

**THE FRAMINGHAM HEART STUDY  
Data and Materials Distribution Agreement**

FHS Project Number: \_\_\_\_\_

**Note: This agreement is a pdf and can be filled in electronically. It must be completed and signed before any DNA or genetic data or biological materials will be released. Any changes or alterations to this document not approved by the National Heart, Lung, and Blood Institute 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:**

**Heather Arruda  
Framingham Heart Study  
Boston University School of Medicine  
72 E. Concord Street, B601  
Boston, MA 02118-2526  
TEL: 617-414-1244  
FAX: 617-638-8086  
Email: [harruda@bu.edu](mailto:harruda@bu.edu)**

The undersigned parties hereby enter into this Data and Materials Distribution Agreement (DMDA) as of the date specified on the final page hereof.

**PRELIMINARY STATEMENT**

The National Heart, Lung, and Blood Institute (NHLBI), in collaboration with Boston University, has supported the collection of biological specimens and clinical data from participants in the Framingham Heart Study (FHS) since 1948. This clinically and genetically well-characterized population is a unique and valuable scientific resource that is maintained under the joint stewardship of Boston University and the NHLBI. The FHS investigators have made a long-term commitment to establishing and maintaining clinical, genetic, and bio-sample databases. The NHLBI and the FHS investigators share a duty to the general public and to the scientific community to facilitate access to these resources in order to promote timely scientific progress, subject to appropriate terms and conditions on their use. The NHLBI and Boston University specifically seek to promote the use of the FHS resources in research beneficial to public health. The NHLBI and Boston University encourage the use of FHS data and materials by investigators not affiliated with the FHS or Boston University, to foster collaborative relationships where appropriate, and to ensure that the FHS investigators are appropriately acknowledged. Collaboration with FHS investigators (past or present) is not required as a condition of receiving biological materials or data, but investigators are encouraged to collaborate with FHS investigators because of the complexity of the data sets. Although every effort has been made to provide documentation of the highest quality (and limited user support is available), working with the existing FHS investigators is likely to enhance the efficiency and productivity of most research efforts.

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 the DMDA could result in denial of further access to Framingham resources and

may leave violators liable to legal action on the part of FHS participants, their families, or the U.S. Government.

## DEFINITIONS

For purposes of this agreement,

**"Clinical Data"** refers to data or images (e.g., computed tomography scans) and associated records collected and recorded from FHS subjects through the periodic examinations conducted pursuant to Boston University's contract with the NHLBI, as well as data provided to the FHS by ancillary studies.

**"Biological 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 Boston University's contract with the NHLBI, as well as Biological Materials returned to the FHS by ancillary studies.

**"Genetic Analysis Data"** refers collectively to "Molecular Genetic Data" and "Statistical Analysis Data" as they are defined below;

**"Molecular Genetic Data"** consists of data derived from analyses of genetic materials contained in Biological Materials including, but not limited to, genotyping analysis, anonymous marker polymorphisms, DNA sequence information, mutation analysis and other genetic analyses.

**"Statistical Analysis Data"** consists of data derived from statistical analyses linking Molecular Genetic Data with Clinical Data including, but not limited to, genetic linkage analysis, transmission disequilibrium analysis, haplotype relative risk analysis and other statistical genetic techniques.

**"Recipient"** refers to the Institution receiving access to the Framingham Clinical Data, Genetic Analysis Data and/or Biological Materials requested in the attached research application at its sole risk.

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

**"Research Project"** refers to the approved research application.

## AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

**1. Biological Materials.** Boston University and NHLBI, agree to transfer to Recipient the Biological Materials described below for use by the Recipient's PI to conduct the research described in section 4 below. These Biological Materials (including the number and type of sample and whether samples are nonrenewable or from a renewable resource (e.g., DNA from immortalized cell lines) are described as follows:

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

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**3. Genetic Analysis Data.** Boston University and NHLBI, agree to provide Recipient with Genetic Analysis Data, if available, described as follows:

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Boston University will provide Recipient with the name and address of any and all other Investigator(s) who generated such "Genetic Analysis Data."

**4. Research Project.**

**4.1** These Biological Materials, Clinical Data, and/or Genetic Analysis Data will be used by Recipient's PI solely in connection with the following research project (Cite Project Number, Project Title and PI) and specifically described in the attached approved project proposal

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**4.2** 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 5.2, such entity is to be named below:

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**4.3** This DMDA covers only the Research Project cited in section 4.1 of this agreement. Recipient must submit a separate Distribution Agreement for each Research Project in which Clinical Data, Genetic Analysis Data and/or Biological Materials are requested.

**5. Non-transferability.** This DMDA is not transferable.

5.1 Recipient and Recipient's PI agree that substantive changes made to the Research Project described above, and/or appointment by Recipient of another Principal Investigator and/or transfer of Recipient's PI to another institution to complete the Research Project, require execution of a separate DMDA. Except as provided in section 5.2 below, Recipient may not distribute Clinical Data, Biological Materials, Genetic Analysis Data, Molecular Genetic Data, or Statistical Analysis Data to any other individual or entity, regardless of the intended use of such data or materials,

except in connection with the publication of Project results through the usual channels of scientific publication.

5.2 Recipient and Recipient's PI may transfer Biological Materials to an entity not affiliated with Recipient but with which Recipient has a fee-for-service or subcontract agreement for performance of assays and/or genetic analyses for the Research Project. A separate DMDA is not required if the derived laboratory and/or genetic data are returned to the Recipient and Recipient's PI upon completion of the assays and/or genetic analyses. No Clinical Data, Genetic Analysis Data, Genetics Data, or Statistical Analysis Data are to be provided to such entity unless a prior DMDA or Data Distribution Agreement with the entity has been approved by Boston University and NHLBI.

**6. Conduct of Research Project.** Recipient's PI is responsible for the conduct of the Research Project, and shall be responsible for assuring that all co-investigators comply with the terms of this DMDA.

**7. 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 with 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 Agreement.

**8. Acknowledgments.** Recipient and Recipient's PI agree to acknowledge the contribution of Boston University and NHLBI FHS staff in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Clinical Data or Biological Materials.

**8.1 Collaborations/Acknowledgments.** If the Research Project involves collaboration with FHS co-investigators, then Recipient and Recipient's PI will acknowledge FHS co-investigators as co-authors, as appropriate, on any publication. In addition, the manuscript will be reviewed by the Boston University/FHS, and the Recipient and Recipient's PI will use the following 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 Framingham Heart Study Investigators for scientific content and consistency of data interpretation with previous Framingham Heart Study publications.

**8.2 Other Studies/Acknowledgments.** If the Research Project does not involve collaboration with FHS co-investigators, then the Recipient and Recipient's PI agree to include in any resultant manuscript the following acknowledgement.

"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 views of the Framingham Heart Study, Boston University, or NHLBI."

**8.3 Acknowledgments/Genetic Analysis Data.** If Genetic Analysis Data are received, the Recipient and Recipient's PI agree to acknowledge the contribution of FHS staff and/or the Investigator(s) who derived such data in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of such Genetic Analysis Data.

**9. Non-Identification.** Recipient and Recipient's PI agree that Biological Materials, Clinical Data, and/or Genetic Analysis 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 subjects from whom Clinical Data, Biological Materials, and/or Genetic Analysis Data were obtained or derived.

**10. Use Limited to Research Project.** Recipient and Recipient's PI agree that Biological Materials, their progeny, or unmodified or modified derivatives thereof and data derived from statistical analyses of Clinical Data or Genetic Analysis Data will not be used in any experiments or procedures that are not disclosed and approved as part of the Research Project.

**11. Use in Human Experimentation Prohibited.** Recipient and Recipient's PI agree that Biological Materials, their progeny, and unmodified or modified derivatives thereof will not be used in human experimentation of any kind.

**12. Compliance with Subjects' Informed Consent.** Recipient and Recipient's PI agree that Biological Materials, their progeny, and unmodified or modified derivatives thereof will not be used for any purpose contrary to a subject's applicable signed informed consent document(s). It is the responsibility of the Recipient's PI to consult with FHS investigators and ascertain, specifically and in detail, the terms and conditions of applicable FHS informed consent documents.

**13. No Distribution, Avoidance of Waste, Return of Materials.** Recipient and Recipient's PI agree to retain control over Clinical Data, Genetic Analysis Data, other statistical analyses data and Biological Materials, their progeny, and unmodified or modified derivatives thereof. Recipient and recipient's PI further agree not to transfer Clinical Data, Genetic Analysis Data or Biological Materials, their progeny, and unmodified or modified derivatives thereof, with or without charge, to any other entity or individual, except for Biological Materials as provided for in section 5.2 above. Recipient and Recipient's PI agree, in handling the Biological Materials, to make reasonable efforts to avoid contamination or waste of the samples. 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. When the Research Project is completed, or three (3) years have elapsed from the effective date of this Distribution Agreement, whichever occurs first, the Biological Materials will be returned to Boston University and NHLBI, unless an extension of this Agreement is obtained.

**14. Resultant Data to be Provided to Boston University and NHLBI.** Recipient and Recipient's PI agree to provide Boston University and NHLBI with a report every twelve (12) months during the term of this DMDA containing data derived by Recipient's PI, in the performance of the Research Project. Such report will cover all data derived by Recipient's PI up to twelve (12) months before the reporting date. Recipient and Recipient's PI agree that Boston University and NHLBI may distribute all such data to all institutions requesting access for

identified qualified scientific investigators through established NHLBI procedures that submit to NHLBI a signed DMDA comparable to this DMDA. Recipient and Recipient's PI will provide Genetic Analysis Data, indexed by genotyping ID number in the precise electronic format specified by NHLBI or Boston University. If genotyping has been conducted, DNA marker names and genotype data must be provided for each individual subject as indexed by the FHS subject ID number along with descriptive information about each typed marker that includes standard marker and allele names, absolute distances in Megabases and in Centimorgans, and the source of information used to determine map location that must be referenced to the NCBI database, if available. Recipient and Recipient's PI also agree to submit all data relevant to errors in family structure, especially paternity, at the time such determinations are made, and to refrain from any disclosure of such data to anyone other than individual(s) specifically identified and authorized by Boston University and NHLBI.

**15. Costs/No Warranties.** Cost for Biological Materials distribution will be determined on a case by case basis, depending upon the needs of the study. 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 BIOLOGICAL MATERIALS, GENETIC ANALYSIS DATA, AND CLINICAL DATA PROVIDED TO RECIPIENT UNDER THIS AGREEMENT, OR THAT THE BIOLOGICAL MATERIALS, GENETIC ANALYSIS DATA, OR CLINICAL DATA MAY BE EXPLOITED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS OF ANY THIRD PARTIES.

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

**17. 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 8. To the extent permitted by law, Recipient and Recipient's PI agree to hold the United States Government, Boston University, and all other investigator(s) who generated Genetic Analysis Data, and the agents and employees of each of them, harmless and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose of Clinical Data, Genetic Analysis Data, and Biological Materials, their byproducts, or modified or unmodified derivatives.

**18. Accuracy of Data.** Recipient agrees that the United States Government, Boston University, and the other investigator(s) who generated Genetic Analysis Data are not responsible for the accuracy of Genetic Analysis Data provided by other Recipients. The United States Government and Boston University are not responsible for the accuracy of Clinical Data or the provenance or integrity of Biological Materials provided.

**19. Recipient's Compliance with IRB Requirements.** Recipient acknowledges that the conditions for use of the Clinical Data, Genetic Analysis Data, and/or Biological Materials have been approved by the Recipient's Institutional Review Board (IRB) 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 subjects' informed consent documents, and any additional conditions that may be imposed by the Boston University Medical Center Institutional Review Board (BUMC IRB). Recipient acknowledges that this project is not eligible for exemption from IRB review. Recipient agrees to report promptly to the BUMC IRB and NHLBI any proposed change in the Research Project and any unanticipated problems involving risks to subjects or others. Recipient remains subject to applicable state and local laws and regulations and institutional policies that provide additional protections for human subjects.

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

**21. Termination.** This DMDA shall terminate three (3) years after the Effective Date unless Boston University, NHLBI, and Recipient agree in writing to extend it. Boston University, in consultation with NHLBI, may terminate this DMDA if Recipient is in default of any of its conditions and such default has not been remedied within 30 days after the date of written notice by NHLBI and Boston University of such default. Upon termination of this DMDA, Recipient agrees to return all unused Biological Materials to Boston University and destroy all copies of the Genetic Analysis Data and Clinical Data previously received from Boston University. Upon termination of this DMDA Recipient's right to publish the results of the Research Project shall terminate immediately, unless otherwise agreed to in writing by NHLBI and Boston University.

**22. Disqualification, Enforcement.** Failure to comply with any of the terms of this DMDA may result in disqualification of Recipient from receiving additional Clinical Data, Biological Materials, and/or Genetic Analysis Data. The United States Government and/or Boston University shall 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 in law or 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 subjects, their families, or both.

**23. Accurate 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.** Execution of this DMDA is contingent upon Recipient's compliance with all terms and conditions of existing DMDAs and Data Distribution Agreements with Boston University and the NHLBI

**Required Signatures begin on the next page**

**RECIPIENT INVESTIGATOR AND CORPORATION/INSTITUTION:**

\_\_\_\_\_  
*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*

\_\_\_\_\_  
*Name of Recipient Corporation/Institution* a [non-profit] OR [for-profit] corporation/institution

organized under the laws of the State of: \_\_\_\_\_

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 Authorized Representative*

**NHLBI:**

\_\_\_\_\_  
*Name and Title of NHLBI's Authorized Representative*

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*Signature and Date of NHLBI Authorized Representative*

**This Distribution Agreement is entered into as of: \_\_\_\_\_ (effective date)**