

## Material Sharing Plan for the MOSES Study Health Effects Institute (HEI)

### INTRODUCTION

The Multicenter Ozone Study in oldEr Subjects (MOSES) is a multicenter controlled exposure study that involved exposure of 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 to 0, 70, and 120 ppb ozone. As part of the study, blood and sputum samples were collected before and after exposure for analyses of soluble markers, and sputum samples were collected after exposure for analyses of inflammatory markers. 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

A limited number of individual-level blood and plasma and sputum samples (referred to as “Material”) were archived and will be made available upon request to qualified researchers on a first-come-first-served basis. Availability of these samples for additional uses was approved by the centers’ IRBs as part of the original consent form or separate specimen storage consent form. HEI maintains ownership of the samples.

#### **This document describes the process for sharing the MOSES Material.**

The documentation about the conduct of the study, as well as the MOSES final reports, is available on the HEI website [www.healtheffects.org/publication/multicenter-ozone-study-older-subjects-moses-part-1-effects-exposure-low-concentrations](http://www.healtheffects.org/publication/multicenter-ozone-study-older-subjects-moses-part-1-effects-exposure-low-concentrations). The MOSES database linked to the Material is posted on a public access data repository at <https://dataverse.harvard.edu/dataverse/MOSES>.

### MATERIAL SHARING

**What samples are available and where are they stored?** Whole blood and plasma samples and some sputum samples (supernatants and Trizol-treated cells) are available. The complete list of Material is provided in Annex 1 at the end of this document. The blood and plasma samples are stored at the ScienceSafe Biological and Pharmaceutical Storage (referred to as the “Material Repository”). A small number of sputum samples are stored at the University of North Carolina at Chapel Hill (Center for Medicine, Asthma, and Lung Biology).

**Who will have access to the Material?** Any qualified researcher from a not-for-profit U.S. research center interested in doing specific analyses can request the samples. In the interest of scientific transparency, HEI will encourage the broadest possible availability of the samples, subject to the limited quantities available.

**When will the Material be shared?** The Material will be shared starting in May 2018. Requests for Materials will be reviewed starting on July 1, 2018.

**Who is responsible for deciding how to distribute the Material?** HEI has delegated the Original Investigators to be custodians of the Material and make decisions on their distribution and use, and to keep HEI informed of all requests and disposition of the Material. HEI reserves the right to intervene, as needed, and would make the decision in the event of a disagreement among the investigators.

**How will researchers request the Material?** Interested researchers will need to fill out a short Material Request Form. The Form should include (1) the types of Materials requested and explanation of their intended use; (2) the rationale and aim of the research project; (3) a description of what the research project will add to scientific knowledge; (4) the experimental methods; (5) the estimated duration of the

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research; and (6) a short *curriculum vitae* of the Recipient (maximum 2 pages). An Original Investigator interested in using the MOSES Material will follow the same process.

The request shall be addressed to the MOSES Study Material Access Committee (MAC), composed of Original Investigators: John Balmes, Phil Bromberg, Mark Frampton, Mehrdad Arjomandi, Milan Hazucha, and David Rich, and an HEI representative (*ex officio*). The MOSES MAC's Authorized Representative is the HEI representative Dr. Annemoon van Erp (*avanerp@healtheffects.org*).

The MOSES MAC will correspond by e-mail or convene by phone and respond within 30 days of receiving a request for Material. Decisions will be made by consensus of the Original Investigators, unless any of them provides a written note authorizing the group to proceed without them. The decision will be communicated to the Requester in a timely fashion by the MAC's Authorized Representative.

**How will the Original Investigators decide how to distribute the Material?** Since the number of samples, especially sputum samples, is limited, the investigators will evaluate each request based on the criteria listed below:

- scientific merit and potential impact of the proposed research;
- the qualifications of the research team;
- relevance of the proposed research to the parent study;
- research question is exploratory, but the work makes efficient use of the available samples.

**How will an approved Recipient receive the Material?** After a Recipient has been granted access to the Material, he or she shall submit a signed Material Transfer Agreement. After the execution of the agreement (no later than one week), the MAC's Authorized Representative will instruct the Material Repository representative to ship the requested samples. The Material Repository representative will ship the approved Material within two weeks from receiving the authorization and provide the Approved Recipient the tracking information.

**What is the cost of obtaining the samples?** There will be a small cost associated with the shipping of the samples to be paid by the Recipient.

**Annex 1. Summary Table of Number and Type of MOSES Material Available**

	Sample label (type) and number					All samples
<b>Center</b> (number of subjects)	vWF (plasma)*\$ number	PL (plasma)* number	BL (blood) number	SPUT SN (sputum supernatant) number	SPUT RNA (sputum cells in Trizol) number	
URMC (32)	1440	864	32	0	17^	
UNC (29)	1305	783	29	22	17	
UCSF (26)	1170	702	26	0	17^	
Total	3915	2349	87	22	51	6,424
<b>Type of tube</b> (volume available)	2 mL PP microtube (0.2 ml x 5 tubes)	2 mL PP microtube (1 ml x 3 tubes)	2 mL PP microtube (1.5 ml)	22	1.5 mL microcentrifuge tube	
<b>When collected</b>	Pre-, 3.5 hr, and 22 hr post-exposure		at screening	22.5 hr post-exposure		

\*Numbers are calculated assuming 87 subjects. Actual numbers are lower.

\$These samples were archived for the possible analysis of von Willebrand factor multimers.

^Number estimated based on samples available at UNC.