2.3 Additional Materials 2. General Forms Subject Packet

GENERAL FORMS 02JUL2013 Page 3

		Note	change 17OCT2012	Change 02JAN2012	Change 02JUL2013
1	Unenrolled Subject Tracking Form 21JUN2012				
	~~Adverse Event Report Form 11APR2012~~				
2	Adverse Event Report Form 24DEC2012			Grade 2 event defintion changed	
3	BMI Table Metrics System				
4	Ultra Sound Maintenance Tracking Form 31JAN2012				
	~~PES Filters Shipping Log (example) 22June2012~~				
5	PES Filters Chain of Custody (shipping) Log 02JUL2013				New document from RTI with columns for Temp and RH
6	Spirometry -NHANES III FEV1 reference values accessed 12 15 11				
7	Protocol Deviation Form 01OCT2012		NEW		
8	Subject Withdrawal Form 01OCT2012		NEW		
9	AssayGateService Order Form 19DEC2012			NEW	

MOSES Study
Unenrolled Subject Tracking Form
This form is to be used for subjects NOT receiving a Study ID number.

Site: ☐ UCSF ☐ UR ☐ UNC

Date	Disposition	Disposition and Comments **Enter a disposition from list below.** **<u>If INEL</u>, enter question # subject screened out on the Initial Phone Screen.** **<u>If OTH</u> - enter any pertinent additional info.**	DC Inits

Dispositions
NOCON = Not able to contact
NOINT = Not Interested
INEL = Ineligible at Initial Phone Screen
NOSHO = Scheduled for screen but no show
OTH = Other

Directions – At the end of every calendar quarter <u>or</u> when page is full, scan and email to MOSES@NERIScience.com.

MOSES Study
Adverse Event Report Form

A1. Subject ID Label
A2. Date site became aware of the AE: __ __ - __ __ __ - __ __ __ __

General Adverse Event Information			
B1.	Is this an initial or follow-up adverse event report?	☐ Initial ☐ Follow Up	
B2.	AE Number (Populated from ADEPT)	__ __ __	
B3.	What is the adverse event term? USE MEDDRA TO POPULATE _____ _____ _____ _____ _____		
B4.	What is the date the adverse event started?	__ __ - __ __ __ - __ __ __ __	
B5.	Time when the adverse event started	__ __ - __ __	
B6.	Is the adverse event still ongoing?	☐ Yes ☐ No	
B7.	What date did the adverse event end?	__ __ - __ __ __ - __ __ __ __	
B8.	At what time did the adverse event end?	__ __ - __ __	
B9.	Enter descriptive narrative: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____		

MOSES Study
Adverse Event Report Form

A1. Subject ID Label
A2. Date site became aware of the AE: __ __ - __ __ __ - __ __ __ __

Adverse Event Severity and Associations		
C1.	What was the severity of the adverse event? ☐ Mild (Grade 1) - transient mild discomfort; no limitation activity; no medical intervention or therapy required. ☐ Moderate (Grade 2) - mild to moderate limitation in activity, some assistance may be needed; minimal noninvasive intervention or therapy (such as over-the-counter medication, application of ice, etc.) is allowed. ☐ Severe (Grade 3) - marked limitation in activity; some assistance required; medical intervention or therapy required, hospitalization possible. ☐ Life threatening (Grade 4) - extreme limitation in activity, significant assistance required; significant medical intervention or therapy required; hospitalization probable.	
C2.	What was the relationship between the adverse event and the study treatment(s)	☐ Definitely related ☐ Probably related ☐ Possibly related ☐ Not related
C3.	Did the adverse event result in hospitalization?	☐ Yes ☐ No
C4.	Did the adverse event result in death?	☐ Yes ☐ No
AE Actions and Outcomes		
D1.	What action was taken with study treatment?	☐ Study treatment/procedure stopped ☐ Study procedure/treatment temporarily stopped and restarted ☐ No action taken ☐ Other
D2.	What other action was taken in response to this adverse event? _____ _____ _____	
D3.	What was the outcome of this adverse event?	☐ Recovered/resolved without sequelae ☐ Recovering/resolving ☐ Not recovered/not resolved ☐ Recovered/resolved with sequelae ☐ Fatal ☐ Unknown
D4.	Did the adverse event cause the subject to be discontinued from the study?	☐ Yes ☐ No

BMI Table Metric System

	140 cm	145 cm	150 cm	155 cm	160 cm	165 cm	170 cm	175 cm
42 kg	21.4	20	18.7	17.5	16.4	15.4	14.5	13.7
45 kg	23	21.4	20	18.7	17.6	16.5	15.6	14.7
48 kg	24.5	22.8	21.3	20	18.8	17.6	16.6	15.7
51 kg	26	24.3	22.7	21.2	19.9	18.7	17.6	16.7
54 kg	27.6	25.7	24	22.5	21.1	19.8	18.7	17.6
57 kg	29.1	27.1	25.3	23.7	22.3	20.9	19.7	18.6
60 kg	30.6	28.5	26.7	25	23.4	22	20.8	19.6
63 kg	32.1	30	28	26.2	24.6	23.1	21.8	20.6
66 kg	33.7	31.4	29.3	27.5	25.8	24.2	22.8	21.6
69 kg	35.2	32.8	30.7	28.7	27	25.3	23.9	22.5
72 kg	36.7	34.2	32	30	28.1	26.4	24.9	23.5
75 kg	38.3	35.7	33.3	31.2	29.3	27.5	26	24.5
78 kg	39.8	37.1	34.7	32.5	30.5	28.7	27	25.5
81 kg	41.3	38.5	36	33.7	31.6	29.8	28	26.4
84 kg	42.9	40	37.3	35	32.8	30.9	29.1	27.4
87 kg	44.4	41.4	38.7	36.2	34	32	30.1	28.4
90 kg	45.9	42.8	40	37.5	35.2	33.1	31.1	29.4
93 kg	47.4	44.2	41.3	38.7	36.3	34.2	32.2	30.4
96 kg	49	45.7	42.7	40	37.5	35.3	33.2	31.3
99 kg	50.5	47.1	44	41.2	38.7	36.4	34.3	32.3
102 kg	52	48.5	45.3	42.5	39.8	37.5	35.3	33.3
105 kg	53.6	49.9	46.7	43.7	41	38.6	36.3	34.3
108 kg	55.1	51.4	48	45	42.2	39.7	37.4	35.3
111 kg	56.6	52.8	49.3	46.2	43.4	40.8	38.4	36.2
114 kg	58.2	54.2	50.7	47.5	44.5	41.9	39.4	37.2
117 kg	59.7	55.6	52	48.7	45.7	43	40.5	38.2
120 kg	61.2	57.1	53.3	49.9	46.9	44.1	41.5	39.2
123 kg	62.8	58.5	54.7	51.2	48	45.2	42.6	40.2
126 kg	64.3	59.9	56	52.4	49.2	46.3	43.6	41.1

180 cm	185 cm	190 cm	195 cm	200 cm	205 cm
13	12.3	11.6	11	10.5	10
13.9	13.1	12.5	11.8	11.3	10.7
14.8	14	13.3	12.6	12	11.4
15.7	14.9	14.1	13.4	12.8	12.1
16.7	15.8	15	14.2	13.5	12.8
17.6	16.7	15.8	15	14.3	13.6
18.5	17.5	16.6	15.8	15	14.3
19.4	18.4	17.5	16.6	15.8	15
20.4	19.3	18.3	17.4	16.5	15.7
21.3	20.2	19.1	18.1	17.3	16.4
22.2	21	19.9	18.9	18	17.1
23.1	21.9	20.8	19.7	18.8	17.8
24.1	22.8	21.6	20.5	19.5	18.6
25	23.7	22.4	21.3	20.3	19.3
25.9	24.5	23.3	22.1	21	20
26.9	25.4	24.1	22.9	21.8	20.7
27.8	26.3	24.9	23.7	22.5	21.4
28.7	27.2	25.8	24.5	23.3	22.1
29.6	28	26.6	25.2	24	22.8
30.6	28.9	27.4	26	24.8	23.6
31.5	29.8	28.3	26.8	25.5	24.3
32.4	30.7	29.1	27.6	26.3	25
33.3	31.6	29.9	28.4	27	25.7
34.3	32.4	30.7	29.2	27.8	26.4
35.2	33.3	31.6	30	28.5	27.1
36.1	34.2	32.4	30.8	29.3	27.8
37	35.1	33.2	31.6	30	28.6
38	35.9	34.1	32.3	30.8	29.3
38.9	36.8	34.9	33.1	31.5	30

MOSES Study

Ultra Sound Maintenance Tracking Form

Date	Performed by	Condition / Comments
__ __ - __ __ __ - __ __ __ __		
__ __ - __ __ __ - __ __ __ __		
__ __ - __ __ __ - __ __ __ __		
__ __ - __ __ __ - __ __ __ __		
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__ __ - __ __ __ - __ __ __ __		
__ __ - __ __ __ - __ __ __ __		
__ __ - __ __ __ - __ __ __ __		

RTI Chain of Custody Form

3040 East Cornwallis Road, Durham NC
Building 6

Project Name: MOSES

Date of form: July 2, 2013

Person/Company/Client Name:
Address:
Phone:
E-mail:
Date Shipped:

For RTI Use Only
Date Received at RTI:
Person Logging in Samples:

						Place 'X' in cell for each species needed							
Sample ID	Use As Blank	Start Date	Start Time	Stop Date	Stop Time	NO2	NOx (+ NO2)	NH3	SO2	O3	Average Temperature (°C)	Average Relative Humidity (%)	Comments

RTI Chain of Custody Form

3040 East Cornwallis Road, Durham NC
Building 6

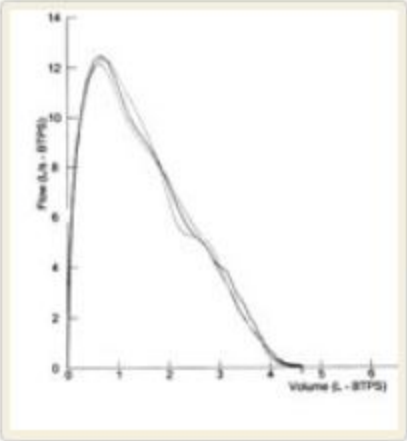
Sample ID	Use As Blank	Start Date	Start Time	Stop Date	Stop Time	NO2	NOx (+ NO2)	NH3	SO2	O3	Average Temperature (°C)	Average Relative Humidity (%)	Comments

SPIROMETRY

Spirometry Training Program

NHANES III Reference Values

These tables are provided for use in practicum sessions for students who wish to compare their own measured spirometry values to NHANES III reference values. The prediction tables are available in PDF format and contain reference values for the following variables: FEV1, FEV6, FVC, PEF, FEF25-75, FEV1/FVC, and FEV6/FVC. Within each gender (men and women), you may choose from three ethnicities: African-American, Caucasian, and Mexican-American. Within each gender/ethnicity category, you must choose a specific age group to use for comparison.



Reference Values for Men

Ethnicity	Age Group (years)			
African-American	16 - 19	20 - 40	41 - 60	61 - 80
Caucasian	16 - 19	20 - 40	41 - 60	61 - 80
Mexican-American	16 - 19	20 - 40	41 - 60	61 - 80

Reference Values for Women

Ethnicity	Age Group (years)		
African-American	18 - 40	41 - 60	61 - 80
Caucasian	18 - 40	41 - 60	61 - 80
Mexican-American	18 - 40	41 - 60	61 - 80

On this Page

- Reference Values for Men
- Reference Values for Women

Contact Us:

National Institute for Occupational Safety and Health (NIOSH)

Centers for Disease Control and Prevention

800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348

New Hours of Operation
8am-8pm ET/Monday-Friday
Closed Holidays

cdcinfo@cdc.gov

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Content source: National Institute for Occupational Safety and Health Division of Respiratory Disease Studies

File Formats Help:

How do I view different file formats (PDF, DOC, PPT, MPEG) on this site? »

MOSES Study

Protocol Deviation Form

A1. Subject ID Label: A2. Today's Date: __ __ - __ __ __ - __ __ __ __

INSTRUCTIONS: This form should be completed if a deviation from the protocol took place. It should be entered into the ADEPT system in the Administrative event.

A3. Visit at which the PD occurred:

□SCRN □PRE1 □PRE2 □PRE3

□TRAIN □EXP1 □EXP2 □EXP3

□ POS1 □ POS2 □ POS3

A4. Date of PD __ __ - __ __ __ - __ __ __ __

A5. Name of person completing form _____ ___ ___ ___

PRINT FULL NAME INITIALS

B1. Deviation – Describe: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

B2. Type of Deviation (check all that apply)

□ Study procedures and/or assessments performed prior to obtaining or reaffirming written informed consent

□ Obtaining informed consent with outdated / expired consent document

□ Enrollment of a subject who did not meet all inclusion/exclusion criteria

□ Performing study procedure not approved by the IRB

□ Implementation of recruitment procedures without IRB approval

□ Enrolling a subject after IRB approval expired

□ Failure to submit continuing review application to IRB prior to expiration

□ Failure to report serious adverse event to the IRB and/or sponsor

□ Failure to follow randomized ozone dosing amount as outlined in protocol

□ Failure to perform study procedure as outlined in protocol

□ Other

This form will be entered into the database

MOSES Study

Subject Withdrawal Form

A1. Subject ID Label: A2. Today's Date: __ __ - __ __ __ - __ __ __ __

INSTRUCTIONS: This form should be completed if a subject will not be completing remaining study visits. It should be entered into the ADEPT system in the BASELINE event.

A2. Last visit at which subject completed <u>any</u> study measures

□SCRN □PRE1 □PRE2 □PRE3

□TRAIN □EXP1 □EXP2 □EXP3

□ POS1 □ POS2 □ POS3

A3. Date subject last seen for study __ __ - __ __ __ - __ __ __ __

A4. Name of person completing form _____ ___ ___ ___

PRINT FULL NAME INITIALS

B1. Date of study withdrawal __ __ - __ __ __ - __ __ __ __

B2. **<u>Primary</u>** reason for withdrawal from study

TAKING TOO MUCH TIME	1
TRAVEL DISTANCE TO/FROM CENTER	2
DOES NOT WANT EXPOSURE	3
SUBJECT INJURED	4 (Complete AE form)
LOST TO FOLLOW UP	5
OTHER	99

Specify other reason _____

_____

_____

This form will be entered into the database

AssayGate Service Order Form – MOSES STUDY

AssayGate, Inc. is pleased to offer assay services for protein biomarkers. Please complete the following information and return this form with your samples. Samples should be shipped on dry ice Monday thru Thursday via FedEx priority or other overnight delivery services to:

AssayGate, Inc.
Attn: Bioassay Services
9607 Dr. Perry Road, #101
Ijamsville, MD 21754

Phone: (301) 874-0417
Fax: (301) 560-8288
www.assaygate.com

Note: The turnaround time for service is approximately eight working days. The service report is for research use only. **WE DO NOT SERVICE INFECTIOUS SAMPLES!**

Quotation number:AGQ-9639-I (of December 23, 2011)

Account number: 4902-4-RFA-10-1

	Send results (by e-mai) to	**Billing information**	
Name	Kathryn Odian	Method of Payment	Account #: 4902-4-RFA-10-1 Send invoice by –e-mail. Assay services will be charged to this account. Payment check will be mailed within 30 days from invoice date.
Company/ Org.	New England Research Institute, Inc.	Contact Name	Maria Costantini Health Effects Institute
Address	9 Galen Street	Billing Address	101 Federal Street, Suite 500
City	Watertown	City	Boston
State, ZIP	MA 02472	State, ZIP	MA 02090
Phone	617-972-3360	Phone	617-488-2302
Fax	617.926.8246	Fax	617-488-2335
E-mail	MOSES@neriscience.com	E-mail	mcostantini@healtheffects.org

Number of Samples _____ Sample Volume __1000___ μL (minimum volume listed on our quotation)

Sample Type: Plasma **Species:** Human

Analytes: CRP, IL-6, 8-isoprostane, nitrotyrosine, fibrinogen, endothelin-1, P-selectin, von Willebrand factor, Clara Cell protein 16

Order date: _____ **Signature:** _____

NOTE: Contact Maria Costantini at HEI before doing the analyses.

For AssayGate Inc. staff only:

Date Received:_____ By:_____ Shipping Conditions: ☐ Acceptable ☐ Unacceptable
Test Completed:_____ Customer ID:_____ Report Emailed/FAX'd on: _____
By: _____