Instructions for completing
Data and Material Distribution Agreements (DMDA)

1. When to fill out a DMDA

If you are requesting data and/or materials from the ARIC study (i.e., for an ancillary study, or a manuscript), you will need to fill out a DMDA. Examples of data requested that will require a DMDA are data derived from genetic materials (**Genetic Analysis Data**), including statistical analyses linking data from genetic materials with other study data (**data**), laboratory, examination, and questionnaire results, images (e.g. computed tomography and MRI scans) and primary signal data (e.g. ECGs, spirometry tracings, polysomnography, or accelerometry) and associated records. **Materials** that require a DMDA are any type of bio-sample, such as urine, blood, and products thereof (e.g. immortalized lymphocytes and extracted DNA).

2. Where to find the ARIC DMDA

ARIC DMDA can be found on the ARIC study website here: https://www2.cscc.unc.edu/aric/distribution-agreements, under the file name: **Data and Materials Distribution Agreement (DMDA) Instructions**

3. How to complete a DMDA

The PI should download the DMDA from the ARIC website and complete the form.

For a DMDA to be valid, it ***must have*** the following sections complete:

- Section 1 "Materials"
- Section 2"Data"
- Section 3 "Research Project"
- Required Signatures

After Sections 1-3 of the form are completed, the Principal Investigator (PI) must sign the agreement. A second signature must be obtained from the Authorized Institutional Representative, as the local institutional authority has to legally commit the institution to this agreement. A final set of signatures must be obtained depending on whether data and/or materials are being requested by the PI.

*For Data requests only (**no NHLBI review needed**):*

1) Send the signed form to ARIC pubs (ARICpub@unc.edu) at the Collaborative Studies Coordinating Center (CSCC).
2) ARIC PI at the CSCC signs the DMDA and keeps the original and sends a copy of the signed and sends a copy of the signed, fully executed DMDA back to the PI.

*For Materials (and Data) that are being transferred from the ARIC Laboratories (**NHLBI review needed**):*

1) Send the signed DMDA to the ARIC project officer at NHLBI (Dr. Jacqueline Wright, Dr.P.H. jacqueline.wright@nih.gov).
2) NHLBI will send the signed DMDA to the CSCC (ARICpubs).
3) ARIC PI at the CSCC signs the DMDA, keeps the original copy and sends a copy of the signed, fully executed DMDA back to the PI.

Note: Faxed and/or scanned copies of the DMDA are acceptable.

If the DMDA relates to an ancillary study (AS), the AS # should be printed in the upper right corner of the DMDA to assist the CSCC with tracking the agreement. Once this process is complete, the CSCC will note on the AS Table that the agreements are complete and send an email to the laboratories with permission to distribute materials and allow data to be distributed.

Addresses to note:

Jacqueline Wright, Dr.P.H. (ARIC Study Project Officer) jacqueline.wright@nih.gov
NIH-National Heart, Lung, and Blood Institute
Two Rockledge Center
6701 Rockledge Drive
Mail Station: 7934, Room 10186
Bethesda, MD 20892-7936 Fedex Address: (Zip Code 20817)

Phone: (301) 435-0384 Fax: (301) 480-1455

Kim Ring (Project Manager) kim_ring@unc.edu
Collaborative Studies Coordinating Center, University of North Carolina
Department of Biostatistics
Carolina Square
123 W. Franklin Street, Suite 450
Mail Station 8030
Chapel Hill, NC
27516
Phone: (919) 962-3096 Fax: (919) 962-3265

If you have any questions related to the ARIC DMDA, please contact: aricpub@unc.edu

Appendix A
NHLBI Atherosclerosis Risk in Communities Study
Data and Materials Distribution Agreement

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 Atherosclerosis Risk in Communities (ARIC) is a multi-center epidemiologic study supported by contracts with the National Heart, Lung, and Blood Institute (NHLBI). The study is designed to monitor the trends in incidence and mortality of coronary heart disease (CHD) and heart failure in communities, and to investigate the etiology and natural history of subclinical and clinical cardiovascular disease.

To protect the confidentiality and privacy of the ARIC Study 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 the ARIC Study and other NHLBI resources, and may leave violators liable to legal action on the part of the ARIC Study 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 the Coordinating Center for the ARIC Study, on behalf of the ARIC Study and under the direction of the ARIC Study Steering 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 the ARIC Study participants or obtained from third parties as authorized by the participants pursuant to the contracts with the NHLBI, as well as data provided to the ARIC Study 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 contracts with the NHLBI, as well as Materials provided to the ARIC Study by ancillary studies.

"ARIC Study Investigator" is a research investigator who works with the ARIC Study 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 ARIC Study 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. The ARIC Study 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. The ARIC Study and NHLBI agree to provide Recipient with Data described as follows:

_____
_____
_____

The ARIC Study 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 the ARIC Study 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. The ARIC Study and NHLBI request that the Recipient's PI provide to the authorized representative for the ARIC Study 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 the ARIC Study 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 ARIC Study.

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

"The Atherosclerosis Risk in Communities (ARIC) Study is conducted and supported by the National Heart, Lung, and Blood Institute (NHLBI) in collaboration with the University of North Carolina (N01-HC-55015, N01-HC-55018), Baylor College of Medicine (N01-HC-55016), University of Minnesota (N01-HC-55019), Johns Hopkins University (N01-HC-55020), and University of Mississippi Medical Center (N01-HC-

55021). This manuscript has been reviewed by the ARIC Study for scientific content and consistency of data interpretation with previous ARIC Study publications."

7.1.b If the manuscript is not approved by the ARIC Study 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 Atherosclerosis Risk in Communities (ARIC) Study is conducted and supported by the National Heart, Lung, and Blood Institute (NHLBI) in collaboration with the University of North Carolina (N01-HC-55015, N01-HC-55018), Baylor College of Medicine (N01-HC-55016), University of Minnesota (N01-HC-55019), Johns Hopkins University (N01-HC-55020), and University of Missicippi Medical Center (N01-HC-55021). This manuscript was not approved by the ARIC Study. The opinions and conclusions contained in this publication are solely those of the authors, and are not endorsed by the ARIC 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 Atherosclerosis Risk in Communities (ARIC) Study is conducted and supported by the National Heart, Lung, and Blood Institute (NHLBI) in collaboration with the University of North Carolina (N01-HC-55015, N01-HC-55018), Baylor College of Medicine (N01-HC-55016), University of Minnesota (N01-HC-55019), Johns Hopkins University (N01-HC-55020), and University of Mississippi Medical Center (N01-HC-55021). This manuscript was not prepared in collaboration with investigators of the ARIC Study and does not necessarily reflect the opinions or conclusions of the ARIC Study or the NHLBI."

7.3 Ancillary Study Investigator Acknowledgments**.** If Data include data provided to the ARIC Study 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 ARIC 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 the ARIC Study and NHLBI. Recipient and Recipient's PI agree to provide the ARIC Study 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 the ARIC Study 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 the ARIC Study. 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 the ARIC Study 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 the ARIC Study 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, the ARIC Study, 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 federal or state law, Recipient agrees to defend and indemnify the United States Government, the ARIC Study, 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 the ARIC Study 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 reviewed 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 participants' informed consent documents, and any additional conditions that may be imposed by the ARIC Study IRB(s). Recipient agrees to report promptly to the ARIC Study 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 the ARIC Study 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 the ARIC Study and consult with the ARIC Study 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 the ARIC Study 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 the ARIC Study 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 the ARIC Study 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 the ARIC Study and/or the NHLBI.

Required Signatures begin on the next page

Required for receipt of data only or data and materials

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

Required for receipt of data only or data and materials

COORDINATING CENTER FOR THE ATHEROSCLEROSIS RISK IN COMMUNITIES (ARIC) STUDY

_____

Name and Title of University of North Carolina, ARIC Coordinating Center, Authorized Representative

_____

Signature and Date of University of North Carolina, ARIC Coordinating Center, Authorized Representative

Required for receipt of data and materials

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)