Cardiovascular Health Study
Data and Materials Distribution Agreement

The undersigned parties hereby enter into this Data and Materials Distribution Agreement (DMDA) on the date the last party hereto signs the SIGNATURE PAGE below (the "Effective Date").

INTRODUCTION

The **Cardiovascular Health Study (CHS)** is described at **https://chs-nhlbi.org/**.

To protect the confidentiality and privacy of **CHS** 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 **CHS** or other National Heart, Lung, and Blood Institute (NHLBI) resources, and may leave violators subject to legal action on the part of **CHS** participants, their families, or actions brought by the United States of America (U.S. Government).

The undersigned parties entering into this DMDA include: the **Recipient** (defined in the next section), the NHLBI, and the Coordinating Center for the **CHS**, on behalf of the **CHS** and under the direction of the **CHS** Steering Committee.

DEFINITIONS

For purposes of this DMDA,

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

"Data" refers to any and all study information, records, statistics, facts, figures, and numbers, including without limitation to, laboratory, examination, and questionnaire results, and **Genetic Analysis Data**, images (e.g., without limitation to computed tomography scans, MRI scans), or primary signal data (e.g., ECG, spirometry tracings, polysomnography, accelerometry) and associated records either obtained directly from **CHS** participants or obtained from third parties as authorized by the participants pursuant to the contracts with the NHLBI, as well as those provided to the **CHS** 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 biological samples including without limitation to: urine, blood (or any part thereof), tissues, or extracted DNA from said biological samples pursuant to the contracts with the NHLBI, as well as biological samples provided to the **CHS** by ancillary studies.

"CHS Study Investigator" is a research investigator who works with the **CHS** 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 **CHS Data** and/or **Materials** requested for the **Research Project** identified in section 3 below as described in the attached research application.

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

TERMS AND CONDITIONS

The Parties hereto agree as follows:

1. Materials. CHS and NHLBI agree to transfer to **Recipient** the **Materials** described below, including the types of samples, amount, and concentration per sample (when applicable), 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. CHS agrees to provide **Recipient** with **Data** described as follows:

_____

_____

CHS 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 for use in conducting 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**, is to be performed by an entity other than the **Recipient** as permitted by section 4.2, such entity is to be named below:

_____

_____

Recipient agrees that it will not employ, contract with, or retain any person, directly or indirectly, who is listed in the federal government's Excluded Parties List (EPL) System for Award Management (SAM) (https://sam.gov/content/exclusions). **Recipient** agrees to notify **CHS** within 30 days of such person's debarment or disqualification under this DMDA.

3.3 This DMDA covers only the **Research Project** set forth in Section 3.1. **Recipient** must submit a separate DMDA for each **Research Project** for which **Data** and/or **Materials** are requested.

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

RECIPIENT'S PI INITIALS:_____

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** will 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**. 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 **CHS** and NHLBI.

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

6. Publication. Prompt publication of the results of the **Research Project** is encouraged. **CHS** and NHLBI request that the **Recipient's PI** provide to the authorized representative for the **CHS** Coordinating Center (named below) 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 **CHS** 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 must be submitted for review by the **CHS**.

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

"The **Cardiovascular Health Study** is supported by contracts 75N92021D00006, HHSN268201200036C, HHSN268200800007C, N01 HC55222, N01HC85079, N01HC85080, N01HC85081, N01HC85082, N01HC85083, N01HC85086 and NHLBI grants U01HL080295 and U01HL130114, with additional contribution from NINDS. Additional support was provided through AG-023629 from the NIA. See also https://chs-nhlbi.org/pubs/PubAcknowGuidelines."

"This manuscript has been reviewed by **CHS** for scientific content and consistency of **data** interpretation with previous **CHS** publications."

7.1.b If the manuscript is not approved by the **CHS** 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 **Cardiovascular Health Study** is supported by contracts 75N92021D00006, HHSN268201200036C, HHSN268200800007C, N01 HC55222, N01HC85079, N01HC85080, N01HC85081, N01HC85082, N01HC85083, N01HC85086 and NHLBI grants U01HL080295 and U01HL130114, with additional contribution from NINDS. Additional support was provided through AG-023629 from the NIA. See also https://chs-nhlbi.org/pubs/PubAcknowGuidelines."

"This manuscript was not approved by the **CHS**. The opinions and conclusions contained in this publication are solely those of the authors, and are not endorsed by the **CHS** 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 **Cardiovascular Health Study** is supported by contracts 75N92021D00006, HHSN268201200036C, HHSN268200800007C, N01 HC55222, N01HC85079, N01HC85080, N01HC85081, N01HC85082, N01HC85083, N01HC85086 and NHLBI grants U01HL080295 and U01HL130114, with additional contribution from NINDS. Additional support was provided through AG-023629 from the NIA. See also https://chs-nhlbi.org/pubs/PubAcknowGuidelines."

"This manuscript was not prepared in collaboration with investigators of the **CHS** and does not necessarily reflect the opinions or conclusions of the **CHS** or the NHLBI."

7.3 Ancillary Study Investigator Acknowledgments**.** If **Data** include **data** provided to the **CHS** 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 **Data**, **Materials**, their progeny, or derivatives thereof 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 experimentation or research involving of any kind with human participants.

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 **CHS** informed consent documents.

12. No Distribution; Confidentiality, and **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. In addition to the provisions set forth in section 19 below, **Recipient** and **Recipient's PI** agree to keep **Data** confidential, encrypted (if stored in an electronic medium), and off of publicly available **Data** storage platforms. **Recipient** and **Recipient's PI** agree to make reasonable efforts to avoid contamination or waste of **Materials**. Please refer to the NIH Best Practices for Controlled-Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy (https://osp.od.nih.gov/wp-content/uploads/NIH_Best_Practices_for_Controlled-Access_Data_Subject_to_the_NIH_GDS_Policy.pdf).

RECIPIENT'S PI INITIALS:_____

13. Resultant Data to be Provided to CHS and NHLBI. Recipient and **Recipient's PI** agree to provide **CHS** 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 **CHS** and NHLBI, in accordance with the NIH Data Sharing Policy (https://grants.nih.gov/grants/policy/data_sharing/index.htm) and NHLBI Policy for Data Sharing from Clinical Trials and Epidemiologic Studies (https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-for-data-sharing-from-clinical-trials-and-epidemiological-studies), 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 **CHS**. If errors in family structure, especially paternity, are identified, **Recipient** and **Recipient's PI** agree to contact the Coordinating Center 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 **CHS** 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 **CHS** with the approval of NHLBI. NO WARRANTIES, EXPRESS OR IMPLIED, ARE PROVIDED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS AND/OR **DATA** PROVIDED TO **RECIPIENT** UNDER THIS AGREEMENT.

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 the United States Government, **CHS**, and all investigator(s) who generated **Data** and **Materials**, and the agents and employees of each of them harmless and release them from all liabilities, demands, damages, expenses, and losses arising out of Recipient's or Recipient's PI's gross negligence.

17. Accuracy of Data. Recipient agrees that the United States Government and **CHS** 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 agrees to use the **Data** and/or **Materials** only 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. **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 **CHS** IRB(s). **Recipient** agrees to report promptly to the **CHS** 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 signatory Parties hereto.

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 **CHS** of such violation, debarment or disqualification.

Upon termination of this DMDA:

> **Recipient** agrees to destroy all copies of all **Data** received from **CHS** and consult with the **CHS** and the NHLBI regarding the disposition of all remaining **Materials**. **Recipient** will verify that the **CHS data** have been destroyed in a written or electronic communication to the **CHS** Coordinating Center.

22. Disqualification, Enforcement. Failure to comply with any of the terms of this DMDA may result in disqualification of **Recipient** and **Recipient's PI** from receiving additional **Data** and/or **Materials**. The United States Government and/or **CHS** may have the right to initiate legal actions at law or in equity against the **Recipient** for violating or manifesting an intent 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 that a breach or manifesting an intent to breach the confidentiality requirements or use limitations of this DMDA may subject **Recipient** and **Recipient's PI** to legal action on the part of **CHS** participants, their families, or both.

RECIPIENT'S PI INITIALS:_____

23. Prior Distribution Agreements. By execution of this DMDA, **Recipient** certifies to the best of its knowledge that it is in compliance with the terms and conditions of all its existing DMDAs with **CHS** and/or the NHLBI.

Required Signatures begin on the next page

SIGNATURE PAGE

RECIPIENT'S PRINCIPAL INVESTIGATOR:

Read and Understood by the Recipient's Principal Investigator:

I agree to abide by the terms and conditions laid out in this agreement and acknowledge that I am steward of the data and/or materials for the duration of this agreement and am responsible for my own actions and those that I supervise or that are working under my direction.

_____
Name and Title of Recipient's Principal Investigator

_____
Mailing 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

RECIPIENT'S AUTHORIZED REPRESENTATIVE:

_____*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

COORDINATING CENTER FOR Cardiovascular Health Study (CHS)

_____

*Name and Title of **CHS** Coordinating Center Authorized Representative*

_____

*Signature and Date of **CHS** Coordinating Center Authorized Representative*

NHLBI (for Materials only):

_____

*Name and Title of NHLBI **CHS** Representative*

_____

*Signature and Date of NHLBI **CHS** Representative*

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