NHLBI Hispanic Community Health Study / Study of Latinos
Data and Materials Distribution Agreement

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

INTRODUCTION

The Hispanic Community Health Study / Study of Latinos (HCHS/SOL) is a multi-center epidemiologic study supported by contracts with the National Heart, Lung, and Blood Institute (NHLBI). This multi-center observational longitudinal heath study is designed to document health status in four Hispanic communities around the United States and to obtain baseline measures of pulmonary function, cardiovascular function, metabolic status, oral health, and measures of neurocognitive and psychological functioning. Approximately 16,000 adults of 18 to 74 years, will be enrolled at four field centers over a 36-month period, and will be followed for 36 months to assess health outcomes.

To protect the confidentiality and privacy of the HCHS/SOL 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 HCHS/SOL or other National Heart, Lung, and Blood Institute (NHLBI) resources, and may leave violators subject to legal action on the part of the HCHS/SOL 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, The University of North Carolina at Chapel Hill and the Coordinating Center for the HCHS/SOL, on behalf of the HCHS/SOL and under the direction of the HCHS/SOL Steering Committee.

DEFINITIONS

For purposes of this DMDA,

"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., computed tomography scans, MRI scans), or primary signal data (e.g., ECG, spirometry tracings, polysomnography, accelerometry) and associated records either obtained directly from the HCHS/SOL 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 HCHS/SOL by ancillary studies.

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

"HCHS/SOL Investigator" is a research investigator who works with the HCHS/SOL either as an employee of the NHLBI or through a current and active award (including contracts, grants, or other transactions) or consulting agreement with the NHLBI or one of its contractors.

"Materials" refers to biological samples, including but not limited 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 HCHS/SOL by ancillary studies.

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

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

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

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

TERMS AND CONDITIONS

The Parties hereto agree as follows:

1. Materials. The HCHS/SOL 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.

[ENTER MATERIALS INFO, IF APPLICABLE]

2. Data. The HCHS/SOL agrees to provide **Recipient** with **Data** described as follows:

Any and all closed HCHS/SOL investigator use (INV) study data that [Institution Name] may request, based on approved ancillary study and/or approved manuscript proposals. Sources include the main study visits, AFU, endpoints, and any closed ancillary study data that are to be prepared/distributed to study investigators.

All datasets will use masked IDs to protect the confidentiality of study participants.

The HCHS/SOL will provide Recipient with the name and contact information of Study Investigators and all other investigator(s) who generated such **Data**. General information for authors can be obtained from the following URL: https://sites.cscc.unc.edu/hchs/publications-pub

DATA USE LIMITATION FOR HCHS/SOL Study:

All research must be related to the purpose of the study, which is to learn about the health of Hispanic/Latinos in the United States and to identify causes of disease of the Hispanic/Latino populations. The HCHS/SOL dbGaP data is intended to promote the discovery of specific genetic loci acting as risk (or protective) factors for health-related traits. Use of the dbGaP data to conduct non-genetic research is prohibited. The data may not be used to investigate individual pedigree structures or to identify individuals, to investigate sensitive issues such as non-maternity or non-paternity, or to assign race or ethnicity using genomic information. Investigators must further consider whether the use of genetic variables could result in inferences that are stigmatizing to members of racial or ethnic groups. If the answer is "yes", such use of genetic data is prohibited. All research must be related to the purpose of

the study which is to learn about the health of Hispanics/Latinos in the United States and to identify causes of disease of the Hispanic/Latino population and must be consistent with the consent document. Data use is limited by consent to the following two groups: a) general research use and b) Non-Profit Use Only. The NHLBI will keep all Data Use Certifications, and all approved studies utilizing HCHS/SOL dbGaP data will be listed on the dbGaP website.

3. Research Project.

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

The Hispanic Community Health Study - Study of Latinos (HCHS-SOL)
UNC IRB #07-1003

3.2 If any aspect of the Research Project is to be performed by an entity other than **Recipient** as permitted by section 4.2, such entity is to be named below:

[ENTER INFO, IF APPLICABLE]

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 HCHS/SOL 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**, 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.

4.3 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

repository 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 HCHS/SOL and NHLBI. The **Recipient** and **Recipient's PI** shall adhere to the study's policy regarding retention and destruction of materials and data.

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) or contractor(s) comply with the terms of this DMDA.

6. Publication. The HCHS/SOL and NHLBI request that the **Recipient's PI** provide to the authorized representative for the HCHS/SOL 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. Please refer to the NHLBI Supplement to the NIH Policy for Data Management and Sharing (https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-for-data-sharing).

7. Acknowledgments. Recipient and **Recipient's PI** agree to acknowledge the contribution of the HCHS/SOL in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of **Data** or **Materials**, in accordance with the guidelines established by the study.

7.1 Collaborations. If a manuscript resulting from the **Research Project** has **Study Investigators** as co-authors, then the manuscript must be reviewed by the HCHS/SOL.

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

"The Hispanic Community Health Study/Study of Latinos is supported by contracts from the National Heart, Lung, and Blood Institute (NHLBI) to the University of North Carolina (N01-HC65233), University of Miami (N01-HC65234), Albert Einstein College of Medicine (N01-HC65235), University of Illinois – Chicago and Northwestern University (N01-HC65236), and San Diego State University (N01-HC65237). The following Institutes/Centers/Offices contribute to the HCHS/SOL through a transfer of funds to the NHLBI: National Center on Minority Health and Health Disparities, the National Institute of Deafness and Other Communications Disorders, the National Institute of Dental and Craniofacial Research, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Neurological Disorders and Stroke, and the Office of Dietary Supplements. This manuscript has been reviewed by the HCHS/SOL for scientific content."

7.1.b If the manuscript is not approved by the HCHS/SOL 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 Hispanic Community Health Study/Study of Latinos is supported by contracts from the National Heart, Lung, and Blood Institute (NHLBI) to the University of North Carolina (N01-HC65233), University of Miami (N01-HC65234), Albert Einstein College of Medicine (N01-HC65235), University of Illinois – Chicago and Northwestern University (N01-HC65236), and San Diego State University (N01-HC65237). The following Institutes/Centers/Offices contribute to the HCHS/SOL through a transfer of funds to the NHLBI: National Center on Minority Health and Health Disparities, the National Institute of Deafness and Other Communications Disorders, the National

Institute of Dental and Craniofacial Research, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Neurological Disorders and Stroke, and the Office of Dietary Supplements. This manuscript was not approved by the HCHS/SOL. The opinions and conclusions contained in this publication are solely those of the authors, and are not endorsed by the HCHS/SOL 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 Hispanic Community Health Study/Study of Latinos is supported by contracts from the National Heart, Lung, and Blood Institute (NHLBI) to the University of North Carolina (N01-HC65233), University of Miami (N01-HC65234), Albert Einstein College of Medicine (N01-HC65235), University of Illinois – Chicago and Northwestern University (N01-HC65236), and San Diego State University (N01-HC65237). The following Institutes/Centers/Offices contribute to the HCHS/SOL through a transfer of funds to the NHLBI: National Center on Minority Health and Health Disparities, the National Institute of Deafness and Other Communications Disorders, the National Institute of Dental and Craniofacial Research, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Neurological Disorders and Stroke, and the Office of Dietary Supplements. This manuscript was not prepared in collaboration with investigators of the HCHS/SOL and does not necessarily reflect the opinions or conclusions of the HCHS/SOL or the NHLBI."

7.3 Ancillary Study Investigator Acknowledgments**.** If **Data** include **Data** provided to the HCHS/SOL by other ancillary study investigators, **Recipient** and **Recipient's PI** also agree to acknowledge the contribution of those other ancillary study investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of such **Data**.

8. Non-Identification/Participant Anonymity. 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 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 HCHS/SOL 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**.

RECIPIENT'S PI INITIALS: _____

13. Resultant Data to be Provided to the HCHS/SOL and NHLBI. Every twelve (12) months, **Recipient** and **Recipient's PI** agree to provide the HCHS/SOL with a report based on the **Resultant Data.** This report shall include a description of the activities performed and **Resultant Data** obtained up to the reporting date. **Recipient** and **Recipient's PI** agree to provide **Resultant Data** to HCHS/SOL in accordance with the applicable NIH and NHLBI data sharing policies in place as of the effective date of this agreement. **Recipient** and **Recipient's PI** agree that HCHS/SOL and NHLBI may distribute all such **Resultant Data** through established NHLBI procedures to any institutions requesting access for their qualified scientific investigators. **Recipient** and **Recipient's PI** will provide all **Resultant Data** in an electronic format specified by NHLBI or HCHS/SOL. If errors in family structure, including 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 on how and to whom to provide such information. **Recipient** and **Recipient's PI** agree to refrain from disclosing identified errors to anyone other than individual(s) specifically identified and authorized by the HCHS/SOL and NHLBI.

RECIPIENT'S PI INITIALS: _____

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 HCHS/SOL 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, the HCHS/SOL, The University of North Carolina at Chapel Hill and all investigator(s) who generated **Data** and **Materials**, and the agents and employees of each of them harmless and release them for all liabilities, demands, damages, expenses, and losses arising out of **Recipient** or **Recipient's PI's** negligence.

17. Accuracy of Data. Recipient agrees that the United States Government, The University of North Carolina at Chapel Hill and the HCHS/SOL 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 and **Recipient's PI** agree use of the **Data** and/or **Materials** in conjunction with the **Research Project** that has 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 or similar human rights oversight committee. **Recipient** and **Recipient's PI** agree to comply fully with all such conditions and with the participants' informed consent documents, and any additional conditions that may be imposed by the HCHS/SOL IRB(s). **Recipient** agrees to report promptly to the HCHS/SOL 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.

RECIPIENT'S PI INITIALS: _____

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 the HCHS/SOL of such violation, debarment or disqualification.

Upon termination of this DMDA:

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

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, The University of North Carolina at Chapel Hill and/or the HCHS/SOL 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 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 HCHS/SOL 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 existing DMDAs with the HCHS/SOL, The University of North Carolina at Chapel Hill and/or the NHLBI.

Required Signatures begin on the next 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

_____

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

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 THE HISPANIC COMMUNITY HEALTH STUDY / STUDY OF LATINOS (HCHS/SOL)

_____

Signature, Title and Date of University of North Carolina – Chapel Hill, HCHS/SOL Coordinating Center, Authorized Representative

_____**Contract Officer**_____

Signature, Title and Date of University of North Carolina – Chapel Hill, Office of Industry Contracts 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)