**MULTICENTER OZONE STUDY IN OLDER SUBJECTS (MOSES)**

**MATERIAL TRANSFER AGREEMENT**

**INSTRUCTIONS**

1. Please fill out and sign this Transfer Agreement.

2. Submit the Agreement and the approved MOSES Study Material Request Form to:

MOSES Study Material Access Committee (MAC) Authorized Representative

Name: Dr. Annemoon van Erp

E-mail: avanerp@healtheffects.org

**TRANSFER AGREEMENT**

It is mutually agreed as follows:

The MOSES Study Original Investigators agree to transfer to the Recipient the Materials described below, including the types of samples, amount per sample, and the number of MOSES subjects from whom samples were obtained, for use by the Recipient Scientist to conduct the attached Research Project. By signing this agreement the Recipient agrees to the Terms and Condition described below.

|  |
| --- |
| Original Material (Description of the Material being transferred) |

|  |  |
| --- | --- |
| **MOSES Study MAC’s Authorized Representative**  Printed Name:  Title and Institution:  E-mail Address:  Signature  Date | **Recipient Scientist**  Printed Name:  Title and Institution:  E-mail Address:  Signature:  Date:  Shipping Address: |

**This Transfer Agreement is entered into as of: (effective date).**

TERMS OF THE AGREEMENT

I. INTRODUCTION

The MOSES Study is a human controlled exposure study, funded by the Health Effects Institute (HEI), in which older subjects (n = 87) were exposed to ozone at 0, 70, and 120 ppb. A large of number of cardiovascular and respiratory outcomes were measured before and after each exposure. Blood samples were collected before and after exposure, and sputum samples were collected after exposure. Aliquots of these samples were archived and can be made available to interested and qualified researchers on a first-come-first-served basis.

II. DEFINITIONS

**“Materials”** refers to blood and sputum samples

**“MOSES Study Original Investigator”** or **“the Provider”** is a principal investigator (or co-investigator) who participated in the conduct of the study:

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

“**MOSES Study Material Access Committee (MAC)**” includes the “MOSES Study Original Investigators” and an HEI staff member (ex officio).

**“MAC Authorized Representative**” is the MAC member designated to represent the MOSES Study Original Investigators.

**“Research Project”** refers to the project described in the Material Request Form.

**“Recipient Scientists” or “Recipient”** refers to the individual who is receiving the Material.

III. TERMS AND CONDITIONS

This Material Transfer Agreement (MTA) covers only the Research Project described in the attached Research Proposal. The Recipient must submit a separate MTA for each Research Project for which Materials are requested.

**1. Non-transferability and usage.** This MTA is not transferable. The Recipient may not distribute Materials to any other individual or entity outside the Recipient’s laboratory, regardless of the intended use of such Materials, with the following exception:

* The Recipient may transfer Materials to anyone else within the Recipient organization or an institution or other entities not affiliated with Recipient but with which Recipient has either a fee-for-service or subcontract agreement (as stipulated in the Proposal).
  + Any usage of the material and/or the data derived from the Material by the Recipient’s contractor and subcontractors will require written approval by the MAC.
  + Any usage of the material outside the approved scope (as stipulated in the Research Proposal) will require written approval by the MAC.

1. **Conduct of Research Project.** The Recipient is responsible for the conduct of the Research Project and shall be responsible for assuring that any co-investigator(s) or sub-contractors comply with the terms of this MTA.
2. **Publication.** TheRecipient is free to publish results of the Research Project through the usual channels of scientific publication. Prompt publication of these results is encouraged. The MOSES Original Investigators request that the Recipient provide a copy of any abstract and manuscript or conference presentations (including abstracts or slides) within 30 days of submission for publication.
3. **Acknowledgments.** The Recipient agrees to acknowledge the contribution of the MOSES Study Original Investigators and HEI in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data or Materials, as described below:
4. If the manuscript does not involve a collaboration with all the MOSES Study Original Investigators, the Recipient agrees to include the following language in an acknowledgment:

“The MOSES study was funded by the Health Effects Institute. The authors thank the MOSES study investigators Drs. Balmes, Bromberg, and Frampton and co-investigators for providing the blood or sputum samples. This manuscript was not prepared in collaboration with the MOSES study investigators and does not necessarily reflect their or HEI’s opinions or conclusions.”

b) If a manuscript resulting from the Research Project has all the MOSES Study Original Investigators as co-authors, then the manuscript will be reviewed by these investigators. The Recipient agrees to include the following language in an acknowledgment.

“The MOSES study was funded by the Health Effects Institute.”

1. **Non-Identification.** The Recipient agrees that Materials will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the participants from whom Materials were obtained.
2. **Use in Human Experimentation Prohibited.** The Recipient agrees that Materials and derivatives will not be used in human experimentation of any kind.
3. **Recipient's Compliance with Recipient IRB’s Requirements.** The Recipient certifies that the conditions for use of the Materials in conjunction with the Research Project have been reviewed by the Recipient's Institutional Review Board (IRB) or similar human subjects oversight body in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. The Recipient agrees to comply fully with all such conditions. The Recipient may be subject to state and local laws and regulations and institutional policies that provide additional protections for human subjects.
4. **Costs/No Warranties.** Cost for Materials preparation and distribution will be the responsibility of the Recipient. No warranties, express or implied, are offered as to the merchantability or fitness for any purpose of the materials provided to the Recipient under this agreement.

1. **Recipient's Responsibility for Handling Materials.** The Recipient acknowledges that the Materials may carry viruses, latent viral genomes, and other infectious agents. The Recipient agrees to treat the Materials as if they were not free of contamination, and affirm that the Materials will be handled by trained persons under laboratory conditions that afford adequate biohazard containment. By accepting the Materials, the Recipient assumes full responsibility for their safe and appropriate handling. HEI and the original investigators will have no liability associated with use and handling of the Materials.
2. **Non-Endorsement, Indemnification.** TheRecipient agrees not to claim, infer, or imply endorsement of the Health Effects Institute and its sponsors of the Research Project, the entity, or personnel conducting the Research Project.
3. Recipient agrees to release the Health Effects Institute and all investigator(s) who generated Materials, and the agents and employees of each of them from all liabilities, demands, damages, expenses, and losses arising out of the Recipient's use for any purpose.
4. **Integrity of Material.** The Recipient agrees that the Health Effects Institute and the MOSES investigators are not responsible for the integrity of the Materials provided.
5. **Amendments.** Amendments to this MTA must be made in writing and signed by authorized representatives of all parties.
6. **Termination.** This MTA shall terminate at the earliest of: the completion of the Research Project; or abandonment of the Research Project – whichever comes first.

a) Under all conditions, the MTA is valid for a maximum of 2 years from the date it was signed.

1. Upon termination of this MTA, the Recipient agrees to consult with the MAC Authorized Representative regarding the disposition of all remaining Materials. **The Recipient shall not dispose of any Materials without written approval from HEI.**

THE RECIPIENT must sign and return a copy of this letter and of the approved Material Request Form to the MAC’s Authorized Representative, who will then authorize the shipment of the Material and inform the Recipient of the associated preparation and shipping costs.