 No

TXF2_12H 12h. Other: _____ ☐ 1 Yes ☐ 0 No

➜ ***If YES (to any Question in #12), please complete the Concomitant Medications Form (CMED_AS).***

TXF2_13 13. Date treatment failure occurred ___ ___ / ___ ___ / ___ ___ (month / day / year)

TXF2_14 14. From a clinical perspective, would you have considered this subject to be a "treatment failure" if he/she were not participating in this double blind trial and, instead, you were seeing him/her in your outpatient clinic?

❑1 Yes ❑0 No

TXF2_15 15. Based on the subject's clinical status at the time he/she met one of the treatment failure criteria, when do you think that the subject reached this status?

❑1 Too early (asthma not that bad)
❑2 At the right time (asthma would be considered clinically unstable, but the subject not in jeopardy)
❑3 Too late (concerned about the subject's safety)

TXF2_16 16. What was the subject's opinion of his/her asthma at the time he/she reached treatment failure?

❑1 Rescued too soon
❑2 Rescued at the right time
❑3 Waited too long before being rescued

TXF2_17 17. Based on your experience with this subject, are you satisfied with the SLIC treatment failure criteria?

➜ ***If NO, please call or email the DCC.***

❑1 Yes ❑0 No