

THE FRAMINGHAM HEART STUDY
Data and Materials Distribution Agreement

Note: This agreement is a pdf and can be filled in electronically. It must be completed and signed before any data or biological materials will be released. Any changes or alterations to this document not approved by the National Heart, Lung, and Blood Institute (NHLBI) and Boston University will make it invalid. Please send a completed copy of this agreement, along with one copy of the proposal application and one copy of the IRB approval, to:

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Boston University School of Medicine
72 E. Concord Street, B601
Boston, MA 02118-2526
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The undersigned parties hereby enter into this Data and Materials Distribution Agreement (DMDA) as of the date specified on the final page hereof.

INTRODUCTION

The Framingham Heart Study (FHS) is an epidemiology study that has collected biological specimens and clinical data from participants in Framingham, Massachusetts, since 1948. This clinically and genetically well-characterized population is a valuable scientific source that is maintained under the joint stewardship of Boston University and the NHLBI.

To protect the confidentiality and privacy of FHS, participants and their families, investigators granted access to Data and Materials must adhere to the requirements of this DMDA. Failure to comply with this DMDA could result in its termination, denial of further access to FHS and other NHLBI resources, and may leave violators liable to legal action on the part of FHS participants, their families, or the U.S. Government.

The undersigned parties entering into this DMDA include: the Recipient and Recipient's Principal Investigator (defined in the next section), the NHLBI, and Boston University, on behalf of the FHS and under the direction of the FHS Executive Committee.

DEFINITIONS

For purposes of this agreement,

"Genetic Analysis Data" refers to any and all information derived from genetic materials and any and all data derived from statistical analyses linking data from genetic materials with other study data.

"Data" refers to any and all study data, including laboratory, examination, and questionnaire results, and Genetic Analysis Data, images (e.g., computed tomography scans, MRI scans), or primary signal data (e.g., ECG, spirometry tracings, polysomnography, accelerometry) and associated records either obtained directly from FHS participants or obtained from third parties as authorized by the participants pursuant to Boston University's contract with the NHLBI, as well as data provided to the FHS by ancillary studies.

"Resultant Data" refers to data derived in whole or in part by Recipient from Data and/or Materials provided under this DMDA.

"Materials" refers to bio-samples, including but not limited to, urine and blood samples and products thereof, including but not limited to, immortalized lymphocytes and extracted DNA from said bio-samples pursuant to the Boston University's contract with the NHLBI, as well as Materials provided to the FHS by ancillary studies.

"Framingham Heart Study Investigator" is a research investigator who works with the FHS either as an employee of the NHLBI or through a current and active contract or consulting agreement with the NHLBI or one of its contractors.

"Research Project" refers to the project described in the attached research application.

"Recipient" refers to the institution or other entity receiving access to the FHS Data and/or Materials requested for the Research Project identified in section 3 below as described in the attached research application.

"Principal Investigator (PI)" refers to the Research Project director for the Recipient.

TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Materials. Boston University and NHLBI agree to transfer to Recipient the Materials described below, including the types of samples, amount per sample, the number of individuals from whom samples are to be provided, and whether samples are nonrenewable or from a renewable resource (e.g., DNA from immortalized cell lines) for use by the Recipient's PI to conduct the Research Project as summarized in section 3 below.

2. Data. Boston University and NHLBI agree to provide Recipient with Data described as follows:

Boston University will provide Recipient with the name and contact information of Study Investigators and all other investigator(s) who generated such Data.

3. Research Project.

3.1 These Materials and Data will be used by Recipient's PI solely in connection with the Research Project, as named and described in the attached research application (insert Research Project name below):

3.2 If any aspect of the Research Project, e.g., biological assays and/or genetic analyses, is to be performed by an entity other than Recipient as permitted by section 4.2, such entity is to be named below:

3.3 This DMDA covers only the Research Project cited in section 3.1 of this DMDA. Recipient must submit a separate DMDA for each Research Project for which Data and/or Materials are requested.

4. Non-transferability. This DMDA is not transferable.

4.1 Recipient and Recipient's PI agree that substantive changes made to the Research Project, and/or appointment by Recipient of another Principal Investigator and/or transfer of Recipient's PI to another institution or other entity to complete the Research Project, require execution of a separate DMDA. Except as provided in section 4.2 below, Recipient may not distribute Data or Materials to any other individual or entity, regardless of the intended use of such Data or Materials. However, nothing in this section precludes Recipient from publishing results of the Research Project through the usual channels of scientific publication.

4.2 Recipient and Recipient's PI may transfer or cause to be transferred Materials to an institution or institutions or other entities not affiliated with Recipient but with which Recipient has either a fee-for-service or subcontract agreement or specific authorization from the NHLBI for performance of assays and/or genetic analyses for the Research Project as identified in section 3.2. A separate DMDA is not required if the derived data are either returned to the Recipient and Recipient's PI or are deposited for Recipient and Recipient's PI in a publicly accessible database authorized by the NHLBI upon completion of the assays. No Data are to be provided to such institutions or other entities unless a separate DMDA has been approved by Boston University and NHLBI.

5. Conduct of Research Project. Recipient's PI is responsible for the conduct of the Research Project and shall be responsible for assuring that any co-investigator(s) comply with the terms of this DMDA.

6. Publication. Prompt publication of the results of the Research Project is encouraged. Boston University and NHLBI request that the Recipient's PI provide to the FHS a copy of any abstract ten (10) days in advance of submission for publication and any manuscript or other disclosure document thirty (30) days in advance of submission for publication, in order to permit review and comment and ensure compliance with the **confidentiality** requirements of this DMDA.

7. Acknowledgments. Recipient and Recipient's PI agree to acknowledge the contribution of FHS staff in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data or Materials.

7.1 Collaborations. If a manuscript resulting from the Research Project has Study Investigators as co-authors, then the manuscript will be reviewed by the FHS.

7.1.a If the manuscript is approved by the FHS, the Recipient and Recipient's PI agree to include the following language in an acknowledgment.

"The Framingham Heart Study is conducted and supported by the National Heart, Lung, and Blood Institute (NHLBI) in collaboration with Boston University (Contract No. N01-HC-25195)."

"This manuscript has been reviewed by the Framingham Heart Study for scientific content and consistency of data interpretation with previous Framingham Heart Study publications."

7.1.b If the manuscript is not approved by the FHS and the Recipient and Recipient's PI wish to proceed to publish without inclusion of Study Investigators as co-authors, the Recipient and Recipient's PI agree to include the following language in an acknowledgment.

"The Framingham Heart Study is conducted and supported by the National Heart, Lung, and Blood Institute (NHLBI) in collaboration with Boston University (Contract No. N01-HC-25195)."

“This manuscript was not approved by the Framingham Heart Study. The opinions and conclusions contained in this publication are solely those of the authors, and are not endorsed by the Framingham Heart Study or the NHLBI and should not be assumed to reflect the opinions or conclusions of either.”

7.2 Other Studies. If the Research Project does not involve collaboration with Study Investigators, then the Recipient and Recipient’s PI agree to include the following language in an acknowledgment.

"The Framingham Heart Study is conducted and supported by the National Heart, Lung, and Blood Institute (NHLBI) in collaboration with Boston University (Contract No. N01-HC-25195)."

“This manuscript was not prepared in collaboration with investigators of the Framingham Heart Study and does not necessarily reflect the opinions or conclusions of the Framingham Heart Study or the NHLBI.”

7.3 Ancillary Study Investigator Acknowledgments. If Data include data provided to the FHS by ancillary study investigators, Recipient and Recipient’s PI also agree to acknowledge their contribution in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of such Data.

8. Non-Identification. Recipient and Recipient’s PI agree that Materials and/or Data 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 Data and/or Materials were obtained or derived.

9. Use Limited to Research Project. Recipient and Recipient’s PI agree that Materials, their progeny, or derivatives thereof, and Resultant Data will not be used in any experiments or procedures unless said experiments or procedures are disclosed and approved as part of the Research Project.

10. Use in Human Experimentation Prohibited. Recipient and Recipient’s PI agree that Materials, their progeny, and derivatives thereof will not be used in human experimentation of any kind.

11. Compliance with Participants' Informed Consent. Recipient and Recipient’s PI agree that Data and/or Materials, their progeny, and derivatives thereof will not be used for any purpose contrary to a participant’s applicable signed informed consent document(s). Recipient and Recipient’s PI agree to consult with Study Investigators and ascertain, specifically and in detail, the terms and conditions of applicable Framingham Heart Study informed consent documents.

12. No Distribution; Avoidance of Waste. Recipient and Recipient’s PI agree to retain control over Data, Materials and their progeny, and derivatives thereof. Recipient and Recipient’s PI further agree not to transfer Data, Materials and their progeny, and derivatives thereof, with or without charge, to any other entity or individual, except for Data and/or Materials as provided for in section 4.2 above. Recipient and Recipient’s PI agree to make reasonable efforts to avoid contamination or waste of Materials. Recipient and Recipient’s PI agree not to distribute any results of the Research Project other than through the usual channels of scientific publication and agree not to distribute any unpublished statistical results of the Research Project.

13. Resultant Data to be Provided to Boston University and NHLBI. Recipient and Recipient’s PI agree to provide Boston University with a report every twelve (12) months during the term of this DMDA. The report shall include a description of the activities performed and Resultant Data obtained during the twelve (12) months before the reporting date. Recipient and Recipient’s PI agree that Boston University and NHLBI may distribute all such Resultant Data through established NHLBI procedures to all institutions requesting access for their identified qualified scientific investigators to such Resultant Data and that submit to NHLBI a signed DMDA comparable to this DMDA. Recipient and Recipient’s PI

will provide all Resultant Data in the precise electronic format specified by NHLBI or Boston University. If errors in family structure, especially paternity, are identified, Recipient and Recipient's PI agree to contact the Boston University's Authorized Representative (named below), at the time such errors are identified, to receive detailed instructions as to how to provide such information and to whom. Recipient and Recipient's PI further agree to refrain from any disclosure of such identified errors to anyone other than individual(s) specifically identified and authorized by Boston University and NHLBI.

14. Costs/No Warranties. Cost for Materials distribution will be determined on a case by case basis. Costs are subject to change following written notification from Boston University with the approval of NHLBI. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS AND/OR DATA PROVIDED TO RECIPIENT UNDER THIS AGREEMENT, OR THAT THE MATERIALS AND/OR DATA MAY BE EXPLOITED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS OF ANY THIRD PARTIES.

15. Recipient's Responsibility for Handling Materials. Recipient and Recipient's PI acknowledge that Materials may carry viruses, latent viral genomes, and other infectious agents. Recipient and Recipient's PI agree to treat Materials as if they were not free of contamination, and affirm that Materials will be handled by trained persons under laboratory conditions that afford adequate biohazard containment. By accepting Materials, Recipient assumes full responsibility for their safe and appropriate handling.

16. Non-Endorsement, Indemnification. Recipient and Recipient's PI agree not to claim, infer, or imply United States Government endorsement of the Research Project, the entity, or personnel conducting the Research Project, or any resulting commercial product(s) except as described in section 7.

Recipient and Recipient's PI agree to hold harmless the United States Government, Boston University, and all investigator(s) who generated Data and Materials, and the agents and employees of each of them for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose.

Except where prohibited by law, Recipient agrees to defend and indemnify the United States Government, Boston University, and all investigator(s) who generated Data and Materials, and the agents and employees of each of them for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose.

17. Accuracy of Data. Recipient agrees that the United States Government and Boston University are not responsible for the accuracy of Data or the provenance or integrity of Materials provided.

18. Recipient's Compliance with Recipient IRB's Requirements. Recipient certifies that the conditions for use of the Data and/or Materials in conjunction with the Research Project have been approved by the Recipient's Institutional Review Board (IRB) or equivalent human subjects oversight body in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions and with the participants' informed consent documents, and any additional conditions that may be imposed by the Boston University Medical Center Institutional Review Board (BUMC IRB). Recipient agrees to report promptly to Boston University and NHLBI any unanticipated problems or proposed changes in the Research Project. Recipient also agrees to report to Recipient's IRB any unanticipated problems or changes in the Research Project that involve additional risks to participants or others. Recipient remains subject to applicable state and local laws and regulations and institutional policies that provide additional protections for human subjects.

19. Recipient's Responsibility to follow Data Security Best Practices. Recipient is aware of computer and data security best practices and will follow them for receipt, storage and use of Data and Resultant Data. An example of best practice guidelines can be found in http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap_2b_security_procedures.pdf.

20. Amendments. Amendments to this DMDA must be made in writing and signed by authorized representatives of all parties.

21. Termination. This DMDA shall terminate at the earliest of: the completion of the Research Project; five (5) years after the effective date of this DMDA; abandonment of the Research Project; or violation by Recipient of any provisions of this DMDA not remedied within 30 days after the date of written notice by NHLBI and Boston University of such violation. Upon termination of this DMDA:

- (a) If Data provided to Recipient include Center for Medicare and Medicaid Services (CMS) data, Recipient agrees to destroy all copies of all Data received from Boston University and consult with Boston University and the NHLBI regarding the disposition of all remaining Materials.
- (b) If Data provided to Recipient do not include Center for Medicare and Medicaid Services (CMS) data, Recipient agrees to consult with Boston University and the NHLBI regarding the disposition of all remaining Data and/or Materials.

22. Disqualification, Enforcement. Failure to comply with any of the terms of this DMDA may result in disqualification of Recipient from receiving additional Data and/or Materials. The United States Government and/or Boston University may have the right to institute and prosecute appropriate proceedings at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this DMDA, the limitations on the use of the Data or Materials provided, or both. Proceedings may be initiated against the violating party, or legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding at law or in equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient and Recipient's PI acknowledge and agree that a breach or threatened breach of the confidentiality requirements or use limitations of this DMDA may subject Recipient and Recipient's PI to legal action on the part of FHS participants, their families, or both.

23. Representations. Recipient and Recipient's PI expressly certify that the contents of any statements made or reflected in this document are truthful and accurate.

24. Prior Distribution Agreements. By execution of this DMDA, Recipient certifies compliance with the terms and conditions of all existing DMDAs with Boston University and/or the NHLBI.

Required Signatures begin on the next page

RECIPIENT'S PRINCIPAL INVESTIGATOR AND RECIPIENT'S AUTHORIZED REPRESENTATIVE:

Name and Title of Recipient's Principal Investigator

Surface Mail Address of Recipient's Principal Investigator

Email Address of Recipient's Principal Investigator

Telephone and Fax Number of Recipient's Principal Investigator

Signature of Recipient's Principal Investigator and Date

_____ a [non-profit] OR [for-profit] corporation/institution
Name of Recipient (Corporation/Institution)

organized under the laws of (State/Country): _____

with a principal address at: _____

Name and Title of Recipient's Authorized Representative

Signature and Date of Recipient's Authorized Representative

TRUSTEES OF BOSTON UNIVERSITY (BOSTON UNIVERSITY):

Name and Title of Boston University's Authorized Representative

Signature and Date of Boston University's Authorized Representative

NHLBI (for Materials only):

Name and Title of NHLBI's Authorized Representative

Signature and Date of NHLBI Authorized Representative

This Distribution Agreement is entered into as of: _____ (effective date)