Asthma Clinical Research Network
NIH/NHLBI

BARGE
CLINICAL ADVERSE EVENTS
cae

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

Subject ID: 8 ____ ____ ____
Subject Initials: ____ ____ ____
Visit Number: 1
Visit Date: ____ ____ / ____ ____ / ____ ____
Month Day Year

(Clinic Coordinator completed)

If the subject experienced any clinical adverse events (including 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) 02 / 3. DATE STOPPED (Bottom Line) 03 — 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
1.	___.__ 01	__/__/____ / __/__/____	❑1 04	___ 05	06	07	08	09	10	11	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).

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

Asthma Clinical Research Network
NIH/NHLBI

BARGE AIRWATCH™ QUALITY CONTROL

air

Subject ID: 8 ___ ___ ___
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

		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	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.*

(Technician Completed)

Complete this form only if the subject has successfully completed the Nitric Oxide and Spirometry Testing form (NO_SPIRO).

POSTBRONCHODILATOR PULMONARY FUNCTION TESTING

→ ***Administer 2 puffs of albuterol immediately following prebronchodilator spirometry and wait 15 minutes.***

01	1.	Time albuterol administered *(based on 24-hour clock)*	___ ___ ___ ___
02	2.	Time spirometry started *(based on 24-hour clock)*	___ ___ ___ ___

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

3. Results of best effort:

03a	3a.	FVC	___ . ___ ___ L
03b	3b.	FEV_1	___ . ___ ___ L
03c	3c.	FEV_1 (% predicted)	___ ___ ___ % predicted
03d	3d.	PEFR	___ ___ . ___ ___ L/S
03e	3e.	FEF_{25-75}	___ . ___ ___ L/S

QUALIFYING CHECKLIST

04 4. Is the subject's postbronchodilator FEV_1 in Question #3b less than 55% of predicted? ☒ 1 Yes ☐ 0 No

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

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

06a 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: _____

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

If ***YES***, explain _____

08 8. 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, pre and postbronchodilator pulmonary function testing and the methacholine challenge should be rescheduled within the visit window.

Clinic Use Only

Use the postbronchodilator FEV_1 value from Question #3b 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***

POSTBRONCHODILATOR METHACHOLINE CHALLENGE

09 9. PC_{20} ___ ___ ___ . ___ ___ ___ mg/ml

09a 9a. Time methacholine challenge was completed (*based on 24-hour clock*) ___ ___ ___ ___

10. Subject's FEV_1 after standard reversal (2 puffs albuterol) from methacholine challenge

10a 10a. FEV_1 ___ . ___ ___ L

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

10c 10c. Time of FEV_1 in 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 above? ❑$_1$ Yes ❑$_0$ No

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

11 11. Was additional treatment used in the first hour? ❑$_1$ Yes ❑$_0$ No

➔ ***If NO, skip to Question #13.***

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

11a 11a. Additional albuterol by MDI ❑$_1$ Yes ❑$_0$ No

➔ ***If NO, skip to Question #11b.***

11ai 11ai. Number of additional puffs of albuterol administered ❑$_1$ two ❑$_2$ four ❑$_3$ > four

11b 11b. Nebulized Beta-agonist ❑$_1$ Yes ❑$_0$ No

11c 11c. Subcutaneous epinephrine ❑$_1$ Yes ❑$_0$ No

11d 11d. Implementation of clinic emergency protocol or algorithm ❑$_1$ Yes ❑$_0$ No

11e 11e. Other _____ ❑$_1$ Yes ❑$_0$ No

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

12a 12a. FEV_1 ___ . ___ ___ L

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

12c 12c. Time of FEV_1 in Question #12a (*based on 24-hour clock*) ___ ___ ___ ___

12d 12d. Was the FEV_1 from Question #12a ≥ the methacholine reversal reference value in the gray box on page 3 of this form? ❑$_1$ Yes ❑$_0$ No

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

13 13. Was additional treatment used after one hour? ❑$_1$ Yes ❑$_0$ No

➔ ***If NO, skip to Question #14.***

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

13a 13a. Additional albuterol by MDI ❑$_1$ Yes ❑$_0$ No

➔ ***If NO, skip to Question #13b.***

13ai 13ai. Number of additional puffs of albuterol administered ❑$_1$ two ❑$_2$ four ❑$_3$ > four

13b 13b. Nebulized Beta-agonist ❑$_1$ Yes ❑$_0$ No

13c 13c. Subcutaneous epinephrine ❑$_1$ Yes ❑$_0$ No

13d 13d. Implementation of clinic emergency protocol or algorithm ❑$_1$ Yes ❑$_0$ No

13e 13e. Treatment in the emergency room ❑$_1$ Yes ❑$_0$ No

13f 13f. Overnight hospitalization ❑$_1$ Yes ❑$_0$ No

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

13g 13g. Other _____ ❑$_1$ Yes ❑$_0$ No

14. Subject's final FEV_1 after methacholine challenge.

14a 14a. FEV_1 ___ . ___ ___ L

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

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

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

apm_sds Physician's Signature: _____

apm_sdd Date: ___/___/_____

apm_sdt Time: ____ *(based on 24-hour clock)*

Asthma Clinical Research Network
NIH/NHLBI

BARGE CLINIC COORDINATOR STUDY TREATMENT QUESTIONNAIRE

ccb

Subject ID: 8 ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Coordinator completed)

This questionnaire is to be completed at Visits 10 and 20 by the ACRN study coordinator who was primarily responsible for the subject's BARGE visits during the preceding four weeks. If a randomized subject terminates prior to Visit 20, this form should be completed at the time of the termination visit.

1. Subjects in the BARGE study were randomized to receive either an active albuterol inhaler during stage 1 (Visits 5-10) followed by a placebo inhaler during stage 2 (Visits 15-20) or to receive a placebo inhaler during stage 1 followed by an active albuterol inhaler during stage 2. You were blinded to the subject's actual treatment assignment. Please check the one box that most closely represents your feelings about the treatment the subject received over the past four weeks.

01

01a

- ☐ 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:
  - ☐ 1 Placebo
  - ☐ 2 Active Drug
- ☐ 4 I think it was probably active drug.
- ☐ 5 I am certain it was active drug.

2. Please comment with respect to any observations you made regarding the subject's scheduled medications that helped you to make your choice in Question #1.

_____

_____

_____

_____

ccb_sdi

ccb_sdd

Coordinator's Initials: ___ ___ ___
Date: ___/___/___ ___ ___ ___

CCBLIND

Asthma Clinical Research Network
NIH/NHLBI

BARGE
CONCOMITANT MEDICATIONS for ASTHMA-RELATED DRUGS

cmed

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year

(Clinic Coordinator completed)

At Visit 1: Please list all concomitant medications related to the treatment of asthma symptoms that the subject is currently taking. This includes all medications started the day of Visit 1 and medications that were taken during the screening interval and continued into the main study. 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-related 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-related 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.	02	03	04	05	__/06/____	__/07/____	☐$_1$ 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.					__/__/____	__/__/____	☐$_1$

BARGE Concomitant Drug Codes

Asthma Clinical Research Network
NHANHLBI

Drug Code	Drug Name (brand or generic name)
1.00	Accolate
1.20	Actifed
2.00	Aero Bid
3.00	albuterol
4.00	Allegra
4.01	Allegra-D
5.00	Alupent
6.00	Aminophylline IV
7.00	astemizole
7.80	Atarax
8.00	Atrovent
9.00	Azmacort
10.00	beclomethasone - nasal
11.00	beclomethasone - MDI
12.00	Beclovent
13.00	Beconase
14.00	Benadryl
15.00	bitolterol
16.00	Brethaire
17.00	Brethine
18.00	Bricanyl
19.00	brompheniramine
19.20	Bronkaid mist
19.30	Bronkometer
20.00	budesonide - nasal
21.00	budesonide - Turbuhaler
22.00	cetirizine
22.50	chlorpheniramine
23.00	Claritin
24.00	clemastine
25.00	Combivent

Drug Code	Drug Name (brand or generic name)
26.00	corticosteroids - MDI
27.00	corticosteroids - nasal
28.00	cromolyn sodium - MDI and nasal
29.00	dexbrompheniramine
30.00	diphenhydramine
30.50	Duo-medihaler
31.00	epinephrine
32.00	fexofenadine
33.00	Flonase
34.00	Flovent MDI
34.20	Flovent Rotadisk
35.00	flunisolide - MDI
36.00	flunisolide - nasal
37.00	fluticasone - MDI
38.00	fluticasone - nasal
39.00	fluticasone - Diskhaler
40.00	Hismanal
41.00	hydrocortisone IV
41.50	hydroxyzine
42.00	Intal
43.00	ipratropium bromide
44.00	isoetharine
45.00	isoproterenol
45.50	levalbuterol
46.00	loratadine
47.00	Maxair
48.00	Medihaler-Epi
49.00	Metaprel
50.00	metaproterenol
51.00	methylprednisolone
51.50	mometasone - nasal

Drug Code	Drug Name (brand or generic name)
51.70	montelukast
52.00	Nasacort
53.00	Nasalcrom
54.00	Nasalide
55.00	Nasarel
55.50	Nasonex
56.00	nedocromil
56.50	Olopatadine
57.00	Optimine
57.50	Patanol
58.00	PBZ
59.00	pirbuterol
60.00	prednisone
61.00	Primatene Mist
62.00	Proventil
63.00	Pulmicort
63.50	Repetabs
64.00	Rhinocort
65.00	salmeterol
66.00	Seldane
67.00	Serevent
68.00	Singulair
69.00	Slo-bid
70.00	Slo-Phyllin
71.00	Tavist
72.00	terbutaline
73.00	terfenadine
74.00	Theo-24
75.00	Theo-Dur
76.00	theophylline - oral
77.00	Tilade
78.00	Tornalate
79.00	triamcinolone - IM
80.00	triamcinolone - nasal
81.00	triamcinolone - MDI

BARGE Concomitant Drug Codes

82.00	tripellenamine
83.00	Uniphyl
84.00	Vancenase
84.50	Vasacon - A
85.00	Vanceril
86.00	Ventolin
86.30	Vistaril
86.50	Volmax
86.80	Xopenex
87.00	zafirlukast
88.00	zileuton
89.00	Zyflo
90.00	Zyrtec
Suspended Study Medications	
99.99	Scheduled Inhaler

BARGE Concomitant Drug Codes

Asthma Clinical Research Network
NIH/NHLBI

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

Codes for Frequency		
Code	Frequency	
1	QD	1 time a day
2	BID	2 times a day
3	TID	3 times a day
4	QID	4 times a day
5	q4h	every 4 hours
6	q5h	every 5 hours
7	q6h	every 6 hours
8	q8h	every 8 hours
9	q12h	every 12 hours
10	q24h	every 24 hours
11	hs	every night at 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	

Asthma Clinical Research Network
NIH/NHLBI

Please use black ink to complete.

BARGE DIARY CARD

Subject's Initials: ___ ___ ___
dry

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Return Visit Number: ___ ___
Inhaler ___
Return Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year

To the subject:
If your peak flow is below _____ liters/minute, use your RESCUE inhalers as instructed in the handout "If Your Asthma Gets Worse."
Contact study personnel if your peak flow does not increase to this value after two hours of RESCUE use, or if you are experiencing extreme symptoms.
If you have taken more than _____ puffs/24 hours for the past 48 hours from your RESCUE 1 and RESCUE 2 inhalers (combined, total puffs), contact study personnel.

		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 AM and 10 AM)								
1. Number of times that you woke up last night due to asthma		01	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
2. Time of AM Peak Flow (Should be between 5 AM and 10 AM but record actual time taken)		02 ___ : ___ ___	___ : ___ ___	___ : ___ ___	___ : ___ ___	___ : ___ ___	___ : ___ ___	___ : ___ ___
3. AM Peak Flow (liters/min)**		03 03r ___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
4. AM FEV_1 (liters)		___ . 04 ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___
Symptoms++ during the night.	5. Shortness of Breath	05						
	6. Chest Tightness	06						
	7. Wheezing	07						
	8. Cough	08						
	9. Phlegm/Mucus	09						
NIGHT-TIME EVALUATION (Between 9 PM and 12 AM)								
10. Time of PM Peak Flow (Should be between 9 PM and 12 AM but record actual time taken)		10 ___ : ___ ___	___ : ___ ___	___ : ___ ___	___ : ___ ___	___ : ___ ___	___ : ___ ___	___ : ___ ___
11. PM Peak Flow (liters/min)**		11 11r ___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
12. PM FEV_1 (liters)		___ . 12 ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___
13. Total number of puffs from scheduled inhaler during past 24 hours		13 ___	___	___	___	___	___	___
14. Total number of puffs from RESCUE 1 inhaler during past 24 hours *(Do not record preventive puffs.)*		14 ___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
15. Total number of puffs from RESCUE 2 inhaler during past 24 hours *(Do not record preventive puffs.)*		15 ___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
Symptoms++ since you woke.	16. Shortness of Breath	16						
	17. Chest Tightness	17						
	18. Wheezing	18						
	19. Cough	19						
	20. Phlegm/Mucus	20						

** Record the best of three attempts. Circle the value if you have taken any medication from your RESCUE inhaler(s) 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.

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BARGE
SCREEN DROPOUT

(Prior to Visit 1)

drop

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete this form only for those subjects who have successfully completed the screening visit and have been terminated or deemed ineligible prior to Visit 1. After the form is completed, fax it immediately to the BARGE primary data manager at the DCC at (717) 531-5779.

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

01a 1a. If ***YES***, indicate the **primary** reason:

- ❑1 no longer interested in participating
- ❑2 difficult access to clinic (location, transportation, parking)
- ❑3 moving out of the area
- ❑4 unable to continue due to personal constraints
- ❑5 unable to continue due to medical condition unrelated to asthma
- ❑6 other _____

02 2. Is the subject being withdrawn from the study due to an ineligible genotype? ❑1 Yes ❑0 No

02a 2a. If ***YES***, was the subject given the standard ACRN notification letter? ❑1 Yes ❑0 No
→ ***All genotype ineligible subjects must receive this letter.***

03 3. Is the subject being withdrawn due to the randomization of a first degree relative? ❑1 Yes ❑0 No

04 4. Has the subject been lost to follow-up? ❑1 Yes ❑0 No

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

sdi **sdd** Subject's Initials: ___ ___ ___
Date: ___ ___ / ___ ___ / ___ ___ ___ ___

06 6. Is the subject being withdrawn for other reasons? ❑1 Yes ❑0 No
If ***YES***, describe _____

SIGNATURE

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

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

s _____ Clinic Coordinator's Signature

dt ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year)

Asthma Clinical Research Network
NIH/NHLBI

BARGE
ELIGIBILITY CHECKLIST 1

e1

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

01 1. ***Did the subject sign the BARGE Informed Consent?*** ☐ 1 Yes ☐ 0 No

01a *If **YES**, record the date the form was signed.* ___ ___ / ___ ___ / ___ ___ ___ ___
month day year

02 2. Did the clinic receive written notification from the DCC that the subject is eligible for enrollment at Visit 1? ☐ 1 Yes ☐ 0 No

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

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

05 5. Have you experienced a significant asthma attack in the past 6 weeks? ☐ 1 Yes ☐ 0 No

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

07 7. Are you potentially able to bear children? (If subject is male, check N/A and go to Question #8.) ☐ 1 Yes ☐ 0 No ☐ 9 N/A

07a 7a. If ***YES***, are you currently 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

07b 7b. If ***YES***, record results of pregnancy test. ☐ 1 Positive ☐ 2 Negative

08 8. 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.***

e1_sdi

e1_sdd

Subject's Initials: __ __ __

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

Asthma Clinical Research Network
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BARGE
ELIGIBILITY CHECKLIST 2
e2

Subject ID: 8 ___ ___ ___ ___
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. Based on input from the subject and the study physician, will the subject need to use intranasal steroids at any time during the study? ☐ 1 Yes ☐ 0 No

04a 4a. If ***YES***, is the subject willing to take beclomethasone [2 puffs (42 μg/puff) or 1 puff (84 μg/puff) each nare BID] continuously for the duration of the study? ☐ 1 Yes ☒ 0 No

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

ELECTROCARDIOGRAM MEASUREMENTS (QUESTIONS #6 - #8)

06 6. Ventricular heart rate ___ ___ ___ beats/min

7. Cardiac cycle measurements

07a 7a. P - R Interval . ___ ___ ___ seconds

07b 7b. QRS Duration . ___ ___ ___ seconds

07c 7c. Q - T Interval . ___ ___ ___ seconds

08 8. 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

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

10 10. Is the subject's methacholine PC_{20} obtained during Visit 1 ≤ 8 mg/ml? ☐ 1 Yes ☐ 0 No

11 11. 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.***

e2_sdi

e2_sdd

Subject's Initials: _ _ _

Date: _ _/_ _/_ _ _ _

Asthma Clinical Research Network
NIH/NHLBI

BARGE
ELIGIBILITY CHECKLIST 3

e3

Subject ID: 8 ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 4
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01	1.	Since Visit 1, has the subject experienced a significant asthma exacerbation as defined in the protocol?	■ 1 Yes	☐ 0 No
02	2.	Since Visit 1, has the subject received treatment with any excluded medications (EXCLDRUG)?	■ 1 Yes	☐ 0 No
03	3.	Have any of the subject's biological first degree relatives (i.e., parents, siblings, children) been randomized in the BARGE study?	■ 1 Yes	☐ 0 No
04	4.	Using the history stored in the Doser™, did the subject take at least 80% of the required puffs from his or her scheduled inhaler during the last two weeks of the run-in period?	☐ 1 Yes	■ 0 No
05	5.	Using the history stored in the Doser™, did the subject take 8 puffs per day (correct daily dose) on at least 70% of the days during the last two weeks of the run-in period?	☐ 1 Yes	■ 0 No
06	6.	During the run-in period, did the subject record both AM and PM peak flow measurements and symptoms on his or her Diary Card (DIARY) an average of at least five days per week?	☐ 1 Yes	■ 0 No
07	7.	During the last four weeks of the run-in period, did the subject use an average of less than 56 puffs per week from his or her rescue inhalers (ipratropium and albuterol combined)?	☐ 1 Yes	■ 0 No
08	8.	Does the subject wish to withdraw consent from the study?	■ 1 Yes	☐ 0 No
09	9.	Is there any new information that makes the subject ineligible according to the eligibility criteria? If ***YES,*** describe: _____	■ 1 Yes	☐ 0 No
10	10.	Is there any other reason why this subject should not be included in the study? If ***YES,*** describe: _____	■ 1 Yes	☐ 0 No
11	11.	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 BARGE, randomize the subject. Otherwise, please complete the Termination of Study Participation (TERM) form.***		
12	12.	Drug Packet Number **(record on LOG)**	8 ___ ___ ___ ___	

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BARGE LABORATORY MEASUREMENTS

lab

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. Eosinophils (absolute count) at Visit 1 ___ ___ ___ ___ /mm^3

BARGE
LONG PHYSICAL EXAM

lx

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

VITAL SIGNS

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

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

02 2. Pulse ___ ___ ___ beats/min

03 3. Respiration ___ ___ breaths/min

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

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

INTRANASAL STEROIDS

06 6. Is the subject currently using nasal beclomethasone dipropionate at an approved study dose [2 puffs (42 μg/puff) each nare BID or equivalent double strength dose]?

❑1 Yes ❑0 No

PHYSICAL FINDINGS

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

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

ADVERSE EVENTS

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) or the Screening Clinical Adverse Events form (SCREEN_AE) (Visit 1 only, when applicable).

URINE PREGNANCY TEST

19. ***(Complete Question #19 for Visits 14 and 24 only.)***
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.***

sdi

sdds

Pregnancy Test Source Documentation
Subject's Initials: _ _ _
Date: _ _/_ _/_ _ _ _

Physician's Signature: _____ sds
Date: _ _/_ _/_ _ _ _ sddp
Time: _ _ _ _ *(based on 24-hour clock)* sdt

Asthma Clinical Research Network
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BARGE MAXIMUM BRONCHODILATOR EFFECT TESTING

mbd

Supervisor ID: ____ ____ ____ ____ ____

Subject ID: 8 ____ ____ ____ ____
Subject Initials: ____ ____ ____
Visit Number: ____ ____
Visit Date: ____ ____ / ____ ____ / ____ ____ (Month / Day / Year)
Technician ID: ____ ____ ____ ____ ____

(Technician completed)

Complete this form only if the subject has successfully completed the Nitric Oxide and Spirometry Testing form (NO_SPIRO).

POSTBRONCHODILATOR PULMONARY FUNCTION TESTING

➔ ***Administer 4 puffs of albuterol immediately following prebronchodilator spirometry and wait 15 minutes.***

01 1. Time albuterol administered *(based on 24-hour clock)* ____ ____ ____ ____

2. Subject's FEV_1 after 4 puffs of albuterol

02a 2a. Time spirometry started *(based on 24-hour clock)* ____ ____ ____ ____

02b 2b. FEV_1 ____ . ____ ____ L

02c 2c. FEV_1 (% predicted) ____ ____ ____ % predicted

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

03 3. Time albuterol administered *(based on 24-hour clock)* ____ ____ ____ ____

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

04a 4a. Time spirometry started *(based on 24-hour clock)* ____ ____ ____ ____

04b 4b. FEV_1 ____ . ____ ____ L

04c 4c. FEV_1 (% predicted) ____ ____ ____ % predicted

04d 4d. Percent difference in FEV_1 $\frac{\textit{(Question \#4b - Question \#2b)}}{\textit{Question \#2b}}$ x 100 ____ ____ . ____ %

04e 4e. Is the percent difference from Question #4d ≤ 5%? ☐$_1$ Yes ☐$_0$ No

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

05 5. Time albuterol administered *(based on 24-hour clock)* ____ ____ ____ ____

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

06a 6a. Time spirometry started *(based on 24-hour clock)* ____ ____ ____ ____

06b 6b. FEV_1 ____ . ____ ____ L

06c 6c. FEV_1 (% predicted) ____ ____ ____ % predicted

Asthma Clinical Research Network
NIH/NHLBI

BARGE MEDICAL HISTORY

mhx

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

DO NOT COMPLETE QUESTIONS # 1 - 3.

DEMOGRAPHY

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

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_____

3. Subject's gender *(Do not ask subject)*
   - ❑1 Male
   - ❑2 Female

ASTHMA HISTORY

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

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

06 6. 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*)

07a 7a. Asthma episodes have you had that required emergency care or an unscheduled office visit? ___ ___

07b 7b. Hospitalizations have you had due to asthma? ___ ___

07c 7c. Courses of oral corticosteroid therapy for asthma (such as prednisone or Medrol) have you taken? ___ ___

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

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.*)

09a	9a. Mother	❑1 Yes	❑0 No	❑8 Don't Know		
09b	9b. Father	❑1 Yes	❑0 No	❑8 Don't Know		
09c	9c. Brothers or Sisters	❑1 Yes	❑0 No	❑8 Don't Know	❑9 N/A	
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 medications. Indicate if you have ever used the medication. If you have, please indicate, to the best of your knowledge, the date last taken.

					If Yes, indicate date medication was last taken month / day / year
10 10x	10.	Short-acting Inhaled Beta-Agonists (MDI) **(Bronkaid Mist, Duo-Medihaler, Medihaler-Epi, Primatene Mist and others)**	❑1 Yes	❑0 No ❑8 Unknown	__/__/__
11 11x	11.	Intermediate-acting Inhaled Beta-Agonists (MDI) **(Alupent, Brethaire, Brethine, Bronkometer, Maxair, Metaprel, Proventil, Tornalate, Ventolin, Xopenex and others)**	❑1 Yes	❑0 No ❑8 Unknown	__/__/__
12 12x	12.	Long-acting Inhaled Beta-Agonists (MDI) **(Serevent)**	❑1 Yes	❑0 No ❑8 Unknown	__/__/__
13 13x	13.	Asthma medication via a Nebulizer Machine	❑1 Yes	❑0 No ❑8 Unknown	__/__/__
14 14x	14.	Intermediate-acting Oral Beta-Agonists **(Alupent, Brethine, Bricanyl, Metaprel, Proventil, Ventolin and others)**	❑1 Yes	❑0 No ❑8 Unknown	__/__/__
15 15x	15.	Long-acting Oral Beta-Agonists **(Repetabs, Volmax)**	❑1 Yes	❑0 No ❑8 Unknown	__/__/__
16 16x	16.	Short-acting Oral Theophylline **(Aminophylline, Slo-Phyllin and others)**	❑1 Yes	❑0 No ❑8 Unknown	__/__/__
17 17x	17.	Sustained release Oral Theophylline **(Slo-bid, Theo-Dur, Uniphyl and others)**	❑1 Yes	❑0 No ❑8 Unknown	__/__/__
18 18x	18.	Inhaled Anticholinergic **(Atrovent, Combivent)**	❑1 Yes	❑0 No ❑8 Unknown	__/__/__
19 19x	19.	Anti-allergic Inhaled Medications **(Intal, Tilade and others)**	❑1 Yes	❑0 No ❑8 Unknown	__/__/__
20 20x	20.	Anti-allergic Nasal Medications **(Nasalcrom and others)**	❑1 Yes	❑0 No ❑8 Unknown	__/__/__

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

21 21x	21.	Anti-allergic Oral Medications **(Allegra, Claritin and others)**	❑1 Yes ❑0 No ❑8 Unknown	__/__/____
22 22x	22.	Oral Steroids **(Prednisone, Medrol and others)**	❑1 Yes ❑0 No ❑8 Unknown	__/__/____
23 23x	23.	Inhaled Steroids **(Azmacort, Beclovent, Vanceril, AeroBid, Flovent, Pulmicort and others)**	❑1 Yes ❑0 No ❑8 Unknown	__/__/____
24 24x	24.	Nasal Steroids **(Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Rhinocort, Nasonex and others)**	❑1 Yes ❑0 No ❑8 Unknown	__/__/____
25 25x	25.	Topical Steroids - Prescription **(Synalar, Lidex, Dermacin, Fluocinonide and others)**	❑1 Yes ❑0 No ❑8 Unknown	__/__/____
26 26x	26.	Topical Steroids - OTC **(Hydrocortisone - multiple strengths and products)**	❑1 Yes ❑0 No ❑8 Unknown	__/__/____
27 27x	27.	Leukotriene Antagonist / 5L0 Inhibitors **(Accolate, Zyflo, Singulair)**	❑1 Yes ❑0 No ❑8 Unknown	__/__/____

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

				If Yes, Comment
28	28.	Skin	❑1 Yes ❑0 No	
29	29.	Blood, Lymph, or Immune Systems	❑1 Yes ❑0 No	
30	30.	Eyes	❑1 Yes ❑0 No	
31	31.	Ears, Nose, or Throat	❑1 Yes ❑0 No	
32	32.	Breasts	❑1 Yes ❑0 No	
33	33.	Endocrine Systems	❑1 Yes ❑0 No	
34	34.	Lung - other than asthma	❑1 Yes ❑0 No	
35	35.	Heart and Blood Vessels	❑1 Yes ❑0 No	
36	36.	Liver or Pancreas	❑1 Yes ❑0 No	
37	37.	Kidneys or Urinary Tract System	❑1 Yes ❑0 No	
38	38.	Reproductive System	❑1 Yes ❑0 No	
39	39.	Stomach or Intestines	❑1 Yes ❑0 No	
40	40.	Muscles or Bones	❑1 Yes ❑0 No	
41	41.	Nervous System	❑1 Yes ❑0 No	
42	42.	Psychiatric	❑1 Yes ❑0 No	
43	43.	Other _____	❑1 Yes ❑0 No	

sdi
sdd

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

Asthma Clinical Research Network
NIH/NHLBI

BARGE METHACHOLINE CHALLENGE TESTING

mth

Supervisor ID: ___ ___ ___ ___ ___

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete this form only if the subject has successfully completed the Nitric Oxide and Spirometry Testing form (NO_SPIRO).

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

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

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: _____

03 3. 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 NO_SPIRO form as the baseline reference.

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

If ***YES***, explain _____

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

Use the prebronchodilator FEV_1 value from the NO_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***

06 6. PC_{20} ___ ___ ___ . ___ ___ ___ mg/ml

06a 6a. Time methacholine challenge was completed (*based on 24-hour clock*) ___ ___ ___ ___

7. Subject's FEV_1 after standard reversal (2 puffs albuterol) from methacholine challenge

07a 7a. FEV_1 ___ . ___ ___ L

07b 7b. FEV_1 (% predicted) ___ ___ ___ % predicted

07c 7c. Time of FEV_1 in Question #7a (*based on 24-hour clock*) ___ ___ ___ ___

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 HERE and continue with remaining visit procedures.***

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.***

08a 8a. Additional albuterol by MDI ☐ 1 Yes ☐ 0 No

➜ ***If NO, skip to Question #8b.***

08ai 8ai. Number of additional puffs of albuterol administered ☐ 1 two ☐ 2 four ☐ 3 > four

08b 8b. Nebulized Beta-agonist ☐ 1 Yes ☐ 0 No

08c 8c. Subcutaneous epinephrine ☐ 1 Yes ☐ 0 No

08d 8d. Implementation of clinic emergency protocol or algorithm ☐ 1 Yes ☐ 0 No

08e 8e. Other _____ ☐ 1 Yes ☐ 0 No

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

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. Was the FEV_1 from Question #9a ≥ 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.***

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.***

10a 10a. Additional albuterol by MDI ❑$_1$ Yes ❑$_0$ No

➜ ***If NO, skip to Question #10b.***

10ai 10ai. Number of additional puffs of albuterol administered ❑$_1$ two ❑$_2$ four ❑$_3$ > four

10b 10b. Nebulized Beta-agonist ❑$_1$ Yes ❑$_0$ No

10c 10c. Subcutaneous epinephrine ❑$_1$ Yes ❑$_0$ No

10d 10d. Implementation of clinic emergency protocol or algorithm ❑$_1$ Yes ❑$_0$ No

10e 10e. Treatment in the emergency room ❑$_1$ Yes ❑$_0$ No

10f 10f. Overnight hospitalization ❑$_1$ Yes ❑$_0$ No

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

10g 10g. Other _____ ❑$_1$ Yes ❑$_0$ No

11. Subject's final FEV_1 after methacholine challenge.

11a 11a. FEV_1 ___ . ___ ___ L

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

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

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.***

sds Physician's Signature: _____

sdd Date: ___/___/_____

sdt Time: ____ *(based on 24-hour clock)*

Asthma Clinical Research Network
NIH/NHLBI

BARGE NITRIC OXIDE AND SPIROMETRY TESTING

nosp

Supervisor ID: ___ ___ ___ ___ ___

Subject ID: 8 ___ ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: ___ ___

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

(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
04	4.	Have you used fexofenadine (e.g. Allegra) or chlorpheniramine (e.g. Chlor-Trimeton) in the past 48 hours?	☐ 1 Yes	☐ 0 No
05	5.	Have you used pseudoephedrine (e.g. Sudafed) or oxymetazoline (e.g. Afrin) in the past 48 hours?	☐ 1 Yes	☐ 0 No
06	6.	***(Complete at Visits 1, 4, 5, 8, 10, 11, 14, 15, 18, 20, 21, 24.)*** Have you used a rescue anticholinergic (e.g. RESCUE 1 inhaler, Atrovent, Combivent) in the past 24 hours?	☐ 1 Yes	☐ 0 No
07	7.	***(Complete at Visits 2, 3, 6, 7, 9, 12, 13, 16, 17, 19, 22, 23.)*** Have you used a rescue anticholinergic (e.g. RESCUE 1 inhaler, Atrovent, Combivent) in the past 6 hours?	☐ 1 Yes	☐ 0 No
08	8.	Have you used a rescue intermediate-acting inhaled beta-agonist (e.g. RESCUE 2 inhaler, Ventolin, Proventil) in the past 6 hours?	☐ 1 Yes	☐ 0 No
09	9.	Have you used your scheduled inhaler in the past 6 hours?	☐ 1 Yes	☐ 0 No
10	10.	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
11	11.	Is there any other reason you should not proceed with the pulmonary function testing? If ***YES***, explain _____	☐ 1 Yes	☐ 0 No

12

12. Is the subject eligible to proceed with nitric oxide collection and pulmonary function testing? ***If any of the shaded boxes are filled in, the subject is NOT eligible.*** ☐ 1 Yes ☐ 0 No

☞ ***If NO, do NOT complete pages 2 and 3. Testing should be rescheduled within the visit window.***

NITRIC OXIDE COLLECTION AND MEASUREMENT

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

13

13. ANORA number: ___ ___

14

14. Collector ID: ___ ___ ___ ___ ___

	(Collector completed)		*(Reader completed)*	
	Balloon Id	**Time Collected** *(based on 24-hour clock)*	**Time Read** *(based on 24-hour clock)*	**Measurement (ppb)**
15.	15a ___ ___ ___	15b ___ ___ ___	15c ___ ___ ___	15d ___ ___ . ___
16.	16a ___ ___ ___	16b ___ ___ ___	16c ___ ___ ___	16d ___ ___ . ___
17.	17a ___ ___ ___	17b ___ ___ ___	17c ___ ___ ___	17d ___ ___ . ___

18

18. Date balloons were read: ___ ___ / ___ ___ / ___ ___ ___ ___
month day year

19

19. Reader ID: ___ ___ ___ ___ ___

Comments:

PREBRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

20 20. Technician ID ___ ___ ___ ___ ___

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

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

22. Results of best effort:

22a 22a. FVC ___.___ ___ L

22b 22b. FEV_1 ___.___ ___ L

22c 22c. FEV_1 (% predicted) ___ ___ ___ % predicted

22d 22d. PEFR ___ ___.___ ___ L/S

22e 22e. FEF_{25-75} ___.___ ___ L/S

Asthma Clinical Research Network
NIH/NHLBI

BARGE QUALITY OF LIFE QUESTIONNAIRE

qol

Subject ID: 8 ___ ___ ___
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
01	1. Activity 1	☐ 1	☐ 2	☐ 3	☐ 4		☐ 5	☐ 6
02	2. Activity 2	☐ 1	☐ 2	☐ 3	☐ 4		☐ 5	☐
03	3. Activity 3	☐ 1	☐ 2	☐ 3	☐ 4		☐ 5	☐ 6
04	4. Activity 4	☐ 1	☐ 2	☐ 3	☐ 4		☐ 5	☐
05	5. Activity 5	☐ 1	☐ 2	☐ 3	☐ 4		☐ 5	☐ 6

		None	Very Little	Some	Moderate Amount	A Good Deal	A Great Deal	A Very Great Deal
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

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
07	7. Feel CONCERNED ABOUT HAVING ASTHMA?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
08	8. Feel SHORT OF BREATH as a result of your asthma?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
09	9. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO CIGARETTE SMOKE?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
10	10. Experience a WHEEZE in your chest?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
11	11. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF CIGARETTE SMOKE?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6

		None	Very Little	Some	Moderate Amount	A Good Deal	A Great Deal	A Very Great Deal
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

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
13	13. Feel FRUSTRATED as a result of your asthma?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
14	14. Experience a feeling of CHEST HEAVINESS?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
15	15. Feel CONCERNED ABOUT THE NEED TO USE MEDICATION for your asthma?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
16	16. Feel the need to CLEAR YOUR THROAT?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
17	17. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO DUST?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
18	18. Experience DIFFICULTY BREATHING OUT as a result of your asthma?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
19	19. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF DUST?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
20	20. WAKE UP IN THE MORNING WITH ASTHMA SYMPTOMS?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
21	21. Feel AFRAID OF NOT HAVING YOUR ASTHMA MEDICATION AVAILABLE?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
22	22. Feel bothered by HEAVY BREATHING?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
23	23. Experience asthma symptoms as a RESULT OF THE WEATHER OR AIR POLLUTION?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
24	24. Were you WOKEN AT NIGHT by your asthma?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
25	25. AVOID OR LIMIT GOING OUTSIDE BECAUSE OF THE WEATHER OR AIR POLLUTION?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6

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
26	26. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO STRONG SMELLS OR PERFUME?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
27	27. Feel AFRAID OF GETTING OUT OF BREATH?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
28	28. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF STRONG SMELLS OR PERFUME?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
29	29. Has your asthma INTERFERED WITH GETTING A GOOD NIGHT'S SLEEP?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6
30	30. Have a feeling of FIGHTING FOR AIR?	❑ 1	❑ 2	❑ 3	❑ 4		❑ 5	❑ 6

		No Limitation		Very Few Not Done		Several Not Done		Most Not Done
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

		Not at all Limited	A Little Limitation	Some Limitation	Moderate Limitation	Very Limited	Extremely Limited	Totally Limited
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

sdi

sdd

Subject's Initials: _ _ _

Date: _ _/_ _/_ _ _ _

Asthma Clinical Research Network
NIH/NHLBI

BARGE SCREENING CHECKLIST

scr

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

ADMINISTRATIVE

01 1. ***Did the subject sign the Screening/Genetics Informed Consent?*** ☐1 Yes ☐0 No

01a 1a. If ***YES***, record the date the form was signed. ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year)

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

02 2. Is the subject willing to give a blood sample for DNA isolation and genotyping? ☐1 Yes ☐0 No

03 3. Did the subject participate in the BAGS trial? ☐1 Yes ☐0 No

03a 3a. If ***YES***, did the subject provide genetic material for DNA analysis in BAGS? (*Ask the subject and confirm with lists provided by DCC.*) ☐1 Yes ☐0 No

04 4. Is the subject's biological mother living? ☐1 Yes ☐0 No ☐8 Unknown

05 5. Is the subject's biological father living? ☐1 Yes ☐0 No ☐8 Unknown

06 6. If either Question #4 or Question #5 is answered ***YES***, will the subject allow the ACRN to contact his/her parent(s) to ask them to provide blood samples for genetic analysis? ☐1 Yes ☐0 No

Only biological parents of eligible, randomized BARGE subjects will be eligible for participation.

DEMOGRAPHICS

07 7. Record subject's date of birth. ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year)

07a 7a. Is the subject between 18 and 55, inclusive? ☐1 Yes ☐0 No

08 8. Subject's gender ☐1 Male ☐2 Female

09 9. Subject's ethnic background *(Ask the subject which category best describes him or her.)*

- ☐ 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_____

MEDICAL HISTORY

10 10. 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_____

11 11. 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_____

12 12. 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_____

13 13. Based on input from the subject and the study physician, will the subject need to use intranasal steroids at any time during the study? ☐ 1 Yes ☐ 0 No

13a 13a. If ***YES***, is the subject willing to take beclomethasone [2 puffs (42 μg/puff) or 1 puff (84 μg/puff) each nare BID] continuously for the duration of the study? ☐ 1 Yes ☐ 0 No

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

15 15. Has the subject experienced a significant asthma attack in the past six weeks? ☐ 1 Yes ☐ 0 No

16 16. Has the subject experienced a life-threatening asthma attack requiring treatment with intubation and mechanical ventilation in the past five years? ☐ 1 Yes ☐ 0 No

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

17a 17a. Is the value recorded in Question #17 less than 56 puffs? ☐ 1 Yes ☐ 0 No

18 18. Has the subject smoked cigarettes, a pipe, cigars, or any other substance in the past year? ☐ 1 Yes ☐ 0 No

19 19. Record smoking history in pack-years. (Enter 00.0 if subject never smoked.) ___ ___ . ___

19a 19a. Does the subject have a total smoking history less than or equal to 10 pack-years? ☐ 1 Yes ☐ 0 No

---

PHYSICAL EXAMINATION

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

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

22 22. Calculate and record the subject's BMI. ___ ___ . ___ ___
(Submit a copy of the ACRN BMI calculator printout with this form.)

22a 22a. Is the subject's BMI greater than or equal to 35? ☐ 1 Yes ☐ 0 No

23sy 23di

23. Resting blood pressure ___ ___ ___ / ___ ___ ___ mm Hg
(Record average value over a three day period, if required. See MOP for details.) systolic diastolic

23a 23a. Is the subject's diastolic blood pressure greater than or equal to 95 mm Hg? ☐ 1 Yes ☐ 0 No

24 24. Is the subject potentially able to bear children? ☐ 1 Yes ☐ 0 No ☐ 9 N/A
(If subject is male, check N/A and go to Question #25.)

24a 24a. If ***YES***, is the subject using one of the approved methods indicated on the Birth Control reference card (BIRCTRL)? ☐ 1 Yes ☐ 0 No

24b 24b. If ***YES***, record results of pregnancy test. ☐ 1 Positive ☐ 2 Negative

sdi1 sdd1

Pregnancy Test Source Documentation
Subject's Initials: ___ ___ ___
Date: ___/___/___ ___ ___ ___

sds sdd sdt

Physical Exam Source Documentation
Physician/CC Signature: _____
Date: ___/___/___ ___ ___ ___
Time: ___ ___ ___ ___ *(based on 24-hour clock)*

SPIROMETRY

25 25. Has the subject consumed caffeine in the past 8 hours? ☐ 1 Yes ☐ 0 No
Examples: *Caffeinated colas (Pepsi, Coke), Coffee, Mello-Yello, Mountain Dew, Tea, Barq's Rootbeer*

26 26. Has the subject used medication with caffeine in the past 8 hours? ☐ 1 Yes ☐ 0 No
Examples: *Anacin, Darvon compound, Esgic, Excedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*

27 27. Has the subject consumed any food containing alcohol or beverages containing alcohol in the past 8 hours? ☐ 1 Yes ☐ 0 No

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

tech Technician ID ___ ___ ___ ___ ___

28. Spirometry results:

28a 28a. FVC ___.___ ___ L

28b 28b. FEV_1 ___.___ ___ L

28c 28c. FEV_1 (% predicted) ___ ___ ___ % predicted

28d 28d. Is the subject's $FEV_1 \geq 70\%$ of predicted? ☐ 1 Yes ☐ 0 No

Perform methacholine challenge and record PC_{20}.

28e 28e. PC_{20} ___ ___ ___.___ ___ ___ mg/ml

28f 28f. Is the subject's $PC_{20} \leq 8$mg/ml? ☐ 1 Yes ☐ 0 No

29 29. Is the subject eligible to proceed with obtaining a blood sample for genotyping? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ☐ 1 Yes ☐ 0 No

☞ ***If YES, proceed with the GAMATCH form and blood sampling procedures.***

sdi2
sdd2

Screening Source Documentation
Subject's Initials: ___ ___ ___
Date: ___/___/___ ___ ___ ___

SCREEN

Asthma Clinical Research Network
NIH/NHLBI

BARGE SERIOUS ADVERSE EVENT REPORTING FORM

ser

Subject ID: 8 ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Current Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form must be faxed to the DCC at (717) 531-4359 within 72 hours of notification of a serious event. Also fax the appropriate Clinical Adverse Events Log (SCREEN_AE or AECLIN), the appropriate Concomitant Medications Log (SCREEN_MED or 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 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

BARGE SHORT PHYSICAL EXAM

sx

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

VITAL SIGNS

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

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

02 2. Pulse ___ ___ ___ beats/min

PULMONARY AUSCULTATION

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

_____
_____

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

ADVERSE EVENTS

04 4. ***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).

INTRANASAL STEROIDS

05 5. Is the subject currently using nasal beclomethasone dipropionate at an approved study dose [2 puffs (42 μg/puff) each nare BID or equivalent double strength dose]? ☐ 1 Yes ☐ 0 No

sds
sddp
sdt

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

URINE PREGNANCY TEST

06

6. ***(Complete Question #6 for Visits 4, 5, 8, 10, 11, 15, 18, 20, 21 only.)***

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.***

sdi

sdds

Pregnancy Test Source Documentation

Subject's Initials: _ _ _

Date: _ _/_ _/_ _ _ _

(Clinic Coordinator completed)

This form must be completed each time a subject experiences an asthma exacerbation according to the definition below. This form applies only to exacerbations occurring after enrollment at Visit 1.

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?

01a 1a. An increase in rescue use (ipratropium and albuterol combined) of ≥ 8 puffs per 24 hours over baseline use for a period of 48 hours? ■ 1 Yes ☐ 0 No

01b 1b. Use of rescue inhaler(s) (ipratropium and albuterol combined) ≥ 16 total puffs per 24 hours for a period of 48 hours? ■ 1 Yes ☐ 0 No

01c 1c. A fall in prebronchodilator PEFR to ≤ 65% of baseline? ■ 1 Yes ☐ 0 No

01d 1d. Treatment with oral, inhaled, or intravenous corticosteroids as a result of rescue intervention or by the opinion of the treating physician? ■ 1 Yes ☐ 0 No

➜ ***If YES, please complete the CMED_AS form.***

02 2. Did the subject experience a significant asthma exacerbation? ■ 1 Yes ☐ 0 No
If any of the shaded boxes are filled in, the subject experienced a SIGEX.

☞ ***If YES, but the subject has not yet been randomized, complete this form, then STOP. The subject is ineligible for the study; please complete the TERM form.***

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

03 3. Date significant asthma exacerbation occurred ___ ___ / ___ ___ / ___ ___ ___ ___ (*month / day / year*)

04 4. Did the subject seek care for the asthma exacerbation? ☐1 Yes ☐0 No
➜ ***If NO, skip to Question #7.***

5. What type of care was sought?

05a 5a. Study Investigator? ☐1 Yes ☐0 No

05a1 If ***YES***, indicate type of contact.
☐1 Scheduled clinic visit
☐2 Unscheduled clinic visit
☐3 Phone contact

05b 5b. Primary Care or Other Physician? ☐1 Yes ☐0 No
If ***YES***, name of physician: _____

05b1 If ***YES***, indicate type of contact.
☐1 Scheduled clinic visit
☐2 Unscheduled clinic visit
☐3 Phone contact

05c 5c. Emergency Room visit? ☐1 Yes ☐0 No
If ***YES,*** name of hospital: _____

06 6. Was the subject hospitalized? ☐1 Yes ☐0 No
➜ ***If YES, please complete the Serious Adverse Event Form (SERIOUS).***

If ***YES***,

06a 6a. Duration of hospital stay? ___ ___ . ___ days

06b 6b. Was intubation or ventilation assistance required? ☐1 Yes ☐0 No

6c. Name of hospital: _____

7. Please indicate whether the following medications were used to treat the asthma exacerbation:

07a	7a.	Ipratropium rescue inhaler (RESCUE 1)	☐ 1 Yes	☐ 0 No
07b	7b.	Albuterol rescue inhaler (RESCUE 2)	☐ 1 Yes	☐ 0 No
07c	7c.	Nebulized beta-agonist ➜ ***If YES, please complete the CMED_AS form.***	☐ 1 Yes	☐ 0 No
07d	7d.	Inhaled corticosteroids ➜ ***If YES, please complete the CMED_AS form.***	☐ 1 Yes	☐ 0 No
07e	7e.	Oral corticosteroids ➜ ***If YES, please complete the CMED_AS form.***	☐ 1 Yes	☐ 0 No
07f	7f.	Intravenous corticosteroids ➜ ***If YES, please complete the CMED_AS form.***	☐ 1 Yes	☐ 0 No

08 8. Was the asthma exacerbation treated as outlined in the protocol? ☐ 1 Yes ☐ 0 No

If ***NO***, explain_____

_____

_____

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

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

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

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

Asthma Clinical Research Network
NIH/NHLBI

BARGE
ALLERGY SKIN TEST RESULTS

skin

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 2
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)* ___ ___ ___ ___

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

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

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

BARGE
SUBJECT STUDY TREATMENT QUESTIONNAIRE

subb

Subject ID: 8 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year

(Subject completed)

This questionnaire is to be completed by the BARGE subject at the end of Visits 10 and 20. If a randomized subject terminates prior to Visit 20, please ask him or her to complete this form during the termination visit.

01

1. As a BARGE study participant you were randomized to receive either an active (ie, real) albuterol inhaler or a look-alike placebo (ie, inactive) inhaler during various stages of the study. Please check the one box that most closely represents your feelings about the treatment you received from your **scheduled inhaler** over the past four weeks.

- ☐ 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.

sdi
sdd

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

02 2. Please comment with respect to the taste of the treatment you received from your scheduled inhaler over the past four weeks.

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

03 3. Please comment with respect to the smell of the treatment you received from your scheduled inhaler over the past four weeks.

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

04 4. Please comment with respect to any physical sensations produced by the treatment you received from your scheduled inhaler over the past four weeks.

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

05 5. Please comment with respect to any other observations you may have made regarding the treatment you received from your scheduled inhaler over the past four weeks.

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

_____

_____

_____

_____

Asthma Clinical Research Network
NIH/NHLBI

BARGE
TERMINATION OF STUDY PARTICIPATION
term

Subject ID: 8 ___ ___ ___ ___
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 24 Only)***

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

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

02 2. Is the subject withdrawing from the study due to pregnancy? ❑1 Yes ❑0 No ❑9 N/A

(Check N/A if the subject is male.)

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

03 ***3. (Visit 1 - Visit 4 Only)***

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

04 ***4. (Visit 1 - Visit 4 Only)***

Is the subject being terminated due to the randomization of a first degree relative? ❑1 Yes ❑0 No

05 ***5. (Visit 1 - Visit 4 Only)***

Has the subject been deemed ineligible according to any eligibility criteria **other than** a significant asthma exacerbation or the randomization of a first degree relative? ❑1 Yes ❑0 No

06 6. Has the subject withdrawn consent? ❑$_1$ Yes ❑$_0$ No

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

- ❑$_1$ no longer interested in participating
- ❑$_2$ no longer willing to follow protocol
- ❑$_3$ difficult access to clinic (location, transportation, parking)
- ❑$_4$ unable to make visits during clinic hours
- ❑$_5$ moving out of the area
- ❑$_6$ unable to continue due to personal constraints
- ❑$_7$ dissatisfied with Atrovent as first-line rescue therapy
- ❑$_8$ dissatisfied with asthma control
- ❑$_9$ unable to continue due to medical condition unrelated to asthma
- ❑$_{10}$ side effects of study medications
- ❑$_{11}$ other _____

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

08 8. 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 form (SERIOUS).***

09 9. Did a physician initiate subject termination? ❑$_1$ Yes ❑$_0$ No

If ***YES***, reason: _____

SIGNATURES

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

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

s1 _____ **dt1** ___ ___ / ___ ___ / ___ ___ ___ ___

Clinic Coordinator's Signature — month day year

s2 _____ **dt2** ___ ___ / ___ ___ / ___ ___ ___ ___

Principal Investigator's Signature — month day year