



GeneSTAR Research Program Limited Access Agreement

Agreement for Limited Use of De-identified Phenotype and Genotype Data

Pursuant to the terms and conditions of this Limited Use Agreement ("Agreement"), The Johns Hopkins University ("JH") will disclose certain de-identified genotype and phenotype data maintained by The Johns Hopkins Sibling and Family Heart Study under the GENESTAR and related protocols ("Covered Data") to _____ ("Institution"). The Covered Data may be used by Institution solely as specified in the Data Use Application at Attachment A, and may not be used or re-disclosed except as permitted by this Agreement.

This Agreement must be executed by an official of Institution who has the authority to bind the Institution to the promises and obligations herein. Upon execution by Institution, Qualified Investigators may be designated by Institution and approved by JH as specified in Section 3 below.

1. **General.** GENESTAR genotype and phenotype data are maintained by JH under agreements with the National Institutes of Health and by other sponsors, each of whom have established criteria for maintaining the security, quality, and confidentiality of these data. JH will provide Investigators access to and the right to use these data only under terms and conditions that meet sponsors' criteria. Specifically, GENESTAR data will be provided only in de-identified form for use during a specified period of time by those qualified Investigators who have signed this Agreement.
2. **Study Steering Committee.** The Study Steering Committee consists of Dr. Diane M. Becker, Co-Chair Professor, Medicine; Dr. Lewis C. Becker, Robert L. Levy Professor, Cardiology Co-Chair; Rasika Mathias, ScD, Genetic Epidemiologist, Assistant Professor, Medicine and Epidemiology, Jay Vaidya, MBBS, PhD, MPH, statistician, Assistant Professor, Medicine, Taryn F. Moy, MS, Research Associate, Co-ordinator of Sibling Study and GeneSTAR Projects; and Lisa R. Yanek, Research Associate, Director GeneSTAR Analysis Unit; all of The Johns Hopkins University School of Medicine, 1830 East Baltimore, Suite 8028, Baltimore, Maryland 21287
3. **Qualified Investigators.** Institutions holding a Federal-Wide Assurance approved by the federal Office of Human Research Protections may designate employees to apply for Qualified Investigator status.
 - a. Any such investigator must complete the Data Use Application at Attachment A, describing in detail the data elements requested and any proposed analyses, and must submit the Data Use Application and documentation of Institutional Review Board approval (or determination of exemption, if applicable) to the Study Steering Committee.
 - b. In Attachment A, the applicant must list every member of the study team who will have access to the data under the applicant's supervision. The applicant and each such study team member must acknowledge their confidentiality obligations by signing Attachment A.
 - c. The Study Steering Committee will review the completed Attachment A and grant written approval for the Institution to designate an applicant as a Qualified Investigator.
4. **Responsibility** Although this Agreement must be signed by an official of Institution, the Qualified Investigator agrees to review and abide by all of the terms and conditions herein, and to ensure that all data users under Qualified Investigator's supervision understand and abide by the same.
5. **Communications.** All updates to a Qualified Investigator's Data Use Application must be submitted to the Steering Committee in writing.
6. **Duration of Permission.** A Qualified Investigator may use the Covered Data for a period of one (1) year from the date upon which the Study Steering Committee grants written approval of the Qualified Investigator's Data Use Application ("Term of Use"). Extensions of time must be granted by the Study Steering Committee in writing, provided that the Term of Use for a given Qualified Investigator shall expire automatically at the end of three (3) months from the completion of final data analyses for the projects described in the Data Use Application. Absent a written extension, a Qualified Investigator's permission to use the Covered Data will expire at the end of the Term of Use.
7. **Expiration of Permission.** Upon expiration of the Term of Use for a given Qualified Investigator, or termination of this Agreement for any reason, a Qualified Investigator will delete or destroy all copies of the Covered Data that exist in any medium, including but not limited to all paper and electronic copies, or return all such copies to the Study Steering Committee. Under no circumstances may a Qualified Investigator or the Institution retain a copy of the Covered Data beyond the end of any Term of Use applicable to those Covered Data.

8. **Scope of Permitted Uses and Disclosures.** One copy of the Covered Data may be created by the Qualified Investigator. During the Term of Use, the original Covered Data supplied by JH (if applicable) and this one copy may be stored as specified in the approved Data Use Application. Neither the Qualified Investigator nor the Institution may make or store any other copies of the Covered Data.
 - a. The Covered Data may be used solely for scientific and academic purposes. No use of the Covered Data or any subset or derivative of the Covered Data may be made for commercial purposes. The Covered Data (including any subset of the Covered Data) may not be sold, reproduced, distributed, or stored in any limited access or public access retrieval system.
 - b. The Institution and the Qualified Investigator agree to take all reasonable precautions to ensure that no one with access to the Covered Data will undertake or permit any attempt, by any direct or indirect means (including unauthorized access to electronic systems) to use the Covered Data for an unauthorized purpose, to re-identify subjects of the Covered Data, or to obtain a listing of subjects' identities.
 - c. JH, at its discretion, may terminate this Agreement immediately upon learning of any unauthorized disclosure of Covered Data or attempt to re-identify the subjects of the Covered Data.
 - d. Neither the Covered Data nor the results of any analyses of the Covered Data may be published, presented, referenced, or included in any grant application without the prior written permission of the Study Steering Committee.
 - e. Pursuant to restrictions contained in the consent forms signed by subjects of the Covered Data, all analyses of Covered Data must pertain to cardiovascular disease or related factors.
9. **Authorized Users, Confidentiality.** Only those persons who have signed an approved version of the Data Use Agreement may access or use the Covered Data, except as provided herein.
 - a. Institution may grant access to Covered Data, to the extent reasonably necessary, to those Institution personnel who must review the Covered Data to fulfill research oversight responsibilities or to maintain Institution's electronic systems. If Institution engages contractors or other third parties to perform these functions, the Institution will bind those contractors or third parties to the restrictions upon use and disclosure of Covered Data that apply to Institution under this Agreement.
 - b. If Institution believes that it is required by law to disclose the Covered Data to any third party not specified herein, Institution shall provide JH reasonable prior notice of the disclosure and an opportunity to resist the disclosure or seek legal protection for subjects' identities.
10. **Location of Data.** The Data must be stored and secured in the manner described in the approved Data Use Application. The Qualified Investigator must provide the Study Steering Committee written notice of any change in the location or storage of the Covered Data or change in security or privacy protections for the Covered Data within three (3) business days. At its discretion, the Study Steering Committee may terminate this Agreement upon learning of any changes that decrease the privacy or security of Covered Data.
11. **Property Rights.** Neither Institution nor any Qualified Investigator or study staff member shall have any right, title, or ownership interest in the Covered Data. All rights, title, and interests in the Covered Data shall belong to JH. Institution and each Qualified Investigator and study staff member agree that none of them shall claim or attempt to exercise any right, title, or interest in the Covered Data, except for the limited right to use the Covered Data strictly as permitted in the approved Data Use Application.
12. **Results.** Institution and Qualified Investigators agree to share the results of any analyses of the Covered Data with the Study Steering Committee within three (3) months of completion of final analyses and prior to the drafting of any manuscript or presentation containing such analyses.
 - a. At its discretion, the Study Steering Committee may require the Qualified Investigator to permit the Johns Hopkins Sibling and Family Heart Study biostatisticians to replicate the results of any analyses prior to granting permission to the Investigator to publish, present, or disclose any results.
 - b. Institution and Qualified Investigator agree to notify the Study Steering Committee immediately and in writing of any result that may be relevant to the health or health care of current or future participants. At the discretion of the Study Steering Committee, such information may be communicated to the reviewing IRB, study participants, or sponsors.
13. **Termination.** JH may terminate this Agreement immediately upon learning of a breach of any of its terms and conditions. Institution may terminate this Agreement at any time by notifying the Study Steering Committee in writing, and by destroying, deleting, or returning all Covered Data to JH. The parties agree that JH may pursue an injunction or any other available legal remedy to enforce the terms of this Agreement against Institution, any Qualified Investigator, any study team member, or any other user of Covered Data.
14. **Assignment.** This Agreement may not be assigned without the prior written permission of JH.
15. **Waiver.** No delay in acting or failure to act shall constitute a waiver of any right or obligation under this Agreement. Any waiver of such right or obligation must be in writing and signed by the Institution and a representative of the Study Steering Committee.

16. **Governing Law.** This Agreement shall be governed by the laws of the State of Maryland. Any dispute shall be brought in the state or federal courts of Maryland.
17. **Indemnification.** Institution shall indemnify and hold harmless JH, The Johns Hopkins Hospital, and their respective employees, agents, faculty, staff, students, trustees, and board members, as well as any of their successors or assigns ("JH Indemnitees"), for any costs or losses arising out of the use or non-use of Covered Data by Institution, including by any Qualified Investigator or study team member or any third party who obtains Covered Data from Institution.
18. **Liability.** IN CONSIDERATION OF JH'S AGREEMENT TO RELEASE COVERED DATA, INSTITUTION, ON BEHALF OF ITSELF AND ITS EMPLOYEES, AGENTS, FACULTY, STAFF, STUDENTS, TRUSTEES, AND BOARD MEMBERS, AND ANY OF THEIR SUCCESSORS OR ASSIGNS, HEREBY VOLUNTARILY WAIVES ALL CLAIMS AND RELEASES AND DISCHARGES JH, THE JOHNS HOPKINS HOSPITAL, AND THEIR RESPECTIVE FACULTY, STAFF, EMPLOYEES, AGENTS, HEIRS, SUCCESSORS, AND ASSIGNS, FROM ANY AND ALL LIABILITY FOR ANY CLAIM, DAMAGE, OR LOSS ARISING OUT OF THE USE OR NON-USE OF THE COVERED DATA FOR ANY PURPOSE WHATSOEVER.

As a duly authorized official of Institution, I hereby agree that Institution shall be bound to the terms and conditions of this Agreement.

Signature

Printed Name and Title

Date

LAA: Attachment A

Data Use Application-*may also be used to update renewals*

Investigators: Please complete this Data Use Application and obtain the signature of every study team member who will have access to the Covered Data. Return the signed Data Use Application to the Study Steering Committee.

The Study Steering Committee will notify you in writing when your Data Use Application is approved and you have permission to use the Covered Data.

1. Title of Proposed Study and Protocol Number:

2. List any co- Investigators who will be managing or analyzing, or interpreting data (note, if not an employee of Institution, the co-investigator's home institution must execute the Limited Use Agreement).

3. Please list all other persons who will have direct access to the data, and indicate their roles in the study (e.g., data management, data analysis, technical support, other)

4. IRB Approval: Yes No NIH IRB Assurance Number _____

Date ___/___/___

Attached Yes No

If there is no IRB approval from the Institution, please explain its absence (if the IRB has determined project is exempt, please attach letter of documentation):

Data Storage and Data Management: All applicants retaining the data (JHPD and/or JHGD)

Describe how Covered Data will be PROCESSED AND MAINTAINED

Please complete the following for each physical site where Covered Data will be processed, maintained, or analyzed:

Name of Site	Address/ Room Number	Locked (Yes, No) Form of Lock	Persons with Access

Will these data and/or analytic output be stored on any additional CPUs maintained by individuals?

Yes No If Yes, please list with address

- Co-Investigators:

[DATE] _____
- Other study staff listed in this Data Use Application:

[DATE] _____

For this proposal to be legally active, signatures of the Steering Committee from GeneSTAR must be affixed below.

APPROVAL:

Upon review of this Data Use Application, the undersigned approve the applicant as a Qualified Investigator and agree to permit applicant and all listed personnel to use and disclose data for the limited purposes described in this Application, subject to the terms and conditions of the Limited Use Agreement.

Please note that the permitted Term of Use expires one (1) year from the date indicated below. The Qualified Investigator must request any extension in writing. All changes or updates to this Data Use Application must be submitted in writing for the prior approval of the Study Steering Committee.

REVIEWED AND APPROVED:

Date ____/____/____ (mm/dd/yy)

Steering Committee Chair, Lewis C. Becker, MD

Steering Committee, Chair, Diane M. Becker, MPH, ScD

Steering Committee, Lisa R. Yanek, MPH (Data Analysis and Archiving Center)

Steering Committee, Brian G. Kral, MD, MPH

Steering Committee, Jay Vaidya, MBBS, PhD, MPH

Steering Committee, Taryn F. Moy, MS (Secretary of the Steering Committee)