Table 1. DICE Forms and Datasets

Form Name	Dataset Name	Variable Prefix	Description	Field Changes/ Comments
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	
CCBLIND	ccblind.sas7bdat	ccb	Clinic Coordinator Post-Study Questionnaire	
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 • Reference the DICE Concomitant Drug Codes List (MED) in the forms packet
COMPLY	comply.sas7bdat	com	Compliance Checklist	

Form Name	Dataset Name	Variable Prefix	Description	Field Changes/ Comments
DIARY	diary.sas7bdat	dry	DICE 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 (albuterol) were used within 2 hours of the peak flow measurement
	drugarms.sas7bdat		DICE Treatment Arm Assignments	File contains the following variables: • 'subjid' = subject ID number • 'arm' = subject's randomized treatment arm
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	• e4_15 (drug packet number) was omitted
LAB	lab.sas7dat	lab	Laboratory Measurements	
LEXAM	lexam.sas7bdat	lx	Long Physical Exam	• lx_01 (height) and lx_02 (weight) were omitted • body mass index (bmi) was added as variable 'bmi'

Form Name	Dataset Name	Variable Prefix	Description	Field Changes/ Comments
MEDHX	medhx.sas7bdat	mhx	Medical History	• mhx_01 (birth date) was omitted • Age at enrollment was added as variable 'age' • mhx_02 (ethnic background) was omitted • variable 'minority' was added (1='minority' ; 0='nonminority')
METHA	metha.sas7bdat	mth	Methacholine Challenge Testing	
	predict.sas7bdat		Predicted Spirometry Values based on each subject's age at enrollment, race, gender and height	File contains the following variables: • 'subjid' • 'FEF25_75' • 'FEV_1' • 'FVC' • 'PEFR'
SERIOUS	serious.sas7bdat	ser	Serious Adverse Event Reporting Form	
SIGEX	sigex.sas7bdat	sae	Significant Asthma Exacerbation	
SPICHECK	spicheck.sas7bdat	spck	Spirometry Testing Checklist	
SPIRO	spiro.sas7bdat	spir	Spirometry Testing	

Form Name	Dataset Name	Variable Prefix	Description	Field Changes/ Comments
SUBBLIND	subblind.sas7bdat	subb	Subject Post-Study Questionnaire	
SUBLIST	sublist.sas7bdat	sbl	Subject Overnight Checklist	
TERM	term.sas7bdat	term	Termination of Study Participation	

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
AECLIN (updated at each visit but recorded as Visit 1 in dataset)		•	•	•	•	•	•
AIRQC	•	•	•	•	•	•	•
CCBLIND		❍	❍	❍	❍	❍	•
CMED_AS (updated at each visit but recorded as Visit 1)		•	•	•	•	•	•
COMPLY			•	•	•	•	•
DIARY		•	•	•	•	•	•
ELIG1	•						
ELIG2	•						
ELIG3	•						
ELIG4		•					
LAB			•	•	•	•	•
LEXAM	•						
MEDHX	•						

Form Name	Visit Number						
	1	2	3	4	5	6	7
METHA	❍						
SERIOUS	❍	❍	❍	❍	❍	❍	❍
SIGEX	❍	❍	❍	❍	❍	❍	❍
SPICHECK			•	•	•	•	•
SPIRO	•						
SUBBLIND		❍	❍	❍	❍	❍	•
SUBLIST			•	•	•	•	•
TERM	❍	❍	❍	❍	❍	❍	•

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D I C E

CLINICAL ADVERSE EVENTS

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

Include adverse events reported during the post Visit 7 phone contact, if appropriate.

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit 1 Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)

(Clinic Coordinator completed)

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

❑0 None

Signature:
Date:

DESCRIPTION OF ADVERSE EVENT	1. ICD9 CODE	2. DATE STARTED (Top Line) / 3. DATE STOPPED (Bottom Line) MONTH / DAY / YEAR	4. ONGOING at final 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**	**cae_01** ___.__	**cae_02** __/__/__ **cae_03** __/__/__	**cae_04**	**cae_05** __	**cae_06**	**cae_07**	**cae_08**	**cae_09**	**cae_10**	**cae_11**	**cae_12**
2.	___.__	__/__/__ __/__/__	❑1	__							
3.	___.__	__/__/__ __/__/__	❑1	__							
4.	___.__	__/__/__ __/__/__	❑1	__							
5.	___.__	__/__/__ __/__/__	❑1	__							

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

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

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DICE

AIRWATCH™ QUALITY CONTROL Visits 1 and 7

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Current Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Technician ID: ___ ___ ___ ___ ___

(Technician completed)

air_01 1. Serial Number of AirWatch™ being tested ___ ___ ___ ___ - ___ ___ ___ ___

air_02 2. Serial Number of mouthpiece being tested ___ ___ ___ ___

air_03 3. Test date ___ ___ / ___ ___ / ___ ___ (*month / day / year*)

air_04 4. Is this a new AirWatch™ device being tested? ❑1 Yes ❑0 No

air_04a If ***YES***, indicate 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	**air_05a** ___ ___ **air_05b**	___ ___ ___	___ ___ ___ . ___ %	___
6.	Trial 2	**air_06a** ___ ___ **air_06b**	___ ___ ___	___ ___ ___ . ___ %	___
7.	Trial 3	**air_07a** ___ ___ **air_07b**	___ ___ ___	___ ___ ___ . ___ %	___
8.	Trial 4	**air_08a** ___ ___ **air_08b**	___ ___ ___	___ ___ ___ . ___ %	___
9.	Trial 5	**air_09a** ___ ___ **air_09b**	___ ___ ___	___ ___ ___ . ___ %	___

Clinic Use Only

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

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

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

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

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

air_10 10. Did the AirWatch™ pass? ❑1 Yes ❑0 No

air_11 11. If ***NO***, is this the third mouthpiece tested with this AirWatch™ at this visit? ❑1 Yes ❑0 No

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

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D I C E

CLINIC COORDINATOR POST-STUDY QUESTIONNAIRE

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Coordinator ID: ___ ___ ___ ___ ___

(Coordinator completed)

This questionnaire is to be completed by the ACRN study coordinator who was primarily responsible for the subject's DICE visits.

ccb_01

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

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

  ccb_01a
  - ☐ 1 Placebo
  - ☐ 2 Active Drug

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

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

_____

_____

_____

_____

Coordinator's Initials:

Date: __ __/__ __/__ __

CCBLIND

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DICE

CONCOMITANT MEDICATIONS for ASTHMA-RELATED DRUGS

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit 1 Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)

(Clinic Coordinator completed)

At Visit 1: Please list, in the table below, all concomitant medications the subject is taking that are related to the treatment of asthma symptoms. Indicate the name of the medication, dose, units, frequency, route, and start date. Refer to the Concomitant Medications list (MED) for the codes. Record all medications the subject is taking at the time of the visit, even if they are stopped the same day.

Subsequent visits: Please update the table below at each visit and following the post Visit 7 phone contact. Indicate any new asthma-related medications started and any medications that were stopped since the last update. If the subject still is taking the medication at the end of the study, please check the "ongoing" box and leave the stop date column blank. Check the "None" box if the subject has not taken any asthma-related concomitant medications during the entire study.

❑0 None

CODE	NAME OF MEDICATION	DOSE	UNITS	FREQUENCY	ROUTE	START DATE (MM/DD/YY)	STOP DATE (MM/DD/YY)	ONGOING AT END OF STUDY
cmed_01	1. cmedno	cmed_02		cmed_04		cmed_06	___/___/___	❑1 cmed_08
	2.		cmed_03		cmed_05	___/___/___	cmed_07	❑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

DICE 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
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

DICE Concomitant Drug Codes

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

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

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

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DICE

COMPLIANCE CHECKLIST
Visits 3 through 7

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Check the following compliance criteria at the beginning of each overnight visit.

com_01 1. Did the subject comply with the study visit schedule, allowing for a minimum of 6 days and a maximum of 8 days between visits? ☐ 1 Yes ☐ 0 No

com_02 2. Has the subject commenced therapy with any steroid formulation (including oral, inhaled, intranasal, topical, intravenous) other than study medications? ☐ 1 Yes ☐ 0 No

com_03 3. Has the subject taken any medications that are known to significantly interact with steroid disposition, including (but not limited to) carbamazepine, macrolide antibiotics, phenobarbital, phenytoin, rifampin, ketoconazole, and sibutramine? ☐ 1 Yes ☐ 0 No

com_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 4 or more of the AM or PM dosing sessions between the last visit and today? ☐ 1 Yes ☐ 0 No

com_05 5. Did the subject show evidence of noncompliance with the daily dosing schedule? ☐ 1 Yes ☐ 0 No

For MDI's: based on the history stored in the Doser™

Day	1	2	3	4	5	6	7	8
Dose								

For BUD: based on the number of clicks remaining in the subject's Turbuhaler®

Used doses: ___ ___ ___ = 200 - Remaining clicks: ___ ___ ___

For FP dry powder: based on the number of used and unused Rotadisks and blisters

Used Rotadisks: ___ ___ Used blisters: ___ ___ ___

com_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 4 or more occasions between the last visit and today? ☐ 1 Yes ☐ 0 No

com_07 7. Did the subject comply with study procedures? ☐ 1 Yes ☐ 0 No
If any of the shaded boxes are completed, the subject was noncompliant and has achieved DICE dropout status.
In this case, STOP the current visit and complete a Termination of Study Participation (TERM) form.

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DICE DIARY CARD

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

Subject ID: 6 __ __ __ __
Subject Initials: __ __ __
Return Visit Number: __
Return Visit Date: __ __ / __ __ / __ __
month day year

Please use black ink to complete.

To the subject:

If your peak flow is below _____ liters/minute, use your Ventolin®(RESCUE) inhaler as instructed in the handout "If Your Asthma Gets Worse." Contact study personnel if your peak flow does not increase to this value after one hour of RESCUE use.

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

	Day 1: _____	Day 2: _____	Day 3: _____	Day 4: _____	Day 5: _____	Day 6: _____	Day 7: _____
dmonth/dday Date	__ / __ month day	__ / __ month day	__ / __ month day	__ / __ month day	__ / __ month day	__ / __ month day	__ / __ month day
MORNING EVALUATION (Between 5 - 10 AM)							
1. Number of times that you woke up last night due to asthma	**dry_01** __ __	__ __	__ __	__ __	__ __	__ __	__ __
2. Time of AM Peak Flow (Should be between 5 and 10 AM but record actual time taken)	**dry_02** __ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
3. AM Peak Flow (liters/min)**	**dry_03** **dry_03r** __ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __
4. AM FEV_1 (liters)	**dry_04** __ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __
5. Total number of puffs from scheduled inhaler **(AM)**	**dry_05** _____	_____	_____	_____	_____	_____	_____
Symptoms++ during the night. 6. Shortness of Breath	**dry_06**						
7. Chest Tightness	**dry_07**						
8. Wheezing	**dry_08**						
9. Cough	**dry_09**						
10. Phlegm/Mucus	**dry_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)	**dry_11** __ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
12. PM Peak Flow (liters/min)**	**dry_12** **dry_12r** __ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __	__ __ __
13. PM FEV_1 (liters)	**dry_13** __ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __
14. Total number of puffs from scheduled inhaler **(PM)**	**dry_14** _____	_____	_____	_____	_____	_____	_____
15. Total number of puffs of Ventolin® **(RESCUE) in past 24 hours** *(Do not record preventive puffs.)*	**dry_15** __ __	__ __	__ __	__ __	__ __	__ __	__ __
Symptoms++ since you woke. 16. Shortness of Breath	**dry_16**						
17. Chest Tightness	**dry_17**						
18. Wheezing	**dry_18**						
19. Cough	**dry_19**						
20. Phlegm/Mucus	**dry_20**						

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

++ Symptom Severity Rating Scale

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

Asthma Clinical Research Network

DICE

ELIGIBILITY CHECKLIST 1

Subject ID: 6 ___ ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: 1

Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)

Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

e1_01	1.	***Did the subject sign the Informed Consent form?***	❑ 1 Yes ❑ 0 No
e1_01a		*If **YES**, record the date the form was signed.*	___ ___ / ___ ___ / ___ ___ (*month / day / year*)
e1_02	2.	Are you planning to move away from this clinical center in the next 2 months such that your ability to complete the study will be jeopardized?	❑ 1 Yes ❑ 0 No
e1_03	3.	Have you used any smokeless tobacco products (chew, snuff) in the past year?	❑ 1 Yes ❑ 0 No
e1_04	4.	Have you smoked cigarettes, a pipe, cigars, or any other substance in the past year?	❑ 1 Yes ❑ 0 No
e1_05	5.	Do you have a smoking history less than 10 pack-years?	❑ 1 Yes ❑ 0 No
e1_05a		Record history in pack-years. (Enter '00' if none)	___ ___
e1_06	6.	Have you had a respiratory tract infection in the past 6 weeks?	❑ 1 Yes ❑ 0 No
e1_07	7.	Have you experienced a significant asthma attack in the past 6 weeks?	❑ 1 Yes ❑ 0 No
e1_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

e1_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

e1_09a 9a. If ***YES,*** are you currently pregnant or lactating? ❑ 1 Yes ❑ 0 No

e1_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

e1_10 10. Are you post-menopausal? ❑ 1 Yes ❑ 0 No

e1_10a 10a. If ***YES***, are you currently on hormone replacement therapy? ❑ 1 Yes ❑ 0 No

e1_11 11. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ❑ 1 Yes ❑ 0 No

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

Subject's Initials:

Date: __ __/ __ __/ __ __

ELIGIBILITY CHECKLIST 2

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

e2_01 1. Does the subject have current evidence of any of the conditions listed on the Medical Conditions reference card (EXCLMED)? ☐1 Yes ☐0 No
If ***YES***, describe _____

e2_02 2. Has the subject taken any medications listed on the Exclusionary Drugs reference card (EXCLDRUG) within the specified time periods? ☐1 Yes ☐0 No
If ***YES***, describe _____

3. 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.***

e2_03a 3a. Oral ☐1 Yes ☐0 No
e2_03b 3b. Inhaled ☐1 Yes ☐0 No
e2_03c 3c. Nasal ☐1 Yes ☐0 No
e2_03d 3d. Topical - prescription ☐1 Yes ☐0 No
e2_03e 3e. Topical - over-the-counter ☐1 Yes ☐0 No
e2_03f 3f. Injectable ☐1 Yes ☐0 No

e2_04 4. Does the subject anticipate the need for intranasal steroids during his or her participation in the study? ☐1 Yes ☐0 No

e2_05 5. Is the subject currently taking prescription or over-the-counter medication(s) other than those listed on the Allowed Medications reference card (MEDALLOW)? ☐1 Yes ☐0 No
If ***YES***, describe _____

e2_06 6. Is the subject currently receiving hyposensitization therapy other than an established maintenance regimen? ☐1 Yes ☐0 No

e2_07 7. Is the subject post-pubertal and ≤ 60 years of age? ☐1 Yes ☐0 No
(A bone age film may be necessary to establish post-pubertal status in adolescents. See the MOP for details.)

e2_08 8. Does the subject have a body mass index (BMI) > 35? ☐ 1 Yes ☐ 0 No

e2_09 9. Does the subject work night shift or have an altered day night cycle for other reasons? ☐ 1 Yes ☐ 0 No

e2_10 10. Does the subject have a positive urine pregnancy test? (Check N/A if the subject is male.) ☐ 1 Yes ☐ 0 No ☐ 9 N/A

e2_11 11. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ☐ 1 Yes ☐ 0 No

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

Subject's Initials:

Date: __ __/ __ __/ __ __

Asthma Clinical Research Network
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DICE

ELIGIBILITY CHECKLIST 3

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

e3_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

e3_02 2. Is the subject's prebronchodilator FEV_1 between 65% and 90% of predicted, inclusive? ❑1 Yes ❑0 No

3. Source Documentation:

e3_03a 3a. Does the subject have source documentation of a ≥ 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:

e3_03a1 Prebronchodilator FEV_1 ___ . ___ ___ L

e3_03a2 Postbronchodilator FEV_1 ___ . ___ ___ L

e3_03a3 Date of source documentation ___ ___ / ___ ___ / ___ ___ (month / day / year)

e3_03b 3b. 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 value below:

e3_03b1 PC_{20} ___ . ___ ___ ___ mg/ml

e3_03b2 Date of source documentation ___ ___ / ___ ___ / ___ ___ (month / day / year)

➜ ***If A OR B is answered YES, go to Question #5.***

4. At Visit 1:

e3_04a 4a. Did the subject demonstrate a ≥ 12% increase in FEV_1 in response to aerosolized albuterol? ❑1 Yes ❑0 No ❑9 Not Done
➜ ***If YES or NO, go to Question #5.***

e3_04b 4b. Was the subject's methacholine $PC_{20} \leq 8$ mg/ml? ❑1 Yes ❑0 No

e3_05 5. Is the subject eligible? ***If any of the shaded boxes are filled in, the subject is ineligible.*** ❑1 Yes ❑0 No

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

Asthma Clinical Research Network
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DICE

ELIGIBILITY CHECKLIST 4

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 2
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

e4_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

e4_02 2. Since Visit 1, has the subject experienced a significant asthma exacerbation as defined in the protocol? ❑1 Yes ❑0 No

e4_03 3. Since Visit 1, has the subject received treatment with any excluded medications (EXCLDRUG)? ❑1 Yes ❑0 No

e4_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 4 or more of the AM or PM dosing sessions between Visit 1 and Visit 2? ❑1 Yes ❑0 No

e4_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

Day	1	2	3	4	5	6	7	8
Dose								

e4_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 4 or more occasions between Visit 1 and today? ❑1 Yes ❑0 No

e4_07 7. During the run-in week, did the subject record both AM and PM peak flow measurements and symptoms on his or her Diary Card (DIARY) on at least 5 days? ❑1 Yes ❑0 No

e4_08 8. Is there any new information that makes the subject ineligible according to the eligibility criteria? ❑1 Yes ❑0 No
If ***YES,*** describe: _____

e4_09 9. Does the subject wish to withdraw consent from the study? ❑1 Yes ❑0 No

e4_10 10. Is there any other reason for which this subject should not be included in the study? ☐1 Yes ☐0 No
If ***YES,*** describe: _____

e4_11 11. Is the subject's morning plasma cortisol concentration ≥ 5 μg/dL? ☐1 Yes ☐0 No

e4_11a 11a. Plasma Cortisol value ___ ___ . ___ μg/dL

e4_12 12. Is the subject's hematocrit less than the lower limit of acceptability as specified by the ACRN clinical center's IRB? ☐1 Yes ☐0 No

e4_12a 12a. Hematocrit value ___ ___ . ___ %

e4_13 13. 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 DICE, randomize the subject. Otherwise, please complete the Termination of Study Participation (TERM) form.***

e4_14 14. Subject's gender **(from MEDHX)** ☐1 Male ☐2 Female

e4_15 15. Drug Packet Number **(record on LOG)** **6** ___ ___ ___ ___ ___ ___

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D I C E

LABORATORY MEASUREMENTS

Visits 3 through 7

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

PLASMA RESULTS

1.	8 PM Cortisol	lab_01	___ ___ . ___	µg/dL	❑1 lab_01a Censored
2.	9 PM Cortisol	lab_02	___ ___ . ___	µg/dL	❑1 lab_02a Censored
3.	10 PM Cortisol	lab_03	___ ___ . ___	µg/dL	❑1 lab_03a Censored
4.	11 PM Cortisol	lab_04	___ ___ . ___	µg/dL	❑1 lab_04a Censored
5.	12 AM Cortisol	lab_05	___ ___ . ___	µg/dL	❑1 lab_05a Censored
6.	1 AM Cortisol	lab_06	___ ___ . ___	µg/dL	❑1 lab_06a Censored
7.	2 AM Cortisol	lab_07	___ ___ . ___	µg/dL	❑1 lab_07a Censored
8.	3 AM Cortisol	lab_08	___ ___ . ___	µg/dL	❑1 lab_08a Censored
9.	4 AM Cortisol	lab_09	___ ___ . ___	µg/dL	❑1 lab_09a Censored
10.	5 AM Cortisol	lab_10	___ ___ . ___	µg/dL	❑1 lab_10a Censored
11.	6 AM Cortisol	lab_11	___ ___ . ___	µg/dL	❑1 lab_11a Censored
12.	7 AM Cortisol	lab_12	___ ___ . ___	µg/dL	❑1 lab_12a Censored
13.	8 AM Cortisol	lab_13	___ ___ . ___	µg/mL	❑1 lab_13a Censored
14.	7 AM Osteocalcin	lab_14	___ ___ . ___	ng/mL	❑1 lab_14a Censored

URINE RESULTS

15.	8 AM - 8 PM Cortisol	lab_15	___ ___ . ___	µg/dL	❑1 lab_15a Censored
16.	8 AM - 8 PM Calculated Creatinine	lab_16	___ ___ . ___	mg/dL	❑1 lab_16a Censored
17.	8 PM - 8 AM Cortisol	lab_17	___ ___ . ___	µg/dL	❑1 lab_17a Censored
18.	8 PM - 8 AM Calculated Creatinine	lab_18	___ ___ . ___	mg/dL	❑1 lab_18a Censored
19.	24 hour Cortisol	lab_19	___ ___ . ___	µg/dL	❑1 lab_19a Censored
20.	24 hour Calculated Creatinine	lab_20	___ ___ . ___	mg/dL	❑1 lab_20a Censored

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D I C E

LONG PHYSICAL EXAM

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

PHYSICAL EXAMINATION

lx_01 1. Height *(without shoes)* ___ ___ . ___ inches

lx_02 2. Weight *(without shoes or heavy clothing)* ___ ___ ___ . ___ pounds

lx_03 3. Does the subject have evidence of oral candidiasis? ❑1 Yes ❑0 No

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

VITAL SIGNS

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

lx_04a **lx_04b**

4. Resting blood pressure ___ ___ ___ / ___ ___ ___ mm Hg (systolic / diastolic)

lx_05 5. Pulse ___ ___ ___ beats/min

lx_06 6. Respiration ___ ___ breaths/min

lx_07 7. Body Temperature ___ ___ ___ . ___ ° F

PULMONARY AUSCULTATION

lx_08 8. 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

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

			Not Done	Normal	Abnormal	
lx_09	9.	Hair and Skin	❑2	❑1	❑0	_____
lx_10	10.	Lymph nodes	❑2	❑1	❑0	_____
lx_11	11.	Eyes (excluding corrective lenses)	❑2	❑1	❑0	_____
lx_12	12.	Ears, Nose, and Throat	❑2	❑1	❑0	_____
lx_13	13.	Respiratory (excluding asthma)	❑2	❑1	❑0	_____
lx_14	14.	Cardiovascular	❑2	❑1	❑0	_____
lx_15	15.	Gastrointestinal	❑2	❑1	❑0	_____
lx_16	16.	Musculoskeletal	❑2	❑1	❑0	_____
lx_17	17.	Neurological	❑2	❑1	❑0	_____
lx_18	18.	Mental Status	❑2	❑1	❑0	_____
lx_19	19.	Other _____ (check Not Done if non-applicable)	❑2	❑1	❑0	_____

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

MEDICAL HISTORY

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

DEMOGRAPHY

mhx_01 1. What is your date of birth? ___ ___ / ___ ___ / ___ ___ (*month / day / year*)

mhx_02 2. What is your ethnic background?

- ❑1 American Indian or Alaskan Native
- ❑2 Asian or Pacific Islander
- ❑3 Black, not of Hispanic Origin
- ❑4 White, not of Hispanic Origin
- ❑5 Hispanic
- ❑6 Other_____

mhx_03 3. Subject's gender *(Do not ask subject)*

- ❑1 Male
- ❑2 Female

ASTHMA HISTORY

mhx_04 4. Approximately how old were you when your asthma first appeared? (*Check one box only*)

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

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

mhx_05 5. How many years have you had asthma? (*Check one box only*)

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

mhx_06 6. What season is your asthma the worst? (*Check one box only*)

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

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

mhx_07a 7a. Asthma episodes have you had that required emergency care or an unscheduled office visit? ___ ___

mhx_07b 7b. Hospitalizations have you had due to asthma? ___ ___

mhx_07c 7c. Courses of oral corticosteroid therapy for asthma (such as prednisone or Medrol) have you taken? ___ ___

➜ ***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.***

mhx_08 8. Have you missed any days of work or school due to asthma in the last 12 months? ❑1 Yes ❑0 No ❑9 N/A

mhx_08a If ***YES***, record your best estimate of the number of days missed. ___ ___

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

mhx_09a	9a. Mother	❑1 Yes	❑0 No	❑8 Don't Know	
mhx_09b	9b. Father	❑1 Yes	❑0 No	❑8 Don't Know	
mhx_09c	9c. Brothers or Sisters	❑1 Yes	❑0 No	❑8 Don't Know	❑9 N/A
mhx_09d	9d. Child(ren)	❑1 Yes	❑0 No	❑8 Don't Know	❑9 N/A

PRIOR ASTHMA TREATMENT

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

					If Yes, indicate date medication was last taken month / day / year
mhx_10	10.	Short-acting Inhaled Beta-Agonists (MDI) (**Bronkaid Mist, Duo-Medihaler, Medihaler-Epi, Primatene Mist and others**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __ mhx_10x
mhx_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	__ __/__ __/__ __ mhx_11x
mhx_12	12.	Long-acting Inhaled Beta-Agonists (MDI) (**Serevent**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __ mhx_12x
mhx_13	13.	Asthma medication via a Nebulizer Machine	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __ mhx_13x
mhx_14	14.	Intermediate-acting Oral Beta-Agonists (**Alupent, Brethine, Bricanyl, Metaprel, Proventil, Ventolin and others**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __ mhx_14x
mhx_15	15.	Long-acting Oral Beta-Agonists (**Repetabs, Volmax**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __ mhx_15x
mhx_16	16.	Short-acting Oral Theophylline (**Aminophylline and others)**	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __ mhx_16x
mhx_17	17.	Sustained release Oral Theophylline (**Slo-bid, Theo-Dur, Uniphyl and others**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __ mhx_17x
mhx_18	18.	Inhaled Anticholinergic (**Atrovent, Combivent**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __ mhx_18x
mhx_19	19.	Anti-allergic Inhaled Medications (**Intal, Tilade and others**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __ mhx_19x
mhx_20	20.	Anti-allergic Nasal Medications (**Nasalcrom and others**)	❑1 Yes	❑0 No ❑8 Unknown	__ __/__ __/__ __ mhx_20x

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

mhx_21	21.	Anti-allergic Oral Medications (**Allegra, Claritin and others**)	❑1 Yes ❑0 No	❑8 Unknown	__ __/__ __/__ __ mhx_21x
mhx_22	22.	Oral Steroids (**Prednisone, Medrol and others**)	❑1 Yes ❑0 No	❑8 Unknown	__ __/__ __/__ __ mhx_22x
mhx_23	23.	Inhaled Steroids (**Azmacort, Beclovent, Vanceril, AeroBid, Flovent, Pulmicort and others**)	❑1 Yes ❑0 No	❑8 Unknown	__ __/__ __/__ __ mhx_23x
mhx_24	24.	Nasal Steroids (**Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Rhinocort and others)**	❑1 Yes ❑0 No	❑8 Unknown	__ __/__ __/__ __ mhx_24x
mhx_25	25.	Topical Steroids - Prescription (**Synalar, Lidex, Dermacin, Fluocinonide and others**)	❑1 Yes ❑0 No	❑8 Unknown	__ __/__ __/__ __ mhx_25x
mhx_26	26.	Topical Steroids - OTC (**Hydrocortisone - multiple strengths and products)**	❑1 Yes ❑0 No	❑8 Unknown	__ __/__ __/__ __ mhx_26x
mhx_27	27.	Leukotriene Antagonist / 5L0 Inhibitors (**Accolate, Zyflo, Singulaire)**	❑1 Yes ❑0 No	❑8 Unknown	__ __/__ __/__ __ mhx_27x

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

					If Yes, Comment
mhx_28	28.	Skin	❑1 Yes	❑0 No	
mhx_29	29.	Blood, Lymph, or Immune Systems	❑1 Yes	❑0 No	
mhx_30	30.	Eyes	❑1 Yes	❑0 No	
mhx_31	31.	Ears, Nose, or Throat	❑1 Yes	❑0 No	
mhx_32	32.	Breasts	❑1 Yes	❑0 No	
mhx_33	33.	Endocrine Systems	❑1 Yes	❑0 No	
mhx_34	34.	Lung - other than asthma	❑1 Yes	❑0 No	
mhx_35	35.	Heart and Blood Vessels	❑1 Yes	❑0 No	
mhx_36	36.	Liver or Pancreas	❑1 Yes	❑0 No	
mhx_37	37.	Kidneys or Urinary Tract System	❑1 Yes	❑0 No	
mhx_38	38.	Reproductive System	❑1 Yes	❑0 No	
mhx_39	39.	Stomach or Intestines	❑1 Yes	❑0 No	
mhx_40	40.	Muscles or Bones	❑1 Yes	❑0 No	
mhx_41	41.	Nervous System	❑1 Yes	❑0 No	
mhx_42	42.	Psychiatric	❑1 Yes	❑0 No	
mhx_43	43.	Other _____	❑1 Yes	❑0 No	

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DICE

METHACHOLINE CHALLENGE TESTING

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Technician ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete this form only if the subject has successfully completed the Spirometry Testing (SPIRO) form and PC_{20} information is necessary to establish eligibility.

mth_01 1. Has the subject had any severe acute illness in the past 4 weeks? ❑1 Yes ❑0 No

mth_01a If ***YES***, has the subject received permission from the supervising physician to proceed with the methacholine challenge testing? ❑1 Yes ❑0 No
Name of physician: _____

mth_02 2. Is there any other reason the subject should not proceed with the methacholine challenge testing? ❑1 Yes ❑0 No
If ***YES***, explain _____

mth_03 3. 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 ineligible 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 and the subject re-enrolled in the study.

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 ___ . ___ ___ ***L***

Methacholine Reversal Reference Value ***FEV_1 x 0.90 =*** ___ . ___ ___ ***L***

mth_04 4. PC_{20} ___ ___ . ___ ___ ___ mg/ml

mth_04a 4a. Time methacholine challenge was completed (*based on 24-hour clock*) ___ ___ ___ ___

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

mth_05a 5a. FEV_1 ___ . ___ ___ L

mth_05b 5b. FEV_1 (% predicted) ___ ___ ___ % predicted

mth_05c 5c. Time of FEV_1 from Question #5a (*based on 24-hour clock*) ___ ___ ___ ___

mth_05d 5d. Was the FEV_1 from Question #5a ≥ the methacholine reversal reference value in the gray box above? ❑1 Yes ❑0 No

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

mth_06 6. Was additional treatment used in the first hour? ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #8.***

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

mth_06a 6a. Additional albuterol by MDI ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #6b.***

mth_06a1 6ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four

mth_06b 6b. Nebulized Beta-agonist ❑1 Yes ❑0 No

mth_06c 6c. Subcutaneous epinephrine ❑1 Yes ❑0 No

mth_06d 6d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

mth_06e 6e. Other _____ ❑1 Yes ❑0 No

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

mth_07a 7a. FEV_1 ___ . ___ ___ L

mth_07b 7b. FEV_1 (% predicted) ___ ___ ___ % predicted

mth_07c 7c. Time of FEV_1 from Question #7a (*based on 24-hour clock*) ___ ___ ___ ___

mth_07d 7d. Was the FEV_1 from Question #7a ≥ 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.***

mth_08 8. Was additional treatment used after one hour? ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #9.***

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

mth_08a 8a. Additional albuterol by MDI ❑1 Yes ❑0 No

➜ ***If NO, skip to Question #8b.***

mth_08a1 8ai. Number of additional puffs of albuterol administered ❑1 two ❑2 four ❑3 > four

mth_08b 8b. Nebulized Beta-agonist ❑1 Yes ❑0 No

mth_08c 8c. Subcutaneous epinephrine ❑1 Yes ❑0 No

mth_08d 8d. Implementation of clinic emergency protocol or algorithm ❑1 Yes ❑0 No

mth_08e 8e. Treatment in the emergency room ❑1 Yes ❑0 No

mth_08f 8f. Overnight hospitalization ❑1 Yes ❑0 No

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

mth_08g 8g. Other _____ ❑1 Yes ❑0 No

9. Subject's final FEV_1 after methacholine challenge.

mth_09a 9a. FEV_1 ___ . ___ ___ L

mth_09b 9b. FEV_1 (% predicted) ___ ___ ___ % predicted

mth_09c 9c. Time of FEV_1 from Question #9a (*based on 24-hour clock*) ___ ___ ___ ___

mth_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 NO, complete the source documentation box below.***

Physician signature: _____

Date: __ __ / __ __ / __ __

Time: __ __ : __ __

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D I C E

SERIOUS ADVERSE EVENT REPORTING FORM

Subject ID: 6 ___ ___ ___ ___
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.

ser_01	1.	Date of Adverse Event	___ ___ / ___ ___ / ___ ___
ser_02	2.	Description of Adverse Event (ICD9 Code) Describe: _____	___ ___ ___ . ___ ___
ser_03	3.	Time interval between taking the study drug (last dose before symptoms) and subsequent onset of symptoms.	___ ___
ser_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?	
ser_05a	5a.	Fatal Event?	❑1 Yes ❑0 No
ser_05b	5b.	Life-threatening event?	❑1 Yes ❑0 No
ser_05c	5c.	Inpatient hospitalization required?	❑1 Yes ❑0 No
ser_05c1	5c1.	Admission date	___ ___/ ___ ___/ ___ ___
ser_05c2	5c2.	Discharge date	___ ___/ ___ ___/ ___ ___
ser_05d	5d.	Hospitalization prolonged?	❑1 Yes ❑0 No
ser_05e	5e.	Disabling or incapacitating?	❑1 Yes ❑0 No
ser_05f	5f.	Overdose?	❑1 Yes ❑0 No
ser_05g	5g.	Cancer?	❑1 Yes ❑0 No
ser_05h	5h.	Congenital anomaly?	❑1 Yes ❑0 No
ser_05i	5i.	Serious laboratory abnormality with clinical symptoms?	❑1 Yes ❑0 No
ser_05j	5j.	Other _____	❑1 Yes ❑0 No

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

ser_06a	6a.	Toxicity of study drug(s)?	❑1 Yes	❑0 No
ser_06b	6b.	Withdrawal of study drug(s)?	❑1 Yes	❑0 No
ser_06c	6c.	Concurrent medication? If ***YES***, describe _____	❑1 Yes	❑0 No
ser_06d	6d.	Concurrent disorder? If ***YES***, describe _____	❑1 Yes	❑0 No
ser_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: __ __ / __ __ / __ __

SIGNIFICANT ASTHMA EXACERBATION

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Current 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?

sae_01a	1a.	An increase in rescue inhaler use of ≥ 8 puffs per 24 hours over baseline rescue inhaler use for a period of 48 hours?	❑ 1 Yes	❑ 0 No
sae_01b	1b.	Use of rescue inhaler ≥ 16 total puffs per 24 hours for a period of 48 hours?	❑ 1 Yes	❑ 0 No
sae_01c	1c.	A fall in prebronchodilator PEFR to ≤ 65% of baseline?	❑ 1 Yes	❑ 0 No

If any of the shaded boxes are filled in, the subject experienced a significant asthma exacerbation.

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

If the subject does not meet the above criteria, STOP HERE. DO NOT SUBMIT THIS FORM TO THE DCC.

sae_02 2. Date of significant asthma exacerbation ___ ___ / ___ ___ / ___ ___ (month / day / year)

sae_03 3. Did the subject seek care for the asthma exacerbation? ☐1 Yes ☐0 No

➜ ***If NO, skip to Question #5.***

4. What type of care was sought?

sae_04a 4a. Study Investigator? ☐1 Yes ☐0 No

sae_04a1 If ***YES***, indicate type of contact.

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

sae_04b 4b. Primary Care or Other Physician? ☐1 Yes ☐0 No

Name of physician: _____

sae_04b1 If ***YES***, indicate type of contact.

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

sae_04c 4c. Emergency Room visit? ☐1 Yes ☐0 No

Name of hospital: _____

sae_05 5. Was the subject hospitalized? ☐1 Yes ☐0 No

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

If ***YES***,

5a. Name of hospital: _____

sae_05b 5b. Duration of hospital stay? ___ ___ days

sae_05c 5c. Was intubation or ventilation assistance required? ☐1 Yes ☐0 No

sae_06 6. Did the asthma exacerbation require treatment with inhaled, oral, or intravenous glucocorticoids? ☐1 Yes ☐0 No

➜ ***If YES, the subject meets DICE dropout criteria and must be terminated from the study. Please complete this form, the Concomitant Medications for Asthma-Related Drugs form (CMED_AS) and the Termination of Study Participation (TERM) form.***

sae_07 7. Was the asthma exacerbation resolved solely by increasing PRN use of the rescue inhaler?

❑1 Yes ❑0 No

sae_08 8. Was the asthma exacerbation treated as outlined in the protocol?

If ***NO***, describe_____

_____

_____

❑1 Yes ❑0 No

sae_09 9. Was the significant asthma exacerbation related to the routine pulmonary function testing? *(Check one box only)*

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

sae_10 10. Was the significant asthma exacerbation related to the methacholine challenge testing? *(Check one box only)*

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

Asthma Clinical Research Network
NIH/NHLBI

DICE

SPIROMETRY TESTING CHECKLIST
Visits 3 through 7

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

Please complete just prior to the AM spirometry session at each overnight visit.

spck_01	1.	Have you used your Ventolin® (**RESCUE**) inhaler in the past 6 hours?	❑1 Yes	❑0 No
spck_02	2.	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
spck_03	3.	Have you used medications with caffeine in the past 8 hours? ***Examples**: Anacin, Darvon compound, Esgic, Excederin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*	❑1 Yes	❑0 No
spck_04	4.	Have you consumed any food containing alcohol or beverages containing alcohol in the past 8 hours?	❑1 Yes	❑0 No
spck_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
spck_06	6.	Is there any reason you should not proceed with the pulmonary function testing? If ***YES***, explain _____ _____	❑1 Yes	❑0 No

SPIROMETRY TESTING
Visit 1

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Technician ID: ___ ___ ___ ___ ___

(Subject Interview completed)

spir_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
spir_02	2.	Have you used medications with caffeine in the past 8 hours? ***Examples**: Anacin, Darvon compound, Esgic, Excederin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*	❑1 Yes	❑0 No
spir_03	3.	Have you consumed any food containing alcohol or beverages containing alcohol in the past 8 hours?	❑1 Yes	❑0 No
spir_04a	4a.	Have you used fexofenadine (e.g. Allegra) or chlorpheniramine (e.g. Chlor-Trimeton) in the past 48 hours?	❑1 Yes	❑0 No
spir_04b	4b.	Have you used pseudoephedrine (e.g. Sudafed) or oxymetazoline (e.g. Afrin) in the past 48 hours?	❑1 Yes	❑0 No
spir_04c	4c.	Have you used short-acting theophylline (e.g. Slo-Phyllin, Aminophylline) in the past 12 hours?	❑1 Yes	❑0 No
spir_04d	4d.	Have you used long-acting theophylline (e.g. Theo-Dur, Slo-bid) in the past 24 hours?	❑1 Yes	❑0 No
spir_04e	4e.	Have you used ultra long-acting theophylline (e.g. Theo-24, Uniphyl) in the past 48 hours?	❑1 Yes	❑0 No
spir_04f	4f.	Have you used a rescue intermediate-acting inhaled beta-agonist (e.g. Ventolin or Proventil) in the past 6 hours?	❑1 Yes	❑0 No
spir_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
spir_06	6.	Is there any other reason you should not proceed with the pulmonary function testing? If ***YES***, explain _____	❑1 Yes	❑0 No

spir_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 ineligible for testing.***

☐ 1 Yes ☐ 0 No

☞ ***If YES, please continue.***

☞ ***If NO, do NOT complete page 2 or 3. Visit 1 must be rescheduled.***

PREBRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

spir_08

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

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

spir_09a

9. Results of best effort

FVC ___ . ___ ___ L

spir_09b

FEV_1 ___ . ___ ___ L

spir_09c

FEV_1 ___ ___ ___ % predicted

spir_09d

PEFR ___ ___ . ___ ___ L/S

spir_09e

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

Complete Page 3 only if subject is performing reversibility testing at Visit 1 to meet eligibility requirements.

POSTBRONCHODILATOR TESTING

spir_10 10. Time bronchodilator given *(based on 24-hour clock)* ___ ___ ___ ___

spir_11 11. 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.

12. Results of best effort postbronchodilator

spir_12a FVC ___ . ___ ___ L

spir_12b FEV_1 ___ . ___ ___ L

spir_12c FEV_1 ___ ___ ___ % predicted

spir_12d PEFR ___ ___ . ___ ___ L/S

spir_12e FEF_{25-75} ___ . ___ ___ L/S

spir_13 13. Did the subject demonstrate a ≥12% increase in FEV_1 in response to aerosolized albuterol during reversibility testing at Visit 1? ☐ 1 Yes ☐ 0 No

If NO, the subject is ineligible to continue. STOP the visit and complete the Termination of Study Participation (TERM) form.

Asthma Clinical Research Network
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DICE

SUBJECT POST-STUDY QUESTIONNAIRE

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___
month day year

(Subject completed)

This questionnaire is to be completed by the DICE subject at the end of his or her final study visit. Subjects under 18 may be assisted by their parents.

subb_01

1. As a DICE study participant you were randomized to receive either an active (ie, real) inhaled steroid inhaler or a look-alike placebo (ie, inactive) inhaler. Please check the box that most closely represents your feelings about the treatment you received.

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

subb_01a

- ☐ 1 Placebo
- ☐ 2 Active Drug

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

Subject's Initials:

Date: __ __/__ __/__ __

subb_02 2. Please comment with respect to the taste of the treatment you received.

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

subb_03 3. Please comment with respect to the smell of the treatment you received.

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

subb_04 4. Please comment with respect to any physical sensations produced by the study treatment.

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

subb_05 5. Please comment with respect to any other observations you may have made regarding your study treatment.

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

_____

_____

_____

_____

Asthma Clinical Research Network
NIH/NHLBI

DICE

SUBJECT OVERNIGHT CHECKLIST
Visits 3 through 7

Subject ID: 6 ___ ___ ___ ___
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
	sbl_01		1. Admit subject to DICE overnight visit.	
1830	sbl_02		2. Obtain urine sample from female subjects for pregnancy test. Collect <u>complete</u> sample in a container separate from the subject's 8 AM - 8 PM collection bottle. Take a small amount of this sample to perform pregnancy test and pour remaining urine into the subject's 8 AM - 8 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 ❑9 N/A sbl_02r Subject's Initials: Date:__ __/ __ __/ __ __
1945	sbl_03		3. Place 18 g. or 20 g. IV catheter for blood draws.	
	sbl_04		4. 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).	
2000	sbl_05		5. Subject to void to complete 8 AM - 8 PM urine collection. Record total volume, then start 8 PM - 8AM urine collection. Refrigerate urine during collection process or put on ice. Do not allow ice to melt.	sbl_05r ___ ml ❑1 Check if sample not collected prior to visit. sbl_05r1
			5a. Indicate the status of the urine at the time of receipt.	❑1 Cold ❑2 Warm sbl_05ar
	sbl_06		6. Observe subject's PM scheduled inhaled steroid dose (subject's scheduled inhaler). Have subject record puffs on Diary Card (DIARY).	
	sbl_07		7. 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.	
	sbl_08		8. Have subject complete nighttime evaluation portion of diary card (DIARY).	

SUBJECT OVERNIGHT CHECKLIST

Subject ID: 6 ___ ___ ___ ___

Visit Number: ___

PROTOCOL TIME	ACTUAL TIME	INITIALS	VISIT CHECKLIST	RESULTS
2100	sbl_09		9. Blood draw for hourly cortisol.	
2200	sbl_10		10. Blood draw for hourly cortisol.	
2300	sbl_11		11. Blood draw for hourly cortisol.	
	sbl_12		12. Lights out. 	
2400	sbl_13		13. Blood draw for hourly cortisol.	
0100	sbl_14		14. Blood draw for hourly cortisol.	
0200	sbl_15		15. Blood draw for hourly cortisol.	
0300	sbl_16		16. Blood draw for hourly cortisol.	
0400	sbl_17		17. Blood draw for hourly cortisol.	
0500	sbl_18		18. Blood draw for hourly cortisol.	
0600	sbl_19		19. Blood draw for hourly cortisol.	
0700	sbl_20		20. Blood draw for hourly cortisol.	
0800	sbl_21		21. Blood draw for hourly cortisol.	
	sbl_22		22. Remove catheter.	
	sbl_23		23. Subject to void to close 8 PM - 8 AM urine collection. Record total volume. Refrigerate urine or put on ice. Do not allow ice to melt.	sbl_23r ___ ___ ___ ___ ml
			23a. If subject collected ONLY 24 hour urine sample, record the total volume. Otherwise, leave this field blank.	sbl_23ar ___ ___ ___ ___ ___ ml
	sbl_24		24. Complete the Spirometry Testing Checklist (SPICHECK).	
	sbl_25		25. Spirometry (3 efforts standing) using spirometer. Record the best of 3 efforts.	PEFR sbl_25r1 ___ L/S FEV_1 sbl_25r2 ___ L TECH ID: sbl_25r3 ___ ___
	sbl_26		26. Discharge subject to ACRN personnel for visit completion.	

TERMINATION OF STUDY PARTICIPATION

Subject ID: 6 ___ ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Current Date: ___ ___ / ___ ___ / ___ ___ (month / day / year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Please indicate the reason for termination of study participation.

term_01 1. ***(DICE Visit 7 Only)***
Has the subject completed the study? ❑1 Yes ❑0 No
➜ ***If YES, skip to the SIGNATURES section on page 2.***

term_02 2. Is the subject withdrawing from the study due to pregnancy? ❑1 Yes ❑0 No

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

term_03 3. ***(Visit 1 and Visit 2 Only***)
During the run-in week, has the subject experienced a significant asthma exacerbation as defined in the protocol? ❑1 Yes ❑0 No

term_04 4. ***(Visit 1 and Visit 2 Only***)
Has the subject been deemed ineligible according to any eligibility criteria **other than** a significant exacerbation? ❑1 Yes ❑0 No

term_05 5. Has the subject withdrawn consent? ❑1 Yes ❑0 No

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

term_05a
- ❑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 other _____

term_06 6. Has the subject been lost to follow-up? ❑1 Yes ❑0 No

term_07 7. 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).***

term_08 8. ***(DICE Visits 3-7 Only)***

Did the subject fail to comply with protocol procedures as indicated on the COMPLY checklist? ❑1 Yes ❑0 No

term_09 9. ***(DICE Visits 2-6 Only)***

Did the subject achieve DICE dropout status between visits to the clinical center? ❑1 Yes ❑0 No

If ***YES***, describe reason _____

SIGNATURES

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

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

_____ ___ ___/___ ___/___ ___

Clinic Coordinator Signature — month day year

_____ ___ ___/___ ___/___ ___

Principal Investigator Signature — month day year