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.


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](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

<table>
<thead>
<tr>
<th>Outcomea</th>
<th>Type of outcome</th>
<th>Source</th>
<th>Time of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>VE</td>
<td>arrhythmia</td>
<td>Holter</td>
<td>Day before exposure</td>
</tr>
<tr>
<td>SE</td>
<td>arrhythmia</td>
<td>Holter</td>
<td>0.5 hr before exposure</td>
</tr>
<tr>
<td>NN (msec) 5-min average</td>
<td>heart rate</td>
<td>Holter</td>
<td>During exposure rest 2 and 4</td>
</tr>
<tr>
<td>NN (msec) 24-hr</td>
<td>heart rate</td>
<td>Holter</td>
<td>During exercise 6</td>
</tr>
<tr>
<td>HF (Hz) 5-min average</td>
<td>HRV</td>
<td>Holter</td>
<td>During 3-hr exposure</td>
</tr>
<tr>
<td>HF (Hz) 24-hr average</td>
<td>HRV</td>
<td>Holter</td>
<td>0–0.25 hr post-exp</td>
</tr>
<tr>
<td>LF (Hz) 5-min average</td>
<td>HRV</td>
<td>Holter</td>
<td>3–4 hr post-exp</td>
</tr>
<tr>
<td>HF (Hz) 24-hr average</td>
<td>HRV</td>
<td>Holter</td>
<td>21–22 hr post-exp</td>
</tr>
<tr>
<td>HF/LF</td>
<td>HRV</td>
<td>Holter</td>
<td>Long-term recording (24-hr)</td>
</tr>
<tr>
<td>RMSSD (msec) 5-min average</td>
<td>HRV</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>RMSSD (msec) 24-hr average</td>
<td>HRV</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>SDNN (msec) 24-hr average</td>
<td>HRV</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>T-wave amplitude (μV) 5-min average</td>
<td>repolarization</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>T-wave amplitude (μV) 24-hr average</td>
<td>repolarization</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>QTC interval (msec) 5-min average</td>
<td>repolarization</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>ST in V5 (μV) 5-min average</td>
<td>ST segment</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>ST in V5 (μV) 24-hr average</td>
<td>ST segment</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>ST segment in V2 (μV) 5-min average</td>
<td>ST segment</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>ST segment in V2 (μV) 24-hr average</td>
<td>ST segment</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>ST in lead II (μV) 5-min average</td>
<td>ST segment</td>
<td>Holter</td>
<td></td>
</tr>
<tr>
<td>ST in lead II (μV) 24-hr average</td>
<td>ST segment</td>
<td>Holter</td>
<td></td>
</tr>
</tbody>
</table>

Note: 
- X indicates presence.
- Blank indicates absence.

*a*: Possible abbreviations for outcomes include VE (ventilation efficiency), SE (sensory efficacy), NN (normalization of nerve activity), HF (high frequency), LF (low frequency), RMSSD (root mean square of successive differences), T-wave (T-wave), ST (ST segment), and QTC (QTc interval).
<p>| 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 | 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 | X |
| IL-6 (ng/ml) | systemic inflammation | plasma | X | X | X | X |
| 8-isoprostane (pg/ml) | systemic oxidative stress | plasma | X | 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 |
| vWF (ng/ml) | prothrombotic | plasma | X | X |
| Monocyte-platelet conjugate count | prothrombotic | whole blood | X | X | X |
| Platelet count (1000/μL) | prothrombotic | whole blood | X | X |
| Platelet microparticle count | prothrombotic | whole blood | X | X |
| Activated platelet count | prothrombotic | whole blood | X | X |
| Activated platelet microparticle count | prothrombotic | whole blood | X | X |
| CD40 Ligand+ microparticle count | prothrombotic | whole blood | X | X |
| CD142+ microparticle count | prothrombotic | whole blood | X | X |
| FEF25-75 (L/sec) | lung function | spirometry | X | X |
| FEV1 (L) | lung function | spirometry | X | X |
| FEV1/FVC | lung function | spirometry | X | X |
| FVC (L) | lung function | spirometry | X | X | X | X |</p>
<table>
<thead>
<tr>
<th></th>
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<th>X</th>
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<tbody>
<tr>
<td>CC16 (ng/ml)</td>
<td>lung injury</td>
<td>plasma</td>
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<tr>
<td>IL-6 (pg/ml)</td>
<td>airway inflammation</td>
<td>sputum</td>
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<tr>
<td>IL-8 (pg/ml)</td>
<td>airway inflammation</td>
<td>sputum</td>
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<tr>
<td>TNF-α (pg/ml)</td>
<td>airway inflammation</td>
<td>sputum</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Total protein</td>
<td>airway inflammation</td>
<td>sputum</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PMN (% of total)</td>
<td>airway inflammation</td>
<td>sputum</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PMN (N/mg sputum)</td>
<td>airway inflammation</td>
<td>sputum</td>
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<td>Symptoms (score 1–4)</td>
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<td>questionnaire</td>
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</tbody>
</table>

* Primary outcomes are bolded.