Asthma Clinical Research Network
NIH/NHLBI

IMPACT
CLINICAL ADVERSE EVENTS

cae

Enter this form after the subject's last visit has been completed.

Subject ID: 9 ___ ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: 1

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

(Clinic Coordinator completed)

If the subject experienced any clinical adverse events (including PICT and intercurrent events) since enrolling at Visit 1, complete this log. If no clinical adverse events occurred throughout the entire study, check none and sign and date this page.

❑0 None

CC's 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 contact	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 STUDY 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
___ NBR EVENT	___.__ 01	__/__/02__ / __/__/03__	❑1 04	__ 05	06	07	08	09	10	11	12
___	___.__	__/__/____ / __/__/____	❑1	__							
___	___.__	__/__/____ / __/__/____	❑1	__							
___	___.__	__/__/____ / __/__/____	❑1	__							
___	___.__	__/__/____ / __/__/____	❑1	__							

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

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

Asthma Clinical Research Network
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IMPACT AIRWATCH™ QUALITY CONTROL

air

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Technician completed)

01 1. Serial Number of AirWatch™ being tested ___ ___ ___ ___ - ___ ___ ___ ___

02 2. Serial Number of mouthpiece being tested ___ ___ ___ ___

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

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

04a If ***YES***, indicate the primary 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

Clinic Use Only

		AirWatch™ (L/Min)	Jones FVC (L/Min)	Relative Bias (AirWatch™ - Jones FVC) / Jones FVC * 100 %	Rank (smallest to largest)
5.	Trial 1	**05a** ___ ___ ___	___ ___ ___	**05b** ___ ___ ___ . ___ %	___
6.	Trial 2	**06a** ___ ___ ___	___ ___ ___	**06b** ___ ___ ___ . ___ %	___
7.	Trial 3	**07a** ___ ___ ___	___ ___ ___	**07b** ___ ___ ___ . ___ %	___
8.	Trial 4	**08a** ___ ___ ___	___ ___ ___	**08b** ___ ___ ___ . ___ %	___
9.	Trial 5	**09a** ___ ___ ___	___ ___ ___	**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.*

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

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
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IMPACT CLINIC COORDINATOR POST-STUDY QUESTIONNAIRE

ccb

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Coordinator completed)

This questionnaire is to be completed at Visit 14 by the ACRN study coordinator who was primarily responsible for the subject's IMPACT visits. If a randomized subject terminates prior to Visit 14, this form should be completed at the time of the termination visit.

01

1. Subjects in the IMPACT study were randomized to receive either an active inhaled steroid inhaler or a placebo inhaler. You were blinded to the actual treatment assignment. Please check the box that most closely represents your feelings about the treatment the subject received.

- ☐ 1 I am certain it was placebo.
- ☐ 2 I think it was probably placebo.
- ☐ 3 I have no idea which treatment the subject received, but my best guess would be:

01a

  - ☐ 1 Placebo
  - ☐ 2 Active Drug

- ☐ 4 I think it was probably active drug.
- ☐ 5 I am certain it was active drug.

02

2. Subjects in the IMPACT study were randomized to receive either an active tablet or a placebo tablet. You were blinded to the actual treatment assignment. Please check the box that most closely represents your feelings about the treatment the subject received.

- ☐ 1 I am certain it was placebo.
- ☐ 2 I think it was probably placebo.
- ☐ 3 I have no idea which treatment the subject received, but my best guess would be:

02a

  - ☐ 1 Placebo
  - ☐ 2 Active Drug

- ☐ 4 I think it was probably active drug.
- ☐ 5 I am certain it was active drug.

Coordinator's Initials: __ __ __

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

CCBLIND

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

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IMPACT
CONCOMITANT MEDICATIONS for ASTHMA and ALLERGIES
cmed

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year

(Clinic Coordinator completed)

At Visit 1: Please list all concomitant medications used to treat **asthma** and **allergies** that the subject has taken since signing the informed consent. Indicate the name of the medication, dose, units, frequency, route, and start date. Refer to the Concomitant Medications list (MED) for applicable codes.

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

❑0 None

CODE	NAME OF MEDICATION	DOSE	UNITS	FREQUENCY	ROUTE	START DATE (MM/DD/YYYY)	STOP DATE (MM/DD/YYYY)	ONGOING AT END OF STUDY
01	1. CMEDNO	02	03	04	05	06	07	08
	2.					___/___/____	___/___/____	❑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

IMPACT Concomitant Drug Codes

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

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

Codes for Routes		
Code	Routes	
1	PO	oral
2	IM	injection into muscle
3	SC	injection into skin
4	SL	sublingual, under tongue
5	IV	intravenous
6	NEB	nebulized
7	patch	
8	oral inhalation (MDI or dry powder)	
9	drop	
10	topical	
11	nasal spray	
12	other	

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IMPACT
CONCOMITANT MEDICATIONS for RELATED EVENTS
cmed

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year

(Clinic Coordinator completed)

Visit 1: Please list all concomitant medications for **related events** (i.e. an antibiotic for the treatment of sinusitis or bronchitis) that the subject has taken since signing the informed consent. Indicate the name of the medication, dose, units, frequency, route, and start date. Refer to the Concomitant Medications list (MED) for applicable codes.

Subsequent visits: Please update the table at each visit. Indicate any new medications started due to an adverse related event experienced because of a study medication or **related event** (i.e. an oral antifungal drug for oral candidiasis). Also, update any medications that were stopped since the last update. If the subject is still taking the medication at the end of the study, please check the"ongoing" box and leave the stop date column blank. Check the "None" box if the subject has not taken any concomitant medications for an adverse related event experienced because of a study medication during the entire study.

❑0 None

CODE	NAME OF MEDICATION	RELATED EVENT (indicate event on AECLIN)	DOSE	UNITS	FREQUENCY	ROUTE	START DATE (MM/DD/YYYY)	STOP DATE (MM/DD/YYYY)	ONGOING AT END OF STUDY
01	1. **CMEDNO**	**NBR**	**02**	**03**	**04**	**05**	**06**	**07**	**08**
	2.	Event ___ ___					___/___/____	___/___/____	❑1
	3.	Event ___ ___					___/___/____	___/___/____	❑1
	4.	Event ___ ___					___/___/____	___/___/____	❑1
	5.	Event ___ ___					___/___/____	___/___/____	❑1
	6.	Event ___ ___					___/___/____	___/___/____	❑1
	7.	Event ___ ___					___/___/____	___/___/____	❑1
	8.	Event ___ ___					___/___/____	___/___/____	❑1
	9.	Event ___ ___					___/___/____	___/___/____	❑1
	10.	Event ___ ___					___/___/____	___/___/____	❑1
	11.	Event ___ ___					___/___/____	___/___/____	❑1
	12.	Event ___ ___					___/___/____	___/___/____	❑1
	13.	Event ___ ___					___/___/____	___/___/____	❑1
	14.	Event ___ ___					___/___/____	___/___/____	❑1
	15.	Event ___ ___					___/___/____	___/___/____	❑1

(Clinic Coordinator completed)

Check the following compliance criteria at **each visit**.

1. eDEM™ Monitor

The information for Question #1a - Question #1d is obtained from the eDEM™ Monitor Report.

01a	1a.	Number of monitored days	___ ___ ___ days
01b	1b.	Number of doses taken	___ ___ ___ doses
01c	1c.	% Prescribed number of doses taken	___ ___ ___ . ___ %
01d	1d.	Doses in time window/prescribed doses	___ ___ ___ . ___ %

Check the following compliance criteria at **Visits 3 through 14 Only**.

2. Turbuhaler®

02a	2a.	Number of scheduled doses since last visit ***(number of full days since last visit x 2 puffs/day, excluding today's visit and subject's last visit date)***	___ ___ ___ doses
02b	2b.	Used doses (180 - remaining clicks)	___ ___ ___ doses
02c	2c.	Percent compliance $\frac{\textit{Question \#2b}}{\textit{Question \#2a}}$ *x 100*	___ ___ ___ . ___ %

➜ If the percent compliance is less than 70%, the subject is non-compliant. Please reeducate the subject about the importance of compliance

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Please use black ink to complete.

IMPACT DIARY CARD

Subject's Initials: __ __ __

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

dry

Subject ID: 9 __ __ __ __

Subject Initials: __ __ __

Return Visit Number: __ __

Return Visit Date: __ __ / __ __ / __ __
Month Day Year

To the subject:
If your symptoms worsen refer to the "Symptom Based Action Plan" handout.

		Day 1: ____	Day 2: ____	Day 3: ____	Day 4: ____	Day 5: ____	Day 6: ____	Day 7: ____
dmonth dday	Date	__ / __ month day	__ / __ month day	__ / __ month day	__ / __ month day	__ / __ month day	__ / __ month day	__ / __ month day
MORNING EVALUATION (Between 5 - 10 AM)								
1. Number of times that you woke up last night due to asthma		01 __ __	__ __	__ __	__ __	__ __	__ __	__ __
2. Time of AM Peak Flow (within 15 minutes of awakening)		02 __ __ . __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
3. AM Peak Flow (liters/min)**		03 03r __ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __
4. Total number of puffs from scheduled inhaler **(AM)**		04	__	__	__	__	__	__
5. Number of pills taken **(AM)**		05	__	__	__	__	__	__
Symptoms++ during the night.	6. Shortness of Breath	06						
	7. Chest Tightness	07						
	8. Wheezing	08						
	9. Cough	09						
	10. Phlegm/Mucus	10						
NIGHT-TIME EVALUATION (Between 8 PM - 1 AM)								
11. Time of PM Peak Flow (between 8 PM and 1 AM)		11 __ __ . __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
12. PM Peak Flow (liters/min)**		12 12r __ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __
13. Total number of puffs from scheduled inhaler **(PM)**		13	__	__	__	__	__	__
14. Number of pills taken **(PM)**		14	__	__	__	__	__	__
Symptoms++ since you woke.	15. Shortness of Breath	15						
	16. Chest Tightness	16						
	17. Wheezing	17						
	18. Cough	18						
	19. Phlegm/Mucus	19						
24 HOUR EVALUATION								
20. Total number of **puffs** from albuterol **(RESCUE1)** inhaler over a 24 hour period. *(Do not record preventive use.)*		20 __ __	__ __	__ __	__ __	__ __	__ __	__ __

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

++ Symptom Severity Rating Scale

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

Asthma Clinical Research Network
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IMPACT DISCHARGE SUMMARY REPORT

disc

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form should only be completed if the subject has been hospitalized during the IMPACT Study. Obtain hospital discharge summary or abstract to complete this form.

DO NOT ENTER. FOR REFERENCE PURPOSES ONLY.

Hospital Name: _____

Hospital Address: _____

_____

_____

01 1. Admission date ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year)

02 2. Discharge date ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year)

03 3. Number of days in ICU/CCU/Stepdown Unit ___ ___

04 4. Number of days in regular care unit ___ ___

05 5. Did the subject visit the ER prior to this hospitalization? ❑ 1 Yes ❑ 0 No
➜ ***If YES, please complete the Emergency Room or Urgent Care Visit (ER_UC) form.***

06 6. Was the subject placed on a ventilator? ❑ 1 Yes ❑ 0 No

07 7. What was the reason for this hospitalization?
❑ 1 Asthma
❑ 2 Other _____

08 8. What was the subject's status at discharge?
❑ 1 Alive
❑ 2 Deceased

(Technician completed)

(Visit 1 Only - Question #1)

01 1. Date eDEM™ monitor was awakened ___ ___ / ___ ___ / ___ ___ ___ ___ (*month / day / year*)

02 2. Serial Number of eDEM™ monitor being tested ___ ___ ___ ___ ___

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

4. Record monitor's validity **04a** (*month*) . **04b** (*year*)

05 5. Record battery voltage ___ ___ . ___ ___ volts

06 6. Is this a new eDEM™ monitor being tested? ❑1 Yes ❑0 No

06a If ***YES***, indicate the primary reason.

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

07 7. Did the eDEM™ monitor pass? ❑1 Yes ❑0 No

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

Asthma Clinical Research Network
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IMPACT
ELIGIBILITY CHECKLIST 1

e1

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

01	1.	***Did the subject sign the Informed Consent?***	❑ 1 Yes ❑ 0 No
01a		*If **YES**, record the date the form was signed.*	____ ____ / ____ ____ / ____ ____ ____ ____ (*month / day / year*)
02	2.	Is the subject between 18 and 65, inclusive?	❑ 1 Yes ❑ 0 No
03	3.	Are you planning to move away from this clinical center in the next 15 months such that your ability to complete the study will be jeopardized?	❑ 1 Yes ❑ 0 No
04	4.	Have you used any smokeless tobacco products (chew, snuff) in the past year?	❑ 1 Yes ❑ 0 No
05	5.	Have you smoked cigarettes, a pipe, cigars, or any other substance in the past year?	❑ 1 Yes ❑ 0 No
06	6.	Do you have a smoking history less than 10 pack-years?	❑ 1 Yes ❑ 0 No
06a		Record history in pack-years. (Enter '00.0' if none)	___ ___ . ___
07	7.	Have you had a respiratory tract infection in the past 6 weeks?	❑ 1 Yes ❑ 0 No
08	8.	Have you experienced a significant asthma attack in the past 6 weeks?	❑ 1 Yes ❑ 0 No

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

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

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

11a 11a. If ***YES,*** are you currently pregnant or lactating? ☐ 1 Yes ☐ 0 No

11b 11b. If ***YES***, are you using one of the approved birth control methods indicated on this reference card? (*Show subject the Birth Control Methods reference card.*) ☐ 1 Yes ☐ 0 No

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

☞ ***If NO, please complete the Termination of Study Participation (TERM) form.***

Subject's Initials: __ __ __

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

Asthma Clinical Research Network
NIH/NHLBI

IMPACT
ELIGIBILITY CHECKLIST 2

e2

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

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

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 _____

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 _____

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

05 5. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible. STOP HERE.*** ☐ 1 Yes ☐ 0 No

☞ ***If NO, please complete the Termination of Study Participation (TERM) form.***

Subjects Initials: __ __ __
Date: __ __ / __ __ / __ __ __ __

Complete Page 2 only if subject meets the eligibility requirements on Page 1.

06	6.	In the past month, on average, did the subject have asthma symptoms more than twice a week?	☐ 1 Yes ☐ 0 No
07	7.	In the past month, did asthma symptoms wake the subject more than two nights?	☐ 1 Yes ☐ 0 No
08	8.	In the past month, on average, did the subject have asthma symptoms more than six days a week?	☐ 1 Yes ☐ 0 No
09	9.	In the past month, did asthma symptoms wake the subject more than four nights?	☐ 1 Yes ☐ 0 No

10	10.	Is **EITHER** Question 6 or Question 7 answered **YES**?	☐ 1 Yes ☐ 0 No

☞ ***If YES, subject is eligible.***

☞ ***If NO, subject may be ineligible and completion of the Termination of Study Participation (TERM) form may be necessary. Clinic Coordinator discretion is permitted. See MOP for further instructions.***

DO NOT COMPLETE QUESTIONS 11 AND 12.

11	11.	Are **BOTH** Question 8 and Question 9 answered **NO**?	☐ 1 Yes ☐ 0 No
12	12.	Are the answers for Question 10 and Question 11 **YES**?	☐ 1 Yes ☐ 0 No

Asthma Clinical Research Network
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IMPACT
ELIGIBILITY CHECKLIST 3

e3

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. Is the subject's prebronchodilator $FEV_1 \geq$ 70% of predicted? ☐ 1 Yes ☐ 0 No

02 2. Does the subject have source documentation of a methacholine PC_{20} < 16 mg/ml (ACRN system only) within the past 2 months? ☐ 1 Yes ☐ 0 No

➜ ***If YES,*** record values below:

02a PC_{20} ___ ___ . ___ ___ ___ ___ mg/ml

02b Date of source documentation ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year)

➜ ***Go to Question #4.***

03 3. Was the subject's methacholine PC_{20} obtained during Visit 1 < 16 mg/ml? ☐ 1 Yes ☐ 0 No

04 4. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ☐ 1 Yes ☐ 0 No

☞ ***If NO, please complete the Termination of Study Participation (TERM) form.***

(Clinic Coordinator completed)

(Visit 5 Only - Question #1)

01 1. During the last two weeks of the run-in period, using the ENACT fax, did the subject take his or her peak flow measurements outside the protocol defined windows (5 - 10 AM and 8 PM - 1 AM) on 8 or more occasions? ☐ 1 Yes ☐ 0 No

02 2. During the last two weeks, did the subject fail to record the AM and PM peak flow measurements and symptoms on the Diary Cards on 4 or more days? ☐ 1 Yes ☐ 0 No

03 3. Using the information recorded on the subject's Diary Cards, did the subject take an incorrect number of puffs from the scheduled inhaler during 8 or more of the AM or PM dosing sessions during the last two weeks? ☐ 1 Yes ☐ 0 No

04 4. Did the subject show evidence of noncompliance (<70%) with the eDEM™ Monitor as determined on the COMPLY form? ☐ 1 Yes ☐ 0 No

05 5. Did the subject show evidence of noncompliance (<70%) with Turbuhaler® as determined on the COMPLY form? ☐ 1 Yes ☐ 0 No

06 6. In the past month, using the information recorded on the subject's Diary Cards for Questions 15 through 19 (based on the symptom severity rating scale), on average, how many days per week did the subject have asthma symptoms?

- ☐ 1 0-2
- ☐ 2 3-6
- ☐ 3 ≥ 7

07 7. In the past month, on average, how many nights did the subject wake up due to asthma?

- ☐ 1 0-2
- ☐ 2 3-4
- ☐ 3 ≥ 5

08 8. In the past two weeks, on average, what was the subject's peak flow variability?

- ☐ 1 < 20%
- ☐ 2 20-30%
- ☐ 3 >30%

COMPLETE QUESTION 9 AT VISIT 3 AND VISIT 5.

09 9. Are any of the shaded boxes filled in for Question 1 through Question 5? ☐ 1 Yes ☐ 0 No

☞ ***If YES, STOP HERE subject is ineligible. Complete the Termination of Study Participation (TERM) form.***

☞ ***If NO, the subject is eligible to continue in the study.***

DO NOT COMPLETE QUESTION 10.

10 10. Are any of the starred boxes filled in for either Question 6, Question 7, or Question 8? ☐ 1 Yes ☐ 0 No

COMPLETE QUESTION 11 AT VISIT 3 ONLY.

11 11. Is an unshaded box filled in for either Question 6, Question 7, or Question 8? ☐ 1 Yes ☐ 0 No

☞ ***If NO, the subject is ineligible. Complete the Termination of Study Participation (TERM) form.***

☞ ***If YES, the subject is eligible to continue in the study.***

DO NOT COMPLETE QUESTION 12.

12 12. Are the answers for Question 9 and Question 10 **NO**, and the answer for Question 11 **YES**? ☐ 1 Yes ☐ 0 No

Subjects Initials: __ __ __

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

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IMPACT
ELIGIBILITY CHECKLIST 5

e5

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 6
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. Did the subject experience any side effect(s) from the Period of Intense Combined Therapy (PICT)? ☐ 1 Yes ☐ 0 No

01a 1a. If ***YES***, has the investigating physician determined that the subject should not be randomized due to the PICT side effect(s)? ☐ 1 Yes ☐ 0 No

If ***YES,*** describe: _____

➜ ***If YES, please complete both sections of the PICT Adverse Event Questionnaire (PAEQ) form.***

02 2. Does the subject wish to withdraw consent from the study? ☐ 1 Yes ☐ 0 No

03 3. Is there any other reason why this subject should not be included in the study? ☐ 1 Yes ☐ 0 No

If ***YES,*** describe: _____

04 4. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ☐ 1 Yes ■ 0 No

☞ ***If the subject is eligible and will participate in IMPACT, randomize the subject. Otherwise, please complete the Termination of Study Participation (TERM) form.***

05 5. Drug Packet Number **(record on LOG)** 9 ___ ___ ___ ___ ___

Asthma Clinical Research Network
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IMPACT EMERGENCY ROOM OR URGENT CARE VISIT

eruc

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. Type of visit
- ❑1 ER
- ❑2 Urgent care

02 2. Date of visit ___ ___ / ___ ___ / ___ ___ ___ ___ (*month / day / year*)

03 3. Was visit due to asthma? ❑1 Yes ❑0 No
➜ ***If NO, STOP HERE. Do NOT complete remainder of form.***

04 4. Was spirometry performed at visit? ❑1 Yes ❑0 No

05 5. Was peak flow measured at visit? ❑1 Yes ❑0 No

06 6. Were any treatments given during visit? ❑1 Yes ❑0 No
➜ ***If NO, skip to Question #7.***
➜ ***If YES, please complete appropriate Concomitant Medications form, if needed.***

06a 6a. Nebulizer ("breathing") treatment ❑1 Yes ❑0 No

06b 6b. IM steroids ❑1 Yes ❑0 No

06c 6c. IV steroids ❑1 Yes ❑0 No

06d 6d. IV aminophylline ❑1 Yes ❑0 No

06e 6e. Other _____ ❑1 Yes ❑0 No

07 7. Were any medications prescribed at discharge? ❑1 Yes ❑0 No
➜ ***If NO, skip to Question #8.***
➜ ***If YES, please complete appropriate Concomitant Medications form, if needed.***

07a 7a. Oral steroids ❑1 Yes ❑0 No

07b 7b. Antibiotics ❑1 Yes ❑0 No

08 8. Was the subject hospitalized after this ER/UC visit? ❑1 Yes ❑0 No
➜ ***If YES, please complete Subject Hospitalization Report (HOSP) form and Discharge Summary Report (DISC) form.***

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IMPACT HEALTHCARE UTILIZATION REVIEW

hur

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

DO NOT ENTER. FOR REFERENCE PURPOSES ONLY.

I am going to ask you some questions based on several events which may have occurred since your last study visit which took place on:

___ ___ / ___ ___ / ___ ___ ___ ___
month *day* *year*

01 1. Since your last study visit, were you admitted to a hospital for an overnight stay of at least one night? ❑1 Yes ❑0 No

01a If ***YES***, how many times were you admitted? ___ ___ time(s)
➜ ***Please complete Subject Hospitalization Report (HOSP) form, Discharge Summary Report (DISC) form, Serious Adverse Event (SERIOUS) form, and School/Work Absenteeism (SWA) form.***

02 2. Since your last study visit, did you go to an emergency room? ❑1 Yes ❑0 No

02a If ***YES***, how many times? ___ ___ time(s)
➜ ***Please complete Emergency Room or Urgent Care Visit (ER_UC) form and School/Work Absenteeism (SWA) form.***

03 3. Since your last study visit, did you have an unscheduled/urgent care visit to a physician? ❑1 Yes ❑0 No

03a If ***YES***, how many times? ___ ___ time(s)
➜ ***Please complete Emergency Room or Urgent Care Visit (ER_UC) form and School/Work Absenteeism (SWA) form.***

04 4. Since your last study visit, did you have a regular clinic/office visit to a physician (does not apply to study visits)? ❑1 Yes ❑0 No

04a If ***YES***, how many times? ___ ___ time(s)
➜ ***Please complete School/Work Absenteeism (SWA) form.***

05 5. Since your last study visit, did you miss at least a half-day of work, house work, or school because of your health (does not apply to time off for study visits)? ❑1 Yes ❑0 No

➜ ***If YES, please complete School/Work Absenteeism (SWA) form.***

06 6. Since your last study visit, were you prescribed any new medicine(s)? ❑1 Yes ❑0 No

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

07 7. Since your last study visit, did you purchase any over-the-counter (OTC) medicine(s)? ❑1 Yes ❑0 No

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

Asthma Clinical Research Network
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IMPACT INTERIM PHONE QUESTIONNAIRE

iq

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

01	1.	In the <u>past 14 days</u>, did you have wheezing, chest tightness, cough, or shortness of breath?	❑1 Yes ❑0 No
01a		If ***YES***, how many days?	___ ___ days
02	2.	In the <u>past 14 days</u>, did you have to slow down or stop activities because of asthma, wheezing, chest tightness, cough, or shortness of breath?	❑1 Yes ❑0 No
02a		If ***YES***, how many days?	___ ___ days
03	3.	In the <u>past 14 days</u>, did you wake up because of asthma, wheezing, chest tightness, cough, or shortness of breath?	❑1 Yes ❑0 No
03a		If ***YES***, how many days?	___ ___ days
04	4.	Thinking about all three asthma signs or symptoms (wheezing, slowing down or stopping activities, and nights awakened), in the <u>past 14 days</u>, did you have <u>any</u> of these day-time or night-time symptoms?	❑1 Yes ❑0 No
04a		If ***YES***, how many days?	___ ___ days
05	5.	In the <u>past 14 days</u>, did you experience any day with <u>NO</u> day-time or night-time symptoms of asthma (including no wheezing, no cough, no chest tightness, or no shortness of breath)?	❑1 Yes ❑0 No
05a		If ***YES***, how many days?	___ ___ days

(Clinic Coordinator completed)

URINE PREGNANCY TEST ***(Visits 1, 5, 7, 13, 14)***

01 1. Pregnancy test results

- ❑1 Positive
- ❑2 Negative
- ❑9 N/A

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

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

URINE DIPSTICK FOR GLUCOSE ***(Visits 5, 6, 13, 14)***

02 2. Glucose test results

- ❑1 Neg
- ❑2 trace
- ❑3 +1
- ❑4 +2
- ❑5 +3
- ❑6 +4

BLOOD PRESSURE ***(Visits 5, 6, 13, 14)***

3. Blood pressure results ___**03a**___ / ___**03b**___ mm Hg
systolic diastolic

BLOOD TESTS ***(Visits 5 and 13)***

04 4. Eosinophils ___ ___ ___ ___ /mm^3

(Clinic Coordinator completed)

VITAL SIGNS

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

1. Resting blood pressure ___ **01a** ___ / ___ **01b** ___ mm Hg
   systolic diastolic

02 2. Pulse ___ ___ ___ beats/min

03 3. Respiratory rate ___ ___ breaths/min

04 4. Body temperature ___ ___ ___ . ___ ° F

LONG PHYSICAL EXAM

(Physician completed)

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

			Not Done	Normal	Abnormal	
05	5.	Hair and Skin	❑2	❑1	❑0	_____
06	6.	Lymph nodes	❑2	❑1	❑0	_____
07	7.	Eyes (excluding corrective lenses)	❑2	❑1	❑0	_____
08	8.	Ears, Nose, and Throat	❑2	❑1	❑0	_____
09	9.	Respiratory (excluding asthma)	❑2	❑1	❑0	_____
10	10.	Cardiovascular	❑2	❑1	❑0	_____
11	11.	Gastrointestinal	❑2	❑1	❑0	_____
12	12.	Musculoskeletal	❑2	❑1	❑0	_____
13	13.	Neurological	❑2	❑1	❑0	_____
14	14.	Mental Status	❑2	❑1	❑0	_____
15	15.	Other _____ (check Not Done if non-applicable)	❑2	❑1	❑0	_____

PULMONARY AUSCULTATION

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

If applicable, describe sounds:

_____
_____
_____

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

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

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

Physician signature: _____

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

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

(Subject Interview completed)

01	1.	Have you consumed caffeine in the past 8 hours? ***Examples**: Caffeinated colas (Pepsi, Coke), Coffee, Mello-Yello, Mountain Dew, Tea, Barq's Rootbeer*	☐ 1 Yes	☐ 0 No
02	2.	Have you used medications with caffeine in the past 8 hours? ***Examples**: Anacin, Darvon compound, Esgic, Excedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*	☐ 1 Yes	☐ 0 No
03	3.	Have you consumed any food containing alcohol or beverages containing alcohol in the past 8 hours?	☐ 1 Yes	☐ 0 No
04a	4a.	Have you used any antihistamines in the past 48 hours?	☐ 1 Yes	☐ 0 No
04b	4b.	Have you used any oral decongestants or cold remedies in the past 48 hours?	☐ 1 Yes	☐ 0 No
04c	4c.	Have you used any nasal steroids in the past 48 hours?	☐ 1 Yes	☐ 0 No
04d	4d.	Have you used a rescue intermediate-acting inhaled beta-agonist [e.g. albuterol (Ventolin or Proventil)] in the past 6 hours?	☐ 1 Yes	☐ 0 No
04e	4e.	Have you used a rescue long-acting inhaled beta-agonist [e.g. Serevent] in the past 48 hours?	☐ 1 Yes	☐ 0 No
04f	4f.	Have you taken any oral corticosteroids in the past 6 weeks? ➜ ***If YES, complete the Concomitant Medications for Asthma (CMED_AS) form.***	☐ 1 Yes	☐ 0 No
04g	4g.	Have you taken any inhaled corticosteroids in the past 6 weeks? ➜ ***If YES, complete the Concomitant Medications for Asthma (CMED_AS) form.***	☐ 1 Yes	☐ 0 No
04h	4h.	Have you taken any other medications (see the EXCLMED reference card) to treat your asthma or allergies in the past 6 weeks? ➜ ***If YES, complete the Concomitant Medications for Asthma (CMED_AS) form.***	☐ 1 Yes	☐ 0 No

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

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

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

If ***YES***, explain _____

_____

07 7. Is the subject eligible to proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No

If any of the shaded boxes are filled in, the subject is NOT eligible for pulmonary function testing.

☞ ***If NO, do NOT complete page 2 or 3.***

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

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

PREBRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

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

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

10. Results of best effort:

10a 10a. FVC ___ . ___ ___ L

10b 10b. FEV_1 ___ . ___ ___ L

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

10d 10d. PEFR ___ ___ . ___ ___ L/S

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

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

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

12. Subject's FEV_1 after 4 puffs of albuterol

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

12b 12b. FEV_1 ___ . ___ ___ L

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

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

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

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

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

14b 14b. FEV_1 ___ . ___ ___ L

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

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

14e 14e. Is the percent difference from Question #14d ≤ 5.0%? ❑$_1$ Yes ❑$_0$ No

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

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

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

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

16b 16b. FEV_1 ___ . ___ ___ L

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

(Clinic Coordinator completed)

01 1. Type of scheduled medications dispensed

❑1 Regular

❑2 Backup

➜ ***If backup medications were dispensed, immediately fax this form to the DCC. Also, explain the circumstances below:***

_____

_____

_____

SCHEDULED MEDICATIONS

Affix the new drug label below:

Copy the drug label number below:

02 **9** ___ ___ ___ ___ ___ ___

Coordinator's Signature: _____

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

By signing in the source documentation box you are:

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

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NIH/NHLBI

IMPACT SCHEDULED MEDICATIONS 2

med2

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form should only be completed prior to the PICT at Visits 5 and 13.

SCHEDULED INHALER

01 1. Type of scheduled inhaler dispensed

❑1 Regular
❑2 Backup

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

➜ ***If a backup inhaler was dispensed, immediately fax this form to the DCC. Also, explain the circumstances below:***

_____
_____
_____

SCHEDULED TABLETS

02 2. Type of scheduled tablets dispensed

❑1 Regular
❑2 Backup

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

➜ ***If backup tablets were dispensed, immediately fax this form to Ron Zimmerman at the DCC at (717) 531-4359. Also, explain the circumstances below:***

_____
_____
_____

Asthma Clinical Research Network
NIH/NHLBI

IMPACT MEDICAL HISTORY

mhx

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

DEMOGRAPHY

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

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_____

03 3. Subject's gender *(Do not ask subject)*

- ❑1 Male
- ❑2 Female

ASTHMA HISTORY

04 4. How old were you when your asthma first appeared? ___ ___ year(s) old

➜ ***If age is UNKNOWN, please complete Question 4a***.

04a 4a. Age unknown ❑8 unknown

05 5. How old were you when a physician first diagnosed your asthma? ___ ___ year(s) old

➜ ***If age is UNKNOWN, please complete Question 5a.***

05a 5a. Age unknown ❑8 unknown

06 6. Does your asthma (breathing through your lungs) worsen in any season? ❑1 Yes ❑0 No

If ***YES***, indicate in what season(s) your asthma symptoms worsen?
(Check 'NO' if the season is not applicable.)

06a 6a. Winter ❑1 Yes ❑0 No
06b 6b. Spring ❑1 Yes ❑0 No
06c 6c. Summer ❑1 Yes ❑0 No
06d 6d. Fall ❑1 Yes ❑0 No

07 7. Do you have allergies (sneezing, itchy eyes, blocked or runny nose) when you do not have the flu or a cold? ❑1 Yes ❑0 No

If ***YES***, indicate in what season(s) your allergies (sneezing, itchy eyes, blocked or runny nose) worsen?
(Check 'NO' if the season is not applicable.)

07a 7a. Winter ❑1 Yes ❑0 No

07b 7b. Spring ❑1 Yes ❑0 No

07c 7c. Summer ❑1 Yes ❑0 No

07d 7d. Fall ❑1 Yes ❑0 No

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

08a 8a. Asthma episodes have you had that required emergency care or an unscheduled office visit? ___ ___

08b 8b. Hospitalizations have you had due to asthma? ___ ___

08c 8c. Courses of oral corticosteroid therapy for asthma (such as prednisone or Medrol) have you taken? ___ ___

➜ ***If any oral corticosteroid therapy were taken within the past 6 weeks, the subject is ineligible to participate in the study at this time. Please remember to record this information on the ELIG2 form.***

08d 8d. Courses of inhaled corticosteroid therapy for asthma have you taken? ___ ___

➜ ***If any inhaled corticosteroid therapy were taken within the past 6 weeks, the subject is ineligible to participate in the study at this time. Please remember to record this information on the ELIG2 form.***

09 9. Have you missed any days of work/housework or school due to asthma in the last 3 months? ❑1 Yes ❑0 No ❑9 N/A

09a If ***YES***, record your best estimate of the number of days missed. ___ ___ . ___
(indicate full or half days in increments of 0.5 days.)

10. Have any of your immediate blood relatives been told by a physician that they have asthma? (*Check the 'N/A' box if the subject does not have siblings or children.*)

10a 10a. Mother ❑1 Yes ❑0 No ❑8 Don't Know

10b 10b. Father ❑1 Yes ❑0 No ❑8 Don't Know

10c 10c. Brothers or Sisters ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A

10d 10d. Child(ren) ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A

PRIOR ASTHMA TREATMENT

Next, I will read a list of medications. Indicate if you have ever used the medication within the **past three years.** If you have, please indicate, to the best of your knowledge, the date last taken.

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

11 11x	11.	Anti-allergic Inhaled Medications (**Intal, Tilade and others**)	❑1 Yes	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __
12 12x	12.	Anti-allergic Nasal Medications (**Nasalcrom and others**)	❑1 Yes	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __
13 13x	13.	Anti-allergic Oral Medications (**Allegra, Claritin and others**)	❑1 Yes	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __
14 14x	14.	Oral Steroids (**Prednisone, Medrol and others**)	❑1 Yes	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __
14a		If ***YES***, indicate number of days oral steroids were taken.				___ ___ ___ days
15 15x	15.	Inhaled Steroids (**Azmacort, Beclovent, Vanceril, AeroBid, Flovent, Pulmicort and others**)	❑1 Yes	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __
15a		If ***YES***, indicate number of days inhaled steroids were taken.				___ ___ ___ days
16 16x	16.	Nasal Steroids (**Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Rhinocort, Nasonex and others)**	❑1 Yes	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __
16a		If ***YES***, indicate number of days nasal steroids were taken.				___ ___ ___ days
17 17x	17.	Leukotriene Antagonist / 5L0 Inhibitors (**Accolate, Zyflo, Singulair)**	❑1 Yes	❑0 No	❑8 Unknown	__ __/__ __/__ __ __ __
17a		If ***YES***, indicate number of days leukotriene antagonist / 5L0 Inhibitors were taken.				___ ___ ___ days

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

				If Yes, Comment
18	18. Skin	❑1 Yes	❑0 No	
19	19. Blood, Lymph, or Immune Systems	❑1 Yes	❑0 No	
20	20. Eyes	❑1 Yes	❑0 No	
21	21. Ears, Nose, or Throat	❑1 Yes	❑0 No	
22	22. Breasts	❑1 Yes	❑0 No	
23	23. Endocrine Systems	❑1 Yes	❑0 No	
24	24. Lung - other than asthma	❑1 Yes	❑0 No	
25	25. Heart and Blood Vessels	❑1 Yes	❑0 No	
26	26. Liver or Pancreas	❑1 Yes	❑0 No	
27	27. Kidneys or Urinary Tract System	❑1 Yes	❑0 No	
28	28. Reproductive System	❑1 Yes	❑0 No	
29	29. Stomach or Intestines	❑1 Yes	❑0 No	
30	30. Muscles or Bones	❑1 Yes	❑0 No	
31	31. Nervous System	❑1 Yes	❑0 No	
32	32. Psychiatric	❑1 Yes	❑0 No	
33	33. Other _____	❑1 Yes	❑0 No	

Subject's Initials: __ __ __

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

(Clinic Coordinator completed)

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

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

01a 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: _____

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

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

04 4. 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

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***

05 5. PC_{20} ___ ___ ___ . ___ ___ ___ mg/ml

05a 5a. Time methacholine challenge was completed (*based on 24-hour clock*) ___ ___ ___ ___

6. 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.

06a 6a. FEV_1 ___ . ___ ___ L

06b 6b. FEV_1 (% predicted) ___ ___ ___ % predicted

06c 6c. Time of FEV_1 in Question #6a (*based on 24-hour clock*) ___ ___ ___ ___

06d 6d. Was the FEV_1 from Question #6a ≥ the methacholine reversal reference value in the gray box above? ❑1 Yes ❑0 No

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

07 7. Was additional treatment used in the first hour? ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #9.***
➜ ***If YES, please complete the appropriate Concomitant Medications form.***

07a 7a. Additional albuterol by MDI ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #7b.***

07ai 7ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four

07b 7b. Nebulized Beta-agonist ❑1 Yes ❑0 No

07c 7c. Subcutaneous epinephrine ❑1 Yes ❑0 No

07d 7d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

07e 7e. Other _____ ❑1 Yes ❑0 No

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

08a 8a. FEV_1 ___ . ___ ___ L

08b 8b. FEV_1 (% predicted) ___ ___ ___ % predicted

08c 8c. Time of FEV_1 in Question #8a (*based on 24-hour clock*) ___ ___ ___ ___

08d 8d. Was the FEV_1 from Question #8a ≥ the methacholine reversal reference value in the gray box on page 2 of this form? ❑1 Yes ❑0 No

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

09 9. Was additional treatment used after one hour? ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #10.***

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

09a 9a. Additional albuterol by MDI ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #9b.***

09ai 9ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four

09b 9b. Nebulized Beta-agonist ❑1 Yes ❑0 No

09c 9c. Subcutaneous epinephrine ❑1 Yes ❑0 No

09d 9d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

09e 9e. Treatment in the emergency room ❑1 Yes ❑0 No

09f 9f. Overnight hospitalization ❑1 Yes ❑0 No

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

09g 9g. Other _____ ❑1 Yes ❑0 No

10. Subject's final FEV_1 after methacholine challenge.

10a 10a. FEV_1 ___ . ___ ___ L

10b 10b. FEV_1 (% predicted) ___ ___ ___ % predicted

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

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

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

Physician signature: _____

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

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

Asthma Clinical Research Network
NIH/NHLBI

IMPACT NITRIC OXIDE COLLECTION

no

Subject ID: 9 ___ ___ ___ ___
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.

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)
___ **BAL1A** ___	___ **BAL1B** ___	___ **BAL1C** ___	___ **BAL1D** . ___
___ **BAL2A** ___	___ **BAL2B** ___	___ **BAL2C** ___	___ **BAL2D** . ___
___ **BAL3A** ___	___ **BAL3B** ___	___ **BAL3C** ___	___ **BAL3D** . ___

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

READ Reader ID: ___ ___ ___ ___ ___

Comments:

Asthma Clinical Research Network
NIH/NHLBI

IMPACT
PICT ADVERSE EVENT QUESTIONNAIRE

pae1

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. Date PICT started ___ ___ / ___ ___ / ___ ___ ___ ___ (*month / day / year*)

02 2. Date PICT ended ___ ___ / ___ ___ / ___ ___ ___ ___ (*month / day / year*)

03 3. Has the subject had any medical problems since his/her last study visit? ❑1 Yes ❑0 No

☞ ***If NO, STOP HERE and continue with remaining visit procedures.***
☞ ***If YES, please record the corresponding PICT adverse event number(s), description, and ICD-9 code from the Clinical Adverse Events (AECLIN) form below.***

PAEQ1

---

pae2

FOR DATA ENTRY PURPOSES.

☞ ***If no PICT adverse events occurred for this visit, mark the PAEQ2 form MISSING.***

	ADVERSE EVENT NUMBER	DESCRIPTION	ICD9 CODE
EVENT	**01** ___ ___		**02** ___ ___ ___ . ___ ___
	___ ___		___ ___ ___ . ___ ___
	___ ___		___ ___ ___ . ___ ___
	___ ___		___ ___ ___ . ___ ___
	___ ___		___ ___ ___ . ___ ___
	___ ___		___ ___ ___ . ___ ___

(Clinic Coordinator completed)

Check the following pill dosing compliance at Visit 4 and Visits 5 through 14.

01 1. Number of pills dispensed in eDEM™ vial ___ ___ ___ pills

02 2. Number of pills returned in eDEM™ vial ___ ___ ___ pills

03 3. Number of prescribed doses ___ ___ ___ doses

04 4. Actual number of pills taken (Question #1 – Question #2) ___ ___ ___ pills

05 5. Percentage of pills taken $\frac{\text{Question \#4}}{\text{Question \#3}}$ x 100 ___ ___ ___ . ___%

(Complete Question #6 at Visits 6 through 14 Only)

06 6. Percent prescribed number of doses taken ___ ___ ___ . ___%
(Obtained from eDEM™ Compliance Report)

(Complete Question #7 - #10 at Visits 6 and 14 Only)

07 7. Number of Prednisone pills dispensed ___ ___ ___ pills

08 8. Number of Prednisone pills returned ___ ___ ___ pills

09 9. Number of Prednisone pills which should have been taken ___ ___ ___ pills
(number of days on PICT ____ x number of pills prescribed daily ____)

10 10. Percentage of Prednisone pills taken $\frac{\text{(Question \#7 - Question \#8)}}{\text{Question \#9}}$ x 100 ___ ___ ___ . ___%

Asthma Clinical Research Network
NIH/NHLBI

IMPACT PEAK FLOW METER QUALITY CONTROL

pkfl

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Technician completed)

01 1. Serial Number of Peak Flow Meter being tested ___ ___ ___ ___ - ___ ___ ___ ___

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

03 3. Is this a new Peak Flow Meter being tested? ❑1 Yes ❑0 No

03a If ***YES***, indicate the primary reason.

- ❑1 "Old" device was recalled
- ❑2 "Old" device failed QC testing
- ❑3 "Old" device was lost
- ❑4 Other

Clinic Use Only

		Peak Flow Meter (L/Min)	Jones FVC (L/Min)	Relative Bias (PFM - Jones FVC) / Jones FVC * 100 %	Rank (smallest to largest)
4.	Trial 1	04a ___ ___ ___	___ ___ ___ 04b	___ ___ ___ . ___ %	___
5.	Trial 2	05a ___ ___ ___	___ ___ ___ 05b	___ ___ ___ . ___ %	___
6.	Trial 3	06a ___ ___ ___	___ ___ ___ 06b	___ ___ ___ . ___ %	___
7.	Trial 4	07a ___ ___ ___	___ ___ ___ 07b	___ ___ ___ . ___ %	___
8.	Trial 5	08a ___ ___ ___	___ ___ ___ 08b	___ ___ ___ . ___ %	___

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

09 9. Did the Peak Flow Meter pass? ❑1 Yes ❑0 No

☞ *If **NO**, issue a new Peak Flow Meter and complete another Peak Flow Meter Quality Control form.*

Asthma Clinical Research Network
NIH/NHLBI

IMPACT SYMPTOM BASED ACTION PLAN

sbap

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

DO NOT ENTER. FOR REFERENCE PURPOSES ONLY.

I am going to ask you some questions based on the use of the Symptom Based Action Plan. These events may have occurred since your last study visit or phone contact which took place on:

___ ___ / ___ ___ / ___ ___ ___ ___
month *day* *year*

01	1. Since your last study visit or phone contact did you take inhaled corticosteroids?	❑1 Yes	❑0 No	
02	2. Since your last study visit or phone contact, did you take oral corticosteroids?	❑1 Yes	❑0 No	
03	3. Since your last study visit or phone contact, do you think that your albuterol use and asthma symptoms remained stable?	❑1 Yes	❑0 No	
	4. Since your last study visit or phone contact:			
04a	4a. Did you awaken from asthma ≥ 3 times in a two week period or on 2 consecutive nights?	❑1 Yes	❑0 No	
04b	4b. Did you use albuterol for relief of symptoms ≥ 4 times a day and for at least 2 consecutive days?	❑1 Yes	❑0 No	
04c	4c. Did albuterol relieve symptoms for < 4 hours after each treatment over a 12 hour period?	❑1 Yes	❑0 No	❑9 N/A
04d	4d. Did you use albuterol daily for the relief of symptoms for 7 consecutive days (and did this use exceed 2 times the weekly use of albuterol in the baseline period)?	❑1 Yes	❑0 No	
04e	4e. Over a 7 day period, did your regular exercise cause unusually severe shortness of breath on 2 or more days?	❑1 Yes	❑0 No	

☞ **Questions #4a through #4e are yellow zone items. If any of the answers for Question #4a through #4e are answered YES, the subject should have begun daily treatment with Pulmicort ®, 4 puffs twice a day, for 10 days.**

05 5. Did you begin daily treatment with open label Pulmicort® 4 puffs twice a day for 10 days? ❑1 Yes ❑0 No

➜ ***If YES, please complete the Concomitant Medications for Asthma and Allergies (CMED_AS) form and check for treatment failure. Skip to Question #6.***

➜ ***If NO, and the subject answered NO or N/A to all questions #4a through #4e, skip to Question #6.***

➜ ***If NO, and the subject answered YES to any of the questions #4a through #4e, go to Question #5a.***

05a 5a. What was your reason for not starting daily treatment with open label Pulmicort?

➜ ***If another medication was taken please complete the Concomitant Medications for Asthma and Allergies (CMED_AS) form and check for treatment failure.***

➜ ***Reeducate subject on use of Symptom Based Action Plan. Proceed to Question #6.***

❑1 Went to next severity level

❑2 Subject thought symptoms were not bad enough

❑3 Took another medication (complete CMED_AS)

❑4 Do not want to take Pulmicort

❑5 Other _____

_____

6. Since your last study visit or phone contact:

06a 6a. Did you have shortness of breath with daily activities that lasted a full day (24 hours) or more? ❑1 Yes ❑0 No

06b 6b. Did you have shortness of breath at rest that lasted a full day (24 hours) or more? ❑1 Yes ❑0 No

06c 6c. Did albuterol relieve symptoms for < 2 hours after each treatment over an eight hour period? ❑1 Yes ❑0 No ❑9 N/A

☞ **Questions #6a through #6c are red zone items. If any of the answers for Question #6a through #6c are answered YES, the subject should have begun daily treatment with Prednisone for 5 days.**

07 7. Did you begin daily treatment with Prednisone for 5 days? ❑1 Yes ❑0 No

➜ ***If YES, please complete the Concomitant Medications for Asthma and Allergies (CMED_AS) form and check for treatment failure. Skip to Question #8.***

➜ ***If NO, and the subject answered NO or N/A to all questions #6a through #6c, skip to Question #8.***

➜ ***If NO, and the subject answered YES to any of the questions #6a through #6c, go to Question #7a.***

07a 7a. What was your reason for not starting daily treatment with Prednisone?

- ➜ ***If another medication was taken please complete the Concomitant Medications for Asthma and Allergies (CMED_AS) form and check for treatment failure.***
- ➜ ***Reeducate subject on use of Symptom Based Action Plan. Proceed to Question #8.***

❑1 Went to next severity level
❑2 Subject thought symptoms were not bad enough
❑3 Took another medication (Complete CMED_AS)
❑4 Do not want to take Prednisone
❑5 Other

8. Since your last study visit or phone contact:

08a 8a. Did you have severe shortness of breath at rest? ❑1 Yes ❑0 No

08b 8b. Did you have difficulty talking because of shortness of breath? ❑1 Yes ❑0 No

08c 8c. Did albuterol relieve symptoms for < 1 hour after each treatment over a 4 hour period (or not relieve symptoms after 2 treatments repeated within a single hour)? ❑1 Yes ❑0 No ❑9 N/A

☞ **Questions #8a through #8c are extra red zone items. If any of the answers for Question #8a through #8c are answered YES, the subject should have begun treatment with albuterol, 4 puffs every 20 minutes (as needed), taken 0.5 mg/kg Prednisone, proceeded to the ER or called 911, and notified Clinic Coordinator of the event.**

09 9. Did you go to the emergency room/hospital? ❑1 Yes ❑0 No

- ➜ ***If YES, please complete the appropriate forms, Healthcare Utilization Review (HUR) form, Emergency Room or Urgent Care Visit (ER_UC) form, Concomitant Medications for Asthma and Allergies (CMED_AS) form, or Subject Hospitalization Report (HOSP) form and check for treatment failure. STOP HERE.***
- ➜ ***If NO, and subject answered NO or N/A to all of the questions #8a through #8c, STOP HERE.***
- ➜ ***If NO, and subject answered YES to any of the questions #8a through #8c, go to Question #9a.***

09a 9a. What was your reason for not going to the emergency room/hospital?

- ➜ ***If a doctor prescribed another medication please complete the Concomitant Medications for Asthma and Allergies (CMED_AS) form and check for treatment failure.***
- ➜ ***Reeducate subject on use of Symptom Based Action Plan.***

❑1 Subject thought symptoms were not bad enough
❑2 Took another medication (Complete CMED_AS)
❑3 Refused to go to the emergency room/hospital
❑4 Other _____

Asthma Clinical Research Network
NIH/NHLBI

IMPACT SERIOUS ADVERSE EVENT REPORTING FORM

ser

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form must be faxed to the DCC 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.

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

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

Describe: _____

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

04 4. Unit of time for above interval

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

5. Why was the event serious?

05a 5a. Fatal Event? ❑ 1 Yes ❑ 0 No

05b 5b. Life-threatening event? ❑ 1 Yes ❑ 0 No

05c 5c. Inpatient hospitalization required? ❑ 1 Yes ❑ 0 No

➜ ***If YES, complete the Emergency Room or Urgent Care Visit (ER_UC) form, Subject Hospitalization Report (HOSP) form and Discharge Summary Report (DISC) form.***

➜ ***If NO, skip to Question #5d.***

05c1 5c1. Admission date ___ ___ / ___ ___ / ___ ___ ___ ___ (*month / day / year*)

05c2 5c2. Discharge date ___ ___ / ___ ___ / ___ ___ ___ ___ (*month / day / year*)

05d 5d. Hospitalization prolonged? ❑ 1 Yes ❑ 0 No

05e 5e. Disabling or incapacitating? ❑ 1 Yes ❑ 0 No

05f 5f. Overdose? ❑ 1 Yes ❑ 0 No

05g 5g. Cancer? ❑ 1 Yes ❑ 0 No

05h 5h. Congenital anomaly? ❑ 1 Yes ❑ 0 No

05i 5i. Serious laboratory abnormality with clinical symptoms? ❑ 1 Yes ❑ 0 No

05j 5j. Other _____ ❑ 1 Yes ❑ 0 No

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

06a 6a. Toxicity of study drug(s)? ❑1 Yes ❑0 No

06b 6b. Withdrawal of study drug(s)? ❑1 Yes ❑0 No

06c 6c. Concurrent medication? ❑1 Yes ❑0 No
If ***YES***, describe _____

06d 6d. Concurrent disorder? ❑1 Yes ❑0 No
If ***YES***, describe _____

06e 6e. Other event? ❑1 Yes ❑0 No
If ***YES***, describe _____

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

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

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

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

REPORTING INVESTIGATOR:

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

_____
_____
_____
_____
_____

Name: _____

Address: _____
_____
_____

Signature: _____

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

Asthma Clinical Research Network
NIH/NHLBI

IMPACT
SHORT PHYSICAL EXAM
SX

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

PHYSICAL EXAMINATION

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

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

VITAL SIGNS

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

3. Resting blood pressure ___ **03a** ___ / ___ **03b** ___ mm Hg (systolic / diastolic)

04 4. Pulse ___ ___ ___ beats/min

PULMONARY AUSCULTATION

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

_____
_____

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

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

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

Physician/CC Signature: _____
Date: __ __ / __ __ / __ __ __ __
Time: __ __ __ __ *(based on 24-hour clock)*

URINE PREGNANCY TEST

07 7. Pregnancy test results (If subject is male, check N/A.)

- ❑ 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.***

Pregnancy Test Source Documentation

Subject's Initials: __ __ __

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

Asthma Clinical Research Network
NIH/NHLBI

IMPACT SYMPTOM-FREE DAY QUESTIONNAIRE

sfdq

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

01	1.	In the <u>past 14 days</u>, how many days did you have wheezing, chest tightness, cough, or shortness of breath?	___ ___ day(s)
02	2.	In the <u>past 14 days</u>, how many days did you have to slow down or stop activities because of asthma, wheezing, chest tightness, cough, or shortness of breath?	___ ___ day(s)
03	3.	In the <u>past 14 days</u>, how many days did you wake up because of asthma, wheezing, chest tightness, cough, or shortness of breath?	___ ___ day(s)
04	4.	Thinking about all three asthma signs or symptoms (wheezing, slowing down or stopping activities, and nights awakened), in the <u>past 14 days</u>, how many days did you have <u>any</u> of these day-time or night-time symptoms?	___ ___ day(s)
05	5.	In the <u>past 14 days</u>, how many days did you experience any day with <u>NO</u> day-time or night-time symptoms of asthma (including no wheezing, no cough, no chest tightness, or no shortness of breath)?	___ ___ day(s)

Asthma Clinical Research Network
NIH/NHLBI

IMPACT
ALLERGY SKIN TEST RESULTS

skin

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 3
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

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

If ***YES***,

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

cc ID of coordinator who performed the skin test ___ ___ ___ ___ ___

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.

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

tm Method
❑1 prick
❑2 puncture

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

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

ALLERGY SKIN TEST RESULTS

Subject ID: 9 ___ ___ ___ ___

Visit Number: 3

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.

	01	Was there a reaction? ❑0 No ❑1 Yes		08	Was there a reaction? ❑0 No ❑1 Yes
	01a	Largest Wheal Diameter ___ ___ ___ mm		08a	Largest Wheal Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
1. Diluting Fluid	01b	Diameter ___ ___ ___ mm	8. Alternaria	08b	Diameter ___ ___ ___ mm
	02	Was there a reaction? ❑0 No ❑1 Yes		09	Was there a reaction? ❑0 No ❑1 Yes
	02a	Largest Wheal Diameter ___ ___ ___ mm		09a	Largest Wheal Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
2. Tree Mix	02b	Diameter ___ ___ ___ mm	9. Cladosporium	09b	Diameter ___ ___ ___ mm
	03	Was there a reaction? ❑0 No ❑1 Yes		10	Was there a reaction? ❑0 No ❑1 Yes
	03a	Largest Wheal Diameter ___ ___ ___ mm		10a	Largest Wheal Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
3. Grass Mix	03b	Diameter ___ ___ ___ mm	10. Aspergillus	10b	Diameter ___ ___ ___ mm
	04	Was there a reaction? ❑0 No ❑1 Yes		11	Was there a reaction? ❑0 No ❑1 Yes
	04a	Largest Wheal Diameter ___ ___ ___ mm		11a	Largest Wheal Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
4. Ragweed	04b	Diameter ___ ___ ___ mm	11. D. Farinae	11b	Diameter ___ ___ ___ mm

	05	Was there a reaction? ❑0 No ❑1 Yes		12	Was there a reaction? ❑0 No ❑1 Yes
		Largest Wheal			Largest Wheal
	05a	Diameter ___ ___ ___ mm		12a	Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
5. Weed Mix	05b	Diameter ___ ___ ___ mm	12. D. Pteryn	12b	Diameter ___ ___ ___ mm
	06	Was there a reaction? ❑0 No ❑1 Yes		13	Was there a reaction? ❑0 No ❑1 Yes
		Largest Wheal			Largest Wheal
	06a	Diameter ___ ___ ___ mm		13a	Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
6. Dogs	06b	Diameter ___ ___ ___ mm	13. Cockroach	13b	Diameter ___ ___ ___ mm
	07	Was there a reaction? ❑0 No ❑1 Yes		14	Was there a reaction? ❑0 No ❑1 Yes
		Largest Wheal			Largest Wheal
	07a	Diameter ___ ___ ___ mm		14a	Diameter ___ ___ ___ mm
		Perpendicular Wheal			Perpendicular Wheal
7. Cats	07b	Diameter ___ ___ ___ mm	14. Histamine	14b	Diameter ___ ___ ___ mm

(Subject Interview completed)

01	1.	Have you consumed caffeine in the past 8 hours? ***Examples**: Caffeinated colas (Pepsi, Coke), Coffee, Mello-Yello, Mountain Dew, Tea, Barq's Rootbeer*	☐ 1 Yes	☐ 0 No
02	2.	Have you used medications with caffeine in the past 8 hours? ***Examples**: Anacin, Darvon compound, Esgic, Excedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*	☐ 1 Yes	☐ 0 No
03	3.	Have you consumed any food containing alcohol or beverages containing alcohol in the past 8 hours?	☐ 1 Yes	☐ 0 No
04a	4a.	Have you used any antihistamines in the past 48 hours?	☐ 1 Yes	☐ 0 No
04b	4b.	Have you used any oral decongestants or cold remedies in the past 48 hours?	☐ 1 Yes	☐ 0 No
04c	4c.	Have you used any nasal steroids in the past 48 hours?	☐ 1 Yes	☐ 0 No
04d	4d.	Have you used a rescue intermediate-acting inhaled beta-agonist [e.g. albuterol (Ventolin or Proventil)] in the past 6 hours?	☐ 1 Yes	☐ 0 No
04e	4e.	Have you used a rescue long-acting inhaled beta-agonist [e.g. Serevent] in the past 48 hours?	☐ 1 Yes	☐ 0 No
04f	4f.	Have you taken any oral corticosteroids in the past 6 weeks? ➜ ***If YES, complete the Concomitant Medications for Asthma (CMED_AS) form.***	☐ 1 Yes	☐ 0 No
04g	4g.	Have you taken any inhaled corticosteroids in the past 6 weeks? ➜ ***If YES, complete the Concomitant Medications for Asthma (CMED_AS) form.***	☐ 1 Yes	☐ 0 No
04h	4h.	Have you taken any other medications (see the EXCLDRUG reference card) to treat your asthma or allergies in the past 6 weeks? ➜ ***If YES, complete the Concomitant Medications for Asthma (CMED_AS) form.***	☐ 1 Yes	☐ 0 No

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

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

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

If ***YES***, explain _____

_____

07 7. Is the subject eligible to proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No

If any of the shaded boxes are filled in, the subject is NOT eligible for pulmonary function testing.

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

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

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

PREBRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

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

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

10. Results of best effort:

10a 10a. FVC ___ . ___ ___ L

10b 10b. FEV_1 ___ . ___ ___ L

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

10d 10d. PEFR ___ ___ . ___ ___ L/S

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

(Technician completed)

Total and Differential Cell Counts

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

The parameters below are calculated following exclusion of squamous cells.

03	3.	Total Cell Count	___ ___ . ___ ___ x 10^5/ml
04	4.	Epithelial Cells	___ ___ ___ . ___ %
05	5.	Macrophages	___ ___ ___ . ___ %
06	6.	Neutrophils	___ ___ ___ . ___ %
07	7.	Eosinophils	___ ___ ___ . ___ %
08	8.	Lymphocytes	___ ___ ___ . ___ %

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

☞ ***If YES, the sputum sample should not be sent for overreading***.

(Technician completed)

01 1. Date of Over-Read ___ ___ / ___ ___ / ___ ___ ___ ___
month day year

02 2. Is the slide quality acceptable? ❑ 1 Yes ❑ 0 No

_____
_____
_____
_____
_____

Total and Differential Cell Counts

03 3. Squamous Cells ___ ___ ___ . ___ %

The parameters below are calculated following exclusion of squamous cells.

04 4. Epithelial Cells ___ ___ ___ . ___ %

05 5. Macrophages ___ ___ ___ . ___ %

06 6. Neutrophils ___ ___ ___ . ___ %

07 7. Eosinophils ___ ___ ___ . ___ %

08 8. Lymphocytes ___ ___ ___ . ___ %

(Technician completed)

01 1. ***(If Visit 5, do not complete Question #1)***

At Visit 5, was the subject able to continue sputum induction for more than 4 minutes and able to produce a satisfactory induced sputum sample (< 80% squamous cells)? ☐ 1 Yes ☐ 0 No

➜ ***If NO, STOP HERE; do NOT proceed with sputum induction.***

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

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

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

03a 3a. Subject's FEV_1 after all reversal from methacholine challenge ___ . ___ ___ L

03b 3b. Subject's FEV_1 (% predicted) after all reversal from methacholine challenge ___ ___ ___ % predicted

03c 3c. Was the subject's FEV_1 from Question #3a ≥ the methacholine reversal reference value on page 2 of the METHA form? ☐ 1 Yes ☐ 0 No

➜ ***Skip to Question #5.***

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

04a 4a. Subject's FEV_1 15 minutes after 4 puffs of albuterol ___ . ___ ___ L

04b 4b. Subject's FEV_1 15 minutes after 4 puffs of albuterol (% predicted) ___ ___ ___ % predicted

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

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

07 7. Is the subject eligible for sputum induction? ☐ 1 Yes ☐ 0 No

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

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

08 8. ***(If Visit 5, do not complete Question #8.)***

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

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

09a 9a. FEV_1 ___ . ___ ___ L

09b 9b. FEV_1 (% predicted) ___ ___ ___ % predicted

09c 9c. Time of FEV_1 in Question #9a (*based on 24-hour clock*) ___ ___ ___ ___

09d 9d. Percent difference in FEV_1 $\frac{(\textit{Question \#3a or 4a - Question \#9a})}{\textit{Question \#3a or 4a}}$ x 100 ___ ___ . ___ %

10 10. Duration of sputum induction at this visit ___ ___ . ___ minutes

11 11. Volume of sputum sample at this visit ___ ___ ___ . ___ ml

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

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

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

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

☞***If YES, proceed with Question #15 on the next page.***
☞***If NO, STOP HERE and continue with remaining visit procedures.***

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

Clinic Use Only

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

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

15a 15a. FEV_1 ___ . ___ ___ L

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

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

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

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

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

16. Subject's final FEV_1 after sputum induction

16a 16a. FEV_1 ___ . ___ ___ L

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

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

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

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

Physician signature: _____

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

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

Asthma Clinical Research Network
NIH/NHLBI

IMPACT SUBJECT POST-STUDY QUESTIONNAIRE
subb

Subject ID: 9 __ __ __ __
Subject Initials: __ __ __
Visit Number: __ __
Visit Date: __ __ / __ __ / __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

(Subject completed)

This questionnaire is to be completed by the IMPACT subject at the end of Visit 14. If a randomized subject terminates prior to Visit 14, please ask him or her to complete this form during the termination visit.

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

- ☐ 1 I am certain it was placebo.
- ☐ 2 I think it was probably placebo.
- ☐ 3 I have no idea which treatment I received, but my best guess would be:

01a

  - ☐ 1 Placebo
  - ☐ 2 Active Drug

- ☐ 4 I think it was probably active drug.
- ☐ 5 I am certain it was active drug.

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

- ☐ 1 I am certain it was placebo.
- ☐ 2 I think it was probably placebo.
- ☐ 3 I have no idea which treatment I received, but my best guess would be:

02a

  - ☐ 1 Placebo
  - ☐ 2 Active Drug

- ☐ 4 I think it was probably active drug.
- ☐ 5 I am certain it was active drug.

Subject's Initials: __ __ __

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

SUBBLIND

03 3. Please comment with respect to the taste of the **scheduled inhaler** you received.

- ☐ 1 Tasted good (*Describe*) _____
- ☐ 2 No noticeable taste
- ☐ 3 Tasted bad (*Describe*) _____

04 4. Please comment with respect to the smell of the **scheduled inhaler** you received.

- ☐ 1 Smelled good (*Describe*) _____
- ☐ 2 No noticeable smell
- ☐ 3 Smelled bad (*Describe*) _____

05 5. Please comment with respect to any physical sensations produced by the **scheduled inhaler** you received.

- ☐ 1 Pleasant sensations (*Describe*) _____
- ☐ 2 No noticeable sensations
- ☐ 3 Unpleasant sensations (*Describe*) _____

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

- ☐ 1 I have no further comments
- ☐ 2 I observed the following: (*Describe below*)

_____

_____

_____

_____

07 7. Please comment with respect to the taste of the **tablets** you received.

- ☐ 1 Tasted good (*Describe*) _____
- ☐ 2 No noticeable taste
- ☐ 3 Tasted bad (*Describe*) _____

08 8. Please comment with respect to the smell of the **tablets** you received.

- ☐ 1 Smelled good (*Describe*) _____
- ☐ 2 No noticeable smell
- ☐ 3 Smelled bad (*Describe*) _____

09 9. Please comment with respect to any physical sensations produced by the **tablets** you received.

- ☐ 1 Pleasant sensations (*Describe*) _____
- ☐ 2 No noticeable sensations
- ☐ 3 Unpleasant sensations (*Describe*) _____

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

- ☐ 1 I have no further comments
- ☐ 2 I observed the following: (*Describe below*)

_____

_____

_____

_____

Asthma Clinical Research Network
NIH/NHLBI

IMPACT SCHOOL/WORK ABSENTEEISM

swa

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. How many full or half days of school/work/housework did the subject miss?
(indicate full or half days in increments of 0.5 days)
___ ___ . ___ day(s)

02 2. Primary activity missed. *(check one box only)*
❑1 Work
❑2 School
❑3 Housework

3. What was the reason for the missed activity?

03a 3a. Due to worsening symptoms caused by your asthma? ❑1 Yes ❑0 No
➜ ***If YES, please complete Clinical Adverse Events (AECLIN) form.***

03b 3b. To see an MD or health-care provider about your asthma (does not apply to time off for study-related visits)? ❑1 Yes ❑0 No

03c 3c. Due to side effects related to asthma medication? ❑1 Yes ❑0 No
➜ ***If YES, please complete Clinical Adverse Events (AECLIN) form.***

03d 3d. Other _____ ❑1 Yes ❑0 No

Asthma Clinical Research Network
NIH/NHLBI

IMPACT
TERMINATION OF STUDY PARTICIPATION
term

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Please indicate the reason for termination of study participation.

01 1. ***(Visit 14 Only - Questions #1 and #2)***
Pregnancy test results
(Check N/A if the subject is male.)

❑1 Positive
❑0 Negative
❑9 N/A

02 2. Has the subject completed the study?
➜ ***If YES, skip to the SIGNATURES section on page 2.***

❑1 Yes ❑0 No

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

❑1 Yes ❑0 No ❑9 N/A

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

04 4. ***(Visit 1 - Visit 6 Only)***
During the run-in period, has the subject taken inhaled or oral corticosteroids?

❑1 Yes ❑0 No

05 5. ***(Visit 1 - Visit 6 Only)***
Has the subject been deemed ineligible by the study investigator due to a side effect from the PICT?

❑1 Yes ❑0 No

06 6. ***(Visit 1 - Visit 6 Only)***
Has the subject been deemed ineligible according to any eligibility criteria?

❑1 Yes ❑0 No

07 7. Has the subject withdrawn consent? ❑$_1$ Yes ❑$_0$ No

07a 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
- ❑$_{11}$ PICT
- ❑$_{12}$ other _____

08 8. Has the subject been lost to follow-up? ❑$_1$ Yes ❑$_0$ No

09 9. Has the subject experienced a serious adverse event (e.g., an adverse event resulting in death or hospitalization, etc.)? ❑$_1$ Yes ❑$_0$ No

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

SIGNATURES

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

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

_____ ___ ___ /___ ___ /___ ___ ___ ___

Clinic Coordinator Signature — month day year

_____ ___ ___ /___ ___ /___ ___ ___ ___

Principal Investigator Signature — month day year

Asthma Clinical Research Network
NIH/NHLBI

IMPACT
TREATMENT FAILURE

txfl

Subject ID: 9 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. Has the subject taken > 4 courses of an inhaled corticosteroid, in a twelve month period, for an asthma exacerbation? ☐ 1 Yes ☐ 0 No

02 2. Has the subject taken > 2 courses of an oral corticosteroid, in a twelve month period, for an asthma exacerbation? ☐ 1 Yes ☐ 0 No

03 3. Has the subject required > 1 emergency department visit, or > 1 hospitalization, for an asthma exacerbation in a twelve month period (two or more of either event within a year)? ☐ 1 Yes ☐ 0 No

04 4. Has the subject been admitted to an intensive care unit for a severe asthma exacerbation? ☐ 1 Yes ☐ 0 No

05 5. Is the subject a treatment failure? ☐ 1 Yes ☐ 0 No
If any of the shaded boxes are filled in, the subject is a treatment failure.

☞ ***If YES, please continue with the Treatment Failure (TXFAIL) form.***

06 6. Date treatment failure occurred ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year)

07 7. Was the subject taken off study drugs as a result of the treatment failure? ☐ 1 Yes ☐ 0 No

08 8. Was the subject started on additional open label therapy as a result of the treatment failure? ☐ 1 Yes ☐ 0 No
➜ ***If YES, please complete the CMED_AS form.***

ACRN ICD9 Adverse Event Codes

Asthma Clinical Research Network
NIH/NHLBI

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

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

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