Table 1. MICE Forms and Datasets

Form Name	Dataset Name	Variable Prefix	Description	Field Changes/ Comments
ACQ	acq.sas7bdat	acq	Asthma Control Questionnaire	
AECLIN	aeclin.sas7bdat	cae	Clinical Adverse Events	• This form was initialized at visit 1 and updated at subsequent visits; all records reflect visit number 1
AIRQC	airqc.sas7bdat	air	AirWatch™ Quality Control	• air_02 was altered to remove the first (center-identifying) digit
CMED_AS	cmed_as.sas7bdat	cmed	Concomitant Medications for Asthma-Related Drugs	• This form was initialized at visit 1 and updated at subsequent visits; all records reflect visit number 1
MED			Concomitant Drug Codes	• Reference card explaining codes found on CMED_AS form
DIARY	diary.sas7bdat	dry	Diary Card	• Each record represents one day • Variable ‘ddate’ was added to each entry to represent the number of days from visit 1 • Dmonth and dday were omitted • Variables with an ‘r’ suffix indicate whether rescue meds were used within 2 hours of the peak flow measurement

Form Name	Dataset Name	Variable Prefix	Description	Field Changes/ Comments
	drugarms.sas7bdat		Treatment Arm Assignments	File contains the following variables: • 'subjid' = subject ID number • 'arm' = subject's randomized treatment arm (Flovent or Vanceril)
ECG	ecg.sas7bdat	ecg	Electrocardiogram Report	
ELIG1	elig1.sas7bdat	e1	Eligibility Checklist 1	
ELIG2	elig2.sas7bdat	e2	Eligibility Checklist 2	
ELIG3	elig3.sas7bdat	e3	Eligibility Checklist 3	
ELIG4	elig4.sas7bdat	e4	Eligibility Checklist 4	
ELIG5	elig5.sas7bdat	e5	Eligibility Checklist 5	• e5_12 (drug packet number) was omitted
FLUID	fluid.sas7bdat	N/A	Fluid Phase Measurements	
INHALER1	inhal1.sas7bdat	inh1	Scheduled Inhalers	• inh1_04 (drug label number) was omitted
INHALER2	inhal2.sas7bdat	inh2	Scheduled Inhalers	• inh2_07 (drug label number) was omitted
LAB	lab.sas7bdat	lab	Laboratory Measurements	
LEXAM	lexam.sas7bdat	lx	Long Physical Exam	• lx_01 was omitted • lx_02 was omitted • body mass index (BMI) added as variable 'bmi'

Form Name	Dataset Name	Variable Prefix	Description	Field Changes/ Comments
MAXREV	maxrev.sas7bdat	max	Maximum Reversibility Testing	• max_08 was omitted
MEDHX	medhx.sas7bdat	mhx	Medical History	• mhx_01 was omitted • Age at enrollment was added as variable 'age' • mhx_02 was omitted • variable 'minority' was added (1='minority' ; 0='nonminority')
METHA	metha.sas7bdat	mth	Methacholine Challenge Testing	
NO	no.sas7bdat	no	Nitric Oxide Collection	• no_read was omitted
NOCHECK	nocheck.sas7bdat	nock	Nitric Oxide Checklist	
	predict.sas7bdat		Predicted Spirometry Values based on each subject's age and height at enrollment, race, and gender	File contains the following variables: • 'subjid' • 'FEF25_75' • 'FEV_1' • 'FVC' • 'PEFR'
QOL	qol.sas7bdat	qol	Quality of Life Questionnaire (Juniper version)	
QXRCISE	qxrcise.sas7bdat	qxr	Qualifying Exercise Challenge	
SERIOUS	serious.sas7bdat	ser	Serious Adverse Event	

Form Name	Dataset Name	Variable Prefix	Description	Field Changes/ Comments
			Reporting Form	
SEXAM	sexam.sas7bdat	sx	Short Physical Exam	
SF36	sf36.sas7bdat	sf36	Health Status Questionnaire SF-36	
SIGEX	sigex.sas7bdat	sae	Significant Asthma Exacerbation	
SKIN	skin.sas7bdat	skin	Allergy Skin Test Results	• skin_cc was omitted
SPIRO	spiro.sas7bdat	spir	Spirometry Testing	• spir_08 was omitted
SPIRO3	spiro3.sas7bdat	spr3	Spirometry Testing Visit 3	• spr3_08 was omitted
SPUTLAB	sputlab.sas7bdat	slab	Sputum Induction Lab Values	• Sputum cell counts were performed by technicians at the various ACRN centers
SPUTOVER	sputover.sas7bdat	spov	Sputum Induction UCSF Over-read	
SPUTUM	sputum.sas7bdat	spt	Sputum Induction	
SUBLIST	sublist.sas7bdat	sub	Subject Overnight Checklist	
TERM	term.sas7bdat	term	Termination of Study Participation	
TXFAIL	txfail.sas7bdat	txfl	Treatment Failure	

Form Name	Dataset Name	Variable Prefix	Description	Field Changes/ Comments
XRCISE	xrcise.sas7bdat	xr	Exercise Challenge	

Table 2. Forms Completed at each Study Visit
(•=mandatory visit procedure; ❍=completed as needed)

Form Name	Visit Number																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	99
ACQ					•			•			•			•			•	•
AECLIN (updated at each visit but recorded as Visit 1 in dataset)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
AIRQC	•		•	•	•	•	•	•	•	•	•	•	•	•	•		•	•
CMED_AS (updated at each visit but recorded as Visit 1)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
DIARY			•	•	•	•	•	•	•	•	•	•	•	•	•		•	•
ECG	•																	
ELIG1	•																	
ELIG2	•																	
ELIG3	•																	
ELIG4		•																
ELIG5					•													
FLUID				•			•			•			•		•			
INHALER1					•	•	•	•	•	•	•	•	•					•

Form Name	Visit Number																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	99
INHALER2														•	•		•	•
LAB					•			•			•			•				
LEXAM	•																•	•
MAXREV					•			•			•			•		•		
MEDHX	•																	
METHA	•			•			•			•			•		•			
NO	•		•	•	•	•	•	•	•	•	•	•	•	•	•		•	•
NOCHECK					•			•			•			•			•	
QOL					•			•			•			•			•	•
QXRCISE		•																
SERIOUS	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
SEXAM					•			•			•			•				
SF36					•			•			•			•			•	•
SIGEX	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
SKIN						•												
SPIRO	•			•		•	•		•	•		•	•		•			•
SPIRO3			•															

Form Name	Visit Number																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	99
SPUTLAB				•			•			•			•		•			
SPUTOVER				•			•			•			•		•			
SPUTUM				•			•			•			•		•			
SUBLIST					•			•			•			•				
TERM	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	•	
TXFAIL																		•
XRCISE					•			•			•			•			•	

Asthma Clinical Research Network
NIH/NHLBI

MICE

ASTHMA CONTROL QUESTIONNAIRE

acq

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Subject completed: Questions 1 - 6)

Check the number of the response that best describes how you have been during the past week.

01 1. On average, during the past week, how often were you woken by your asthma during the night?

- ❑0 Never
- ❑1 Hardly ever
- ❑2 A few times
- ❑3 Several times
- ❑4 Many times
- ❑5 A great many times
- ❑6 Unable to sleep because of asthma

02 2. On average, during the past week, how bad were your asthma symptoms when you woke up in the morning?

- ❑0 No symptoms
- ❑1 Very mild symptoms
- ❑2 Mild symptoms
- ❑3 Moderate symptoms
- ❑4 Quite severe symptoms
- ❑5 Severe symptoms
- ❑6 Very severe symptoms

03 3. In general, during the past week, how limited were you in your activities because of your asthma?

- ❑0 Not limited at all
- ❑1 Very slightly limited
- ❑2 Slightly limited
- ❑3 Moderately limited
- ❑4 Very limited
- ❑5 Extremely limited
- ❑6 Totally limited

04 4. In general, during the past week, how much shortness of breath did you experience because of your asthma?

- ❑0 None
- ❑1 A very little
- ❑2 A little
- ❑3 A moderate amount
- ❑4 Quite a lot
- ❑5 A great deal
- ❑6 A very great deal

05 5. In general, during the past week, how much of the time did you wheeze?

- ❑0 Not at all
- ❑1 Hardly any of the time
- ❑2 A little of the time
- ❑3 A moderate amount of the time
- ❑4 A lot of the time
- ❑5 Most of the time
- ❑6 All the time

06 6. On average, during the past week, how many puffs of short-acting bronchodilator (eg. Ventolin) have you used each day?

- ❑0 None
- ❑1 1 - 2 puffs most days
- ❑2 3 - 4 puffs most days
- ❑3 5 - 8 puffs most days
- ❑4 9 - 12 puffs most days
- ❑5 13 - 16 puffs most days
- ❑6 More than 16 puffs most days

Subject's Initials: __ __ __

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

(Clinic Coordinator completed)

7. FEV_1 pre-bronchodilator: __.__ __ L **07a**

FEV_1 predicted: __ __ __ % predicted **07b**

FEV_1 % predicted:
(Record the actual values on the lines above and score the FEV_1 % predicted in the next column.) **07**

- ❑0 > 95 % predicted
- ❑1 95 - 90 %
- ❑2 89 - 80 %
- ❑3 79 - 70 %
- ❑4 69 - 60 %
- ❑5 59 - 50 %
- ❑6 < 50 % predicted

Asthma Clinical Research Network
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MICE

CLINICAL ADVERSE EVENTS

cae

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

Subject ID: 7 ___ ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: 1

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

(Clinic Coordinator completed)

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

❑0 None

Signature:

Date:

DESCRIPTION OF ADVERSE EVENT	1. ICD9 CODE	2. DATE STARTED (Top Line) **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 TEST DRUG (1 - NONE, 2 - UNLIKELY (REMOTE), 3 - POSSIBLE, 4 - PROBABLE, 5 - HIGHLY PROBABLE)	10. CHANGE IN STUDY MEDICATIONS (1 - DISCONTINUED, 2 - REDUCED, 3 - INTERRUPTED, BUT RESUMED AT CURRENT DOSE, 4 - UNCHANGED, 5 - INCREASED)	11. OUTCOME *(Skip if #4 is checked.)* (1 - COMPLETELY RECOVERED, 2 - RECOVERED, BUT WITH LASTING EFFECTS, 3 - DEATH *)	12. TREATMENT REQUIRED (1 - NONE, 2 - MEDICATION **, 3 - HOSPITALIZATION *, 4 - OTHER)
1. **event**	_ _ _._ _ **01**	_ _/_ _/_ _ _ _ / _ _/_ _/_ _ _ _ **02 / 03**	❑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).

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MICE

AIRWATCH™ QUALITY CONTROL

air

Subject ID: 7 ___ ___ ___ ___
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.*

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MICE

CONCOMITANT MEDICATIONS for ASTHMA-RELATED DRUGS

Subject ID: 7 ___ ___ ___ ___
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 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 the 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.

cmed ❑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
cmedno	**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

page

MICE Pilot Concomitant Drug Codes

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Drug Code	Drug Name (brand or generic name)
1.00	Accolate
2.00	Aero Bid
3.00	albuterol
4.00	Allegra
4.01	Allegra-D
5.00	Alupent
6.00	Aminophylline IV
7.00	astemizole
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
20.00	budesonide - nasal
21.00	budesonide - Turbuhaler
22.00	cetirizine
23.00	Claritin
24.00	clemastine
25.00	Combivent
26.00	corticosteroids - MDI
27.00	corticosteroids - nasal
28.00	cromolyn sodium - MDI and nasal
29.00	dexbrompheniramine
30.00	diphenhydramine

Drug Code	Drug Name (brand or generic name)
31.00	epinephrine
32.00	fexofenodine
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
42.00	Intal
43.00	ipratropium bromide
44.00	isoetharine
45.00	isoproterenol
46.00	loratadine
47.00	Maxair
48.00	Medihaler-Epi
49.00	Metaprel
50.00	metaproterenol
51.00	methylprednisolone
52.00	Nasacort
53.00	Nasalcrom
54.00	Nasalide
55.00	Nasarel
56.00	nedocromil
57.00	Optimine
58.00	PBZ
59.00	pirbuterol
60.00	prednisone

Drug Code	Drug Name (brand or generic name)
61.00	Primatene Mist
62.00	Proventil
63.00	Pulmicort
64.00	Rhinocort
65.00	salmeterol
66.00	Seldane
67.00	Serevent
68.00	Singulaire
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
82.00	tripellenamine
83.00	Uniphyl
84.00	Vancenase
85.00	Vanceril
86.00	Ventolin
87.00	zafirlukast
88.00	zileuton
89.00	Zyflo
90.00	Zyrtec
Suspended Study Medications	
77.77	Flovent - MDI
88.88	Vanceril
99.99	Flovent - Rotadisk

MICE Pilot 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	

Asthma Clinical Research Network
NIH/NHLBI

Please use black ink to complete.

MICE DIARY CARD

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

Subject ID: 7 _ _ _ _ _ _ _
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 Ventolin®(RESCUE) inhaler as instructed in the handout "If Your Asthma Gets Worse."
Contact study personnel if your peak flow does not increase to this value after one hour of RESCUE use.
If you have used your Ventolin®(RESCUE) inhaler more than _____ puffs/24 hours for the past 48 hours, contact study personnel.

		Day 1: _____	Day 2: _____	Day 3: _____	Day 4: _____	Day 5: _____	Day 6: _____	Day 7: _____
dmonth / dday Date		_ _ / _ _ (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 (Should be between 5 and 10 AM but record actual time taken)		02 _ _ . _ _	_ _ : _ _	_ _ : _ _	_ _ : _ _	_ _ : _ _	_ _ : _ _	_ _ : _ _
3. AM Peak Flow (liters/min)**		03 03r _ _ _	_ _ _	_ _ _	_ _ _	_ _ _	_ _ _	_ _ _
4. AM FEV_1 (liters)		04 _ . _ _	_ . _ _	_ . _ _	_ . _ _	_ . _ _	_ . _ _	_ . _ _
5. Total number of puffs from scheduled inhaler **(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 9 - 11 PM)								
11. Time of PM Peak Flow (Should be between 9 and 11 PM but record actual time taken)		11 _ _ . _ _	_ _ : _ _	_ _ : _ _	_ _ : _ _	_ _ : _ _	_ _ : _ _	_ _ : _ _
12. PM Peak Flow (liters/min)**		12 12r _ _ _	_ _ _	_ _ _	_ _ _	_ _ _	_ _ _	_ _ _
13. PM FEV_1 (liters)		13 _ . _ _	_ . _ _	_ . _ _	_ . _ _	_ . _ _	_ . _ _	_ . _ _
14. Total number of puffs from scheduled inhaler **(PM)**		14 _	_ _	_ _	_ _	_ _	_ _	_ _
15. Total number of puffs of Ventolin® **(RESCUE) in 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 Ventolin® (**RESCUE**) inhaler medication in the last two hours.

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

ELECTROCARDIOGRAM REPORT

ecg

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. Ventricular heart rate ___ ___ ___ beats/min

2. Cardiac cycle measurements

02a 2a. P - R Interval . ___ ___ ___ seconds

02b 2b. QRS Duration . ___ ___ ___ seconds

02c 2c. Q - T Interval . ___ ___ ___ seconds

03 3. 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

☞ ***If YES, the subject is NOT eligible for the study. Please complete the Termination of Study Participation (TERM) form.***

Asthma Clinical Research Network
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MICE

ELIGIBILITY CHECKLIST 1

e1

Subject ID: 7 ___ ___ ___ ___
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.	Are you planning to move away from this clinical center in the next 6 months such that your ability to complete the study will be jeopardized?	☐ 1 Yes ☐ 0 No
03	3.	Have you used any smokeless tobacco products (chew, snuff) in the past year?	☐ 1 Yes ☐ 0 No
04	4.	Have you smoked cigarettes, a pipe, cigars, or any other substance in the past year?	☐ 1 Yes ☐ 0 No
05	5.	Do you have a smoking history less than 10 pack-years?	☐ 1 Yes ☐ 0 No
05a		Record history in pack-years. (Enter '00.0' if none)	___ ___ . ___
06	6.	Have you had a respiratory tract infection in the past 6 weeks?	☐ 1 Yes ☐ 0 No
07	7.	Have you experienced a significant asthma attack in the past 6 weeks?	☐ 1 Yes ☐ 0 No
08	8.	Have you experienced a life-threatening asthma attack requiring treatment with intubation and mechanical ventilation in the past 10 years?	☐ 1 Yes ☐ 0 No

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

09a 9a. If ***YES,*** are you currently pregnant or lactating? ☐ 1 Yes ☐ 0 No

09b 9b. 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

10 10. Are you post-menopausal? ☐ 1 Yes ☐ 0 No

10a 10a. If ***YES***, are you currently on hormone replacement therapy? ☐ 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.***

Subject's Initials: __ __ __

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

ELIGIBILITY CHECKLIST 2

e2

Subject ID: 7 ___ ___ ___ ___
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 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 _____

4. Is the subject eligible on the basis of established washout criteria for the following steroid medications?
➜***See the MOP for rules regarding specific classes of steroids.***

04a	4a.	Oral	☐1 Yes ☐0 No
04b	4b.	Inhaled	☐1 Yes ☐0 No
04c	4c.	Nasal	☐1 Yes ☐0 No
04d	4d.	Topical - prescription	☐1 Yes ☐0 No
04e	4e.	Topical - over-the-counter	☐1 Yes ☐0 No
04f	4f.	Injectable	☐1 Yes ☐0 No

05 5. Does the subject anticipate the need for intranasal steroids during his or her participation in the study? ☐1 Yes ☐0 No

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

07 7. Is the subject post-pubertal and ≤ 45 years of age? ☐ 1 Yes ☐ 0 No

(A bone age film may be necessary to establish post-pubertal status in adolescents. If the subject is < 18 and the bone age film was waived, the P.I. must sign and date at the right. See the MOP for details.)

P.I. Signature: _____

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

08 8. Does the subject have a body mass index (BMI) > 35? ☐ 1 Yes ☐ 0 No

09 9. Does the subject work night shift or have an altered day night cycle for other reasons? ☐ 1 Yes ☐ 0 No

10 10. Pregnancy test results

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

☐ 1 Positive
☐ 0 Negative
☐ 9 N/A

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.***

Subject's Initials: __ __ __

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

Asthma Clinical Research Network
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MICE

ELIGIBILITY CHECKLIST 3

e3

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. 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

02 2. Is the subject's prebronchodilator FEV_1 between 60% and 80% of predicted, inclusive? ❑ 1 Yes ❑ 0 No

03 3. Does the subject have source documentation of a methacholine $PC_{20} \leq 8$ mg/ml (ACRN system only) within the past 6 months? ❑ 1 Yes ❑ 0 No

➜ ***If YES,*** record values below:

03a PC_{20} ___ . ___ ___ ___ ___ mg/ml

03b Date of source documentation ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year)

➜ ***Go to Question #5.***

04 4. Was the subject's methacholine PC_{20} obtained during Visit 1 $\leq$ 8 mg/ml? ❑ 1 Yes ❑ 0 No

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

➜ ***If YES,*** record values below:

05a Prebronchodilator FEV_1 ___ . ___ ___ L

05b Postbronchodilator FEV_1 ___ . ___ ___ L

05c Date of source documentation ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year)

➜ ***Go to Question #7.***

06 6. Did the subject reverse to $\geq$ 112% of pre-challenge baseline FEV_1 after receiving initial puffs of albuterol following the challenge? ❑ 1 Yes ❑ 0 No

➜ ***If NO, reversibility testing must be performed at Visit 3 and the subject must demonstrate $\geq$ 12% FEV_1 response to aerosolized albuterol to continue in the study.***

07 7. 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.***

ELIGIBILITY CHECKLIST 4

e4

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 2
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. Is the subject's morning plasma cortisol concentration ≥ 5 µg/dL? ❑ 1 Yes ❑ 0 No

01a 1a. Plasma Cortisol value ___ ___ . ___ µg/dL

02 2. Is the subject's hematocrit value acceptable, as specified by the ACRN clinical center's IRB? ❑ 1 Yes ❑ 0 No

02a 2a. Hematocrit value ___ ___ . ___ %

03 3. Is the subject eligible? ***If either of the shaded boxes is filled in, the subject is ineligible.*** ❑ 1 Yes ❑ 0 No

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

Asthma Clinical Research Network
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ELIGIBILITY CHECKLIST 5

e5

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 5
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01	1.	Is the subject's pre-bronchodilator FEV_1 obtained during maximum reversibility testing < 60% predicted?	☐ 1 Yes ☐ 0 No
02	2.	Since Visit 1, has the subject experienced a significant asthma exacerbation as defined in the protocol?	☐ 1 Yes ☐ 0 No
03	3.	Since Visit 1, has the subject received treatment with any excluded medications (EXCLDRUG)?	☐ 1 Yes ☐ 0 No
04	4.	Using information recorded on the subject's Diary Card, did the subject take an incorrect number of puffs from his or her scheduled inhaler during 12 or more of the AM or PM dosing sessions between Visit 1 and today?	☐ 1 Yes ☐ 0 No
05	5.	Using the history stored in the Doser™, did the subject show evidence of noncompliance with the daily dosing schedule?	☐ 1 Yes ☐ 0 No
06	6.	Using the subject's ENACT fax, did the subject take his or her peak flows outside the protocol defined windows (5-10 AM and 9-11 PM) on 12 or more occasions between Visit 1 and today?	☐ 1 Yes ☐ 0 No
07	7.	During the run-in period, did the subject miss either AM or PM peak flow measurements or symptoms on his or her Diary Card (DIARY) for 7 or more days?	☐ 1 Yes ☐ 0 No
08	8.	Pregnancy test results *(Check N/A if the subject is male.)*	☐ 1 Positive ☐ 0 Negative ☐ 9 N/A
09	9.	Does the subject wish to withdraw consent from the study?	☐ 1 Yes ☐ 0 No
10	10.	Is there any other reason for which 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 MICE, randomize the subject. Otherwise, please complete the Termination of Study Participation (TERM) form.***	
12	12.	Drug Packet Number **(record on LOG)**	7 ___ ___ ___ ___ ___

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FLUID PHASE MEASUREMENTS

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

(Technician completed)

					Non-detectable limit	Quantity not sufficient to dilute
ecp	1.	ECP	___ ___ ___ ___ ___	mcg/L	**ecp_non** ❑	**ecp_suff** ❑
tryptase	2.	Tryptase	___ ___ ___ . ___	mcg/L	**try_non** ❑	**try_suff** ❑

SCHEDULED INHALERS

inh1

Subject ID: 7 __ __ __ __
Subject Initials: __ __ __
Visit Number: __ __
Visit Date: __ __ / __ __ / __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

(Clinic Coordinator completed)

01 1. What type of visit is this?

❑1 Scheduled visit
❑2 Unscheduled visit

SCHEDULED INHALER

Questions #2 and #3 should only be completed at scheduled visits. Please complete the appropriate Compliance Worksheet in order to complete this section of the form.

Evaluation of Subject Compliance

02 2. Number of days since the previous visit __ __ days

03 3. Number of days the correct number of puffs were taken since the previous visit __ __ days

➜ ***If there is evidence of noncompliance with the daily dosing schedule and the subject has not been randomized, the subject is ineligible. Please complete the Termination of Study Participation (TERM) form. If there is evidence of noncompliance and the subject has been randomized, re-emphasize to the subject the importance of maintaining the daily dosing schedule.***

SCHEDULED INHALER

Affix the new drug label below:

Copy the drug label number below:

04

7 __ __ __ __ __ __

Coordinator Signature: _____

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

By signing in the source documentation box you are:

1) confirming that the label on the inhaler 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 this medication.
3) confirming that this is the correct medication to be distributed at this visit.

SCHEDULED INHALERS

inh2

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. What type of visit is this?

❑1 Scheduled visit
❑2 Unscheduled visit

SCHEDULED INHALER

Questions #2, #3, #5 and #6 should only be completed at scheduled visits. Please complete the appropriate Compliance Worksheet in order to complete this section of the form.

Evaluation of Subject Compliance *(Visits 14 Only, or Visit 99 if replacing Visit 14)*

02 2. Number of days since the previous visit ___ ___ days

03 3. Number of days the correct number of puffs were taken since the previous visit ___ ___ days

FLOVENT ROTADISK®

Dispensation *(Visits 14 - 16, 99)*

04 4. Number of dispensed Rotadisks® ___ ___

Return *(Visits 15 - 17, 99)*

05 5. Number of used Rotadisks® ___ ___

06 6. Number of used blisters ___ ___ ___

➜ ***If there is evidence of noncompliance, re-emphasize to the subject the importance of maintaining the daily dosing schedule.***

(Visits 14 - 16, 99)

07 Affix the new drug label below:

Copy the drug label number below:

7 __ __ __ __ __ __

Coordinator Signature: _____

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

By signing in the source documentation box you are:

1) confirming that the label on the inhaler 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 this medication.
3) confirming that this is the correct medication to be distributed at this visit.

Asthma Clinical Research Network
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MICE

LABORATORY MEASUREMENTS

lab

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

PLASMA RESULTS

01	1.	7 PM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	01a
02	2.	8 PM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	02a
03	3.	9 PM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	03a
04	4.	10 PM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	04a
05	5.	11 PM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	05a
06	6.	12 AM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	06a
07	7.	1 AM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	07a
08	8.	2 AM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	08a
09	9.	3 AM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	09a
10	10.	4 AM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	10a
11	11.	5 AM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	11a
12	12.	6 AM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	12a
13	13.	7 AM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	13a

URINE RESULTS

14	14.	7 AM - 7 PM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	14a
15	15.	7 AM - 7 PM Creatinine	___ ___ ___ . ___ mg/dL	❑1 Censored	15a
16	16.	7 PM - 7 AM Cortisol	___ ___ . ___ µg/dL	❑1 Censored	16a
17	17.	7 PM - 7AM Creatinine	___ ___ ___ . ___ mg/dL	❑1 Censored	17a

LONG PHYSICAL EXAM

Ix

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

PHYSICAL EXAMINATION

01 ***1. (MICE Visit 1 Only - Questions #1 and #2)***

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.

		03a	**03b**
3.	Resting blood pressure	___ ___ ___ systolic	/ ___ ___ ___ diastolic mm Hg
04	4. Pulse	___ ___ ___ beats/min	
05	5. Respiration	___ ___ breaths/min	
06	6. Body temperature	___ ___ ___ . ___ ° F	

PULMONARY AUSCULTATION

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

If applicable, describe sounds:

_____
_____
_____

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

LONG PHYSICAL EXAM

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

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

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

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

Physician signature: _____

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

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

Asthma Clinical Research Network
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MICE

MAXIMUM REVERSIBILITY TESTING

max

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Subject Interview completed)

01 1. Have you 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*

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

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 fexofenadine (e.g. Allegra) or chlorpheniramine (e.g. Chlor-Trimeton) in the past 48 hours? ☐ 1 Yes ☐ 0 No

04b 4b. Have you used pseudoephedrine (e.g. Sudafed) or oxymetazoline (e.g. Afrin) in the past 24 hours? ☐ 1 Yes ☐ 0 No

04c 4c. Have you used a rescue intermediate-acting inhaled beta-agonist (e.g. Ventolin or Proventil) in the past 6 hours? ☐ 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
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 compete 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. FEV_1 ___ . ___ ___ L

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

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

➜ ***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. FEV_1 ___ . ___ ___ L

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

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

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

14e 14e. Is the percent difference from Question #14d ≤ 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.***

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

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

16a 16a. FEV_1 ___ . ___ ___ L

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

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

16d 16d. Percent difference in FEV_1 $\frac{(\textit{Question \#16a - Question \#14a})}{\textit{Question \#14a}} \times 100$ ___ ___ . ___ %

16e 16e. Is the percent difference from Question #16d ≤ 5%? ❑1 Yes ❑0 No

MEDICAL HISTORY

mhx

Subject ID: 7 ___ ___ ___ ___
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. 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? ___ ___

➜ ***If any oral corticosteroid therapy was taken, the subject is ineligible to participate in the study. Please remember to record this information on the ELIG2 form.***

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

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

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

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 _____

Subject's Initials: __ __ __

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

METHACHOLINE CHALLENGE TESTING

mth

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

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

01 1. ***(If Visit 1 or Visit 4, do not complete Question #1)***
Has the subject been deemed a treatment failure within 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 FEV_1? ☐ 1 Yes ☐ 0 No
Use the prebronchodilator FEV_1 value from the 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 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 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.

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 form 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, if needed.***

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

➜ ***If NO, skip to Question #8b.***

08a1 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 form 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, if needed.***

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

➜ ***If NO, skip to Question #10b.***

10a1 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.***

Physician signature: _____

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

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

NITRIC OXIDE COLLECTION

no

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

Nitric Oxide measurements should be taken after completing either the spirometry checklist or the nitric oxide checklist.

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

MICE

NITRIC OXIDE CHECKLIST

nock

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Subject Interview completed)

01 1. Have you 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*

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

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 fexofenadine (e.g. Allegra) or chlorpheniramine (e.g. Chlor-Trimeton) in the past 48 hours? ☐ 1 Yes ☐ 0 No

04b 4b. Have you used pseudoephedrine (e.g. Sudafed) or oxymetazoline (e.g. Afrin) in the past 24 hours? ☐ 1 Yes ☐ 0 No

04c 4c. Have you used a rescue intermediate-acting inhaled beta-agonist (e.g. Ventolin or Proventil) in the past 6 hours? ☐ 1 Yes ☐ 0 No

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

06 6. Is there any other reason you should not proceed with nitric oxide collection? ☐ 1 Yes ☐ 0 No
If ***YES***, explain _____
_____

07 7. Is the subject eligible to proceed with nitric oxide collection? ☐ 1 Yes ☐ 0 No
If any of the shaded boxes are filled in, the subject is NOT eligible for nitric oxide collection.

Asthma Clinical Research Network
NIH/NHLBI

MICE

QUALITY OF LIFE QUESTIONNAIRE

qol

Subject ID: 7 ___ ___ ___ ___
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	❑ 7
02	2. Activity 2	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
03	3. Activity 3	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
04	4. Activity 4	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
05	5. Activity 5	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

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

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

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

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

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

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

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

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

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

Subject's Initials: __ __ __

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

QUALIFYING EXERCISE CHALLENGE

qxr

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 2
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01 1. Has the subject exercised vigorously in the past 24 hours? ☐ 1 Yes ☐ 0 No

02 2. Has the subject used his/her rescue medication in the past 6 hours? ☐ 1 Yes ☐ 0 No

03 3. Has the subject eaten a major meal in the past 3 hours? ☐ 1 Yes ☐ 0 No

04 4. Has the subject eaten in the past hour? ☐ 1 Yes ☐ 0 No

05 5. 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*

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

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

08 8. Is there any other reason the subject should not proceed with the Exercise Challenge? ☐ 1 Yes ☐ 0 No
If ***YES***, explain _____

09 9. Is the subject eligible for the Qualifying Exercise Challenge? ☐ 1 Yes ☐ 0 No
If any of the shaded boxes are filled in, the subject is NOT eligible for the Qualifying Exercise Challenge.

☞ ***If NO, do NOT complete the rest of this form. The Qualifying Exercise Challenge should be rescheduled within the visit window.***

10. ***(Calculating Target Heart Rate)***

10a 10a. Subject's age ___ ___ years

10b 10b. Maximum heart rate *(220 - Question #10a)* ___ ___ ___ bpm

10c 10c. Target heart rate *(Question #10b x 0.8)* ___ ___ ___ bpm

PRE-EXERCISE CHALLENGE VITAL SIGNS

		11a	11b
11.	Blood pressure	___ ___ ___ /	___ ___ ___ mm Hg
		systolic	diastolic
12	12. Pulse	___ ___ ___ beats/min	

PRE-EXERCISE CHALLENGE

13. First FEV_1 measurement (approximately 20 minutes prior to the Exercise Challenge):

13a	13a. FEV_1	___ . ___ ___ L
13b	13b. FEV_1 (% predicted)	___ ___ ___ % predicted
13c	13c. Time of FEV_1 in Question #13a *(based on 24-hour clock)*	___ ___ ___ ___

14. Second FEV_1 measurement (approximately 5 minutes prior to the Exercise Challenge):

14a	14a. FEV_1	___ . ___ ___ L
14b	14b. FEV_1 (% predicted)	___ ___ ___ % predicted
14c	14c. Time of FEV_1 in Question #14a *(based on 24-hour clock)*	___ ___ ___ ___

➜ ***Compute the percent difference in FEV_1 between Question #13a and Question #14a. If the percent difference is > 10%, repeat spirometry in 5 minutes. Please see the MOP for further details.***

15	15. Is the FEV_1 (% predicted) from Question #14b ≥ 60% predicted?	☐ 1 Yes	☐ 0 No
16	16. Has the subject verbally consented to the Exercise Challenge procedure?	☐ 1 Yes	☐ 0 No
17	17. Is the subject's baseline ECG within normal limits?	☐ 1 Yes	☐ 0 No
18	18. Is the subject's baseline SpO_2 within normal limits?	☐ 1 Yes	☐ 0 No
19	19. Are the subject's vital signs within normal limits?	☐ 1 Yes	☐ 0 No
20	20. Is the subject eligible for the Qualifying Exercise Challenge? ***If any of the shaded boxes are filled in, the subject is NOT eligible for the Qualifying Exercise Challenge.***	☐ 1 Yes	☐ 0 No

☞ ***If NO, the subject is NOT eligible for the study. Please complete the Termination of Study Participation (TERM) form.***

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

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

Clinic Use Only

Use the average of the FEV_1 values 20 minutes and 5 minutes prior to the Exercise Challenge.

Exercise Challenge Reversal Reference Value: $\frac{(\text{Question \#13a + Question \#14a})}{2}$ ***x 0.90*** = ___ . ___ ___ L

Target Heart Rate: (from Question #10c) ___ ___ ___ bpm

Adjust the incline and speed until target heart rate is reached.
Then, proceed with the challenge, maintaining target heart rate for 6 minutes.

21 21. Dry gas apparatus

❑1 mouthpiece
❑2 face mask

EXERCISE CHALLENGE
(Complete the following table once the target heart rate is met)

Scheduled Time	Actual Time (based on 24-hour clock)	Pulse (bpm)	Oxygen Saturation (%)	Speed (mph)	Incline (%)
22. Start 6 Minute Exercise Challenge	22a 22as __ __ __ __ : __ __	22b __ __ __	22c __ __	22d __ . __	22e __ __
23. 1 Minute	23a 23as __ __ __ __ : __ __	23b __ __ __	23c __ __	23d __ . __	23e __ __
24. 2 Minute	24a 24as __ __ __ __ : __ __	24b __ __ __	24c __ __	24d __ . __	24e __ __
25. 3 Minute	25a 25as __ __ __ __ : __ __	25b __ __ __	25c __ __	25d __ . __	25e __ __
26. 4 Minute	26a 26as __ __ __ __ : __ __	26b __ __ __	26c __ __	26d __ . __	26e __ __
27. 5 Minute	27a 27as __ __ __ __ : __ __	27b __ __ __	27c __ __	27d __ . __	27e __ __
28. Stop 6 Minute Exercise Challenge	28a 28as __ __ __ __ : __ __	28b __ __ __	28c __ __	28d __ . __	28e __ __

29 29. Was the Exercise Challenge procedure stopped prior to 6 minutes? ❑1 Yes ❑0 No

If ***YES***, why? _____

_____

_____

30 30. Were rescue medications given during the Exercise Challenge procedure? ❑1 Yes ❑0 No

If ***NO***, skip to Question #31.

30a 30a. Albuterol by MDI ❑1 Yes ❑0 No

If ***NO***, skip to Question #30b.

30a1 30ai. Number of puffs of albuterol administered ___ ___ puffs

30b 30b. Nebulized Beta-agonist ❑1 Yes ❑0 No

30c 30c. Subcutaneous epinephrine ❑1 Yes ❑0 No

30d 30d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

30e 30e. Other _____ ❑1 Yes ❑0 No

31 31. Was the overall interpretation of the ECG during the Exercise Challenge within normal limits? ❑1 Yes ❑0 No

If ***NO***, please describe: _____

_____

_____

POST-EXERCISE CHALLENGE

Scheduled Time	Actual Time (based on 24-hour clock)	FEV_1	Blood Pressure (systolic/diastolic) mm Hg	Pulse (BPM)	Were rescue meds necessary?	If ***YES,*** MDI albuterol? (# puffs)	If ***YES,*** Nebulized Beta-agonist?
32. 5 Minute Post-Exercise Challenge	**32a** ____	**32b** __.__ L	**32c** ___ / **32d** ___	**32e** ___	❑1 Yes ❑0 No **32f**	**32g** __	❑1 Yes ❑0 No **32h**
33. 10 Minute Post-Exercise Challenge	**33a** ____	**33b** __.__ L	**33c** ___ / **33d** ___	**33e** ___	❑1 Yes ❑0 No **33f**	**33g** __	❑1 Yes ❑0 No **33h**
34. 15 Minute Post-Exercise Challenge	**34a** ____	**34b** __.__ L	**34c** ___ / **34d** ___	**34e** ___	❑1 Yes ❑0 No **34f**	**34g** __	❑1 Yes ❑0 No **34h**
35. 30 Minute Post-Exercise Challenge	**35a** ____	**35b** __.__ L	**35c** ___ / **35d** ___	**35e** ___	❑1 Yes ❑0 No **35f**	**35g** __	❑1 Yes ❑0 No **35h**
36. 45 Minute Post-Exercise Challenge	**36a** ____	**36b** __.__ L	**36c** ___ / **36d** ___	**36e** ___	❑1 Yes ❑0 No **36f**	**36g** __	❑1 Yes ❑0 No **36h**
37. 60 Minute Post-Exercise Challenge	**37a** ____	**37b** __.__ L	**37c** ___ / **37d** ___	**37e** ___	❑1 Yes ❑0 No **37f**	**37g** __	❑1 Yes ❑0 No **37h**
38. Additional Time, if necessary	**38a** ____	**38b** __.__ L	**38c** ___ / **38d** ___	**38e** ___	❑1 Yes ❑0 No **38f**	**38g** __	❑1 Yes ❑0 No **38h**

39 39. What was the lowest observed FEV_1 during the Post-Exercise Challenge? ___ . ___ ___ L

40 40. Percent difference in FEV_1 $\frac{((\text{Question \#13a} + \text{Question \#14a})/2) - \text{Question \#39}}{(\text{Question \#13a} + \text{Question \#14a})/2} \times 100$ ___ ___ . ___ %

41 41. Was the last FEV_1 (from the table on page 4 of this form) ≥ the exercise challenge reversal reference value in the gray box on page 3 of this form? ☐ 1 Yes ☐ 0 No

Physician/CC signature: _____

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

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

42 42. During the Exercise Challenge, was the subject able to adequately maintain the target heart rate for 6 minutes? ☐ 1 Yes ☐ 0 No

➜ ***Please see the MOP for further details.***

43 43. Did the subject demonstrate a ≥ 12% fall in FEV_1 following the Exercise Challenge, as indicated in Question #40? ☐ 1 Yes ☐ 0 No

44 44. Is the subject eligible? ☐ 1 Yes ☐ 0 No
If either of the shaded boxes in Question #42 or Question #43 is filled in, the subject is ineligible.

☞ ***If NO, the subject is NOT eligible for the study. Please complete the Termination of Study Participation (TERM) form.***

Asthma Clinical Research Network
NIH/NHLBI

MICE

SERIOUS ADVERSE EVENT REPORTING FORM

ser

Subject ID: ___ ___ ___ ___ ___
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 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 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? If ***YES***, describe _____	❑1 Yes	❑0 No
06d	6d.	Concurrent disorder? If ***YES***, describe _____	❑1 Yes	❑0 No
06e	6e.	Other event? If ***YES***, describe _____	❑1 Yes	❑0 No

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: __ __ / __ __ / __ __ __ __

SHORT PHYSICAL EXAM

SX

Subject ID: 7 ___ ___ ___ ___
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.

		01a	**01b**
	1. Resting blood pressure	___ ___ ___ (systolic)	/ ___ ___ ___ (diastolic) mm Hg
02	2. Pulse	___ ___ ___ beats/min	

PULMONARY AUSCULTATION

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

_____

_____

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

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

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

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

ADVERSE EVENTS

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

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

HEALTH STATUS QUESTIONNAIRE SF-36

sf36

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject completed)

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

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

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

02 2. COMPARED TO ONE YEAR AGO, how would you rate your health in general NOW?

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

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

			Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
03a	3a.	VIGOROUS ACTIVITIES, such as running, lifting heavy objects, participating in strenuous sports	❑1	❑2	❑3
03b	3b.	MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	❑1	❑2	❑3
03c	3c.	Lifting or carrying groceries	❑1	❑2	❑3
03d	3d.	Climbing SEVERAL flights of stairs	❑1	❑2	❑3
03e	3e.	Climbing ONE flight of stairs	❑1	❑2	❑3
03f	3f.	Bending, kneeling, or stooping	❑1	❑2	❑3
03g	3g.	Walking MORE THAN A MILE	❑1	❑2	❑3
03h	3h.	Walking SEVERAL BLOCKS	❑1	❑2	❑3
03i	3i.	Walking ONE BLOCK	❑1	❑2	❑3
03j	3j.	Bathing or dressing yourself	❑1	❑2	❑3

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

04a	4a.	Cut down on the AMOUNT OF TIME you spent on work or other activities	❑1 Yes	❑0 No
04b	4b.	ACCOMPLISHED LESS than you would like	❑1 Yes	❑0 No
04c	4c.	Were limited in the KIND of work or other activities	❑1 Yes	❑0 No
04d	4d.	Had DIFFICULTY performing the work or other activities (for example, it took extra effort)	❑1 Yes	❑0 No

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

05a	5a.	Cut down on the AMOUNT OF TIME you spent on work or other activities	❑ 1 Yes	❑ 0 No
05b	5b.	ACCOMPLISHED LESS than you would like	❑ 1 Yes	❑ 0 No
05c	5c.	Didn't do work or other activities AS CAREFULLY as usual	❑ 1 Yes	❑ 0 No

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

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

07 7. How much BODILY pain have you had during the PAST 4 WEEKS?

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

08 8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?

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

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

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

			All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
09a	9a.	Did you feel full of pep?	❑1	❑2	❑3	❑4	❑5	❑6
09b	9b.	Have you been a very nervous person?	❑1	❑2	❑3	❑4	❑5	❑6
09c	9c.	Have you felt so down in the dumps that nothing could cheer you up?	❑1	❑2	❑3	❑4	❑5	❑6
09d	9d.	Have you felt calm and peaceful?	❑1	❑2	❑3	❑4	❑5	❑6
09e	9e.	Did you have a lot of energy?	❑1	❑2	❑3	❑4	❑5	❑6
09f	9f.	Have you felt downhearted and blue?	❑1	❑2	❑3	❑4	❑5	❑6
09g	9g.	Did you feel worn out?	❑1	❑2	❑3	❑4	❑5	❑6
09h	9h.	Have you been a happy person?	❑1	❑2	❑3	❑4	❑5	❑6
09i	9i.	Did you feel tired?	❑1	❑2	❑3	❑4	❑5	❑6

10 10. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?

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

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

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

Subject's Initials: __ __ __

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

SIGNIFICANT ASTHMA EXACERBATION

sae

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form must be completed each time a subject experiences an asthma exacerbation according to the definition below.

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

01a 1a. An increase in rescue inhaler use of ≥ 8 puffs per 24 hours over baseline rescue inhaler use for a period of 48 hours? ☐ 1 Yes ☐ 0 No

01b 1b. Use of rescue inhaler ≥ 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. A fall in prebronchodilator FEV_1 to ≤ 80% of baseline? ☐ 1 Yes ☐ 0 No

02 2. Were oral or parenteral corticosteroids given to the subject for his/her asthma exacerbation as a result of rescue intervention or by the opinion of the treating physician? ☐ 1 Yes ☐ 0 No

03 3. 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 the subject has experienced a significant asthma exacerbation and has been randomized, please complete this form and continue with the treatment failure packet.

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

04 4. Date of significant asthma exacerbation ___ ___ / ___ ___ / ___ ___ ___ ___
month *day* *year*

05 5. Did the subject seek care for the asthma exacerbation? ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #8.***

6. What type of care was sought?

06a 6a. Study Investigator? ❑1 Yes ❑0 No

06a1 If ***YES***, indicate type of contact.
❑1 Scheduled clinic visit
❑2 Unscheduled clinic visit
❑3 Phone contact

06b 6b. Primary Care or Other Physician? ❑1 Yes ❑0 No

Name of physician: _____

06b1 If ***YES***, indicate type of contact.
❑1 Scheduled clinic visit
❑2 Unscheduled clinic visit
❑3 Phone contact

06c 6c. Emergency Room visit? ❑1 Yes ❑0 No

Name of hospital: _____

07 7. Was the subject hospitalized? ❑1 Yes ❑0 No

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

If ***YES***,

7a. Name of hospital: _____

07b 7b. Duration of hospital stay? ___ ___ days

07c 7c. Was intubation or ventilation assistance required? ❑1 Yes ❑0 No

08 8. Did the asthma exacerbation require treatment with inhaled, oral, or intravenous glucocorticoids? ❑1 Yes ❑0 No

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

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

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

If ***NO***, describe_____

_____

_____

☐1 Yes ☐0 No

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

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

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

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

13 13. Was the significant asthma exacerbation related to the sputum induction procedure? *(Check one box only)*

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

14 14. Was the significant asthma exacerbation related to the exercise challenge procedure? *(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

MICE

ALLERGY SKIN TEST RESULTS

skin

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 5
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 subject skin **tested** (based on 24-hour clock) ___ ___ ___ ___

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

ALLERGY SKIN TEST RESULTS

Subject ID: 7 ___ ___ ___ ___

Visit Number: 5

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
1. Diluting Fluid	**01b**	Perpendicular Wheal Diameter ___ ___ ___ mm	8. Alternaria	**08b**	Perpendicular Wheal 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
2. Tree Mix	**02b**	Perpendicular Wheal Diameter ___ ___ ___ mm	9. Cladosporium	**09b**	Perpendicular Wheal 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
3. Grass Mix	**03b**	Perpendicular Wheal Diameter ___ ___ ___ mm	10. Aspergillus	**10b**	Perpendicular Wheal 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
4. Ragweed	**04b**	Perpendicular Wheal Diameter ___ ___ ___ mm	11. D. Farinae	**11b**	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

SPIROMETRY TESTING

spir

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(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 fexofenadine (e.g. Allegra) or chlorpheniramine (e.g. Chlor-Trimeton) in the past 48 hours?	☐ 1 Yes	☐ 0 No
04b	4b.	Have you used pseudoephedrine (e.g. Sudafed) or oxymetazoline (e.g. Afrin) in the past 24 hours?	☐ 1 Yes	☐ 0 No
04c	4c.	Have you used a rescue intermediate-acting inhaled beta-agonist (e.g. Ventolin or Proventil) in the past 6 hours?	☐ 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? If ***YES***, explain _____ _____	☐ 1 Yes	☐ 0 No

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

☞ ***If NO, do NOT complete page 2 unless this is a treatment failure visit.***
If this is a regular protocol visit, the pulmonary function 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 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

Asthma Clinical Research Network
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SPIROMETRY TESTING
Visit 3

spr3

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 3
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Subject Interview completed)

01 1. Have you 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*

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

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 fexofenadine (e.g. Allegra) or chlorpheniramine (e.g. Chlor-Trimeton) in the past 48 hours? ☐ 1 Yes ☐ 0 No

04b 4b. Have you used pseudoephedrine (e.g. Sudafed) or oxymetazoline (e.g. Afrin) in the past 24 hours? ☐ 1 Yes ☐ 0 No

04c 4c. Have you used a rescue intermediate-acting inhaled beta-agonist (e.g. Ventolin or Proventil) in the past 6 hours? ☐ 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
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. The pulmonary function 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 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

Complete Page 3 only if subject is performing reversibility testing at Visit 3 to meet eligibility requirements.

POSTBRONCHODILATOR TESTING

(Postbronchodilator spirometry should be performed 15 minutes after dose is administered)

11 11. Time bronchodilator given *(based on 24-hour clock)* ___ ___ ___ ___

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

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

13. Results of best effort postbronchodilator:

13a 13a. FVC ___ . ___ ___ L

13b 13b. FEV_1 ___ . ___ ___ L

13c 13c. FEV_1 (% predicted) ___ ___ ___ % predicted

13d 13d. PEFR ___ ___ . ___ ___ L/S

13e 13e. FEF_{25-75} ___ . ___ ___ L/S

14 14. Percent difference in FEV_1 $\frac{(\text{Question \#13b - Question \#10b})}{\text{Question \#13b}}$ x 100 ___ ___ . ___ %

15 15. Did the subject demonstrate a ≥ 12% increase in FEV_1 in response to aerosolized albuterol, as indicated in Question #14? ☐ 1 Yes ☐ 0 No

☞ ***If NO, the subject is NOT eligible for the study. Please complete the Termination of Study Participation (TERM) form.***

SPUTUM INDUCTION LAB VALUES

slab

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Read Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(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***.

SPUTUM INDUCTION
UCSF OVER-READ

spov

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___

(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 ___ ___ ___ . ___ %

Asthma Clinical Research Network
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MICE

SPUTUM INDUCTION

spt

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Technician completed)

01 1. Has sputum induction been waived by the P.I. for the remainder of the study? ☐ 1 Yes ☐ 0 No

➜ ***If YES, and the P.I. has waived sputum induction at the current visit, the P.I. must sign and date at the right. If sputum induction has been waived, STOP HERE; do NOT proceed with sputum induction.***

P.I. Signature: _____

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

02 2. ***(If Visit 4, do not complete Question #2 or #3)***

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

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

03 3. Has the subject been deemed a treatment failure within the past 4 weeks? ☐ 1 Yes ☐ 0 No

➜ ***If YES, STOP HERE; do NOT proceed with sputum induction.***

04 4. Did the subject complete the methacholine challenge? ☐ 1 Yes ☐ 0 No

➜ ***If YES, complete Question #5.***
➜ ***If NO, skip to Question #6.***

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

05a 5a. Subject's FEV_1 after all reversal from methacholine challenge ___ . ___ ___ L

05b 5b. Subject's FEV_1 (% predicted) after all reversal from methacholine challenge ___ ___ ___ % predicted

05c 5c. Was the subject's FEV_1 from Question #5a ≥ the methacholine reversal reference value on page 2 of the METHA form? ☐ 1 Yes ☐ 0 No

➜ ***Skip to Question #7.***

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

06a 6a. Subject's FEV_1 15 minutes after 4 puffs of albuterol ___ . ___ ___ L

06b 6b. Subject's FEV_1 15 minutes after 4 puffs of albuterol (% predicted) ___ ___ ___ % predicted

07 7. Was the subject's FEV_1 (% predicted) from Question #5b or Question #6b ≥ 60% predicted? ☐ 1 Yes ☐ 0 No

08 8. Is there any other reason the subject should not proceed with sputum induction? ☐ 1 Yes ☐ 0 No

If ***YES***, explain _____

09 9. 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.***

10 10. ***(If Visit 4, do not complete Question #10.)***

What was the duration of sputum induction the first time it exceeded 4 minutes, not including current visit? ___ ___ . ___ minutes

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

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

11a 11a. FEV_1 ___ . ___ ___ L

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

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

11d 11d. Percent difference in FEV_1 $\frac{(\textit{Question \#5a or 6a - Question \#11a})}{\textit{Question \#5a or 6a}}$ x 100 ___ ___ . ___ %

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

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

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

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

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

If either of the shaded boxes in Question #14 or Question #15 is filled in, the sputum sample is not adequate and should not be sent for analysis of squamous cell counts.

17 17. Did the subject's FEV_1 immediately after completion of sputum induction drop > 20% (from post-albuterol baseline) as indicated in Question #11d? ☐ 1 Yes ☐ 0 No

☞***If YES, proceed with Question #18 on the next page.***

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

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

Clinic Use Only

Sputum Induction Reversal Reference Value (Question #5a or Question #6a) x 0.90 = __.__ L

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

18a 18a. FEV_1 ___.___ L

18b 18b. FEV_1 (% predicted) ___ ___ ___ % predicted

18c 18c. Time of FEV_1 from Question #18a (*based on 24-hour clock*) ___ ___ ___ ___

18d 18d. Was the FEV_1 from Question #18a ≥ the sputum induction reversal reference value in the gray box above? ❑1 Yes ❑0 No

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

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

➜ ***If NO, skip to Question #21.***

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

19a 19a. Additional albuterol by MDI ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #19b.***

19a1 19ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four

19b 19b. Nebulized Beta-agonist ❑1 Yes ❑0 No

19c 19c. Subcutaneous epinephrine ❑1 Yes ❑0 No

19d 19d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

19e 19e. Other _____ ❑1 Yes ❑0 No

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

20a 20a. FEV_1 ___.___ L

20b 20b. FEV_1 (% predicted) ___ ___ ___ % predicted

20c 20c. Time of FEV_1 from Question #20a (*based on 24-hour clock*) ____ ____ ____ ____

20d 20d. Was the FEV_1 from Question #20a ≥ the sputum induction reversal reference value in the gray box on page 3 of this form? ❑1 Yes ❑0 No

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

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

➜ ***If NO, skip to Question #22.***

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

21a 21a. Additional albuterol by MDI ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #21b.***

21a1 21ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four

21b 21b. Nebulized Beta-agonist ❑1 Yes ❑0 No

21c 21c. Subcutaneous epinephrine ❑1 Yes ❑0 No

21d 21d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

21e 21e. Treatment in the emergency room ❑1 Yes ❑0 No

21f 21f. Overnight hospitalization ❑1 Yes ❑0 No

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

21g 21g. Other _____ ❑1 Yes ❑0 No

22. Subject's final FEV_1 after sputum induction

22a 22a. FEV_1 ____ . ____ ____ L

22b 22b. FEV_1 (% predicted) ____ ____ ____ % predicted

22c 22c. Time of FEV_1 from Question #22a (*based on 24-hour clock*) ____ ____ ____ ____

22d 22d. Was the FEV_1 from Question #22a ≥ 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
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MICE

SUBJECT OVERNIGHT CHECKLIST

sub

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___
Month Day Year

(Clinic Coordinator completed)

Please list, by printing, the initials for all individuals responsible for the subject's visit, along with the times they began and ended subject contact. Record all times using MILITARY TIME.

INITIALS:	START TIME :	STOP TIME :
___ ___ ___	___ ___ ___ ___	___ ___ ___ ___
___ ___ ___	___ ___ ___ ___	___ ___ ___ ___
___ ___ ___	___ ___ ___ ___	___ ___ ___ ___

PROTOCOL TIME	ACTUAL TIME	INITIALS	VISIT CHECKLIST	RESULTS
	__ **01** __		1. Admit subject to MICE overnight visit.	
1730	__ **02** __		***(Visits 8, 11, 14 Only)*** 2. Obtain urine sample from female subjects for pregnancy test. Collect <u>complete</u> sample in a container separate from the subject's 7 AM - 7 PM collection bottle. Take a small amount of this sample to perform pregnancy test and pour remaining urine into the subject's 7 AM - 7 PM collection bottle. Record results. Have female subjects acknowledge test results by initialing and dating in box. ***If test is positive, STOP the visit and terminate subject from study.***	❑1 Positive ❑2 Negative **02r** ❑9 N/A Subject's Initials: __ __ __ Date:__ __/ __ __/ __ __ __ __
1845	__ **03** __		3. Place 18 g. or 20 g. IV catheter for blood draws.	
1900	__ **04** __		4. Subject to void to complete 7 AM - 7 PM urine collection. Record total volume, then start 7 PM - 7AM urine collection. Refrigerate urine during collection process or put on ice. Do not allow ice to melt.	___ ___ ___ ___ ml **04r** ❑1 Check if sample not collected prior to visit. **04r1**
			4a. Indicate the status of the urine at the time of receipt.	❑1 Cold ❑2 Warm **04ar**
	__ **05** __		5. Blood draw for hourly cortisol. **For all blood draws:** Draw 3 ml of blood from the IV line into a 3 ml vacutainer tube and discard. Draw 5 ml of blood into a 5 ml heparinized green top vacutainer tube. Invert 5 times and refrigerate.	
2000	__ **06** __		6. Blood draw for hourly cortisol.	

SUBJECT OVERNIGHT CHECKLIST

Subject ID: 7 ___ ___ ___ ___

Visit Number: ___ ___

PROTOCOL TIME	ACTUAL TIME	INITIALS	VISIT CHECKLIST	RESULTS
2100	__ **07** __		7. Blood draw for hourly cortisol.	
	__ **08** __		8. Peak flow and FEV_1 (3 efforts standing) using subject's AirWatch™. Ask the subject to record the best of 3 efforts on Diary Card (DIARY).	
	__ **09** __		9. Observe subject's PM scheduled inhaled steroid dose (subject's scheduled inhaler). Have subject record puffs on Diary Card (DIARY).	
	__ **10** __		10. Have subject complete nighttime evaluation portion of diary card (DIARY).	
2200	__ **11** __		11. Blood draw for hourly cortisol.	
2300	__ **12** __		12. Blood draw for hourly cortisol.	
	__ **13** __		13. Lights out.	
2400	__ **14** __		14. Blood draw for hourly cortisol.	
0100	__ **15** __		15. Blood draw for hourly cortisol.	
0200	__ **16** __		16. Blood draw for hourly cortisol.	
0300	__ **17** __		17. Blood draw for hourly cortisol.	
0400	__ **18** __		18. Blood draw for hourly cortisol.	
0500	__ **19** __		19. Blood draw for hourly cortisol.	
0600	__ **20** __		20. Blood draw for hourly cortisol.	
0700	__ **21** __		21. Blood draw for hourly cortisol.	
	__ **22** __		22. Remove catheter.	
	__ **23** __		23. Subject to void to close 7 PM - 7 AM urine collection. Record total volume. Refrigerate urine or put on ice. Do not allow ice to melt.	___ **23r** ___ ml
			23a. If subject collected ONLY 24 hour urine sample, record the total volume and indicate the status of the urine at the time of receipt. Otherwise, leave these fields blank.	___ ___ ___ ___ ___ ml ❑1 Cold ❑2 Warm
	__ **24** __		24. Discharge subject to ACRN personnel for visit completion.	

TERMINATION OF STUDY PARTICIPATION

term

Subject ID: 7 ___ ___ ___ ___
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. ***(MICE Visit 17 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 5 Only***)
During the run-in period, has the subject experienced a significant asthma exacerbation as defined in the protocol?

❑1 Yes ❑0 No

05 5. ***(Visit 2 Only)***
Has the subject been deemed ineligible due to the qualifying exercise challenge?

❑1 Yes ❑0 No

06 6. ***(Visit 1 - Visit 5 Only***)
Has the subject been deemed ineligible according to any eligibility criteria **other than** the criteria in Question #4 and Question #5?

❑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
- ❑$_{11}$ 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 form (SERIOUS).***

SIGNATURES

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

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

_____ ___ ___ /___ ___ /___ ___ ___ ___

Clinic Coordinator Signature — month day year

_____ ___ ___ /___ ___ /___ ___ ___ ___

Principal Investigator Signature — month day year

Asthma Clinical Research Network
NIH/NHLBI

MICE

TREATMENT FAILURE

txfl

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 9 9
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

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

01a If ***YES***, indicate visit number of scheduled visit ___ ___

01b If ***NO***, indicate last regular visit completed ___ ___

02 2. Were oral or parenteral corticosteroids given to the subject for his/her asthma exacerbation as a result of rescue intervention or by the opinion of the treating physician? ☐ 1 Yes ☐ 0 No

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

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

04 4. Is the subject a treatment failure? ***If either of the shaded boxes are filled in, the subject is a treatment failure.*** ☐ 1 Yes ☐ 0 No

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

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

05a	5a.	Inhaled or Oral Steroids	☐ 1 Yes	☐ 0 No
05b	5b.	Theophylline	☐ 1 Yes	☐ 0 No
05c	5c.	Beta-Agonist via nebulizer	☐ 1 Yes	☐ 0 No
05d	5d.	Cromolyn	☐ 1 Yes	☐ 0 No
05e	5e.	Nedocromil	☐ 1 Yes	☐ 0 No
05f	5f.	Ipratropium bromide	☐ 1 Yes	☐ 0 No
05g	5g.	Zafirlukast	☐ 1 Yes	☐ 0 No
05h	5h.	Other: _____	☐ 1 Yes	☐ 0 No

➜ ***If YES (to any Question in #5), please complete the Concomitant Medications Form (CMED_AS).***

06 6. Date treatment failure occurred

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

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

❑1 Yes ❑0 No

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

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

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

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

10 10. Based on your experience with this subject, are you satisfied with the MICE treatment failure criteria?

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

❑1 Yes ❑0 No

Asthma Clinical Research Network
NIH/NHLBI

MICE

EXERCISE CHALLENGE

xr

Subject ID: 7 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (Month / Day / Year)
Technician ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

01	1.	Has the subject exercised vigorously in the past 24 hours?	☐ 1 Yes	☐ 0 No
02	2.	Has the subject used his/her rescue medication in the past 6 hours?	☐ 1 Yes	☐ 0 No
03	3.	Has the subject eaten a major meal in the past 3 hours?	☐ 1 Yes	☐ 0 No
04	4.	Has the subject eaten in the past hour?	☐ 1 Yes	☐ 0 No
05	5.	Has the subject 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
06	6.	Has the subject 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
07	7.	Has the subject consumed any food containing alcohol or beverages containing alcohol in the past 8 hours?	☐ 1 Yes	☐ 0 No
08	8.	Has the subject had an acute asthma attack requiring oral steroids (prednisone or a similar drug) in the past 4 weeks?	☐ 1 Yes	☐ 0 No
09	9.	Has the subject been deemed a treatment failure within the past 4 weeks?	☐ 1 Yes	☐ 0 No
10	10.	Is there any other reason the subject should not proceed with the Exercise Challenge? If ***YES***, explain _____	☐ 1 Yes	☐ 0 No
11	11.	Is the subject eligible for the Exercise Challenge? ***If any of the shaded boxes are filled in, the subject is NOT eligible for the Exercise Challenge.*** ☞ ***If NO, do NOT complete the rest of this form.***	☐ 1 Yes	■ 0 No

PRE-EXERCISE CHALLENGE VITAL SIGNS

12. Blood pressure — **12a** ___ ___ ___ / **12b** ___ ___ ___ mm Hg (systolic / diastolic)

13 13. Pulse ___ ___ ___ beats/min

PRE-EXERCISE CHALLENGE

14. First FEV_1 measurement (approximately 20 minutes prior to the Exercise Challenge):

14a 14a. FEV_1 ___ . ___ ___ L

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

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

15. Second FEV_1 measurement (approximately 5 minutes prior to the Exercise Challenge):

15a 15a. FEV_1 ___ . ___ ___ L

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

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

➜ ***Compute the percent difference in FEV_1 between Question #14a and Question #15a. If the percent difference is > 10%, repeat spirometry in 5 minutes. Please see the MOP for further details.***

16 16. Is the FEV_1 (% predicted) from Question #15b ≥ 60% predicted? ☐ 1 Yes ☐ 0 No

17 17. Has the subject verbally consented to the Exercise Challenge procedure? ☐ 1 Yes ☐ 0 No

18 18. Is the subject's baseline ECG within normal limits? ☐ 1 Yes ☐ 0 No

19 19. Is the subject's baseline SpO_2 within normal limits? ☐ 1 Yes ☐ 0 No

20 20. Are the subject's vital signs within normal limits? ☐ 1 Yes ☐ 0 No

21 21. Is the subject eligible for the Exercise Challenge? ☐ 1 Yes ☐ 0 No

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

☞ ***If NO, do NOT complete the rest of this form. The subject is NOT eligible for the Exercise Challenge.***

Subject's Initials: __ __ __

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

Physician signature: _____

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

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

Clinic Use Only

Use the average of the FEV_1 values 20 minutes and 5 minutes prior to the Exercise Challenge.

Exercise Challenge Reversal Reference Value: $\frac{\text{(Question \#14a + Question \#15a)}}{2}$ ***x 0.90 =*** ____ . ____ ____ L

Values from the Qualifying Exercise Challenge at Visit 2:

Target heart rate ____ ____ ____ **bpm**

Treadmill settings **Speed** ____ . ____ **mph**

Incline ____ ____ **%**

Dry Gas Apparatus ❑ mouthpiece ❑ face mask

22 22. Dry gas apparatus ❑1 mouthpiece ❑2 face mask

EXERCISE CHALLENGE
(Complete the following table once the target heart rate is met)

Scheduled Time	Actual Time (based on 24-hour clock)	Pulse (bpm)	Oxygen Saturation (%)	Speed (mph)	Incline (%)
23. Start 6 Minute Exercise Challenge	23a : 23as	23b	23c	23d	23e
24. 1 Minute	24a : 24as	24b	24c	24d	24e
25. 2 Minute	25a : 25as	25b	25c	25d	25e
26. 3 Minute	26a : 26as	26b	26c	26d	26e
27. 4 Minute	27a : 27as	27b	27c	27d	27e
28. 5 Minute	28a : 28as	28b	28c	28d	28e
29. Stop 6 Minute Exercise Challenge	29a : 29as	29b	29c	29d	29e

30 30. Was the Exercise Challenge procedure stopped prior to 6 minutes? ❑1 Yes ❑0 No

If ***YES***, why? _____

_____

_____

31 31. Were rescue medications given during the Exercise Challenge procedure? ❑1 Yes ❑0 No

If ***NO***, skip to Question #32.

31a 31a. Albuterol by MDI ❑1 Yes ❑0 No

If ***NO***, skip to Question #31b.

31a1 31ai. Number of puffs of albuterol administered ___ ___ puffs

31b 31b. Nebulized Beta-agonist ❑1 Yes ❑0 No

31c 31c. Subcutaneous epinephrine ❑1 Yes ❑0 No

31d 31d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

31e 31e. Other _____ ❑1 Yes ❑0 No

32 32. Was the overall interpretation of the ECG during the Exercise Challenge within normal limits? ❑1 Yes ❑0 No

If ***NO***, please describe: _____

_____

_____

POST-EXERCISE CHALLENGE

Scheduled Time	Actual Time (based on 24-hour clock)	FEV_1	Blood Pressure (systolic/diastolic) mm Hg	Pulse (BPM)	Were rescue meds necessary?	If ***YES,*** MDI albuterol? (# puffs)	If ***YES,*** Nebulized Beta-agonist?
33. 5 Minute Post-Exercise Challenge	**33a** __ __ __ __	**33b** __.__ __ L	**33c** __ __ __ / **33d** __ __ __	**33e** __ __ __	❑1 Yes ❑0 No **33f**	**33g** __ __	❑1 Yes ❑0 No **33h**
34. 10 Minute Post-Exercise Challenge	**34a** __ __ __ __	**34b** __.__ __ L	**34c** __ __ __ / **34d** __ __ __	**34e** __ __ __	❑1 Yes ❑0 No **34f**	**34g** __ __	❑1 Yes ❑0 No **34h**
35. 15 Minute Post-Exercise Challenge	**35a** __ __ __ __	**35b** __.__ __ L	**35c** __ __ __ / **35d** __ __ __	**35e** __ __ __	❑1 Yes ❑0 No **35f**	**35g** __ __	❑1 Yes ❑0 No **35h**
36. 30 Minute Post-Exercise Challenge	**36a** __ __ __ __	**36b** __.__ __ L	**36c** __ __ __ / **36d** __ __ __	**36e** __ __ __	❑1 Yes ❑0 No **36f**	**36g** __ __	❑1 Yes ❑0 No **36h**
37. 45 Minute Post-Exercise Challenge	**37a** __ __ __ __	**37b** __.__ __ L	**37c** __ __ __ / **37d** __ __ __	**37e** __ __ __	❑1 Yes ❑0 No **37f**	**37g** __ __	❑1 Yes ❑0 No **37h**
38. 60 Minute Post-Exercise Challenge	**38a** __ __ __ __	**38b** __.__ __ L	**38c** __ __ __ / **38d** __ __ __	**38e** __ __ __	❑1 Yes ❑0 No **38f**	**38g** __ __	❑1 Yes ❑0 No **38h**
39. Additional Time, if necessary	**39a** __ __ __ __	**39b** __.__ __ L	**39c** __ __ __ / **39d** __ __ __	**39e** __ __ __	❑1 Yes ❑0 No **39f**	**39g** __ __	❑1 Yes ❑0 No **39h**

40 40. Was the last FEV_1 (from the table on page 4 of this form) ≥ the exercise challenge reversal reference value in the gray box on page 3 of this form? ❑ 1 Yes ❑ 0 No

Physician/CC signature: _____

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

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