May 15, 2018

Data Sharing Plan for the MOSES Study

INTRODUCTION

It is the policy of the Health Effects Institute to provide access expeditiously to data for studies that it has funded and to provide that data in a manner that facilitates review and verification of the work but also protects the confidentiality of any volunteers who may have participated in the study and respects the intellectual interests of the original investigator of the work. Toward this goal, HEI is making available the data from the Multicenter Ozone Study in oldEr Subjects (MOSES), as described below. The database was prepared for public use by WESTAT.

BACKGROUND ON THE MOSES STUDY

The MOSES Study is a multicenter controlled exposure study the exposed 87 healthy volunteers, aged 55–70 years, to ozone. It evaluated changes in a large number of health endpoints in response to 3-hour exposures, with moderate exercise, to clean air and to 70 and 120 ppb ozone. The MOSES Original Investigators are:

Drs. John Balmes and Mehrdad Arjomandi – University of California at San Francisco

Drs. Mark Frampton and David Rich – The University of Rochester

Drs. Phil Bromberg and Milan Hazucha – The University of North Carolina at Chapel Hill

This document describes the plan for sharing the MOSES Study data.

In addition to these data, a limited number and amount of materials (blood and plasma) collected during the study are available, and a separate document describes the plan for sharing such materials. Please visit the HEI website or information about the materials.

The MOSES final report and associated documentation are available on the HEI website *www.healtheffects.org/publication/multicenter-ozone-study-older-subjects-moses-part-1-effects-exposure-low-concentrations*.

DATA SHARING

What data will be shared? All the data collected as part of the MOSES study, with the exception of personal identifiers will be shared. The list of outcomes for the data can be found in Annex 1 at the end of this document.

Who will have access to the data? The database may be accessed by anyone who is interested, without restrictions.

When will the data be shared? Starting on May 15, 2018.

Where will the data to be shared be located? The database is located on the Harvard Dataverse repository *https://dataverse.harvard.edu/dataverse/MOSES*. This link also allows access to all the supporting documentation for the MOSES study (which is currently provided on the HEI website as noted above).

How will researchers access the data? Access to the database requires a log-in step that includes a brief questionnaire about the person making the request and the intended use of the database, and terms and conditions for publications resulting from the research.

How will researchers find out about the availability of the data? HEI will announce the availability of the database on the HEI website and at scientific meetings.

How long will the data be available? It is anticipated that the data will be available indefinitely.

Annex 1. List of MOSES Primary and Secondary Outcomes and Time of Measurements

Outcome[a]	Type of outcome	Source	Time of measurement								
			Day before exposure	0.5 hr before exposure	During exposure rest 2 and 4	During exposure exercise 6	During 3-hr exposure	0–0.25 hr post-exp	3–4 hr post-exp	21–22 hr post-exp	Long-term recording (24-hr)
VE	arrhythmia	Holter					X				X
SE	arrhythmia	Holter					X				X
NN (msec) 5-min avearge	heart rate	Holter		X		X		X	X	X	
NN (msec) 24-hr	heart rate	Holter									X
HF (Hz) 5-min average	**HRV**	**Holter**		**X**		X		**X**	**X**	**X**	
HF (Hz) 24-hr average	HRV	Holter									X
LF (Hz) 5-min average	**HRV**	**Holter**		**X**		X		**X**	**X**	**X**	
HF (Hz) 24-hr average	HRV	Holter									X
HF/LF	HRV	Holter		X				X	X	X	
RMSSD (msec) 5-min average	HRV	Holter		X		X		X	X	X	
RMSSD (msec) 24-hr average	**HRV**	**Holter**									**X**
SDNN (msec) 24-hr average	HRV	Holter		X		X		X	X	X	X
T-wave amplitude (µV) 5-min average	**repolarization**	**Holter**		**X**		X		**X**	**X**	**X**	
T-wave amplitude (µV) 24-hr average	**repolarization**	**Holter**									**X**
QTc interval (msec) 5-min average	repolarization	Holter		X				X	X	X	
ST in V5 (µV) 5-min average	**ST segment**	**Holter**		**X**		X		**X**	**X**	**X**	**X**
ST in V5 (µV) 24-hr average	**ST segment**	**Holter**									**X**
ST segment in V2 (µV) 5-min average	ST segment	Holter		X				X	X	X	
ST segment in V2 (µV) 24-hr average	ST segment	Holter									X
ST in lead II (µV) 5-min average	ST segment	Holter		X				X	X	X	
ST in lead II (µV) 24-hr average	ST segment	Holter									X

SBP (mm Hg)	**endothelial function**	**vital signs**	**X**	**X**	X			**X**	**X**	**X**	
DBP (mm Hg)	**endothelial function**	**vital signs**	**X**	**X**	X			**X**	**X**	**X**	
FMD (%)	**endothelial function**	**BAU**	**X**						**X**		
VTI (cm)	endothelial function	BAU	X						X		
BAD (mm)	endothelial function	BAU	X						X		
ET-1 (pg/ml)	endothelial function	plasma	X						X	X	
P-selectin (ng/ml)	endothelial function	plasma	X						X	X	
CRP (mg/L)	**systemic inflammation**	**plasma**	**X**						**X**	**X**	
IL-6 (ng/ml)	systemic inflammation	plasma	X						X	X	
8-isoprostane (pg/ml)	systemic oxidative stress	plasma	X						X	X	
nitrotyrosine (nM)	systemic oxidative stress	plasma	X						X	X	
MP-TFA (ng/ml)	**prothrombotic**	**plasma**	**X**						**X**	**X**	
Fibrinogen (ng/ml)	prothrombotic	plasma	X						X	X	
vWF (ng/ml)	prothrombotic	plasma	X						X	X	
Monocyte-platelet conjugate count	**prothrombotic**	**whole blood**	**X**						**X**	**X**	
Platelet count (1000/µL)	prothrombotic	whole blood	X						X	X	
Platelet microparticle count	prothrombotic	whole blood	X						X	X	
Activated platelet count	prothrombotic	whole blood	X						X	X	
Activated platelet microparticle count	prothrombotic	whole blood	X						X	X	
CD40 Ligand+ microparticle count	prothrombotic	whole blood	X						X	X	
CD142+ microparticle count	prothrombotic	whole blood	X						X	X	
FEF_{25-75} (L/sec)	lung function	spirometry	X					X		X	
FEV_1 (L)	lung function	spirometry	X					X		X	
FEV_1/FVC	lung function	spirometry	X					X		X	
FVC (L)	lung function	spirometry	X					X		X	

CC16 (ng/ml)	lung injury	plasma	X						X	X	
IL-6 (pg/ml)	airway inflammation	sputum								X	
IL-8 (pg/ml)	airway inflammation	sputum								X	
TNF-α (pg/ml)	airway inflammation	sputum								X	
Total protein	airway inflammation	sputum								X	
PMN (% of total)	airway inflammation	sputum								X	
PMN (N/mg sputum)	airway inflammation	sputum								X	
Symptoms (score 1–4)	symptoms	questionnaire		X				X	X	X	

[a] Primary outcomes are bolded.

For a list of abbreviations, see the end of the report at *www.healtheffects.org/publication/multicenter-ozone-study-older-subjects-moses-part-1-effects-exposure-low-concentrations*.