

**The Framingham Heart Study  
Data Distribution Agreement**

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

**Note: This agreement is a pdf and can be filled in electronically. It must be completed and signed by yourself and your institution before any data can 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**

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

**PRELIMINARY STATEMENT**

To protect the confidentiality and privacy of the Framingham Heart Study (FHS) participants, the Recipient who is granted access to these data must adhere to the requirements of this DDA. Failure to comply with the provisions of this DDA could result in denial of further access to FHS Data. Violation of the confidentiality requirements of this DDA may leave Requestor, its Principal Investigator, and any other investigators involved in the research liable to legal action on the part of FHS participants, their families, Boston University and/or the U. S. Government.

The FHS Investigators have made a substantial long-term contribution in establishing and maintaining the clinical database. The FHS seeks to encourage appropriate collaborative relationships with outside investigators while ensuring that the contributions of the FHS Investigator are acknowledged.

## DEFINITIONS

For purposes of this DDA,

**“Data”** refers to the Clinical Data or Images (e.g., computed tomography scans) that have been collected and recorded from FHS participants through the periodic examinations and follow-up contacts conducted pursuant to Boston University’s contract with the National Heart, Lung, and Blood Institute (NHLBI), as well as data provided to the FHS by ancillary studies.

A **“FHS Study Investigator”** is defined as 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.

**“Recipient”** refers to the Institution receiving access to the Framingham data requested in the attached research application at its sole risk.

**“Recipient’s Principal Investigator (PI)”** refers to the Research Project director for the Recipient.

**“Research Project”** refers to the research described in this DDA.

## AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

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

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### **2. Research Project.**

**2.1.** Data will be used by Recipient's PI solely in connection with the following research project (cite Project Number and Title) and specifically described in the attached approved project proposal:

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**2.2.** This DDA covers only the Research Project cited in section 2.1. Recipient must submit a separate DDA for each research project for which Data are requested.

**3. Non-transferability.** This DDA is not transferable. Recipient agrees 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 new DDA. Recipient may not distribute Clinical Data or

Images to any other individual or entity, regardless of the intended use of such data, except in connection with the publication of Research Project results through the usual channels of scientific publication.

**4. 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 DDA.

**5. Publication.** Prompt publication or any public disclosure 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 ensure compliance with the **confidentiality** requirements of this Agreement.

**6. Acknowledgments.** Recipient and Recipient's PI agree to acknowledge the contribution of Boston University and NHLBI FHS Investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data.

**6.1. Collaborations/Acknowledgments.** Recipients will acknowledge FHS Investigators as co-authors, as appropriate, on any publication. In addition, Recipient and Recipient's PI agree to provide the manuscript for review by FHS collaborators prior to submission for publication and to 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.

**6.2 Other Studies/Acknowledgments.** If the Research Project does not involve collaboration with FHS co-investigators, then 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."

**7. Non-Identification.** Recipient and Recipient's PI agree that Data will not be used, either alone or in conjunction with any other information, in any effort to establish the individual identities of any of the subjects from whom Data were obtained.

**8. Use Limited to Research Project.** Recipient and Recipient's PI agree that Data will not be used in any research that is not disclosed and approved as part of the Research Project.

**9. Compliance with Subjects' Informed Consent.** Recipient and Recipient's PI agree that Data, and modified or unmodified 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 the FHS Investigators and ascertain, specifically and in detail, the terms and conditions of applicable FHS informed consent documents.

**10. No Distribution.** Recipient and Recipient's PI agree to retain control over Data, and further agree not to transfer Data, with or without charge, to any other entity or individual.

**11. Non-Data.** Notwithstanding the definition of "Data" or the agreed Terms and Conditions of this DDA, the obligations of the Recipient and the Recipient's PI under this DDA shall not extend to any information that:

- (a) can be demonstrated to have been publicly known at the time of disclosure; or
- (b) can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to Recipient from another source prior to the disclosure; or
- (c) becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Recipient; or
- (d) can be demonstrated as independently developed or acquired by Recipient without reference to or reliance upon Data provided under this Agreement; or
- (e) is required to be disclosed by law, provided the Recipient takes responsible and lawful actions to avoid and/or minimize such disclosure.

**12. Non-Endorsement, Indemnification.** Recipient and Recipient's PI agree not to claim, infer, or imply United States Governmental endorsement of the Research Project, the entity, or personnel conducting the Research Project, or any resulting commercial product(s) except as described in section 4. To the extent permitted by law, Recipient and Recipient's PI agree to hold the United States Government, Study Investigators, and all other investigator(s) who generated 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 Data.

**13. Accuracy of Data.** Recipient agrees that the United States Government and Boston University are not responsible for the accuracy of Clinical Data or Images provided.

**14. Recipient's Compliance with IRB Requirements.** Recipient acknowledges that the conditions for use of these Data are not exempt from review and have been approved by the Recipient's Institutional Review Board (IRB) operating under an Office of Human Research Protections (OHRP) - approved Assurance and in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions. Recipient agrees to report promptly to the FHS as indicated by the FHS website (<http://www.framinghamheartstudy.org/research/review.html>) any proposed change in the Research Project and any unanticipated problems involving risks to subjects or others. This DDA is made in addition to, and does not supersede, any of Recipient's institutional policies or any local, State, and/or Federal laws and regulations which provide additional protections for human subjects.

**15. Amendments.** Amendments to this DDA must be made in writing and signed by authorized representatives of all parties.

**16. Termination.** The FHS may terminate this DDA if Recipient is in default of any of its provisions and such default has not been remedied within 30 days after the date of written notice by Authorized Representative of the FHS of such default.

**17. Disqualification, Enforcement.** Failure to comply with any of the terms of this DDA may result in disqualification of Recipient from receiving additional Data. Boston University and/or the United States Government shall have the right to institute and prosecute any proceeding at law or in equity against the Recipient or Recipient's PI for violating or threatening to violate the confidentiality requirements of this DDA, the limitations on the use of the data provided, or both. Proceedings may be initiated against the violating party, 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 DDA may subject Recipient and Recipient's PI to legal action on the part of FHS subjects, their families, or both.

**18. 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.

**19. Prior Distribution Agreements.** Execution of this DDA is contingent upon Recipient's compliance with all terms and conditions of existing Distribution Agreements with Boston University and the NHLBI.

**Required signatures begin on the next page.**

**RECIPIENT INVESTIGATOR AND CORPORATION/INSITUTION:**

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

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