2.1 Additional Materials 2. Screening and Training Subject Packet

PHONE SCREENING	Note	Change 10SEP2102	Change 17OCT2012	Change 02JAN2013	Change 225MAR2013
1 Locator Information 30MAR2011					
2 Initial Phone Screen Questionnaire UR (PAGE 1 ONLY) 04APR2012					
3 Initial Phone Screen Questionnaire UCSF and UNC (PAGE 1 ONLY) 24APR2012					
~~Initial Phone Screen Questionnaire 04APR2012~~ ~~Initial Phone Screen Questionnaire 10OCT2012~~ 4 Initial Phone Screen Questionnaire 10DEC2012			deleted osteoporosis drugs	removed shading in Yes box for thyroid disease	
~~Medication Lists for phone screen 01FEB2012~~ ~~Medication List for Phone Screen 10OCT2012~~ ~~Medication List for Phone Screen 25MAR2013~~ Medication List for Phone Screen 11JUN2013 5			deleted some medications		Deleted levothyroxine from list of exclusionary drugs
6 ~~Inclusion Exclusion Checklist 24APR2012~~ Inclusion Exclusion Checklist 12JUL2013	complete as you screen and train subject				
SCREENING VISIT					
~~Screening Visit Check List 24MAY2012~~					
1 Screening Visit Check List 10SEP2012		added written documentation that cardiologist reviewed the ECG			
2 Health and Home Screening Questionnaire 01MAR2012					
3 Medication List for Health and Home Questionnaire 08MAR2012					
~~Vital Signs and Blood Pressure –Screening Training Data Form 04MAY2012~~ 4 Vital Signs and Blood Pressure –Screening Training Data Form 16OCT2013					
5 Spirometry Data Form 16APR2012					
6 LabCorp Shipment Alert Form 07MAY2012					
TRAINING VISIT					
1 Training Visit Check List 24MAY2012					
~~Vital Signs and Blood Pressure – Screening Training Data Form 04MAY2012~~ Vital Signs and Blood Pressure –Screening Training Data Form 16OCT2013 2					
~~Training Exercise Data Form 08MAR2012~~ 3 Training Exercise Data Form 10OCT2012			edits of column headers		

4	PES Tracking Form 04MAY2012	sample, fill out in ADEPT
5	Subject Instructions for use of PES 02MAR2012	
6	Subject Instructions Before Exposure Visit 25MAY2012	
7	MOSES Activity Diary 20APR2012	
8	Subject Instruction for Filling Out the Activity Diary 23MAR2012	

Affix ID label here

Locator Information

Date Last Updated: ___ ___ / ___ ___ / ___ ___ ___ ___

Name: First _____Last _____

Street 1:_____

Street 2:_____

City: _____

State: ___ ___ ZIP: ___ ___ ___ ___ ___ - ___ ___ ___ ___

Home: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Work: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Cell: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Email: _____

Preferred method of contact: _____

Best time to contact you: _____

Emergency Contact Info:

Name: First _____Last _____

Street 1:_____

Street 2:_____

City: _____

State: ___ ___ ZIP: ___ ___ ___ ___ ___ - ___ ___ ___ ___

Phone: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Relationship: _____

Physician: _____

Physician Phone: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Do you have medical insurance? Yes No

MOSES Study
Initial Phone Screen Questionnaire UR (PAGE 1 ONLY)

A1. Subject Initials: ___ ___ ___

A3. Date of phone screen: __ __ - __ __ __ - __ __ __ __

A4. Initial of person screening ___ ___ ___

Phone script:

"I would like to describe a research study that Dr. Mark Frampton from the University of Rochester is conducting.
Would you like to hear more about this study?

The purpose of this research study is to see if exposure to ozone, a common air pollutant, increases the risk of developing cardiovascular disease. We estimate that about 30 subjects at the University of Rochester will complete this study.
If you decide to be in this study, we will ask you to come to the Clinical Research Center at the University of Rochester for a screening visit to see if you are eligible to be in the study. If you are eligible, you will have a training visit to test your ability to ride an exercise bike. Each of these visits will last about three hours. If you qualify, we will ask you to come back to the Clinical Research Center for three separate exposure visits. Each exposure visit is spread over a three day period, and there will be at least two weeks between each exposure visit.

If you are interested in this study, I would like to ask you some general screening questions. Are you willing to participate in this 15-20 minute phone interview to determine if you are eligible to schedule a screening visit?"
If subject does not have time "If not now, would you be available to participate in the phone screen at a more convenient time?" Phone # (__ __ __) __ __ __ - __ __ __ __

Instructions to screener: If a subject answers a question such that it excludes him or her from participation (bold answer in gray cell), stop the screening session and proceed to the Subject does not qualify - Thank You text at the end of this questionnaire.

MOSES Study
Initial Phone Screen Questionnaire UCSF and UNC (PAGE 1 ONLY)

A1. Subject Initials: ___ ___ ___

A3. Date of phone screen: __ __ / __ __ / __ __ __ __

A4. Initial of person screening ___ ___ ___

Phone script:

"The purpose of this research study is to see if we can find subtle changes in heart function or lung function in healthy older people after an exposure to ozone, which is a component of air pollution. Each study volunteer will undergo three exposures, one will be to filtered clean air, one will be to 70ppb (parts per billion) of ozone, and the other will be to 120ppb of ozone. These are levels of ozone which you could possibly be exposed to in real life. There will be a screening visit, and if admitted to the study a training day visit, each lasting about 3 hours. During these visits, we will make some health measurements for the study, and if you qualify, we will ask you to come back for the exposure sessions. We will ask you to abstain from some over the counter medications for one week before each exposure session and to wear a small personal ozone sampler for 3 days before each exposure session.

An exposure session will begin with you coming to the research unit on the day before the exposure. You will be provided with a low fat diet. You will spend the night in the hotel /hospital research unit (at no cost to you). You will be required to abstain from caffeinated and alcoholic beverages during your exposure visits.

On the day of exposure you will come back to the research lab and after breakfast at the research unit we will begin the study procedures. You will be in the exposure chamber for about 3 hours, and you will be intermittently resting and walking briskly on a treadmill/bicycle for 15 min. Then you will spend the rest of the day with us performing post-exposure tests. We expect to complete all the study procedures and discharge you to home about 4:00-4:30 that afternoon. You will be with us for about 3 hours on the last day of the session starting at 8:00 am.

We will ask you to wait at least 2 weeks between each exposure session. Each exposure session is identical in how much time and effort you will spend.

If you are interested in this study, I would like to ask you some general screening questions. If you qualify to come in for the screening based on this phone call and if you are willing to participate in the exposures we will schedule you for a screening visit. At that time you will be given more details of the study and sign a consent form. Are you willing to participate in this 15-20 min phone screen to determine if you are eligible for the study?"

If subject does not have time "If not now, would you be available to participate in the phone screen at a more convenient time?" Phone # (__ __ __) __ __ __ - __ __ __ __

MOSES Study
Initial Phone Screen Questionnaire

A1. Subject Initials: ___ ___ ___

A3. Date of phone screen: __ __ - __ __ __ - __ __ __ __

A4. Initial of person screening ___ ___ ___

DIRECTION TO SITE

INSERT THE PROPER FIRST PAGE HERE

MOSES Study
Initial Phone Screen Questionnaire

General criteria/conditions		
Shaded areas in Y/N boxes indicate exclusion criteria – If an exclusion criteria is identified, read 'Subject does not qualify' text on last page.		
B1. Gender	Male	Female
B2. Are you at least 55 and no more than 70 years of age?	Yes	**No**
B3.a If female – Are you currently pregnant?	**Yes**	No
B3.b If female – Are you currently nursing?	**Yes**	No
B4. Do you speak English?	Yes	**No**
B5. What is your estimated height:_____in weight:_____lbs ***Screener:*** *Use the tables provided to find/estimate BMI* B5a. ***Screener:*** *Is BMI between 16 and 37?*	Yes	**No**
B6. Do you have any orthopedic limitations, physical or health conditions that would prevent you from repeatedly walking for 15 min on a treadmill, or riding a bike without rest or shortness of breath?	**Yes**	No
B7. Have you smoked anything (tobacco, marijuana, hookah, recreational substances) in the **past 5 years**?	**Yes**	No
B8. Have you **ever** smoked anything (tobacco, marijuana, hookah, recreational substances)? (If Subject answers NO, go to B9)	Yes	No
B8a. If **YES:** If tobacco, # packs/day_____ for # years _____ = _____ pack years (< 10 p.y.) If marijuana, # joints/day_____ for # years _____ = _____ joint years (<1 joint-year) ***Screener:*** *Add the number of tobacco pack years and marijuana joint years*: _____ ***Is this number less than 10?***	Yes	**No**
B9. Are you living with a smoker who regularly smokes (any substance) ***inside*** the house?	**Yes**	No
B10. Do you drink alcohol? (If subject answers no, go to B10b)	Yes	No
B10a. If **YES**: Do you drink more than 3 drinks (beer, wine or liquor) per day?	**Yes**	No
B10b. Can you abstain from drinking alcohol for 3 days?	Yes	**No**
B11. I am going to list some practices. Please listen to all of them. When I'm finished tell me if you have done any of them in the past 6 months or are currently doing them. I don't need to know exactly which ones: crack cocaine inhaled or used intravenously (i.v.), other illicit drugs Do you do or have you done any of the above mentioned activities in the past 6 months?	**Yes**	No

B12. I am going to list a few medication types. Please listen to all of them and when I'm finished tell me if you are currently using any of them. I don't need to know exactly which ones:

Prednisone	Systemic Estrogen therapy	Urology agents
Cholesterol medication (statins)	Tamoxifen	Chronic pain drugs
Beta-blockers	Arthritis drugs	Heart drugs
Anticoagulants (Blood thinners)	Neurological agents (see Medication List for specific agents)	

B12a. Are you using any of the above mentioned medications? **Yes** No

B13. Are you taking any prescription medication which I have not mentioned? Yes No

Medication	Dose	Frequency	For how long

(Use back of page for additional medications)

B14. Have you taken any over the counter medications – For instance, things like Anti Inflammatories, Aspirin, antihistamines, nasal sprays, decongestants, vitamins or supplements, fish oil, arginine, herbal remedies over the past month? Yes No

If YES: (Fill in table, put additional ones on back of this page)

Medication	Dose	Frequency	For how long

B14a. Can you abstain from taking this (these) medication(s) 1 week at a time for three times if admitted to the study? Yes **No**

B15. Are you exposed frequently to noxious fumes, excessive dust, chemical vapors, or high air pollution at work? At home? When engaged in a hobby? **Yes** No

Do you have or have you been diagnosed with any of the following medical conditions?		
C1. Asthma	**Yes**	No
C2. Allergies, allergic rhinitis that you regularly take prescription(s) (e.g., antihistamines, systemic steroids) to treat it?	**Yes**	No
C3. Chronic Bronchitis	**Yes**	No
C4. Chronic cough	**Yes**	No
C5. Emphysema	**Yes**	No
C6. Chronic obstructive lung disease	**Yes**	No
C7. Breathing problems for which you were hospitalized	**Yes**	No
C8. Bleeding blood disorder, anemia	**Yes**	No
C9. Gastro-intestinal problems (ulcers, bleeding from the intestines / stomach)	**Yes**	No
C10. Diabetes	**Yes**	No
C11. Thyroid disease	**Yes**	No
C12. Glaucoma treated with medication or other vision problems	**Yes**	No
C13. History of cardiovascular disease (e.g., exertional chest pain, chest pain typical of angina)	**Yes**	No
C14. Heart attack, coronary bypass surgery, cardiac stent(s)	**Yes**	No
C15. Heart rhythm problems (ventricular tachycardia, irregular heart beat)	**Yes**	No
C16. Pacemaker, internal cardiac defibrillator	**Yes**	No
C17. High blood pressure C17a. If YES, what anti hypertension medication(s) are you taking? _____ Screener: check the list of hypertension drugs not allowed Is the subject taking any medications on the list of medications not allowed?	Yes **Yes**	No No
C18. Stroke, mini stroke (TIA)	**Yes**	No
C19. Neurological disorders	**Yes**	No
C20. Mental illness	Yes	No
C21. Chronic kidney disease, kidney dialysis	**Yes**	No
C22. Liver disease	**Yes**	No
C23. Skin sensitivity, disease	**Yes**	No
C24. Cancer	Yes	No
C25. I don't need to know exactly which one, but have you ever tested positive for a disease that could affect your immune system (such as HIV, lymphoma, or leukemia?)	**Yes**	No

C26. Are you currently: employed part time_____ full time_____ not currently working_____ If employed Full Time – Probe for availability	Yes	No
C27. Are you available for 3 sessions of 3 consecutive days each separated by at least 2 weeks?	Yes	**No**
C28. Are you currently participating in another research study? If yes – What type of study (Probe for impact)	Yes	No

Subject does not qualify:
If subject **does not qualify** for the study read the following text, then record this disposition on the Ineligible Count tracking Form and then shred this document.

Thank you for taking time to answer these questions. You have been very helpful. However the study design is based on specific criteria and based on the answers you have provided, you are not eligible to participate. Thank you.

Subject is not disqualified, but clarification needed:
Read the following text – Thank you for taking time to answer these questions. Before determining your eligibility to come in for the screening visit, I will need to consult with the investigator on this study. Is there a good day and time to call you back?

Call back Date __ __ - __ __ __ - __ __ __ __ Time __ __ __ __

Phone Number to call back. (__ __ __) __ __ __ - __ __ __ __

Subject qualifies for In-Person Screen:
Read the following text – Thank you for taking time to answer these questions. Based on your responses, you are eligible to come to the Clinical Research Center and participate in the screening visit. This visit will last approximately three hours.

May I book an appointment for you to come in?

Schedule screening visit

Appointment Date __ __ - __ __ __ - __ __ __ __ Time __ __ __ __

Data Collector signature _____

Medication Lists for Phone Screen

The following is a list of prescription medications that may be mentioned by subjects during the phone screen when asked at question **B13**. The use of any of these medications **would exclude** the subject.

Acebutolol	Fexofenadine	Paroxetine
Advicor	Fluvastatin	Penbutolol
Albuterol	Fragmin	Pindolol
Altocor	Heparin	Pravachol
Amitriptyline	Inderal	Pravastatin
Amlodipine	Kerlone	Prednisone
Atenolol	Labetalol	Propanolol
Atorvastatin	~~Lansoprazole~~ (proton pump inhibitor)	Propoxyphene
Atromid-S	Lescol	Questran
Betaxolol	Levatol	Quinapril
Bisoprolol	~~Levothyroxine~~	~~Rofecoxib~~ (not on the market)
Blocadren	Lipitor	Rosuvastatin
Caduet	Lisinopril	Sectral
Carvedilol	Locholest	Sertraline
Celecoxib	Lopressor	Simvastatin
~~Cephalexin~~ (antibiotic)	Lovastatin	Slo-Niacin
Cholestyramine	Lovenox	Tenormin
Citalopram	Metformin	Timolol
Clofibrate	Metoprolol	Toprol-XL
Coreg	Mevacor	Trandate
Corgard	Nadolol	Tricor
Coumadin	Niacin	Visken
Crestor	Niacor	Vytorin
~~Esomeprazole~~ (proton pump inhibitor)	Niaspan ER	Warfarin
Estrogens_Conj	Nicobid Tempules	Zebeta
Estrogens_Ester	Nicolar	Zocor
Ezetimibe	Norelgestromin	
Fenofibrate	Normodyne	

~~The following is a list of over the counter medications, Anti Inflammatory, Aspirin, Antihistamines, Nasal sprays, Decongestants that may be mentioned by subjects during the phone screen when asked at question **B14**. The use of any of these medications **would not exclude** the subject.~~

~~Acetaminophen~~	~~Cetirizine~~	~~Naproxen~~
~~Advil~~	~~Chlortrimetron~~	~~Neo-Synephrine~~
~~Afrin~~	~~Claritin~~	~~NasalCrom~~
~~Alavert~~	~~Dimetap~~	~~NyQuil~~
~~Aleve~~	~~Dramamine~~	~~Nytol~~
~~Alka-Seltzer Plus~~	~~Flonase~~	~~Panadol~~
~~Aspercreme~~	~~Ibuprofen~~	~~Sominex~~
~~Aspirin~~	~~Ketoprophen~~	~~Sportscreme~~
~~Benadryl~~	~~Loratadine~~	~~Tylenol~~
~~Bengay~~	~~Motrin~~	~~Zyrtec~~

~~The following is a list of diuretics to be read to subjects during the phone screen when asked at question **C17a**. The use of any of these medications **would not** exclude the subject.~~

~~Acetazolamide~~	~~Edecrin~~	~~Metolazone~~
~~Aldactone~~	~~Esidrix~~	~~Microzide~~
~~Amiloride hydrochloride~~	~~Ethacrynic acid~~	~~Midamor~~
~~Bumetanide~~	~~Furosemide~~	~~Mykrox~~
~~Bumex~~	~~Hydrochlorothiazide~~	~~Spironolactone~~
~~Chlorthalidone~~	~~HydroDiuril~~	~~Thalitone~~
~~Demadex~~	~~Indapamide~~	~~Torsemide~~
~~Diamox~~	~~Lasix~~	~~Triamterene~~
~~Dyrenium~~	~~Lozol~~	~~Zaroxolyn~~

MOSES Study

Inclusion Exclusion Checklist

AA1. Subject ID Label AA2. Date completed: __ __ - __ __ __ - __ __ __ __

Start filling out this form after Informed Consent has been signed. Continue to fill in with data obtained from the Health and Home Questionnaire (HHQ), the Screening and Training Visits and complete after all screening and training results have been obtained. Any answer in the grayed out section of this form disqualifies the subject from participation. **The checklist should be completed no later than a day before the first pre-exposure session and before a random order of exposures has been assigned. Enter this form into ADEPT within 5 business days of completing this form but prior to first exposure visit.**

	Inclusion Criteria	YES	NO
A1.	Subject agrees to avoid the following medication supplements for 1 week before each exposure - Non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen, aspirin, PED5 inhibitors such as Viagra, Cialis, Levitra, Supplemental vitamins, Antihistamines, Anti-oxidants, Fish oil, Niacin, Arginine, Over-the counter decongestants (Informed Consent)		
A2.	Subject is at least 55 and no more than 70 years of age (HHQ B1)		
A3.	Subject is non smoking (HHQ D5)		
A4.	Subject has a normal baseline 12-lead resting ECG (Screening Visit Checklist B12)		
A5.	Subject has normal spirometry (FEV_1 and FVC ≥ 75% of predicted and FEV_1/FVC ≥ 0.65) (Screening Visit Checklist B13)		
A6.	Subject has acceptable CBC and metabolic profile (Screening Visit Lab Results).		
A7.	Subject has an absence of significant ST depression while performing the 15-minute required level of exercise targeted for the exposure period (Training Visit Check List)		
A8.	Subject has the ability to complete the training exercise regimen chosen to induce an expired minute ventilation rate of 15 to 17 L/min/m^2 BTPS without exceeding 80% of predicted maximal heart rate. (Training Visit Check List).		

	Exclusion Criteria	YES	NO
B1.	Subject is nursing (Initial Phone Screen)		
B2.	Subject is non-English speaking (Initial Phone Screen)		
B3.	Subject has tested positive for immune system disease such as HIV, Lymphoma, or Leukemia (Initial Phone Screen)		
B4.	Subject participating in another protocol that may conflict with the MOSES Protocol (Initial Phone Screen)		
B5.	Subject takes any of the following medications: prednisone, statins, beta-blockers, anticoagulants, systemic estrogen therapy, tamoxifen (Meds List from Initial Phone Screen)		
B6.	Subject unable to avoid the following medications for 1 week prior to each exposure. Non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen, aspirin, PED5 inhibitors such as Viagra, Cialis, Levitra, Supplemental vitamins, Antihistamines, Anti-oxidants, Fish oil, Niacin, Arginine, Over-the counter decongestants (Informed Consent).		
B7.	Subject living with a smoker who smokes inside the house (HHQ C3)		

Inclusion Exclusion Checklist

AA1. Subject ID Label AA2. Date completed: __ __ - __ __ __ - __ __ __ __

	Exclusion Criteria	YES	NO
B8.	Subject is exposed to high levels of vapors, dust, gases, or fumes at work (HHQ C4)		
B9.	Subject is exposed to high levels of vapors, dust, gases or fumes at home/hobby (HHQ C5)		
B10.	Subject reports current drug or alcohol abuse (HHQ D3)		
B11.	Subject has history of >10 pack year for tobacco or > 1 joint year for marijuana (HHQ D4)		
B12.	Subject smoked tobacco or marijuana during the last five years (HHQ D5)		
B13.	Subject has diabetes (HHQ E8) or other organ or system dysfunction (HHQ Medical History)		
B14.	Subject has active psychiatric disorders that would affect his/her participation (HHQ E11)		
B15.	Subject has chronic cardiovascular (such as ischemic heart disease), respiratory (such as asthma or COPD) or cerebrovascular disease (HHQ Medical History, Sec. F)		
B16.	Subject has untreated hypertension (defined as blood pressure >140 systolic or >90 diastolic) (HHQ F6 and vital signs)		
B17.	A. Subject is hypertensive (defined as blood pressure >140 systolic or >90 diastolic) and takes anti-hypertension medications other than diuretics (HHQ and Medication list for HHQ)		
	B. Subject has a blood pressure ~~<100/60~~ <90/50 (safety criterion in SOP #2)		
B18.	Subject has atopy or allergic rhinitis requiring regular treatment with antihistamines or systemic steroids (HHQ F31 and Medication list for HHQ)		
B19.	Subject takes other medications not allowed (Medication list for HHQ)		
B20.	Subject has a positive pregnancy test (Screening Visit Check List B9)		
B21.	Subject has BMI >35 OR <18 (Vitals and BP- Screening Visit Check List B11)		
B22.	Subject has blood cotinine level >3 ng/mL (Clinical lab results Screening Visit Check List B15): level_____		

Physician Signature

I have reviewed all screening and training data for this subject and approve him/her for inclusion in the MOSES Study.

_____ _____

Signature Print Name

__ __ - __ __ __ - __ __ __ __
D D M M M Y Y Y Y

MOSES Study
Screening Visit Check List

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

		Done	Following SOP #
	Subject arrives at the clinic	☐	
B1.	Explain study to subject in detail (update contact information if needed).	☐	
B2.	All the questions by subject are adequately answered	☐	
B3.	Subject signs all copies of Informed Consent	☐	
B4.	Subject signs all copies Repository Consent for samples storage	☐	
B5.	Subject signs all copies of HIPAA Consent if applicable	☐	
B6.	Subject is provided with a signed copy of Informed, HIPAA and Repository Consent (Applicable documents)	☐	
B7.	Assign the next available Subject ID – affix label to top of page	☐	
B8.	Signed copy of Informed and Repository Consent is filed in subject's study folder	☐	
B9.	Is pregnancy test indicated (Female and < 1 year since Last Menstrual Period)? ☐Yes ☐No -- Proceed If Yes, administer pregnancy test Is test positive? ☐Yes -- Discharge subject ☐ No -- Proceed	☐	
B10.	Health and Home Questionnaire process:		
	a. Subject sits at computer and fills out the Health and Home Questionnaire	☐	
	b. Print Health and Home Questionnaire from ADEPT	☐	
	c. Review Health and Home Questionnaire with subject	☐	
	d. Ask about medication use / Record on Medication List for Health and Home Questionnaire	☐	
B11.	Measure height and weight. Record on Vital Signs and Blood Pressure – Screening Training Data Form	☐	H&W #1
B12.	Prepare subject for Vital Signs measurement. **Subject sits quietly for 5 minutes before measurements**	☐	VS/BP SCREEN TRAIN #2
B13.	Take Vital Signs and record on Vital Signs and Blood Pressure –Screening Training Data Form	☐	

MOSES Study
Screening Visit Check List

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

		Done	Following SOP #
B14.	Obtain 12-lead ECG. Physician evaluates ECG. If normal ECG, physician should sign ECG printout. Physician signed Normal ECG printout? ☐Yes ☐No If any abnormalities such as ST depression, arrhythmias, or other abnormalities, are detected, ECG is reviewed by cardiologist. In consultation with the cardiologist, the local study physician makes the decision whether the subject should be included. The cardiologist approved in writing inclusion of subject? ☐Yes ☐No	☐	12-LEAD ECG #21
B15.	Spirometry is measured. Record on Spirometry Data Form	☐	SPIR #6
B16.	Complete physical exam	☐	
	Review inclusion and exclusion criteria and complete Inclusion/Exclusion Checklist. Subject meets inclusion criteria up to this point ☐ Yes -- Proceed ☐ No -- Discharge subject	☐	
B17.	Phlebotomy (use kit from LabCorp)		PLHEB SCREEN #11 (LabCorp Manual)
	Chemistry Panel (Yellow top, 3.5 ml)	☐	
	Hematology Panel (Lavender top, 3 ml)	☐	
	Nicotine and cotinine (Lavender Top, 3 ml)	☐	
	Gene profiling (Lavender Top, 3 ml) –store on site (not part of the kit)	☐	
	Fill out Lab Corp Laboratory Test Request Form (included in the kit)	☐	
B18.	Ship blood samples to laboratory on same day using provided FedEx label Fax LabCorp Shipment Alert Form	☐ ☐	
After review of the health, tests and lab results:			
B19.	Subject meets the criteria for admittance into the study (use Inclusion/Exclusion Checklist) a. If **Yes**, schedule training visit on (date) __ __ -__ __ __ - __ __ __ __ b. If **No,** discharge subject	Yes ☐	No ☐

MOSES Study

Health and Home Screening Questionnaire

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

DEMOGRAPHICS

B1. What is your age? ___ ___ a. Gender? ☐Male ☐Female

B2. Are you…

- ☐ Hispanic/Latino/Spanish
- ☐ Not Hispanic/Latino/Spanish
- ☐ Unknown

B3. Are you… (pick all that apply)

- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ African American
- ☐ White
- ☐ Native Hawaiian / Pacific Islander
- ☐ Unknown
- ☐ Other a. Specify _____

B4. Are you currently…

- ☐ Unemployed
- ☐ Employed part-time
- ☐ Employed full-time
- ☐ Retired
- a. If employed, what is your occupation?_____

B5. What is your combined annual family income?

- ☐ Under $12,000
- ☐ $12,000 - $29,999
- ☐ $30,000 – $59,999
- ☐ $60,000 – $99,999
- ☐ over $100,000

B6. What is the highest level or degree of school you have completed?

- ☐ Elementary
- ☐ High School
- ☐ College / Tech School
- ☐ Graduate School

MOSES Study

Health and Home Screening Questionnaire

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

HOME ENVIRONMENT

C1. Do you live in….

- ☐ An apartment/condo
- ☐ A single house
- ☐ A trailer

a. What is your zip code? ___ ___ ___ ___ ___

C2. How far is your dwelling to any very busy road or highway? _____ ☐feet ☐ yards ☐ miles

C3. Are you living with a smoker who regularly smokes (any substance) ***inside*** the house?		☐ Yes	☐ No
	a. Please describe		
C4. Are you exposed frequently to noxious fumes, excessive dust, chemical vapors, or high air pollution at work?		☐ Yes	☐ No
	a. If YES, does this exposure make you cough, wheeze or be short of breath?	☐ Yes	☐ No
	ai. If ***YES***, please describe your symptoms:		
C5. Are you exposed frequently to noxious fumes, excessive dust, chemical vapors, or high air pollution outside of work, for instance at home or when engaged in a hobby?		☐ Yes	☐ No
	a. If YES, does this exposure make you cough, wheeze or be short of breath?	☐ Yes	☐ No
	ai. If ***YES***, please describe:		
C6. Are there any gas burning appliances used in your home on a regular basis or used in the past few weeks (stoves, unvented heaters, etc.)?		☐ Yes	☐ No
C7. Do you use a kerosene heater in your home?		☐ Yes	☐ No
C8. Do you have a central heating system in your house?		☐ Yes	☐ No
	a. if YES, what type ☐ Radiators ☐ Forced air ☐ Other _____		
C9. Do you have air conditioning in your house?		☐ Yes	☐ No
	a. Do you have window air conditioners in your house?	☐ Yes	☐ No
	b. Do you have central air conditioning in your house?	☐ Yes	☐ No

MOSES Study

Health and Home Screening Questionnaire

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

ALCOHOL USE AND SMOKING HISTORY

D1. Do you drink alcoholic beverages?		☐ Yes	☐ No
	a. How many cans/bottles of beer per week? _____ cans/bottles per week		
	b. How many glasses of wine per week? _____ glasses per week		
	c. How many shots of hard liquor per week? _____ shots per week		
	d.. How many 8 oz drinks of hard liquor per week? _____ 8 oz drinks per week		
D2.	Do you drink more heavily now than you did in the past?	☐ Yes	☐ No
D3.	Can you abstain from drinking alcohol for 3 days?	☐ Yes	☐ No
	Please think about any time you have smoked any substance. Think about how much you smoked in terms of how many per day over the number of years you smoked.		
D4a	Have you ever smoked cigars? If **YES:** # cigars/day_____ for # years _____	☐Yes	☐No
b	Have you ever smoked cigarettes? If **YES:** # cigarettes/day_____ for # years _____	☐Yes	☐No
c	Have you ever smoked a pipe? If **YES: #** pipes/day_____ for # years _____	☐Yes	☐No
d	Have you ever smoked marijuana? If YES: # joints/day_____ for # years _____	☐Yes	☐No
e	Have you ever smoked a hookah? If YES: # times/day_____ for # years _____	☐Yes	☐No
f	Have you ever smoked any other recreational substance? If YES: # times/day_____ for # years _____	☐Yes	☐No
D5.	Have you smoked anything (cigars, cigarettes, pipes, marijuana, hookah, other recreational substance) in the **past 5 years?**	☐Yes	☐No

MOSES Study

Health and Home Screening Questionnaire

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

MEDICAL HISTORY

Do you have or have you ever had….		
E1. Arthritis?	☐ Yes	☐ No
E2. Gastro-intestinal problems (ulcer or bleeding of the stomach or duodenum)	☐ Yes	☐ No
E3. Bleeding blood disorders	☐ Yes	☐ No
E4. Anemia	☐ Yes	☐ No
E5. Liver disease	☐ Yes	☐ No
E6. Thyroid disease	☐ Yes	☐ No
E7. Glaucoma, vision problems	☐ Yes	☐ No
E8. Diabetes	☐ Yes	☐ No
E9. Stroke, mini stroke (TIA)	☐ Yes	☐ No
E10. Neurological disorders	☐ Yes	☐ No
E11. Mental Illness	☐ Yes	☐ No
E12. Kidney disease	☐ Yes	☐ No
E13. Eczema, skin sensitivity (serious skin rash)	☐ Yes	☐ No
E14. Cancer	☐ Yes	☐ No
E15. (For Females) Have you gone through menopause? If YES When was your last menstrual period: _____ / _____ MM/YYYY	☐ Yes	☐ No
Other questions about your health		
F1a. How many times a week do you exercise? _____ b. What Type(s) of exercise do you do?_____		
F2. Have you ever been dizzy during or after exercise?	☐ Yes	☐ No
F3. Have you ever fainted during or after exercise?	☐ Yes	☐ No
F4. Have you ever had chest pains during or after exercise?	☐ Yes	☐ No

MOSES Study

Health and Home Screening Questionnaire

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

F5. Do you bruise easily?	☐ Yes	☐ No
F6. Do you have or have you ever been diagnosed with high blood pressure defined as greater than 140 systolic or greater than 90 diastolic?	☐ Yes	☐ No
a. If **YES**, are you **currently** taking any medication(s) for high blood pressure? b. Which one(s) _____	☐ Yes	☐ No
F7. Has any doctor advised you not to participate in a sport due to a heart problem?	☐ Yes	☐ No
F8. Do you have any heart conditions?	☐ Yes	☐ No
F9. Are you taking any drugs for your heart?	☐ Yes	☐ No
F10. Have you ever been told that you have a heart murmur?	☐ Yes	☐ No
F11. Have you ever had heart tests such as an ECG, Echocardiogram, heart catheterization, etc. carried out by a doctor?	☐ Yes	☐ No
F12. Have you ever had a very rapid heart beating that has begun and ended for no apparent reason?	☐ Yes	☐ No
F13. In the past six weeks have you had any symptoms of a cold, flu or any other respiratory infection?	☐ Yes	☐ No
F14. In the PAST TWO years, have you had a chest X-ray? If ***YES*** , for what reason_____	☐ Yes	☐ No
F15. Have you ever had chest or lung surgery?	☐ Yes	☐ No
F16. Do you usually cough first thing in the morning regardless of the weather?	☐ Yes	☐ No
F17. Do you usually cough first thing in the morning in cold, rainy, or foggy weather?	☐ Yes	☐ No
F18. Do you usually bring up phlegm, sputum, or mucous from your chest first thing in the morning in cold, rainy, or foggy weather?	☐ Yes	☐ No
F19. Do you usually bring up phlegm, sputum or mucous from your chest during the day or night regardless of weather?	☐ Yes	☐ No
F20. ***If YES* to F18 *or F19, please answer:*** a. Do you bring up phlegm, sputum or mucous from your chest on most days for as much as 3 months of the year? b. How many years have you raised phlegm, sputum or mucous from your chest? _____	☐ Yes	☐ No

MOSES Study

Health and Home Screening Questionnaire

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

F21. How often do you bring up phlegm from your chest? *Please circle appropriate number* **1**_____**2**_____**3**_____**4**_____**5** never rarely sometimes often very often		
F22. Do you ever notice a wheezing or whistling sound from your chest? If **YES**, please answer the following:	☐ Yes	☐ No
a. Do you notice this when you have a cold?	☐ Yes	☐ No
b. Do you notice this even when you don't have a cold?	☐ Yes	☐ No
c. Do you notice this on most days?	☐ Yes	☐ No
F23. Have you ever had shortness of breath with wheezing? *If **YES,** please answer the following:* How often are you bothered by shortness of breath with wheezing? *Please circle appropriate number* **1**_____**2**_____**3**_____**4**_____**5** never rarely sometimes often very often	☐ Yes	☐ No
F24. Did you have any respiratory trouble before age 16?	☐ Yes	☐ No
F25. Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?	☐ Yes	☐ No
F26. Have you ever had any other kind of chest trouble that we haven't talked about yet? If ***YES***, please explain:	☐ Yes	☐ No
F27. During the past THREE years, how often were you unable to do your usual activities because of chest colds, bronchitis, or pneumonia? *Please DO NOT Include head colds.*	☐Never ☐1 - 5 times ☐ 6 times or more	
F28. During the PAST year, how many days have you been unable to do your usual activities because of chest colds, bronchitis or pneumonia? _____day(s)		
F29. Did a doctor ever tell you that you have any of the following? If unsure, please check NO.		
a. Chronic Bronchitis	☐ Yes	☐ No
b. Bronchiectasis	☐ Yes	☐ No
c. Emphysema	☐ Yes	☐ No
d. Asthma	☐ Yes	☐ No
*If **YES** to any of the above, please continue...* I. Have you taken medication or treatment for these condition(s)?	☐ Yes	☐ No

Health and Home Screening Questionnaire

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

	II. How old were you when you FIRST developed symptoms from the above conditions? _____yrs		
	III. Do you still have any of these conditions?	☐ Yes	☐ No
F30. Have you had any of the following? *If unsure, check NO.*			
	a. Tuberculosis	☐ Yes	☐ No
	b. Valley Fever (coccidiodomycosis)	☐ Yes	☐ No
	c. Histo (histoplasmosis)	☐ Yes	☐ No
	d. Pneumonia or bronchopneumonia	☐ Yes	☐ No
F31. Are you allergic to any plants, food, animal dander, house dust mites, chemicals or medicine? If ***YES***, choose all that apply: ☐cats ☐dogs ☐house dust mites ☐grasses ☐molds ☐pollen ☐ flowers ☐trees ☐drugs (Specify)_____ ☐food (Specify)_____ ☐other (Specify)_____		☐ Yes	☐ No
If ***YES***, Do you take any medication(s) (e.g., antihistamines, systemic steroids) to treat the allergy(ies)? Medication Name(s): _____ (This will trigger a medication list for coordinator to enter)		☐ Yes	☐ No
F32. Have you ever been told by any doctor that you had "hay fever" or "allergic rhinitis'?		☐ Yes	☐ No
F33. Have you ever had other allergies that make your nose runny or stuffy apart from colds? *If **YES,** please continue...* a. During the past year, how much have you been bothered by it? **1**_____**2**_____**3**_____**4**_____**5** very little very much b. Circle the months in which your episodes have been most frequent. Jan Feb Mar April May June July Aug Sept Oct Nov Dec OR ☐ No correlation to time of year		☐ Yes	☐ No
F34. Are you *currently* getting allergy shots?		☐ Yes	☐ No

Health and Home Screening Questionnaire

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

F35. Have you ever had allergy skin testing?	☐ Yes	☐ No

If subject identified any other research study participation in the Initial Phone Screener, please discuss / review any research study that the subject is currently participating in.

MOSES Study

Medication List for Health and Home Questionnaire

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

B1. Are you currently taking any prescription medications? ☐Yes ☐No If YES, please list below.

Medication Name	Dose	Indication (Reason)
a.		
b.		
c.		
d.		
e.		
g.		

B2. Are you currently taking any Over the Counter medications? This includes supplements, pain relievers, anti-allergic drugs, anti-inflammatories, antioxidants or vitamins, herbal remedies and others. ☐Yes ☐No If YES, please list below.

Medication Name	Dose	Indication (Reason)
a.		
b.		
c.		
d.		
e.		
f.		
g		

MOSES Study
Vital Signs and Blood Pressure – Screening Training Data Form

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

A3. Initials of data collector: __ __ __ A4. Visit: ☐ Screening ☐ Training

Height and Weight (SCREENING ONLY)

B1. a. Height (cm) __ __ __

b. Weight (kg) __ __ __ . __

c. BMI (kg/(cm/100)$^{2)}$ __ __ . __ (>35 or < 18 are excluded)

d. BSA SQRT((cm*kg)/3600) __ . __ __

Vital Signs

C1. Time Seated: __ __ : __ __

C2. Temperature: __ __. __ °C (Normal range: 36.5 – 37.5°C) (Temperature is optional)

C3. Breathing Rate: __ __ __ bpm (Normal range: 12 - 20 bpm)

Blood Pressure

D1. Time	D2 a/b .B/P – mmHg	D3. Heart Rate - bpm	D4. Method
__ __ : __ __	__ __ __ / __ __ __	__ __ __	☐ Automatic BP ☐ Manual BP
If above blood pressure is within normal ranges (For Screening 140/90 – 90/50, For Training 155/95 – 90/50) mmHg enter this value into ADEPT. If not within normal ranges, pause 3 min and redo.			
__ __ : __ __	__ __ __ / __ __ __	__ __ __	☐ Automatic BP ☐ Manual BP
If above blood pressure is within normal ranges (For Screening 140/90 – 90/50, For Training 155/95 – 90/50) mmHg enter this value into ADEPT. If not within normal ranges, pause 3 min and redo.			
__ __ : __ __	__ __ __ / __ __ __	__ __ __	☐ Automatic BP ☐ Manual BP
Enter this value into ADEPT – within or not within normal ranges.			

D5. Comments:_____

MOSES Study

Spirometry Data Form

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

A3. Visit: ☐SCRN ☐EXP1 - Before Exposure ☐EXP1 - After Exposure ☐POS1

☐EXP2 - Before Exposure ☐EXP2 - After Exposure ☐POS2

☐EXP3 - Before Exposure ☐EXP3 - After Exposure ☐POS3

A4. Initials of data collector: __ __ __ A5.Start time of first maneuver __ __ : __ __

B1. Spirometry Trials				
Trial	FVC In Liters	FEV_1 In Liters	FEF 25 – 75% In Liters per Second	Comments
1.	__ . __ __ L	__ . __ __ L	__ . __ __ LPS	
2.	__ . __ __ L	__ . __ __ L	__ . __ __ LPS	
3.	__ . __ __ L	__ . __ __ L	__ . __ __ LPS	
4.	__ . __ __ L	__ . __ __ L	__ . __ __ LPS	
5.	__ . __ __ L	__ . __ __ L	__ . __ __ LPS	
6.	__ . __ __ L	__ . __ __ L	__ . __ __ LPS	
7.	__ . __ __ L	__ . __ __ L	__ . __ __ LPS	
8.	__ . __ __ L	__ . __ __ L	__ . __ __ LPS	

Print output charts and enclose in subject's study folder.

AT SCREENING ONLY				
C1.	Predicted	Best (From ADEPT)	% of Predicted (From ADEPT)	% of Predicted must be ≥ 75 for inclusion (From ADEPT)
FVC	__ . __ __ L	__ . __ __ L	__ __ __%	≥ 75? ☐ Yes ☐No
FEV_1	__ . __ __ L	__ . __ __ L	__ __ __%	≥ 75? ☐ Yes ☐No
C2. Best FEV_1/FVC (From ADEPT) __ . __ __ > 0.65? (From ADEPT) ☐ Yes ☐No				

LabCorp CLINICAL TRIALS

SHIPMENT ALERT FORM

On the Day of Shipment, please complete this form and fax to:

LabCorp Clinical Trials
FAX: 919-474-4385

ATTENTION: Tamika Hawkins
(Phone: 919-474-4368)

Sponsor / Protocol: Health Effects Institute/
MOSES Common Protocol 10-01-4

Investigator Last Name: _____

SiteNumber: _____

Contact Person at Site: _____

Phone Number: _____

Date of Shipment: _____/_____/_____
DD / MMM / YYYY

Number of Boxes Shipped
to Cranford, NJ: _____

FedEx Airbill Number(s): _____

_____

LSN: 101904

LabCorp Monitor: Tamika Hawkins, Phone # 919-474-4368
LabCorp Project Manager: Abigail Berens, Phone # 952-563-4072

MOSES Study

Training Visit Check List

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

During Exercise, Actual Times will be recorded on Training Exercise Data Form

Time			Done	SOP #
Relative	Actual			
		Subject arrives at the clinic	☐	
		Is pregnancy test indicated (Female and < 1 year since Last Menstrual Period)? ☐Yes ☐No -- Proceed If Yes, administer pregnancy test Is test positive? ☐Yes -- Discharge subject ☐ No -- Proceed	☐	
		Prepare subject for Vital Signs measurements. Subject sits quietly for 5 minutes before measurement	☐	VS/BP SCREEN TRAIN #2
		Take vital signs and record on Vital Signs and Blood Pressure – Screening Training Data Form	☐	
		Attach 3-or-12-lead ECG - Print out at least 6 second ECG tracing	☐	MINVEN TRAIN #4
		Explain use of exercise/ventilation equipment	☐	
0:00		*Exercise period 1 begins (15 minutes).* Physician should be present at the test site during this period	☐ ☐	MINVEN TRAIN #4
5:00		Print out at least 6-second ECG tracing Measure heart rate and (optional) SpO_2. Record on Training Exercise Data Form	☐ ☐	MINVEN TRAIN #4 VS/BP #2
7:00		Measure BP(optional) and record on Training Exercise Data Form	☐	VS/BP #2
7:30		Instruct subject to get ON the mouthpiece, nose clip ON	☐	
8:00		Begin measuring minute ventilation. Continue measuring for 2 minutes.	☐	MINVEN #4

MOSES Study

Training Visit Check List

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

Time			Done	SOP #
Relative	Actual			
10:00		Print out at least 6 second ECG tracing Measure heart rate and (optional) SpO_2. Record on Training Exercise Data Form Report average of minute ventilation during last minute and treadmill/bicycle speed on Training Exercise Data Form Instruct subject to get OFF the mouthpiece, nose clip OFF Adjust level of exercise to achieve the target minute ventilation and record Training Exercise Data Form	☐ ☐ ☐ ☐ ☐	MINVEN #4 VS/BP #2
12:30		Instruct subject to get ON the mouthpiece, nose clip ON	☐	
13:00		Begin measuring minute ventilation. Continue measuring for 2 minutes.	☐	MINVEN #4
15:00		Print out at least 6 second ECG tracing. Measure heart rate and (optional) SpO2. Record on Training Exercise Data Form Report average of minute ventilation during last minute and treadmill/bicycle speed on Training Exercise Data Form Instruct subject to get OFF the mouthpiece, nose clip OFF, stop exercise and rest	☐ ☐ ☐	MINVEN #4 VS/BP #2
		Rest period 1 begins (15 minutes)	☐	
15:30		Print out at least 6 second ECG tracing; Measure heart rate and (optional) SpO2. Record on Training Exercise Data Form	☐ ☐	MINVEN #4 VS/BP #2
20:00		Print out at least 6 second ECG tracing; Measure heart rate and (optional) SpO2. Record on Training Exercise Data Form Measure blood pressure. Record on Training Exercise Data Form	☐ ☐ ☐	MINVEN #4 VS/BP #2
30:00		*Exercise period 2 begins (15 minutes).* Physician should be in the building during this period	☐	
35:00		Print out at least 6 second ECG tracing, Measure heart rate and (optional) SpO2. Record on Training Exercise Data Form	☐ ☐	MINVEN #4 VS/BP #2
37:00		Measure BP(optional) and record on Training Exercise Data Form	☐	VS/BP #2

MOSES Study

Training Visit Check List

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

Time			Done	SOP #
Relative	Actual			
37:30		Instruct subject to get ON the mouthpiece, nose clip ON	☐	
38:00		Begin measuring minute ventilation. Continue measuring for 2 minutes.	☐	MINVEN #4
40:00		Print out at least 6 second ECG tracing Measure heart rate and (optional) SpO_2. Record Training Exercise Data Form Report average of minute ventilation during last minute and treadmill/bicycle speed on Training Exercise Data Form Instruct subject to get OFF the mouthpiece, nose clip OFF Adjust level of exercise to achieve the target minute ventilation and record Training Exercise Data Form	☐ ☐ ☐ ☐ ☐	MINVEN #4 VS/BP #2
42:30		Instruct subject to get ON the mouthpiece, nose clip ON	☐	
43:00		Begin measuring minute ventilation. Continue measuring for 2 minutes.	☐	MINVEN #4
45:00		Print out at least 6 second ECG tracing. Measure heart rate and (optional) SpO2. Record on Training Exercise Data Form Report average of minute ventilation during last minute and treadmill/bicycle speed on Training Exercise Data Form Instruct subject to get OFF the mouthpiece, nose clip OFF, stop exercise and rest	☐	MINVEN #4 VS/BP #2
		Rest period 2 begins	☐	
45:30		Print out at least 6 second ECG tracing; Measure heart rate and (optional) SpO2. Record on Training Exercise Data Form	☐ ☐	MINVEN #4 VS/BP #2
50:00		Print out at least 6 second ECG tracing Measure heart rate and (optional) SpO2. Record on Training Exercise Data Form Measure blood pressure. Record on Training Exercise Data Form	☐ ☐	MINVEN #4 VS/BP #2
		Can subject complete the exercise protocol without exceeding 80% of predicted maximal heart rate? ☐Yes -- Proceed ☐No -- Discharge subject	☐	

MOSES Study

Training Visit Check List

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

Time			Done	SOP #
Relative	Actual			
		Physician review and sign ECG printouts Is ECG normal? ☐ Yes - Physician initials ECG printouts ☐ No - If any abnormalities such as ST depression, arrhythmias, or other abnormalities are detected, ECG must be reviewed by cardiologist.	☐	
		If ECG sent for review to cardiology, Cardiologist asserts that subject is eligible based on ECG and cardiologist signs below ☐Yes ☐No Signature _____ __ __ - __ __ __ - __ __ __ __	☐	
		Is subject eligible based on ECG? ☐Yes -- Proceed ☐No -- Discharge subject	☐	
		Review and Complete Inclusion/Exclusion checklist DOES SUBJECT MEET ALL CRITERIA FOR INCLUSION AND MEETS NO EXCLUSION *CRITERIA*? ☐Yes -- Proceed ☐No -- Discharge subject	☐	
		Have PES ready and fill out PES Tracking Form in ADEPT	☐	
		Make appointment for pre-exposure visit and discharge subject with • PES and Subject Instruction for Use of PES • Subject Instructions Before Pre-Exposure Visit • MOSES Activity diary and Subject Instruction for Activity Diary.	☐	PES #41, TAD #42

Explain below any item not done, done out of order or done at a time other than specified.

Item/Time Scheduled	Explanation

MOSES Study
Vital Signs and Blood Pressure – Screening Training Data Form

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

A3. Initials of data collector: __ __ __ A4. Visit: ☐ Screening ☐ Training

Height and Weight (SCREENING ONLY)

B1. a. Height (cm) __ __ __

b. Weight (kg) __ __ __ . __

c. BMI (kg/(cm/100)$^{2)}$ __ __ . __ (>35 or < 18 are excluded)

d. BSA SQRT((cm*kg)/3600) __ . __ __

Vital Signs

C1. Time Seated: __ __ : __ __

C2. Temperature: __ __. __ °C (Normal range: 36.5 – 37.5°C) (Temperature is optional)

C3. Breathing Rate: __ __ __ bpm (Normal range: 12 - 20 bpm)

Blood Pressure

D1. Time	D2 a/b .B/P – mmHg	D3. Heart Rate - bpm	D4. Method
__ __ : __ __	__ __ __ / __ __ __	__ __ __	☐ Automatic BP ☐ Manual BP
If above blood pressure is within normal ranges (For Screening 140/90 – 90/50, For Training 155/95 – 90/50) mmHg enter this value into ADEPT. If not within normal ranges, pause 3 min and redo.			
__ __ : __ __	__ __ __ / __ __ __	__ __ __	☐ Automatic BP ☐ Manual BP
If above blood pressure is within normal ranges (For Screening 140/90 – 90/50, For Training 155/95 – 90/50) mmHg enter this value into ADEPT. If not within normal ranges, pause 3 min and redo.			
__ __ : __ __	__ __ __ / __ __ __	__ __ __	☐ Automatic BP ☐ Manual BP
Enter this value into ADEPT – within or not within normal ranges.			

D5. Comments:_____

MOSES Study
Training Exercise Data Form

If heart rate exceeds 80% of maximal predicted heart rate during first 10 minutes of exercise reduce the load to bring HR to ≤80%.
If blood pressure exceeds 230/120 or drops below 90/60 stop exercise and monitor subject.
If any abnormality is noticed in ECG stop exercise, alert physician and monitor subject.

A1. Subject ID Label: A2. Today's date: __ __ - __ __ __ - __ __ __ __ A3. Initials of data collector: __ __ __

B. Calculate target ventilation and predicted heart rates. Fill in BSA from Vital Signs and Blood Pressure – Screening Form and Age in Years from Home and Health Questionnaire.

15 L/min/m^2 * BSA_____ = Lower Target V_E_____L/min 17 L/min/m^2 * BSA_____ = Upper Target V_E_____L/min

Target Heart Rate: [(208 – (0.7 * ____ years)] * 0.80 = _____

		Treadmill		Bike						
Relative Time	**Actual Time**	**KMPH/MPH**	**Slope %**	**WATTS**	**RPM**	**V_E Avg Last Min Ven (L/min)**	**HR (bpm)**	**BP (mmHg)**	**ECG print (at least 6 seconds)**	**Comments (and optional SpO_2)**
Before Exercise	__ __ :__ __							__ __ __ / __ __ __	Y N	
0.00	__ __ :__ __	EXERCISE PERIOD 1 BEGINS								
5.00	__ __ :__ __								Y N	
7.00	__ __ :__ __							__ __ __ / __ __ __		
7.30	__ __ :__ __	Instruct subject to get on mouthpiece, nose clip on								
8.00	__ __ :__ __	Begin recording minute ventilation								
10.00	__ __ :__ __								Y N	
10.00	__ __ :__ __	Instruct subject to get off mouthpiece, nose clip off								
12.30	__ __ :__ __	Instruct subject to get on mouthpiece, nose clip on								

MOSES Study
Training Exercise Data Form

If heart rate exceeds 80% of maximal predicted heart rate during first 10 minutes of exercise reduce the load to bring HR to ≤80%.
If blood pressure exceeds 230/120 or drops below 90/60 stop exercise and monitor subject.
If any abnormality is noticed in ECG stop exercise, alert physician and monitor subject.

A1. Subject ID Label: A2. Today's date: __ __ - __ __ __ - __ __ __ __ A3. Initials of data collector: __ __ __

		Treadmill		Bike						
Relative Time	**Actual Time**	**KMPH/MPH**	**Slope %**	**WATTS**	**RPM**	**V_E Avg Last Min Ven (L/min)**	**HR (bpm)**	**BP (mmHg)**	**ECG print (at least 6 seconds)**	**Comments (and optional SpO_2)**
13.00	__ __ :__ __	Begin recording minute ventilation								
15.00	__ __ :__ __								Y N	
15.00	__ __ :__ __	Instruct subject to get off mouthpiece, nose clip off								
15.00	__ __ :__ __	STOP AND REST								
15.30	__ __ :__ __								Y N	
20.00	__ __ :__ __							__ __ __ / __ __ __	Y N	
30.00	__ __ :__ __	PERIOD 2 EXERCISE BEGINS								
35.00	__ __ :__ __								Y N	
37.00	__ __ :__ __							__ __ __ / __ __ __		
37.30	__ __ :__ __	Instruct subject to get on mouthpiece, nose clip on								
38.00	__ __ :__ __	Begin recording minute ventilation								
40.00	__ __ :__ __								Y N	
40.00	__ __ :__ __	Instruct subject to get off mouthpiece, nose clip off								

This data will not be entered into the database

MOSES Study
Training Exercise Data Form

If heart rate exceeds 80% of maximal predicted heart rate during first 10 minutes of exercise reduce the load to bring HR to ≤80%.
If blood pressure exceeds 230/120 or drops below 90/60 stop exercise and monitor subject.
If any abnormality is noticed in ECG stop exercise, alert physician and monitor subject.

A1. Subject ID Label: A2. Today's date: __ __ - __ __ __ - __ __ __ __ A3. Initials of data collector: __ __ __

		Treadmill		Bike						
Relative Time	**Actual Time**	**KMPH/MPH**	**Slope %**	**WATTS**	**RPM**	**V_E Avg Last Min Ven (L/min)**	**HR (bpm)**	**BP (mmHg)**	**ECG print (at least 6 seconds)**	**Comments (and optional SpO_2)**
42.30	__ __:__ __	Instruct subject to get on mouthpiece, nose clip on								
43.00	__ __:__ __	Begin recording minute ventilation								
45.00	__ __:__ __								Y N	
45.00	__ __:__ __	Instruct subject to get off mouthpiece, nose clip off								
45.00	__ __:__ __	STOP AND REST								
45.30	__ __:__ __								Y N	
50.00	__ __:__ __							__ __ __ / __ __ __	Y N	
50.00		END								

What exercise regimen made subject achieve Target V_E? These settings will be used as a basis for the exposure exercise sessions.

_____ KMPH/MPH and _____ Slope % OR _____ WATTS and _____ RPM

PES Tracking Form

A1. Subject ID Label:

A4. Visit assigned at:

☐ Training

☐ POST 1

☐ POST2

A2. Date assigned: __ __ - __ __ __ - __ __ __ __

A3. PES ID assigned: {Site Abbreviation} MOSES __ __ __

MOSES

Subject instructions for use of the personal exposure sampler (PES)

You will be given a zip-lock bag containing:

(1) a plastic backing with a clip,

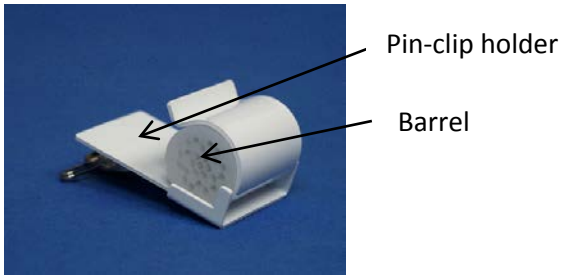
(2) a plastic vial that contains a resealable bag and the PES (and a small gel packet) inside of it. The PES consists of a pin-clip holder that holds a barrel (or body of the sampler).

(3) Time Activity Diary daily forms (see separate instruction sheet).

Put the zip-lock bag (with its content) in the refrigerator as soon as possible after leaving the clinic and leave it there until the 3rd day before your exposure visit. You will receive a call to remind you.

START WEARING THE PES at 12:00 noon of the 3rd day before the exposure visit

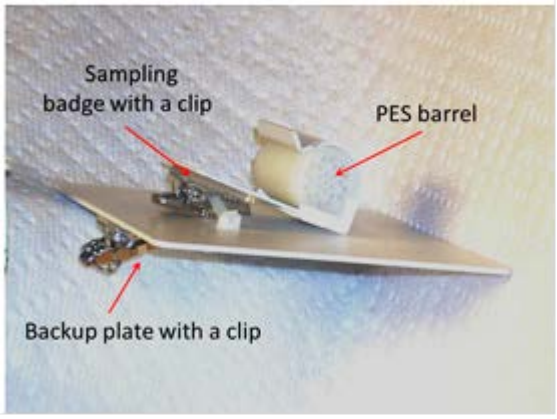
1. When it is time for you to start wearing the PES, open the zip lock bag and empty its content.
2. Open the vial and remove the PES from the resealable bag. Do not touch the ends of the PES barrel. Only touch the pin-clip holder.



Brown vial with PES inside resealable bag

PES consisting of a badge that holds the barrel

3. Replace the re-sealable bag (with the gel packet still inside) in the brown storage vial and tighten cap securely.
4. Put the vial in the zip lock bag. Keep the bag in a safe place as you will need to bring it to the clinic.
5. Secure the PES to the plastic backing as follows (see picture below): clip the pin-clip holder onto the wire tie loop of the backing so that the PES barrel (with little round holes on two ends) is in the middle of the backing. The air diffuses through the holes to the coated filters inside, so placing the PES barrel in the center of the backing (as shown in the picture below) minimizes losses on clothing.
6. Attach the backing to your clothes: If there is a pocket on the clothing at the height of your chest, use the clip to attach the backing. If not, use the safety pin on the clip to attach it.



7. On the Time Activity Diary, indicate the date and time you start wearing the PES; check off each hour you wear it in the Monitor column. If you do not wear it for a time period, please record where the device was and why you did not wear it in the NOTES column. Keep the diary with you or near you at all times.
8. You should not wear the PES, or bring it in the bathroom, if you take a shower (or bath). You should not wear the PES while in bed (i.e., at night), taking a nap, or participating in an activity where the monitor could break. When not worn, place the backing plate with the sampler facing up on a table outside the bathroom or near the bed, or close to where you are doing the activity.
9. Do not allow the PES to get wet outside in the rain, snow or heavy fog. Also do not allow the PES to be at temperatures below freezing. In all these instances wear the PES under a jacket or a coat.
10. Continue wearing the PES until you arrive at the clinic for the pre-exposure visit. Bring (1) the Activity Diary forms and (2) the plastic bag with the brown vial with the resealable bag inside to the clinic. It will be needed to store the PES until it is sent to the lab for analysis.

Your next visit is on __ __ / __ __ / __ __ __ __ at __ __ : __ __

Please do the following in preparation:

Starting on __ __ / __ __ / __ __ __ __ (one week before your visit) please avoid aspirin, ibuprofen, naproxen, multivitamins, vitamin C, vitamin E, antihistamines, antioxidants, decongestants, fish oil, niacin, arginine, Viagra, Cialis, and Levitra.

Three days before coming in on __ __ / __ __ / __ __ __ __, please put on the Personal Exposure Monitor (PES) at 12:00 noon. We will take it off on the day that you come in for your study visit. The attached set of instructions describes the specific instructions for the PES.

While you are wearing the exposure monitor, please remember to fill out the activity diary. Please refer to the attached instructions for completing the diary.

Please call us with any changes in your health or medication. This includes receiving shots, getting a cold or the flu or seeing a doctor for anything but a routine visit.

Please remember, you are allowed caffeine on the morning that you come in for your study visit, but you will need to avoid any caffeinated beverage after that. You will also need to abstain from alcoholic beverages for three days beginning on the day that you come in for your visit. Finally, on the morning that you come in, you are to avoid strenuous exercise and heavy lifting.

You will receive a reminder call 4 – 5 days before your scheduled visit.

If you have any questions, call _____

Multicenter Ozone Study in Elderly Subjects
ACTIVITY DIARY

Subject ID: _____

Date of this report: _____

Date/Time **directed by Technician to start wearing personal sampler** __ __ / __ __ / __ __ (MM / DD / YY) __ __ : __ __ (HH : MM) AM / PM Circle One

Date/Time **you First put on the personal sampler:** __ __ / __ __ / __ __ (MM / DD / YY) __ __ : __ __ (HH : MM) AM / PM Circle One

Please check ***all*** the circles in the table that apply to you. If during any portion of the indicated time period, the item/activity occurred, please check the box.

	MONITOR	LOCATION												ACTIVITIES								HEATING		COOLING	
		I am travelling by…						I am currently at…						I am…							Someone is smoking in the same room				
TIME	I am wearing my ***personal*** sampler*	foot	bike	motor-cycle	car/ taxi	bus	train or sub-way	home		work		other place		cooking or near cooking	sleeping	exercising, or other type of exertion	sweeping, dusting, vacuuming (at work or home)*	painting, welding, (at work or home)	watching TV, reading, sitting at desk	eating a meal or snack		I am in a room being heated by a kerosene heater	I am in a room being heated by a woodstove or fireplace	I am in a room being cooled by an air conditioner	NOTES
								inside	outside	inside	outside	inside	outside												
AM 6:00-6:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 7:00-7:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 8:00-8:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 9:00-9:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 10:00-10:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 11:00-11:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 12:00-12:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 1:00 - 1:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 2:00 - 2:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 3:00 - 3:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 4:00 - 4:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 5:00 - 5:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 6:00 - 6:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 7:00 - 7:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 8:00 - 8:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 9:00 - 9:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 10:00 - 10:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
PM 11:00 - 11:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 0:00-0:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 1:00-1:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 2:00-2:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 3:00-3:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 4:00-4:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	
AM 5:00-5:59	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	

* If you are not wearing the sampler, please explain in the NOTES column where you put the sampler.

Explanatory notes:
"I am traveling" column - include time spent waiting for bus, etc.
"Home, inside" column - include garage, basement, laundry room
"Home, outside" column - include yard, garden, patio, porch
"Other place, inside" column - include shopping mall, supermarket, restaurant, neighbor's home, movie theater, indoor stadium, rink, church
"I am, cooking" column - include outside barbecue (BBQ)
"I am, exercising" column - include playing sports (baseball, soccer, etc.)
"I am, painting, welding" column - include working on a hobby, e.g., sawing wood, sanding, etc.

For more information see the Subject Instructions for Flling Out the Activity Diary

MOSES

Subject Instruction for Filling Out the Activity Diary

Please carry the diary with you during the day and fill out the times when you change from one of these locations to another and from one activity to another.

1. TIME column.

The time column shows the time breakdown into 1 hour increments. On the first day, start filling the diary at 12:00 noon, the time when you should put on the personal sampler. Please note the exact date/time when you first wear it. On the other 3 days start filling the diary at 6:00 AM.

2. MONITOR column

Mark the boxes corresponding to the times when you are wearing the personal exposure sampler. If you are only wearing it for any portion of that hour, check the box for that hour. Explain in the NOTES section all the way to the right of the Diary where the sampler is at a given time if it is not being worn. Make sure it is as near you as possible. (See also instructions for wearing the Personal Exposure Sampler)

3. LOCATION columns

Here you are asked to record where you are during each hour.

3.1 If you are <u>traveling</u> check whether it is by foot, bicycle/bike, motorcycle, car/taxi, bus, or train/subway. If you are traveling by a method (e.g. foot, bike, etc.) any portion of that hour check the box for that hour. You might have to check off multiple "traveling by" boxes for that hour if you use different means of transportation. If you are in transit for less than one hour, indicate the transit period in the NOTES column.

3.2 If you are <u>currently at home, at work, or other places</u> specify the location and whether you are indoor or outdoor. If you are in a location for any portion of an hour, you should check that box for the whole hour. You might have to check off multiple "I am currently at" boxes for the same hour.

a) "Home - Indoors" should be checked whenever you are inside the home, (including the garage or basement) or anywhere inside an apartment building (including the laundry room).

b) "Work – Indoors" should be checked when you are at work

c) "Other place" refers to the time spent in other indoor or outdoor locations (a friend's house, a park, a restaurant, a shopping mall, a church, a grocery store, a gym, a movie theater, a stadium, a rink, a church.

d) "Outside" should be checked whenever you are outside of your own home ("Home – Outside") or a neighbor's home ("Other place – Outside"). This column would also refer to time spent on a porch, patio, or balcony. If you

travel to a neighbor's house and walk outside to do so, then "traveled, by foot" should also be checked.

4. ACTIVITIES columns

4.1 Here you are asked to indicate what you are doing in a location during each hour. If you do more than one activity in a 1-hour period, check all the appropriate boxes. Examples of which activities should be noted include sleeping, eating, watching TV, exercising, sweeping/dusting/vacuuming, painting/welding (and also sawing wood and sanding), and cooking.

4.2 Information about cooking and cleaning activities is strongly desired. We are particularly interested in the *type* of cooking, such as frying, grilling, broiling, toasting, barbecuing, etc., which should be noted in the NOTES column.

4.3. Please identify the person doing the cooking or cleaning activity for each entry in the NOTES column.

5. SMOKING column. Fill out this column if someone is smoking the room you are in during any portion of that hour.

6. HEATING AND COOLING columns

You should fill this column if you are in a room with a kerosene heater or a wood stove on or with a live fire. Please abstain from lighting a fire while you are wearing the personal exposure sampler to avoid exposure to smoke.