Project Renewal

Project #33119 : NIH PRIMED Consortium Coordinated Application

Project name	NIH PRIMED Consortium Coordinated Application
Project ID	33119
Approved user name	Kenneth Rice
Institute affiliation	UNIVERSITY OF WASHINGTON (Non-Profit)
Request date : 2023-07-27	Next Renewal date : 2023-12-01

Applicant Organization

Legal Name :	**UNIVERSITY OF WASHINGTON**						
Department :	Biostatistics			Division :			
Street 1 :	4333 Brooklyn Ave NE						
City :	Seattle	State :	WA	Zip :		Country :	United States

PI Contact Information

Name :	**Kenneth Rice**			Position :	Principal Investigator		
Organization:	UNIVERSITY OF WASHINGTON						
Street 1 :	4333 Brooklyn Ave NE						
City :	Seattle	State :	WA	Zip :	98195	Country :	United States
Phone :	206-384-5685	:		Email :	kenrice@u.washington.edu		

SO Contact Information

Name :	**Elizabeth Walker-Tilley**			Position :	Signing Official		
Organization:	UNIVERSITY OF WASHINGTON						
Street 1 :	University of Washington				4333 Brooklyn Ave NE, Box 359472		
City :	Seattle	State :	WA	Zip :	98195	Country :	United States
Phone :	206-616-1343	:		Email :	ewtilley@uw.edu		

IT Director Contact Information

Name :	**Robert Moulton**			Position :	System Administrator		
Organization:	UNIVERSITY OF WASHINGTON						
Street 1 :	3980 15th Avenue NE				Box 351617		
City :	Seattle	State :	WA	Zip :	98195-1617	Country :	USA
Phone :	2066858772	:		Email :	rmoulton@uw.edu		

Approved Research Use Statement

The Polygenic Risk Methods in Diverse Populations (PRIMED) Consortium will use phenotypic and genomic data from existing datasets to generate and refine polygenic risk scores (PRS) for populations of diverse race, ethnicities, and genetic ancestry. Uses of the requested data will include, but are not limited to:
developing PRS and improve the ability of PRS to predict health measures and disease risk across diverse populations;
developing new methods for genetic risk prediction across diverse populations;
adjusting for measures of local and/or global ancestry in populations of diverse genetic ancestry;
integrating both summary statistics and individual-level datasets;
statistically imputing genotypes for individuals with incomplete data;
PRIMED Consortium investigators will not use the requested data to investigate individual identity in any analyses. Consent type and other Data Use Limitations (DUL) for each study will be respected in all analyses. When an individual's DUL prohibits investigation of population genetics, ancestry, or population history, that data will be excluded from analyses that address those issues as outcomes. In PRIMED, PRS will be developed across different domains, such as cardiometabolic diseases, diabetes, cancer, smoking, and inflammation. Datasets with disease-specific DULs will only be used in the development or improvement of PRS for the corresponding disease. We intend to publish or otherwise broadly share any findings from this study with the scientific community. However, genomic summary results from datasets with a "sensitive" designation will not be disseminated beyond publications to support study's conclusions. This request anticipates collaboration among PRIMED investigators from multiple institutions, who are named in an external collaborators lists and are submitting coordinated dbGaP data access requests. External Collaborators to this request consist of investigators eligible to enter into PRIMED Consortium-wide data sharing. A list of currently eligible PRIMED investigators can be found at https://primedconsortium.org/eligibility. Data from PRIMED may be combined with data from other studies to improve the power for novel genetic discoveries or other advances. We do not anticipate any additional risk to participants when combining datasets.

Non-Technical Summary

Polygenic risk scores (PRS), are a genetic estimate of a person's risk for specific diseases. PRS are calculated by comparing the genomic data of people with and without a particular disease. Research shows that early approaches to calculating PRS, developed from mostly European ancestry populations, are not effective when used in diverse populations. Researchers have used available genomic datasets to develop the ability to calculate PRS for numerous conditions, such as diabetes, and to identify people who are at high risk. This allows clinicians to use PRS in combination with a person's lifestyle and environmental factors to tailor their medical management. The Polygenic RIsk MEthods in Diverse populations Consortium will use existing datasets from dbGaP and elsewhere to improve PRS by studying much larger numbers of non-European individuals and developing methods to better adjust for ancestry. The data will help the consortium to develop better methods for using datasets of different types, such as those with only summary-level data, or datasets with missing genotype data.

Cloud computing permissions requested.

Cloud Use Statement

AnVIL is operated by the Broad Institute at the FISMA (Federal Information Systems Management Act) "moderate" level and received Authority to Operate from several NIH ICs including NCI, NHLBI and NIH Common Fund beginning in 2016. FISMA is a practice of documentation, audit, and organizational risk acceptance. It is centered on the controls outlined in NIST (National Institute of Standards and Technology) Special Publications 800-30 and 800-53. AnVIL's underlying platform, Terra, is hosted on Google's Cloud Platform. See below for details. Since AnVIL requires that users utilize Google logins, the application operates on top of Google's world-class security that protects from nation-state level attacks. As a FISMA Moderate system, all logs are audited continually and various levels of security layering are required. These include Web Application Firewalls, weekly scanning, code scanning (dynamic and static), dependency scanning and manual penetration testing. Data analysis is constrained to computing nodes that are sandboxed using Docker within Google's Pipelines API and specially operated versions of interactive analysis such as Jupyter notebooks. Google undergoes several independent third party audits on a regular basis to provide verification of security, privacy and compliance controls including annual audits for SSAE 16/ISAE 3402 Type II, FedRAMP High and various ISO certifications. Google's infrastructure provides reliable information security that can meet or exceed the requirements of HIPAA and protected health information. The Google Cloud Platform has summarized its services with respect to genomics data processing in a white paper here: https://cloud.google.com/files/genomics-data-wp.pdf and it's security posture here https://cloud.google.com/security. All data operations are intended to be kept on the AnVIL platform and not to be downloaded or accessed from another system.

Cloud Provider(s) Information

AnVIL, Commercial
AnVIL is operated by the Broad Institute at the FISMA (Federal Information Systems Management Act) “moderate” level and received Authority to Operate from several NIH ICs including NCI, NHLBI and NIH Common Fund beginning in 2016. FISMA is a practice of documentation, audit, and organizational risk acceptance. It is centered on the controls outlined in NIST (National Institute of Standards and Technology) Special Publications 800-30 and 800-53. AnVIL's underlying platform, Terra, is hosted on Google’s Cloud Platform. See below for details. Since AnVIL requires that users utilize Google logins, the application operates on top of Google’s world-class security that protects from nation-state level attacks. As a FISMA Moderate system, all logs are audited continually and various levels of security layering are required. These include Web Application Firewalls, weekly scanning, code scanning (dynamic and static), dependency scanning and manual penetration testing. Data analysis is constrained to computing nodes that are sandboxed using Docker within Google’s Pipelines API and specially operated versions of interactive analysis such as Jupyter notebooks. Google undergoes several independent third party audits on a regular basis to provide verification of security, privacy and compliance controls including annual audits for SSAE 16/ISAE 3402 Type II, FedRAMP High and various ISO certifications. Google's infrastructure provides reliable information security that can meet or exceed the requirements of HIPAA and protected health information. The Google Cloud Platform has summarized its services with respect to genomics data processing in a white paper here: https://cloud.google.com/files/genomics-data-wp.pdf and it's security posture here https://cloud.google.com/security. All data operations are intended to be kept on the AnVIL platform and not to be downloaded or accessed from another system.

Collaborators

Internal

Matthew Conomos
Research Scientist
UNIVERSITY OF WASHINGTON
4333 Brooklyn Ave NE
Seattle, WA 98195 United States
Phone: 206-543-3464 Email: mconomos@uw.edu

Stephanie Gogarten
Research Scientist
UNIVERSITY OF WASHINGTON
4333 Brooklyn Ave NE
Seattle, WA 98195 United States
Phone: 206-221-0757 Email: sdmorris@uw.edu

Ben Heavner
Research Scientist
UNIVERSITY OF WASHINGTON
4333 Brooklyn Ave NE
Seattle, WA 98195 United States
Phone: 206-543-3893 Email: bheavner@uw.edu

Susan Heckbert
Professor
UNIVERSITY OF WASHINGTON
4333 Brooklyn Ave NE
Seattle, WA 98195 United States
Phone: 206 221-7775 Email: heckbert@uw.edu

Alyna Khan
Research Scientist
UNIVERSITY OF WASHINGTON
4333 Brooklyn Ave NE
Seattle, WA 98195 United States
Phone: 206-543-3284 Email: alynak@uw.edu

Sarah Nelson
Research Scientist
UNIVERSITY OF WASHINGTON -- Division: Rosie Rice, invoice number 605720
4333 Brooklyn Ave NE
Seattle, WA 98195 United States
Phone: 206-543-1850 Email: sarahcn@uw.edu

Adrienne Stilp
Research Scientist

UNIVERSITY OF WASHINGTON
4333 Brooklyn Ave NE
Seattle, WA 98195 United States
Phone: 206-543-4090 Email: amstilp@uw.edu

Quenna Wong
Research Scientist
UNIVERSITY OF WASHINGTON
4333 Brooklyn Ave NE
Seattle, WA 98195 United States
Phone: 206-543-5320 Email: qwong@uw.edu

External

Name	Institution	Role	Position	Email
PRIMED Collaboration	several	several	several	N/A

Change Log

Date	Changed Details
2023-11-29 14:00	Research Progress
2023-11-29 14:00	Publications and Manuscripts
2023-11-29 14:00	Signing Official
2023-11-29 14:00	Presentations
2023-11-29 14:00	Inappropriate Data Use
2023-10-11 01:00	IRB document
2023-07-25 13:00	IRB document
2023-05-03 15:00	IRB document

Research Progress

Research Summary

As the Coordinating Center (CC) for the NIH-funded PRIMED (Polygenic Risk Methods in Diverse Populations) Consortium, we use the data requested in this application to support several areas of work, described briefly below.

Data Harmonization

We are developing standards and workflows for consistent formatting, processing, and harmonization of individual-level phenotype and genotype data into PRIMED Consortium data models on AnVIL. For 6 studies (ARIC, CARDIA, HCHS/SOL, JHS, RPGEH, WHI), we have set up workspaces on ANVIL to enable data sharing via the dbGaP PRIMED Coordinated Application; either we or investigators from PRIMED Study Sites have uploaded, harmonized, and formatted data following consortium instructions. This work supports PRIMED consortium investigators in combining data across multiple studies (dbGaP and others).

PRS methods development
The combined and harmonized data is being used by Consortium members for PRS methods development and benchmarking as well as generating and evaluating new PRS models across diverse populations.

Consortium data sharing in AnVIL
We have developed a web-based tool (https://github.com/UW-GAC/primed-django) to manage Consortium member data permissions in AnVIL for studies available via dbGaP. To implement this system, we require approved DARs to any study-consent group being shared within the Consortium, limited to those members with similarly approved DARs via a PRIMED dbGaP Coordinated Application. To date we have set up Consortium data sharing workspaces for 24 phs-consent groups.

Tools and Workflows
Data accessed through this application supported the development and testing of tools and workflows developed for community use and available on Dockstore, GitHub, and/or in AnVIL. We wrote an R package to support validation of data uploaded to AnVIL against a data model, and used it as

a basis for a collection of workflows validating data of different types (genotype, phenotype, genomic summary results) and importing the data to AnVIL workspaces. This data is also being used to test analysis workflows developed by PRIMED members, including workflows for harmonized genetic ancestry inference, PRS value calculation, and PRS model generation.

Scientific Presentations

None

Publications

Principles and methods for transferring polygenic risk scores across global populations.
Kachuri L, Chatterjee N, Hirbo J, Schaid DJ, Martin I, Kullo IJ, Kenny EE, Pasaniuc B, Witte JS, Ge T
Nat Rev Genet; 2023 Aug 24;
PMID: 37620596 (https://www.ncbi.nlm.nih.gov/pubmed/37620596)

Intellectual Property

none

Data Security

Datasets not described in the Research Use Statement

none

Inappropriate Data Use

None

Consent Group(s) Information

phs000018.v2.p1 : GoKinD: Search for Susceptibility Genes for Diabetic Nephropathy in Type 1 Diabetes

DUC : see attached

IRB : see attached after DUC

DAR : 117118

Request Date : 2022-12-21 Last Renewal Date : 2023-09-30

Name : Disease-Specific (Type 1 Diabetes, Complications, and Related Traits, IRB)

Consent Group # : 1

Abbreviation : DS-T1DCR-IRB

Data Use Limitation : Use of the data must be related to Type 1 Diabetes, Complications, and Related Traits.
Requestor must provide documentation of local IRB approval.

Requestors requesting access before 8/28/14 do not need to re-register for access. Requestors requesting access on 8/28/14 or thereafter must complete a new registration.

phs000007.v33.p14 : Framingham Cohort

DUC : see attached

IRB : see attached after DUC

DAR : 117119

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, MDS)

Consent Group # : 1

Abbreviation : HMB-IRB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the Framingham data deposited in dbGaP is restricted to research on: genotypephenotype associations; molecular phenotype (e.g., gene expression; microRNA)-phenotype associations; and proteomics/metabolomics-phenotype associations. All other phenotype-only analyses are prohibited (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC). Additionally, the Framingham data may not be used
to:
o Investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; or explore issues such as non-maternity or non-paternity.
o Investigate topics that could be considered as stigmatizing an individual or group.
o Assess outcomes that are not related to health or disease conditions (note: methodological research that will serve as a prelude to health or disease research is permitted).
Please note that only full or expedited approvals will be accepted.

DAR : 117120

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, NPU, MDS)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the Framingham data deposited in dbGaP is restricted to research on: genotypephenotype associations; molecular phenotype (e.g., gene expression; microRNA)-phenotype associations; and proteomics/metabolomics-phenotype associations. All other phenotype-only analyses are prohibited (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC). Additionally, the Framingham data may not be used
to:
o Investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; or explore issues such as non-maternity or non-paternity.
o Investigate topics that could be considered as stigmatizing an individual or group.
o Assess outcomes that are not related to health or disease conditions (note: methodological research that will serve as a prelude to health or disease research is permitted).
Please note that only full or expedited approvals will be accepted.

phs000086.v3.p1 : Diabetes Control and Complications Trial (DCCT) and Epidemiology of Diabetes Interventions and Complications Study (EDIC)

DUC : see attached

IRB : see attached after DUC

DAR : 117121

Request Date : 2022-12-21 Last Renewal Date : 2023-09-30

Name : Disease-Specific (Type 1 Diabetes, IRB)

Consent Group # : 1

Abbreviation : DS-T1D-IRB

Data Use Limitation : Use of the data must be related to Type 1 Diabetes.
Requestor must provide documentation of local IRB approval.

DAR : 117122

Request Date : 2022-12-21 Last Renewal Date : 2023-09-30

Name : Disease-Specific (Diabetes and Related Complications, IRB)

Consent Group # : 2

Abbreviation : DS-DRC-IRB

Data Use Limitation : Use of the data must be related to Diabetes and Related Complications.
Requestor must provide documentation of local IRB approval.

phs000091.v2.p1 : GENEVA Diabetes Study (NHS/HPFS)

DUC : see attached

DAR : 117123

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : Non-Profit Use Only

Consent Group # : 1

Abbreviation : NPU

Data Use Limitation : General research use, but not for distribution to commercial entities.

phs000180.v3.p2 : Type 1 Diabetes Genetics Consortium (T1DGC) GWAS

DUC : see attached

IRB : see attached after DUC

DAR : 117124

Request Date : 2022-12-21 Last Renewal Date : 2023-09-30

Name : Disease-Specific (Type 1 diabetes, its complications and other autoimmune diseases, IRB)

Consent Group # : 1

Abbreviation : DS-T1DR-IRB

Data Use Limitation : Use of the data must be related to Type 1 diabetes, its complications and other autoimmune diseases.
Requestor must provide documentation of local IRB approval.

phs000147.v3.p1 : CGEMS Breast Cancer

DUC : see attached

DAR : 117125

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : CGEMS Breast Data Use Limitations: The informed consent document signed by the CGEMS Breast Cancer Study Participants allows use of these data by investigators for discovery and hypothesis generation in the investigation of the genetic contributions to cancer and other diseases as well as development of novel analytical approaches for GWAS.

phs000200.v12.p3 : Women's Health Initiative

DUC : see attached

IRB : see attached after DUC

DAR : 117126

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

All requestors and data users must provide a local Institutional Review Board (IRB) letter from their respective institution approving conduct of the proposed research project. Only full or expedited approvals will be accepted.

Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were primarily dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree not to use the data to infer tribal status or affiliation.

DAR : 117144

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

All requestors and data users must provide a local Institutional Review Board (IRB) letter from their respective institution approving conduct of the proposed research project. Only full or expedited approvals will be accepted.

Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were primarily dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree not to use the data to infer tribal status or affiliation.

phs000209.v13.p3 : MESA Cohort

DUC : see attached

DAR : 117127

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical

Consent Group # : 1

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through the NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity and perceptions of racial/ethnic identity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in MESA.

DAR : 117128

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (NPU)

Consent Group # : 2

Abbreviation : HMB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

Data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through the NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity and perceptions of racial/ethnic identity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in MESA.

phs000096.v4.p1 : GENEVA GWA mapping: Maternal Metabolism-Birth Weight Interactions

DUC : see attached

DAR : 117129

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : GWA mapping: Maternal Metabolism-Birth Weight Interactions

Consent Group # : 1

Abbreviation : T2DMBIRTHWT

Data Use Limitation : Limited to research on genes that may be important for the development of type 2 diabetes and related conditions as well as fetal growth and metabolism. Related conditions and maternal phenotypes include body mass index,

blood pressure, hemoglobin A1c, and glucose and C-peptide levels. Measures of fetal growth and metabolism include birth weight, head circumference, skin-fold thickness, length, glucose and C-peptide.

phs000280.v8.p2 : Atherosclerosis Risk in Communities (ARIC) Cohort

DUC : see attached

IRB : see attached after DUC

DAR : 117130

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Use of the ARIC Study data deposited in dbGaP is restricted to research on associations between phenotypes and genotypes. ARIC data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity, non-paternity, and perceptions of racial/ethnic identity. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

This Data Use Certification will be reviewed and approved by the NHLBI Data Access Committee. The NHLBI will keep all Data Use Certifications, and all approved studies utilizing ARIC dbGaP data will be listed on the dbGaP website. Annual updates regarding publications, etc. will be provided by the NHLBI to the ARIC study when and if necessary.

DAR : 117131

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (Cardiovascular Disease, IRB)

Consent Group # : 2

Abbreviation : DS-CVD-IRB

Data Use Limitation :

Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.

Use of the ARIC Study data deposited in dbGaP is restricted to research on associations between phenotypes and genotypes. ARIC data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity, non-paternity, and perceptions of racial/ethnic identity. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

This Data Use Certification will be reviewed and approved by the NHLBI Data Access Committee. The NHLBI will keep all Data Use Certifications, and all approved studies utilizing ARIC dbGaP data will be listed on the dbGaP website. Annual updates regarding publications, etc. will be provided by the NHLBI to the ARIC study when and if necessary.

phs000287.v7.p1 : Cardiovascular Health Study (CHS) Cohort

DUC : see attached

DAR : 117132

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (MDS)

Consent Group # : 1

Abbreviation : HMB-MDS
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117133

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (NPU, MDS)
Consent Group # : 2
Abbreviation : HMB-NPU-MDS
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117134

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Cardiovascular Disease, MDS)
Consent Group # : 3
Abbreviation : DS-CVD-MDS
Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117135

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Cardiovascular Disease, NPU, MDS)
Consent Group # : 4
Abbreviation : DS-CVD-NPU-MDS
Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs000294.v1.p1 : Myocardial Infarction Genetics Consortium (MIGen)

DUC : see attached

DAR : 117136

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : General Research Use
Consent Group # : 1
Abbreviation : GRU
Data Use Limitation : This dataset has no restrictions on use.

phs000289.v2.p1 : GENEVA GWAS of Venous Thrombosis

DUC : see attached

DAR : 117137

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : General Research Use
Consent Group # : 1
Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs000285.v3.p2 : CARDIA Cohort

DUC : see attached

IRB : see attached after DUC

DAR : 117138

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Data may not be used to investigate individual pedigree structures; individual participant genotypes; phenotype-only analyses; issues such as non-maternity and non-paternity; assess variables or proxies that could be considered stigmatizing to an individual or a group; or assess individual participant racial/ethnic identity. All research must be consistent with the CARDIA informed consent documents. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. population consistent with the demographic distribution in the CARDIA Study. Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

DAR : 117148

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Data may not be used to investigate individual pedigree structures; individual participant genotypes; phenotype-only analyses; issues such as non-maternity and non-paternity; assess variables or proxies that could be considered stigmatizing to an individual or a group; or assess individual participant racial/ethnic identity. All research must be consistent with the CARDIA informed consent documents. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. population consistent with the demographic distribution in the CARDIA Study. Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

phs000284.v2.p1 : NHLBI Cleveland Family Study (CFS) Candidate Gene Association Resource (CARe)

DUC : see attached

IRB : see attached after DUC

DAR : 117139

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (Heart, Lung, Blood, and Sleep Disorders, IRB, NPU)

Consent Group # : 1

Abbreviation : DS-HLBS-IRB-NPU

Data Use Limitation : Use of the data must be related to Heart, Lung, Blood, and Sleep Disorders.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Data use is limited to academic researchers conducting research in heart, lung, blood and sleep disorders, and their risk factors, and does not include the study of population origins and ancestry. CFS data may not be used to investigate individual pedigree structures, individual participant genotypes, phenotype-only analyses or issues such as non-maternity and non-paternity. All researchers requesting CFS data will be required to obtain approval from their IRB for their proposed project using CFS data.

phs000286.v6.p2 : The Jackson Heart Study (JHS)

DUC : see attached

IRB : see attached after DUC

DAR : 117140

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 1

Abbreviation : HMB-IRB-NPU

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

This JHS consent group allows for health/medical/biomedical research by investigators employed by non-profit organizations only.

DAR : 117141

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (Focused Disease Only, IRB, NPU)

Consent Group # : 2

Abbreviation : DS-FDO-IRB-NPU

Data Use Limitation :

Use of the data must be related to Focused Disease Only.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

This JHS consent group allows for study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only. Use of these data to study other diseases (e.g. cancer, schizophrenia) is NOT allowed under the current consent. This consent group allows for use by investigators employed by non-profit organizations only.

DAR : 117142

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 3

Abbreviation : HMB-IRB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

This JHS consent group allows for health/medical/biomedical research.

DAR : 117143

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (Focused Disease Only, IRB)

Consent Group # : 4

Abbreviation : DS-FDO-IRB

Data Use Limitation : Use of the data must be related to Focused Disease Only.
Requestor must provide documentation of local IRB approval.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

This JHS consent group allows for study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only. Use of these data to study other diseases (e.g. cancer, schizophrenia) is NOT allowed under the current consent.

phs000179.v6.p2 : Genetic Epidemiology of COPD (COPDGene)

DUC : see attached

DAR : 117145

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical

Consent Group # : 1

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

DAR : 117146

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (COPD and Smoking)

Consent Group # : 2

Abbreviation : DS-CS

Data Use Limitation : Use of the data must be related to COPD and Smoking.

The full list of diseases or conditions for which smoking is considered to be a risk factor can be found at: www.copdgene.org/smoking-related-disorders.

phs000333.v1.p1 : Family Investigation of Nephropathy and Diabetes (FIND) Study

DUC : see attached

IRB : see attached after DUC

DAR : 117147

Request Date : 2022-12-21 Last Renewal Date : 2023-09-30

Name : diabetes, kidney disease, retinopathy and/or related diseases

Consent Group # : 1

Abbreviation : DNAR

Data Use Limitation : These data may be used only for studies related to diabetes, kidney disease, retinopathy and/or related diseases. The data may not be bought and/or sold. All reasonable efforts must be made to secure the data with adequate security controls, maintain appropriate control over the dataset, and maintain the privacy of the participants.

phs000220.v2.p2 : PAGE: Multiethnic Cohort (MEC)

DUC : see attached

DAR : 117149

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : Disease-Specific (Cancer Research and Methods, PUB, MDS)

Consent Group # : 1

Abbreviation : DS-CRM-PUB-MDS

Data Use Limitation : Use of the data must be related to Cancer Research and Methods.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the data is limited to scientific research relevant to the etiology, prevention, treatment and late complications of treatment of cancer appropriate to the age group, including applications proposing analytical methods, software or other research tool development. Investigators must state in the Data Access Request their intention to publish or otherwise broadly share any finding from his/her study with the scientific community.

DAR : 117150

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : General Research Use

Consent Group # : 2

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs000297.v1.p1 : eMERGE Resistant Hypertension

DUC : see attached

DAR : 117151

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : Health Research - Group Health Seattle

Consent Group # : 1

Abbreviation : HR_GHS

Data Use Limitation : These data will be used only for health related research, including research to improve methods for health related research.

DAR : 117152

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : Dementia or Aging - Group Health Seattle
Consent Group # : 2
Abbreviation : AGING_GHS
Data Use Limitation : Limited to health research on dementia or other adult conditions related to the aging process. This includes research to improve methods for conducting research that could be applied to dementia or other adult conditions related to the aging process. For example, studies of conditions like cataract, diabetes, and psoriasis might be appropriate, while conditions like attention deficit hyperactivity disorder (ADHD) and neuroblastoma might not be appropriate. Studies of conditions that are common in both children and the elderly, such as schizophrenia or depression, would not be appropriate if they focused on children or young adults. Studies focused primarily on pediatric populations are not permitted.

DAR : 117153

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Health Research - Marshfield Clinic
Consent Group # : 3
Abbreviation : HR_MC
Data Use Limitation : May be used for genetic studies to learn about, prevent, or treat health problems.
No Permitted Use: Insurance companies

DAR : 117154

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Health Research - Vanderbilt U
Consent Group # : 4
Abbreviation : HR_VU
Data Use Limitation : May be used for genetic studies to learn about, prevent, or treat health problems.

DAR : 117155

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Health Research - Mayo Clinic
Consent Group # : 5
Abbreviation : HR_MYO
Data Use Limitation : Mayo Clinic Data may only be used for genetic studies to learn about, prevent, or treat health problems.

Investigators must state in the Data Use Request their intention to publish or otherwise broadly share any findings from his or her study with the scientific community.

DAR : 117156

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Health Research - Northwestern U
Consent Group # : 6
Abbreviation : HR_NWU
Data Use Limitation : May be used for genetic studies to learn about, prevent, or treat health problems

No Permitted Use: Insurance companies

phs000517.v3.p1 : GWAS of Breast Cancer in the Multiethnic Cohort

DUC : see attached

DAR : 117157

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Cancer)
Consent Group # : 1

Abbreviation : DS-CA
Data Use Limitation : Use of the data must be related to Cancer.
Data can NOT be used for general methods development research.

DAR : 117158

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : General Research Use (MDS)
Consent Group # : 2
Abbreviation : GRU-MDS
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117159

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical (MDS)
Consent Group # : 5
Abbreviation : HMB-MDS
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs000356.v2.p1 : Population Architecture using Genomics and Epidemiology, summary data (PAGE-summary)

DUC : see attached

DAR : 117160

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : General Research Use
Consent Group # : 1
Abbreviation : GRU
Data Use Limitation : General Research Use

phs000360.v3.p1 : eMERGE-I Genome Wide Association Studies of Network Phenotypes

DUC : see attached

DAR : 117161

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical
Consent Group # : 1
Abbreviation : HMB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
These data will be used only for health related research, including research to improve methods for health related research.

DAR : 117162

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Dementia)
Consent Group # : 2

Abbreviation : DS-DEM

Data Use Limitation : Use of the data must be related to Dementia.

Use of the data must be related to health research on dementia or other adult conditions related to the aging process. This includes research to improve methods for conducting research that could be applied to dementia or other adult conditions related to the aging process. For example, studies of conditions like cataract, diabetes, and psoriasis might be appropriate, while conditions like attention deficit hyperactivity disorder (ADHD) and neuroblastoma might not be appropriate. Studies of conditions that are common in both children and the elderly, such as schizophrenia or depression, would not be appropriate if they focused on children or young adults. Studies focused primarily on pediatric populations are not permitted.

DAR : 117163

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical - Genetic Studies Only-No Insurance Companies

Consent Group # : 3

Abbreviation : HM-B-GSO-NIC

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data is limited to genetic studies only. No permitted use: Insurance Companies

DAR : 117164

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical (GSO)

Consent Group # : 4

Abbreviation : HMB-GSO

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

Investigators must state in the Data Use Request their intention to publish or otherwise broadly share any findings from his or her study with the scientific community.

phs000722.v3.p2 : Whole Exome Sequencing of Colorectal Cancer Patients from the Nurses' Health Study (NHS) and Health Professionals Follow-up Study (HPFS)

DUC : see attached

DAR : 117165

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

DAR : 117166

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : Disease-Specific (Men's Health)

Consent Group # : 2

Abbreviation : DS-MH

Data Use Limitation : Use of the data must be related to Men's Health.

phs000615.v1.p1 : The CIDR NINDS International Stroke Genetics Consortium Study

DUC : see attached

DAR : 117167

Request Date : 2022-11-28 Last Renewal Date : 2023-08-06
Name : Disease-Specific (Stroke, NPU)
Consent Group # : 2
Abbreviation : DS-STK-NPU
Data Use Limitation : Use of the data must be related to Stroke.
Use of the data is limited to not-for-profit organizations.

Stroke Academic Research Use Only. Limited to academic research on stroke, including stroke risk factors.

DAR : 117168

Request Date : 2022-11-28 Last Renewal Date : 2023-08-06
Name : General Research Use (NPU)
Consent Group # : 3
Abbreviation : GRU-NPU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Use of the data is limited to not-for-profit organizations.

phs000779.v1.p1 : Ontario Familial Colon Cancer Registry Single Nucleotide Polymorphisms and CpG methylation (OFCCR SNP-CpG)

DUC : see attached
IRB : see attached after DUC

DAR : 117169

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Cancer, IRB)
Consent Group # : 1
Abbreviation : DS-CA-IRB
Data Use Limitation : Use of the data must be related to Cancer.
Requestor must provide documentation of local IRB approval.

The Requestor must provide documentation of local IRB approval.
The Requestor must get Colon Cancer family Registries or mount Sinai Hospital (Toronto) Research Ethics Boards approval. See http://coloncfr.org/collaboration

phs000784.v3.p1 : Genetic Epidemiology Network of Salt Sensitivity (GenSalt)

DUC : see attached
IRB : see attached after DUC
Request Date :
Name : Disease-Specific (High blood pressure and related cardiovascular-renal disease, IRB)
Consent Group # : 1
Abbreviation : DS-HCR-IRB
Data Use Limitation : Use of the data must be related to High blood pressure and related cardiovascular-renal disease.
Requestor must provide documentation of local IRB approval.

Please note that only full or expedited IRB approvals will be accepted.

phs000812.v1.p1 : Characterizing Genetic Susceptibility to Breast and Prostate Cancer - BPC3

DUC : see attached

DAR : 117170

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : General Research Use (MDS)
Consent Group # : 1
Abbreviation : GRU-MDS
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117171

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical (PUB, MDS)
Consent Group # : 2
Abbreviation : HMB-PUB-MDS
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117172

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Cancer in all age groups, other disease in adults only and methods
Consent Group # : 4
Abbreviation : CADM
Data Use Limitation : The informed consent document signed by the study participants allows use of these data by investigators for discovery and hypothesis generation in the investigation of the genetic contributions to cancer in all age groups and other diseases in adults only, as well as development of novel analytical approaches for GWAS.

DAR : 117173

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Breast, Ovarian, or Endometrial Disease, MDS)
Consent Group # : 3
Abbreviation : DS-BOED-MDS
Data Use Limitation : Use of the data must be related to Breast, Ovarian, or Endometrial Disease.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs000964.v5.p1 : NHLBI TOPMed: The Jackson Heart Study (JHS)

DUC : see attached
IRB : see attached after DUC

DAR : 117188

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (IRB)
Consent Group # : 3
Abbreviation : HMB-IRB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note

that only full or expedited approvals will be accepted).

There are four consent groups for JHS: 1) Health/Medical/Biomedical; 2) Non-profit Health/Medical/Biomedical; 3) Focus Diseases only, limiting analysis to the study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only; and 4) Non-profit Focus Diseases only.

DAR : 117189

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 1

Abbreviation : HMB-IRB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

There are four consent groups for JHS: 1) Health/Medical/Biomedical; 2) Non-profit Health/Medical/Biomedical; 3) Focus Diseases only, limiting analysis to the study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only; and 4) Non-profit Focus Diseases only.

DAR : 117190

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (Focused Disease Only, IRB)

Consent Group # : 4

Abbreviation : DS-FDO-IRB

Data Use Limitation : Use of the data must be related to Focused Disease Only.
Requestor must provide documentation of local IRB approval.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

There are four consent groups for JHS: 1) Health/Medical/Biomedical; 2) Non-profit Health/Medical/Biomedical; 3) Focus Diseases only, limiting analysis to the study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only; and 4) Non-profit Focus Diseases only.

DAR : 117191

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (Focused Disease Only, IRB, NPU)

Consent Group # : 2

Abbreviation : DS-FDO-IRB-NPU

Use of the data must be related to Focused Disease Only.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Data Use Limitation : Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

There are four consent groups for JHS: 1) Health/Medical/Biomedical; 2) Non-profit Health/Medical/Biomedical; 3) Focus Diseases only, limiting analysis to the study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only; and 4) Non-profit Focus Diseases only.

phs000951.v5.p5 : NHLBI TOPMed: Genetic Epidemiology of COPD (COPDGene)

DUC : see attached

DAR : 117192

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical

Consent Group # : 1

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

DAR : 117193

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (COPD and Smoking, RD)

Consent Group # : 2

Abbreviation : DS-CS-RD

Use of the data must be related to COPD and Smoking and related disorders.

Data Use Limitation : Use of this data is limited to studies of COPD and other smoking-related disorders. The full list of diseases or conditions for which smoking is considered to be a risk factor can be found at: www.copdgene.org/smoking-related-disorders. The institutional certification assured that data submission was compliant with, and limited to, local and federal policies, and Massachusetts state law; To the extent possible, consideration was given to individuals and groups for subsequent data sharing and are reviewed by the National Institutes of Health's Data Access Committees.

phs000954.v4.p2 : NHLBI TOPMed: The Cleveland Family Study (CFS)

DUC : see attached

IRB : see attached after DUC

DAR : 117205

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (Heart, Lung, Blood, and Sleep Disorders, IRB, NPU)

Consent Group # : 1

Abbreviation : DS-HLBS-IRB-NPU

Use of the data must be related to Heart, Lung, Blood, and Sleep Disorders.
Requestor must provide documentation of local IRB approval.
Data Use Limitation : Use of the data is limited to not-for-profit organizations.

Data use is limited to academic researchers conducting research in heart, lung, blood and sleep disorders, and

their risk factors, and does not include the study of population origins and ancestry. CFS data may not be used to investigate individual pedigree structures, individual participant genotypes, phenotype-only analyses or issues such as non-maternity and non-paternity. All researchers requesting CFS data will be required to obtain approval from their IRB for their proposed project using CFS data (please note only full or expedited approvals will be accepted).

phs000974.v5.p4 : NHLBI TOPMed: Genomic Activities such as Whole Genome Sequencing and Related Phenotypes in the Framingham Heart Study

DUC : see attached

IRB : see attached after DUC

DAR : 117197

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, MDS)

Consent Group # : 1

Abbreviation : HMB-IRB-MDS

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the Framingham data deposited in dbGaP is restricted to research on: genotype-phenotype associations; molecular phenotype (e.g., gene expression; microRNA)-phenotype associations; and proteomics/metabolomics-phenotype associations. All other phenotype-only analyses are prohibited (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC). Additionally, the Framingham data may not be used to:

• Investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; or explore issues such as non-maternity or non-paternity.
• Investigate topics that could be considered as stigmatizing an individual or group.
• Assess outcomes that are not related to health or disease conditions (note: methodological research that will serve as a prelude to health or disease research is permitted).

Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted). It is anticipated that, at least in some cases, the FHS data will be updated with additional information and will be so identified by an appropriate version number.

DAR : 117198

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, NPU, MDS)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU-MDS

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the Framingham data deposited in dbGaP is restricted to research on: genotype-phenotype associations; molecular phenotype (e.g., gene expression; microRNA)-phenotype associations; and proteomics/metabolomics-phenotype associations. All other phenotype-only analyses are prohibited (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC). Additionally, the Framingham data may not be used to:

• Investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; or explore issues such as non-maternity or non-paternity.
• Investigate topics that could be considered as stigmatizing an individual or group.
• Assess outcomes that are not related to health or disease conditions (note: methodological research that will serve as a prelude to health or disease research is permitted).

Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users

will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted). It is anticipated that, at least in some cases, the FHS data will be updated with additional information and will be so identified by an appropriate version number.

phs000956.v5.p1 : NHLBI TOPMed: Genetics of Cardiometabolic Health in the Amish

DUC : see attached

IRB : see attached after DUC

DAR : 117196

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, MDS)

Consent Group # : 2

Abbreviation : HMB-IRB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of these data is limited to health/medical/biomedical purposes. The data can be used only for health related research, including research to improve methods for health related research. It is not permissible to use the genetic or relationship information to attempt to identify these individuals or to link these data to other databases (e.g., the Anabaptist Genealogy Database). These data may not be used for analyses whose primary purpose is to study population origins or ancestry or for the study of inbreeding, non-paternity rates, etc. without the express approval of the Amish study PI.

phs000993.v5.p2 : NHLBI TOPMed: Heart and Vascular Health Study (HVH)

DUC : see attached

IRB : see attached after DUC

DAR : 117194

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, MDS)

Consent Group # : 1

Abbreviation : HMB-IRB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117195

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (Cardiovascular Disease, IRB, MDS)

Consent Group # : 2

Abbreviation : DS-CVD-IRB-MDS

Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs000925.v1.p1 : PAGE: The Charles Bronfman Institute for Personalized Medicine (IPM) BioMe Biobank

DUC : see attached

DAR : 117200

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : General Research Use
Consent Group # : 1
Abbreviation : GRU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs001033.v1.p1 : PAGE: Global Reference Panel

DUC : see attached

DAR : 117199

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : General Research Use
Consent Group # : 1
Abbreviation : GRU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs000810.v1.p1 : Hispanic Community Health Study / Study of Latinos (HCHS/SOL)

DUC : see attached

DAR : 117174

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical
Consent Group # : 2
Abbreviation : HMB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

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 these data to conduct non-genetic research is prohibited. The data may not be used to investigate individual participant genotypes for the purpose of identifying study participants. Investigation of relatedness among individuals, and of genomic composition in terms of genetic ancestry, may be used as tools to detect and characterize genetic risk factors for health-related traits. However, publications based on HCHS/SOL data may not provide specific pedigree structures, results concerning sensitive issues such as non-paternity, or in any way compromise the anonymity of study participants (either directly or indirectly). Publication of genetic associations with traits should focus on specific genetic variants rather than overall genetic ancestry profiles. Publications may not report results that could be considered as stigmatizing to an individual or group. Data use must be consistent with the HCHS/SOL informed consent, which is limited to the following two groups: a) Health/Medical/Biomedical (HMB) and b) Health/Medical/Biomedical Non-Profit Use Only (HMB-NPU). The NHLBI will keep all Data Use Certifications, and all approved studies utilizing HCHS/SOL dbGaP data will be listed on the dbGaP website.

DAR : 117175

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (NPU)
Consent Group # : 1
Abbreviation : HMB-NPU
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

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 these data to conduct non-genetic research is prohibited. The data may not be used

to investigate individual participant genotypes for the purpose of identifying study participants. Investigation of relatedness among individuals, and of genomic composition in terms of genetic ancestry, may be used as tools to detect and characterize genetic risk factors for health-related traits. However, publications based on HCHS/SOL data may not provide specific pedigree structures, results concerning sensitive issues such as non-paternity, or in any way compromise the anonymity of study participants (either directly or indirectly). Publication of genetic associations with traits should focus on specific genetic variants rather than overall genetic ancestry profiles. Publications may not report results that could be considered as stigmatizing to an individual or group. Data use must be consistent with the HCHS/SOL informed consent, which is limited to the following two groups: a) Health/Medical/Biomedical (HMB) and b) Health/Medical/Biomedical Non-Profit Use Only (HMB-NPU). The NHLBI will keep all Data Use Certifications, and all approved studies utilizing HCHS/SOL dbGaP data will be listed on the dbGaP website.

phs000788.v2.p3 : Research Program on Genes, Environment and Health (RPGEH)

DUC : see attached

IRB : see attached after DUC

DAR : 117176

Request Date : 2022-12-02 Last Renewal Date : 2023-08-15

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 1

Abbreviation : HMB-IRB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

phs000944.v1.p1 : eMERGE Phase III: Clinical Center at Partners HealthCare

DUC : see attached

DAR : 117177

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical (MDS)

Consent Group # : 1

Abbreviation : HMB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs001013.v3.p2 : Heart and Vascular Health Study (HVH)

DUC : see attached

IRB : see attached after DUC

DAR : 117178

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, MDS)

Consent Group # : 1

Abbreviation : HMB-IRB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117179

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Cardiovascular Disease, IRB, MDS)
Consent Group # : 2
Abbreviation : DS-CVD-IRB-MDS
Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs000963.v1.p1 : PGRN – RIKEN: Genetic Determinants of Clinical Cardiovascular Events in Patients Receiving Statins

DUC : see attached
Request Date :
Name : Health/Medical/Biomedical
Consent Group # : 1
Abbreviation : HMB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

phs001093.v1.p1 : UK South Asian T2D-GENES Exome Sequencing Study

DUC : see attached
IRB : see attached after DUC
Request Date :
Name : Disease-Specific (Type 2 Diabetes, IRB, RD)
Consent Group # : 1
Abbreviation : DS-T2D-IRB-RD
Data Use Limitation : Use of the data must be related to Type 2 Diabetes and related disorders.
Requestor must provide documentation of local IRB approval.

phs001167.v1.p1 : Type 2 Diabetes in African Americans, GWAS and Exome Sequencing

DUC : see attached
IRB : see attached after DUC

DAR : 117180

Request Date : 2022-12-21 Last Renewal Date : 2023-09-30
Name : Disease-Specific (Type 2 Diabetes, IRB, RD)
Consent Group # : 1
Abbreviation : DS-T2D-IRB-RD
Data Use Limitation : Use of the data must be related to Type 2 Diabetes and related disorders.
Requestor must provide documentation of local IRB approval.

phs001166.v1.p1 : Type 2 Diabetes Starr County GWAS and Exome Sequencing

DUC : see attached
IRB : see attached after DUC

DAR : 117181

Request Date : 2022-12-21 Last Renewal Date : 2023-09-30
Name : General Research Use (IRB)

Consent Group # : 1
Abbreviation : GRU-IRB
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.

phs000888.v1.p1 : eMERGE Network Imputed GWAS for 41 Phenotypes

DUC : see attached

DAR : 117182

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical
Consent Group # : 1
Abbreviation : HMB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

These data will be used only for health related research, including research to improve methods for health related research.

DAR : 117183

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Dementia)
Consent Group # : 2
Abbreviation : DS-DEM
Data Use Limitation : Use of the data must be related to Dementia.

Use of the data must be related to health research on dementia or other adult conditions related to the aging process. This includes research to improve methods for conducting research that could be applied to dementia or other adult conditions related to the aging process. For example, studies of conditions like cataract, diabetes, and psoriasis might be appropriate, while conditions like attention deficit hyperactivity disorder (ADHD) and neuroblastoma might not be appropriate. Studies of conditions that are common in both children and the elderly, such as schizophrenia or depression, would not be appropriate if they focused on children or young adults. Studies focused primarily on pediatric populations are not permitted.

DAR : 117184

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical - Genetic Studies Only-No Insurance Companies
Consent Group # : 3
Abbreviation : HM-B-GSO-NIC
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data is limited to genetic studies only. No permitted use: Insurance Companies

DAR : 117185

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical (GSO)
Consent Group # : 4
Abbreviation : HMB-GSO
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

Investigators must state in the Data Use Request their intention to publish or otherwise broadly share any findings from his or her study with the scientific community.

DAR : 117186

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : General Research Use
Consent Group # : 5
Abbreviation : GRU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

DAR : 117187

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Childhood Diseases)
Consent Group # : 6
Abbreviation : DS-CHILDD
Data Use Limitation : Use of the data must be related to Childhood Diseases.
Approved use for studies of the genetic and environmental factors that contribute to childhood health, development and disease

phs001143.v4.p1 : NHLBI TOPMed: The Genetics and Epidemiology of Asthma in Barbados

DUC : see attached
IRB : see attached after DUC

DAR : 117203

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : General Research Use (IRB)
Consent Group # : 1
Abbreviation : GRU-IRB
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.

phs001215.v4.p2 : NHLBI TOPMed: San Antonio Family Heart Study (SAFHS)

DUC : see attached
IRB : see attached after DUC

DAR : 117228

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Diabetes and Heart Disease, IRB, PUB, MDS, RD)
Consent Group # : 1
Abbreviation : DS-DHD-IRB-PUB-MDS-RD
Data Use Limitation : Use of the data must be related to Diabetes and Heart Disease and related disorders.
Requestor must provide documentation of local IRB approval.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data includes methods development research (e.g., development of software or algorithms).
Use of the data is limited to genetic studies of the specified disease and related conditions, such as phenotypes relevant for aging.

phs001217.v3.p1 : NHLBI TOPMed: Genetic Epidemiology Network of Salt Sensitivity (GenSalt)

DUC : see attached
IRB : see attached after DUC
Request Date :
Name : Disease-Specific (High blood pressure and related cardiovascular-renal disease, IRB)

Consent Group # : 1
Abbreviation : DS-HCR-IRB
Data Use Limitation : Use of the data must be related to High blood pressure and related cardiovascular-renal disease.
Requestor must provide documentation of local IRB approval.

Please note that only full or expedited IRB approvals will be accepted.

phs001211.v4.p3 : NHLBI TOPMed - NHGRI CCDG: Atherosclerosis Risk in Communities (ARIC)

DUC : see attached
IRB : see attached after DUC

DAR : 117201

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (IRB)
Consent Group # : 1
Abbreviation : HMB-IRB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Use of the ARIC Study data deposited in dbGaP is restricted to research on associations between phenotypes and genotypes. ARIC data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity, non-paternity, and perceptions of racial/ethnic identity. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted). One consent group is available for the ARIC Study: health/medical/biomedical research.
This Data Use Certification will be reviewed and approved by the NHLBI Data Access Committee. The NHLBI will keep all Data Use Certifications, and all approved studies utilizing ARIC dbGaP data will be listed on the dbGaP website. Annual updates regarding publications, etc. will be provided by the NHLBI to the ARIC study when and if necessary.

DAR : 117202

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Cardiovascular Disease, IRB)
Consent Group # : 2
Abbreviation : DS-CVD-IRB
Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.

phs001218.v3.p1 : NHLBI TOPMed: Genetic Study of Atherosclerosis Risk (GeneSTAR)

DUC : see attached
IRB : see attached after DUC

DAR : 117226

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Cardiovascular Disease, IRB, NPU, MDS)
Consent Group # : 2
Abbreviation : DS-CVD-IRB-NPU-MDS
Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs001237.v3.p1 : NHLBI TOPMed: Women's Health Initiative (WHI)

DUC : see attached

IRB : see attached after DUC

DAR : 117222

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

All requestors and data users must provide a local Institutional Review Board (IRB) letter from their respective institution approving conduct of the proposed research project. Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution.

Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were primarily dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree not to use the data to infer tribal status or affiliation.

DAR : 117223

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Use of the data is limited to not-for-profit organizations.
All requestors and data users must provide a local Institutional Review Board (IRB) letter from their respective institution approving conduct of the proposed research project. Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution.

Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were primarily dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree not to use the data to infer tribal status or affiliation.

phs001293.v3.p1 : NHLBI TOPMed: HyperGEN - Genetics of Left Ventricular (LV) Hypertrophy

DUC : see attached

IRB : see attached after DUC

DAR : 117229

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : General Research Use (IRB)

Consent Group # : 1

Abbreviation : GRU-IRB

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.

DAR : 117230

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Cardiovascular Disease, IRB, RD)
Consent Group # : 2
Abbreviation : DS-CVD-IRB-RD
Data Use Limitation : Use of the data must be related to Cardiovascular Disease and related disorders.
Requestor must provide documentation of local IRB approval.

phs001120.v2.p2 : ELLIPSE Prostate Cancer Meta-Analysis and Genotyping

DUC : see attached

DAR : 123423

Request Date : 2023-07-05 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Prostate Cancer, MDS)
Consent Group # : 1
Abbreviation : DS-PC-MDS
Data Use Limitation : Use of the data must be related to Prostate Cancer.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 123424

Request Date : 2023-07-05 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical (PUB)
Consent Group # : 3
Abbreviation : HMB-PUB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.

DAR : 123425

Request Date : 2023-07-05 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Cancer, PUB)
Consent Group # : 2
Abbreviation : DS-CA-PUB
Data Use Limitation : Use of the data must be related to Cancer.
Requestor agrees to make results of studies using the data available to the larger scientific community.

General methods development research is NOT permitted.

DAR : 123426

Request Date : 2023-07-05 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Prostate Cancer)
Consent Group # : 4
Abbreviation : DS-PC
Data Use Limitation : Use of the data must be related to Prostate Cancer.

General methods development research is NOT permitted.

phs001345.v3.p1 : NHLBI TOPMed: Genetic Epidemiology Network of Arteriopathy (GENOA)

DUC : see attached

DAR : 117227

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Arteriosclerosis and its Risk Factors, NPU)
Consent Group # : 1
Abbreviation : DS-ASC-RF-NPU
Data Use Limitation : Use of the data must be related to Arteriosclerosis and its Risk Factors.
Use of the data is limited to not-for-profit organizations.

phs001368.v4.p2 : NHLBI TOPMed: Trans-Omics for Precision Medicine (TOPMed) Whole Genome Sequencing Project: Cardiovascular Health Study

DUC : see attached

DAR : 117207

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (NPU, MDS)
Consent Group # : 2
Abbreviation : HMB-NPU-MDS
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117208

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (MDS)
Consent Group # : 1
Abbreviation : HMB-MDS
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117209

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Cardiovascular Disease, NPU, MDS)
Consent Group # : 4
Abbreviation : DS-CVD-NPU-MDS
Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117250

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Cardiovascular Disease, MDS)
Consent Group # : 3
Abbreviation : DS-CVD-MDS
Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs001395.v2.p1 : NHLBI TOPMed - NHGRI CCDG: Hispanic Community Health Study/Study of Latinos (HCHS/SOL)

DUC : see attached

DAR : 117251

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical
Consent Group # : 2
Abbreviation : HMB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

DAR : 117252

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (NPU)
Consent Group # : 1
Abbreviation : HMB-NPU
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

phs001402.v3.p1 : NHLBI TOPMed: Whole Genome Sequencing of Venous Thromboembolism (WGS of VTE)

DUC : see attached

DAR : 117211

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : General Research Use
Consent Group # : 1
Abbreviation : GRU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs001412.v3.p1 : NHLBI TOPMed: Diabetes Heart Study (DHS) African American Coronary Artery Calcification (AA CAC)

DUC : see attached
IRB : see attached after DUC

DAR : 117224

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (IRB, COL, NPU)
Consent Group # : 1
Abbreviation : HMB-IRB-COL-NPU
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Requestor must provide a letter of collaboration with the primary study investigator(s).
Use of the data is limited to not-for-profit organizations.

DAR : 117225

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Disease-Specific (Diabetes and Heart Disease, IRB, COL, NPU)
Consent Group # : 2
Abbreviation : DS-DHD-IRB-COL-NPU

Data Use Limitation : Use of the data must be related to Diabetes and Heart Disease.
Requestor must provide documentation of local IRB approval.
Requestor must provide a letter of collaboration with the primary study investigator(s).
Use of the data is limited to not-for-profit organizations.

Use of the data is limited to Type 2 Diabetes and Cardiovascular Disease.

phs001416.v3.p1 : NHLBI TOPMed: MESA and MESA Family AA-CAC

DUC : see attached

DAR : 117238

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical

Consent Group # : 1

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through the NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity and perceptions of racial/ethnic identity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in MESA.

DAR : 117239

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (NPU)

Consent Group # : 2

Abbreviation : HMB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

Data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through the NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity and perceptions of racial/ethnic identity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in MESA.

phs001238.v2.p1 : Genetic Epidemiology Network of Arteriopathy (GENOA)

DUC : see attached

DAR : 117204

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Disease-Specific (Arteriosclerosis and its Risk Factors, NPU)

Consent Group # : 1

Abbreviation : DS-ASC-RF-NPU

Data Use Limitation : Use of the data must be related to Arteriosclerosis and its Risk Factors.
Use of the data is limited to not-for-profit organizations.

phs001426.v1.p1 : Type 1 Diabetes Genetics Consortium (T1DGC): Case-only RNA-Seq Study

DUC : see attached

IRB : see attached after DUC

DAR : 117206

Request Date : 2022-12-21 Last Renewal Date : 2023-09-30

Name : Disease-Specific (Type 1 diabetes, its complications and other autoimmune diseases, IRB, RD)

Consent Group # : 1

Abbreviation : DS-T1DR-IRB-RD

Data Use Limitation : Use of the data must be related to Type 1 diabetes, its complications and other autoimmune diseases and related disorders.
Requestor must provide documentation of local IRB approval.

phs001612.v2.p2 : NHLBI TOPMed: Coronary Artery Risk Development in Young Adults (CARDIA)

DUC : see attached

IRB : see attached after DUC

DAR : 117253

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Data may not be used to investigate individual pedigree structures; individual participant genotypes; phenotype-only analyses; issues such as non-maternity and non-paternity; assess variables or proxies that could be considered stigmatizing to an individual or a group; or assess individual participant racial/ethnic identity. All research must be consistent with the CARDIA informed consent documents. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. population consistent with the demographic distribution in the CARDIA Study. Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

DAR : 117254

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Data may not be used to investigate individual pedigree structures; individual participant genotypes; phenotype-only analyses; issues such as non-maternity and non-paternity; assess variables or proxies that could be considered stigmatizing to an individual or a group; or assess individual participant racial/ethnic identity. All research must be consistent with the CARDIA informed consent documents. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. population consistent with the demographic distribution in the CARDIA Study. Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

phs001644.v3.p2 : NHLBI TOPMed - NHGRI CCDG: The BioMe Biobank at Mount Sinai

DUC : see attached

DAR : 117255

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (NPU)
Consent Group # : 1
Abbreviation : HMB-NPU
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

phs001398.v1.p1 : Center for Common Disease Genomics [CCDG] - Cardiovascular: The Bangladesh Risk of Acute Vascular Events (BRAVE) Study

DUC : see attached

DAR : 117210

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : General Research Use
Consent Group # : 1
Abbreviation : GRU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs001624.v3.p2 : NHLBI TOPMed - NHGRI CCDG: The Vanderbilt University BioVU Atrial Fibrillation Genetics Study

DUC : see attached

DAR : 117258

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (GSO)
Consent Group # : 1
Abbreviation : HMB-GSO
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

phs001672.v11.p1 : Veterans Administration (VA) Million Veteran Program (MVP) Summary Results from Omics Studies

DUC : see attached

DAR : 117212

Request Date : 2022-12-05 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (MDS)
Consent Group # : 1
Abbreviation : HMB-MDS
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs001078.v1.p1 : Common Variant GWAS, GECCO

DUC : see attached
IRB : see attached after DUC

DAR : 117213

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.
Only full or expedited IRB approvals will be accepted. Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree to not use the data to infer tribal status or affiliation.

DAR : 117214

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Disease-Specific (Colorectal Cancer, NPU, GSO)

Consent Group # : 5

Abbreviation : DS-CC-NPU-GSO

Data Use Limitation : Use of the data must be related to Colorectal Cancer.
Use of the data is limited to not-for-profit organizations.
Use of the data is limited to genetic studies only.

DAR : 117215

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical (PUB, NPU, MDS, GSO)

Consent Group # : 4

Abbreviation : HMB-PUB-NPU-MDS-GSO

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).
Use of the data is limited to genetic studies only.

DAR : 117216

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Cancer in all age groups, other diseases in adults only, and methods

Consent Group # : 3

Abbreviation : CADM

Data Use Limitation : The informed consent document signed by the study participants allows use of these data by investigators for discovery and hypothesis generation in the investigation of the genetic contributions to cancer in all age groups and other diseases in adults only, as well as development of novel analytical approaches for GWAS.

DAR : 117217

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

DAR : 117218

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Colorectal Cancer, MDS)
Consent Group # : 6
Abbreviation : DS-CC-MDS
Data Use Limitation : Use of the data must be related to Colorectal Cancer.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117219

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical (IRB)
Consent Group # : 7
Abbreviation : HMB-IRB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Only full or expedited IRB approvals will be accepted. Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree to not use the data to infer tribal status or affiliation.

DAR : 117220

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Cancer, PUB)
Consent Group # : 8
Abbreviation : DS-CA-PUB
Data Use Limitation : Use of the data must be related to Cancer.
Requestor agrees to make results of studies using the data available to the larger scientific community.

General methods development research is NOT permitted.

DAR : 117221

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical (PUB)
Consent Group # : 9
Abbreviation : HMB-PUB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.

phs001286.v3.p2 : The Prostate, Lung, Colon, Ovary Screening Trial (PLCO)

DUC : see attached
Request Date :
Name : Research relating to adults diseases and methods
Consent Group # : 1
Abbreviation : CADM
Data Use Limitation : The informed consent document signed by the PLCO study participants allows use of these data by investigators for discovery and hypothesis generation in the investigation of the genetic contributions to cancer and other adult diseases as well as development of novel analytical approaches for GWAS.

phs001483.v1.p1 : DRIVE Breast Cancer Whole Genome Sequencing

DUC : see attached

DAR : 117231

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Disease-Specific (Cancer, PUB)

Consent Group # : 1

Abbreviation : DS-CA-PUB

Data Use Limitation : Use of the data must be related to Cancer.
Requestor agrees to make results of studies using the data available to the larger scientific community.

General methods development research is NOT allowed.

DAR : 117232

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : General Research Use

Consent Group # : 2

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

DAR : 117233

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Disease-Specific (Breast Diseases, MDS)

Consent Group # : 3

Abbreviation : DS-BRD-MDS

Data Use Limitation : Use of the data must be related to Breast Diseases.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117234

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Disease-Specific (Breast Diseases)

Consent Group # : 4

Abbreviation : DS-BRD

Data Use Limitation : Use of the data must be related to Breast Diseases.

General methods development research is NOT permitted.

DAR : 117235

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Disease-Specific (Colorectal, ovarian, and/or breast cancer, NPU, MDS)

Consent Group # : 5

Abbreviation : DS-COBC-NPU-MDS

Data Use Limitation : Use of the data must be related to Colorectal, ovarian, and/or breast cancer.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117236

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical (PUB)

Consent Group # : 7

Abbreviation : HMB-PUB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.

DAR : 117237

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical (PUB, NPU)

Consent Group # : 6

Abbreviation : HMB-PUB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data is limited to not-for-profit organizations.

phs001616.v2.p2 : eMERGE Network Phase III Clinical Sequencing: eMERGEseq Panel

DUC : see attached

IRB : see attached after DUC

DAR : 123427

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical (GSO)

Consent Group # : 7

Abbreviation : HMB-GSO

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

DAR : 123428

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01

Name : General Research Use (IRB, NPU)

Consent Group # : 4

Abbreviation : GRU-IRB-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

DAR : 123429

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

Limited from use by insurance companies.

DAR : 123430

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01

Name : General Research Use (IRB)

Consent Group # : 3

Abbreviation : GRU-IRB

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.

DAR : 123431

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01

Name : General Research Use (IRB, PUB, NPU)

Consent Group # : 5

Abbreviation : GRU-IRB-PUB-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data is limited to not-for-profit organizations.

DAR : 123432

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical

Consent Group # : 6

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

DAR : 123433

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical (NPU)

Consent Group # : 8

Abbreviation : HMB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

DAR : 123434

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01

Name : General Research Use (NPU)

Consent Group # : 9

Abbreviation : GRU-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Use of the data is limited to not-for-profit organizations.

DAR : 123445

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical (IRB, PUB)

Consent Group # : 10

Abbreviation : HMB-IRB-PUB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Requestor agrees to make results of studies using the data available to the larger scientific community.

phs001584.v2.p2 : eMERGE Network Phase III: HRC Imputed Array Data

IRB : see attached after DUC

DAR : 123435

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01

Name : General Research Use

Consent Group # : 1
Abbreviation : GRU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

DAR : 123436

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01
Name : General Research Use (IRB, PUB, GSO)
Consent Group # : 2
Abbreviation : GRU-IRB-PUB-GSO
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data is limited to genetic studies only.

DAR : 123437

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01
Name : General Research Use (IRB, NPU)
Consent Group # : 3
Abbreviation : GRU-IRB-NPU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

DAR : 123438

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical
Consent Group # : 4
Abbreviation : HMB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

DAR : 123439

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical (MDS)
Consent Group # : 5
Abbreviation : HMB-MDS
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 123440

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Childhood Diseases)
Consent Group # : 6
Abbreviation : DS-CHILDD
Data Use Limitation : Use of the data must be related to Childhood Diseases.
Approved use for studies of the genetic and environmental factors that contribute to childhood health, development and disease.

DAR : 123441

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Dementia)

Consent Group # : 7
Abbreviation : DS-DEM
Data Use Limitation : Use of the data must be related to Dementia.

Use of the data must be related to health research on dementia or other adult conditions related to the aging process. This includes research to improve methods for conducting research that could be applied to dementia or other adult conditions related to the aging process. For example, studies of conditions like cataract, diabetes, and psoriasis might be appropriate, while conditions like attention deficit hyperactivity disorder (ADHD) and neuroblastoma might not be appropriate. Studies of conditions that are common in both children and the elderly, such as schizophrenia or depression, would not be appropriate if they focused on children and young adults. Studies focused primarily on pediatric populations are not permitted.

DAR : 123442

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical (PUB, GSO)
Consent Group # : 8
Abbreviation : HMB-PUB-GSO
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data is limited to genetic studies only.

DAR : 123443

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01
Name : General Research Use (IRB, PUB)
Consent Group # : 9
Abbreviation : GRU-IRB-PUB
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.
Requestor agrees to make results of studies using the data available to the larger scientific community.

DAR : 123444

Request Date : 2023-07-06 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical (GSO)
Consent Group # : 10
Abbreviation : HMB-GSO
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

No permitted use: Insurance companies.

phs000929.v1.p1 : High-Risk Breast Cancer GWAS

DAR : 117240

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Cancer, MDS)
Consent Group # : 2
Abbreviation : DS-CA-MDS
Data Use Limitation : Use of the data must be related to Cancer.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117241

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : General Research Use

Consent Group # : 1
Abbreviation : GRU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

DAR : 117242

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Breast Cancer, MDS)
Consent Group # : 3
Abbreviation : DS-BRCA-MDS
Data Use Limitation : Use of the data must be related to Breast Cancer.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117243

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Breast and Ovarian cancer, GSO)
Consent Group # : 5
Abbreviation : DS-BROC-GSO
Data Use Limitation : Use of the data must be related to Breast and Ovarian cancer.
Use of the data is limited to genetic studies only.

DAR : 117244

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Cancer, GSO)
Consent Group # : 6
Abbreviation : DS-CA-GSO
Data Use Limitation : Use of the data must be related to Cancer.
Use of the data is limited to genetic studies only.

DAR : 117245

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Cancer, Benign Neoplasms, or Hematopoietic Diseases (MDS)
Consent Group # : 4
Abbreviation : CABNHD-MDS
Data Use Limitation : Use the data must related to cancer, benign neoplasms, or hematopoietic diseases related to cancer or risk of cancer. Benign neoplasms and hematopoietic diseases are understood as having potential for significant morbidity in themselves, such as benign brain tumors, neuroendocrine tumors, desmoid tumors, myelodysplastic syndromes, which are reportable or potentially reportable to cancer registries. This data may also be used for general methods research (e.g. development of software or algorithms).

DAR : 117246

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Breast Diseases)
Consent Group # : 8
Abbreviation : DS-BRD
Data Use Limitation : Use of the data must be related to Breast Diseases.
General methods development research is NOT allowed.

DAR : 117247

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Breast Cancer, PUB, MDS)
Consent Group # : 7

Abbreviation : DS-BRCA-PUB-MDS

Data Use Limitation : Use of the data must be related to Breast Cancer.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data includes methods development research (e.g., development of software or algorithms).

DAR : 117248

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Health/Medical/Biomedical (PUB)

Consent Group # : 10

Abbreviation : HMB-PUB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.

DAR : 117249

Request Date : 2022-11-15 Last Renewal Date : 2023-08-01

Name : Disease-Specific (Cancer, PUB)

Consent Group # : 9

Abbreviation : DS-CA-PUB

Data Use Limitation : Use of the data must be related to Cancer.
Requestor agrees to make results of studies using the data available to the larger scientific community.

General methods development research is NOT permitted.

phs001927.v1.p1 : NHLBI TOPMed: SubPopulations and InteRmediate Outcome Measures In COPD Study (SPIROMICS)

Request Date :

Name : General Research Use

Consent Group # : 4

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

Request Date :

Name : General Research Use (NPU)

Consent Group # : 3

Abbreviation : GRU-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Use of the data is limited to not-for-profit organizations.

Request Date :

Name : Disease-Specific (Chronic Obstructive Pulmonary Disease)

Consent Group # : 2

Abbreviation : DS-COPD

Data Use Limitation : Use of the data must be related to Chronic Obstructive Pulmonary Disease.

Request Date :

Name : Disease-Specific (Chronic Obstructive Pulmonary Disease, NPU)

Consent Group # : 1

Abbreviation : DS-COPD-NPU

Data Use Limitation : Use of the data must be related to Chronic Obstructive Pulmonary Disease.
Use of the data is limited to not-for-profit organizations.

phs002018.v1.p1 : Center Common Disease Genomics [CCDG] - Cardiovascular: Partners Biobank

DAR : 117256

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Health/Medical/Biomedical (MDS)
Consent Group # : 1
Abbreviation : HMB-MDS
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs001222.v1.p1 : CCDG - Whole Genome Sequencing in Type 1 Diabetes (T1DGC)

IRB : see attached after DUC

DAR : 117257

Request Date : 2022-11-16 Last Renewal Date : 2023-08-01
Name : Disease-Specific (Diabetes and Related Complications, IRB, NPU)
Consent Group # : 1
Abbreviation : DS-DRC-IRB-NPU
Data Use Limitation : Use of the data must be related to Diabetes and Related Complications.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

phs002719.v1.p1 : Reasons for Geographic and Racial Differences in Stroke Cardiorenal GWAS

IRB : see attached after DUC

DAR : 123446

Request Date : 2023-07-11 Last Renewal Date : 2023-08-07
Name : Health/Medical/Biomedical (IRB)
Consent Group # : 1
Abbreviation : HMB-IRB
Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution.

phs001119.v1.p1 : Subpopulations and Intermediate Outcome Measures in COPD Study (SPIROMICS)

IRB : see attached after DUC
Request Date :
Name : General Research Use
Consent Group # : 1
Abbreviation : GRU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Request Date :
Name : General Research Use (NPU)
Consent Group # : 2
Abbreviation : GRU-NPU

Data Use Limitation :	Use of the data is limited only by the terms of the model Data Use Certification. Use of the data is limited to not-for-profit organizations.
Request Date :	
Name :	Disease-Specific (Chronic Obstructive Pulmonary Disease)
Consent Group # :	3
Abbreviation :	DS-COPD
Data Use Limitation :	Use of the data must be related to Chronic Obstructive Pulmonary Disease.
Request Date :	
Name :	Disease-Specific (Chronic Obstructive Pulmonary Disease, NPU)
Consent Group # :	4
Abbreviation :	DS-COPD-NPU
Data Use Limitation :	Use of the data must be related to Chronic Obstructive Pulmonary Disease. Use of the data is limited to not-for-profit organizations.
Request Date :	
Name :	General Research Use (COL)
Consent Group # :	5
Abbreviation :	GRU-COL
Data Use Limitation :	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide a letter of collaboration with the primary study investigator(s).
Request Date :	
Name :	General Research Use (COL, NPU)
Consent Group # :	6
Abbreviation :	GRU-COL-NPU
Data Use Limitation :	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide a letter of collaboration with the primary study investigator(s). Use of the data is limited to not-for-profit organizations.
Request Date :	
Name :	Disease-Specific (Chronic Obstructive Pulmonary Disease, COL)
Consent Group # :	7
Abbreviation :	DS-COPD-COL
Data Use Limitation :	Use of the data must be related to Chronic Obstructive Pulmonary Disease. Requestor must provide a letter of collaboration with the primary study investigator(s).
Request Date :	
Name :	Disease-Specific (Chronic Obstructive Pulmonary Disease, COL, NPU)
Consent Group # :	8
Abbreviation :	DS-COPD-COL-NPU
Data Use Limitation :	Use of the data must be related to Chronic Obstructive Pulmonary Disease. Requestor must provide a letter of collaboration with the primary study investigator(s). Use of the data is limited to not-for-profit organizations.

DATA USE CERTIFICATION AGREEMENT

(March 19, 2019, version)

This Data Use Certification Agreement outlines the terms of use for requested controlled-access datasets maintained in NIH-designated data repositories under the NIH Genomic Data Sharing Policy (e.g., the NIH database of Genotypes and Phenotypes (dbGaP)). The Addendum to this Agreement outlines additional terms and information which are specific to each requested dataset such as:

- Data Use Limitation(s)
- Sponsoring NIH Institute or Center
- Responsible Data Access Committee
- Study Description
- Suggested Acknowledgement Statement

INTRODUCTION AND STATEMENT OF POLICY

The National Institutes of Health (NIH) has established NIH-designated data repositories (e.g., database of Genotypes and Phenotypes (dbGaP), Sequence Read Archive (SRA), NIH Established Trusted Partnerships) for securely storing and sharing controlled-access human data submitted to NIH under the NIH Genomic Data Sharing (GDS) Policy. Because the volume of human genomic and phenotypic data maintained in these repositories is substantial and, in some instances, potentially sensitive (e.g., data related to the presence or risk of developing particular diseases or conditions and information regarding family relationships or ancestry), data must be shared in a manner consistent with the research participants' informed consent, and the confidentiality of the data and the privacy of participants must be protected.

Access to human genomic data will be provided to research investigators who, along with their institutions, have certified their agreement with the expectations and terms of access detailed below. NIH expects that, through Data Access Request (DAR) process, approved users of controlled-access datasets recognize any restrictions on data use established by the Submitting Institutions through the Institutional Certification, and as stated on the dbGaP study page.

Definitions of the underlined terminology in this document are found in section 13.

The parties to this Agreement include: the Principal Investigator (PI) requesting access to the genomic study dataset (an "Approved User"), the PI's home institution (the "Requester") as represented by the Institutional Signing Official designated through the eRA Commons system, and the NIH. The effective date of this Agreement shall be the DAR Approval Date, as specified in the notification of approval of the Data Access Committee (DAC).

TERMS OF ACCESS

1. Research Use

The Requester agrees that if access is approved, (1) the PI named in the DAR and (2) those named in the "Senior/Key Person Profile" section of the DAR, including the Information Technology Director and any

trainee, employee, or contractor[1] working on the proposed research project under the direct oversight of these individuals, shall become Approved Users of the requested dataset(s). Research use will occur solely in connection with the approved research project described in the DAR, which includes a 1-2 paragraph description of the proposed research (i.e., a Research Use Statement). Investigators interested in using Cloud Computing for data storage and analysis must request permission to use Cloud Computing in the DAR and identify the Cloud Service Provider (CSP) or providers and/or Private Cloud System (PCS) that they propose to use. They must also submit a Cloud Computing Use Statement as part of the DAR that describes the type of service and how it will be used to carry out the proposed research as described in the Research Use Statement. If the Approved Users plan to collaborate with investigators outside the Requester, the investigators at each external site must submit an independent DAR using the same project title and Research Use Statement, and if using the cloud, Cloud Computing Use Statement. New uses of these data outside those described in the DAR will require submission of a new DAR; modifications to the research project will require submission of an amendment to this application (e.g., adding or deleting Requester Collaborators from the Requester, adding datasets to an approved project). Access to the requested dataset(s) is granted for a period of **one (1) year**, with the option to renew access or close-out a project at the end of that year.

Submitting Investigator(s), or their collaborators, who provided the data or samples used to generate controlled-access datasets subject to the NIH GDS Policy and who have Institutional Review Board (IRB) approval and who meet any other study specific terms of access, are exempt from the limitation on the scope of the research use as defined in the DAR.

2. Requester and Approved User Responsibilities

The Requester agrees through the submission of the DAR that the PI named has reviewed and understands the principles for responsible research use and data management of the genomic datasets as defined in the NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy. The Requester and Approved Users further acknowledge that they are responsible for ensuring that all uses of the data are consistent with national, tribal, and state laws and regulations, as appropriate, as well as relevant institutional policies and procedures for managing sensitive genomic and phenotypic data. The Requester certifies that the PI is in good standing (i.e., no known sanctions) with the institution, relevant funding agencies, and regulatory agencies and is eligible to conduct independent research (i.e., is not a postdoctoral fellow, student, or trainee). The Requester and any Approved Users may use the dataset(s) only in accordance with the parameters described on the study page and in the Addendum to this Agreement for the appropriate research use, as well as any limitations on such use, of the dataset(s), as described in the DAR, and as required by law.

Through the submission of this DAR, the Requester and Approved Users acknowledge receiving and

[1] If contractor services are to be utilized, PI requesting the data must provide a brief description of the services that the contractor will perform for the PI (e.g., data cleaning services) in the research use statement of the DAR. Additionally, the Key Personnel section of the DAR must include the name of the contractor's employee(s) who will conduct the work. These requirements apply whether the contractor carries out the work at the PI's facility or at the contractor's facility. In addition, the PI is expected to include in any contract agreement requirements to ensure that any of the contractor's employees who have access to the data adhere to the NIH GDS Policy, this Data Use Certification Agreement, and the NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy. Note that any scientific collaborators, including contractors, who are not at the Requester must submit their own DAR.

reviewing a copy of the Addendum which includes Data Use Limitation(s) for each dataset requested. The Requester and Approved Users agree to comply with the terms listed in the Addendum.

Through submission of the DAR, the PI and Requester agree to submit a Project Renewal or Project Close-out prior to the expiration date of the one (1) year data access period. The PI also agrees to submit an annual Progress Update prior to the one (1) year anniversary[2] of the project, as described under *Research Use Reporting* (Term 10) below.

By approving and submitting the attached DAR, the Institutional Signing Official provides assurance that relevant institutional policies and applicable local, state, tribal, and federal laws and regulations, as applicable, have been followed, including IRB approval, if required. Approved Users may be required to have IRB approval if they have access to personal identifying information for research participants in the original study at their institution, or through their collaborators. The Institutional Signing Official also assures, through the approval of the DAR, that other institutional departments with relevant authorities (e.g., those overseeing human subjects research, information technology, technology transfer) have reviewed the relevant sections of the NIH GDS Policy and the associated procedures and are in agreement with the principles defined.

The Requester acknowledges that controlled-access datasets subject to the NIH GDS Policy may be updated to exclude or include additional information. Unless otherwise indicated, all statements herein are presumed to be true and applicable to the access and use of all versions of these datasets.

3. Public Posting of Approved Users' Research Use Statement

The PI agrees that information about themselves and the approved research use will be posted publicly on the dbGaP website. The information includes the PI's name and Requester, project name, Research Use Statement, and a Non-Technical Summary of the Research Use Statement. In addition, and if applicable, this information may include the Cloud Computing Use Statement and name of the CSP or PCS. Citations of publications resulting from the use of controlled-access datasets obtained through this DAR may also be posted on the dbGaP website.

4. Non-Identification

Approved Users agree not to use the requested datasets, either alone or in concert with any other information, to identify or contact individual participants from whom data and/or samples were collected. Approved Users also agree not to generate information (e.g., facial images or comparable representations) that could allow the identities of research participants to be readily ascertained. These provisions do not apply to research investigators operating with specific IRB approval, pursuant to 45 CFR 46, to contact individuals within datasets or to obtain and use identifying information under an IRB-approved research protocol. All investigators including any Approved User conducting "human subjects research" within the scope of 45 CFR 46 must comply with the requirements contained therein.

5. Certificate of Confidentiality

[2] The project anniversary date can be found in "My Projects" after logging in to the dbGaP authorized-access portal.

Effective June 11, 2017 the Certificate of Confidentiality (Certificate) issued for the database of Genotypes and Phenotypes (dbGaP) is subject to the requirements of section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)). Moreover, as of October 1, 2017 dbGaP is required to adhere to the *NIH Policy for Issuing Certificates of Confidentiality* (NOT-OD-17-109). Therefore, Approved Users of dbGaP, whether or not funded by the NIH, who access a copy of information protected by a Certificate held by dbGaP, are also subject to the requirements of the Certificate of Confidentiality and subsection 301(d) of the Public Health Service Act.

Under Section 301(d) of the Public Health Service Act and the *NIH Policy for Issuing Certificates of Confidentiality*, recipients of a Certificate of Confidentiality shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

6. Non-Transferability

The Requester and Approved Users agree to retain control of NIH controlled-access datasets obtained through the attached DAR, and any Data Derivatives of controlled-access datasets, and further agree not to distribute controlled-access datasets and Data Derivatives of controlled-access datasets to any entity or individual not identified in the submitted DAR. If the Approved Users are provided access to controlled-access datasets subject to the NIH GDS Policy for inter-institutional collaborative research described in the Research Use Statement of the DAR, and all members of the collaboration are also Approved Users through their home institution(s), data obtained through the attached DAR may be securely transmitted within the collaborative group. Each Approved User will follow all data security practices and other terms of use defined in this Agreement, the NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy, and the Requester's IT security requirements and

policies.

The Requester and Approved Users acknowledge responsibility for ensuring the review and agreement to the terms within this Agreement and the appropriate research use of controlled-access data obtained through the attached DAR and any Data Derivatives of controlled-access datasets by research staff associated with any approved project, subject to applicable laws and regulations. Requester and Approved Users agree that controlled-access datasets obtained through the attached DAR and any Data Derivatives of controlled-access datasets, in whole or in part, may not be sold to any individual at any point in time for any purpose.

The PI agrees that if they change institutions during the access period they will complete the Project Close-out process (See Term 12 for more details) before moving to their new institution. A new DAR, in which the new Requester agrees to the Data Use Certification Agreement and the Genomic Data User Code of Conduct, must be approved by the relevant NIH DAC(s) before controlled-access data may be re-accessed.

7. Data Security and Unauthorized Data Release

The Requester and Approved Users, including the Requester's IT Director, acknowledge NIH's expectation that they have reviewed and agree to manage the requested controlled-access dataset(s) and any Data Derivatives of controlled-access datasets according to NIH's expectations set forth in the current NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy and the Requester's IT security requirements and policies. The Requester, including the Requester's IT Director, agree that the Requester's IT security requirements and policies are sufficient to protect the confidentiality and integrity of the NIH controlled-access data entrusted to the Requester.

If approved by NIH to use cloud computing for the proposed research project, as outlined in the Research and Cloud Computing Use Statements of the Data Access Request, the Requester acknowledges that the IT Director has reviewed and understands the cloud computing guidelines in the NIH Security Best Practices for Controlled-Access Data Subject to the NIH GDS Policy.

The Requester and PI agree to notify the appropriate DAC(s) of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified. As permitted by law, notifications should include any known information regarding the incident and a general description of the activities or process in place to define and remediate the situation fully. Within 3 business days of the DAC notification, the Requester agrees to submit to the DAC(s) a detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action. The Requester agrees to provide documentation verifying that the remediation plans have been implemented. Repeated violations or unresponsiveness to NIH requests may result in further compliance measures affecting the Requester.

All notifications and written reports of data security incidents and policy compliance violations should be sent to the DAC(s) indicated in the Addendum to this Agreement.

NIH, or another entity designated by NIH may, as permitted by law, also investigate any data security incident or policy violation. Approved Users and their associates agree to support such investigations

and provide information, within the limits of applicable local, state, tribal, and federal laws and regulations. In addition, Requester and Approved Users agree to work with the NIH to assure that plans and procedures that are developed to address identified problems are mutually acceptable and consistent with applicable law.

8. Policy Compliance Violations

The Requester and Approved Users acknowledge that the NIH may terminate the DAR, including this Agreement and immediately revoke or suspend access to all controlled-access datasets subject to the NIH GDS Policy at any time if the Requester is found to be no longer in agreement with the principles outlined in the NIH GDS Policy, the terms described in this Agreement, or the Genomic Data User Code of Conduct. The Requester and PI agree to notify the NIH of any violations of the NIH GDS Policy, this Agreement, or the Genomic Data User Code of Conduct data within 24 hours of when the incident is identified. Repeated violations or unresponsiveness to NIH requests may result in further compliance measures affecting the Requester.

The Requester and PI agree to notify the appropriate DAC(s) of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified. As permitted by law, notifications should include any known information regarding the incident and a general description of the activities or process in place to define and remediate the situation fully. Within 3 business days of the DAC notification(s), the Requester agrees to submit to the DAC(s) a detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action. The Requester agrees to provide documentation verifying that the remediation plans have been implemented. Repeated violations or unresponsiveness to NIH requests may result in further compliance measures affecting the Requester.

All notifications and written reports of data management incidents should be sent to the DAC(s) indicated in the Addendum to this Agreement.

NIH, or another entity designated by NIH may, as permitted by law, also investigate any data security incident or policy violation. Approved Users and their associates agree to support such investigations and provide information, within the limits of applicable local, state, tribal, and federal laws and regulations. In addition, Requester and Approved Users agree to work with the NIH to assure that plans and procedures that are developed to address identified problems are mutually acceptable and consistent with applicable law.

9. Intellectual Property

By requesting access to genomic dataset(s), the Requester and Approved Users acknowledge the intent of the NIH that anyone authorized for research access through the attached DAR follow the intellectual property (IP) principles in the NIH GDS Policy as summarized below:

> Achieving maximum public benefit is the ultimate goal of data distribution through the NIH-designated data repositories. The NIH encourages broad use of NIH-supported genotype-phenotype data that is consistent with a responsible approach to management of intellectual

property derived from downstream discoveries, as outlined in the NIH Best Practices for the Licensing of Genomic Inventions and its Research Tools Policy.

The NIH considers these data as pre-competitive and urges Approved Users to avoid making IP claims derived directly from the genomic dataset(s). It is expected that these NIH-provided data, and conclusions derived therefrom, will remain freely available, without requirement for licensing. However, the NIH also recognizes the importance of the subsequent development of IP on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products to benefit the public.

10. Dissemination of Research Findings and Acknowledgement of Controlled-Access Datasets Subject to the NIH GDS Policy

It is NIH's intent to promote the dissemination of research findings from use of controlled-access dataset(s) subject to the NIH GDS Policy as widely as possible through scientific publication or other appropriate public dissemination mechanisms. Approved Users are strongly encouraged to publish their results in peer-reviewed journals and to present research findings at scientific meetings.

Approved Users agree to acknowledge the Submitting Investigator(s) who submitted data from the original study to an NIH-designated data repository, the primary funding organization that supported the Submitting Investigator(s), and the NIH-designated data repository, in all oral and written presentations, disclosures, and publications resulting from any analyses of controlled-access data obtained through the attached DAR. Approved Users further agree that the acknowledgment shall include the dbGaP accession number to the specific version of the dataset(s) analyzed. A sample acknowledgment statement is provided for each dataset in the Addendum to this Agreement.

11. Research Use Reporting

To assure adherence to NIH GDS Policy, the PI agrees to provide annual Progress Updates as part of the annual Project Renewal or Project Close-out processes, prior to the expiration of the one (1) year data access period. The PI who is seeking Renewal or Close-out of a project agree to complete the appropriate online forms and provide specific information such as how the data have been used, including publications or presentations that resulted from the use of the requested dataset(s), a summary of any plans for future research use (if the PI is seeking renewal), any violations of the terms of access described within this Agreement and the implemented remediation, and information on any downstream intellectual property generated from the data. The PI also may include general comments regarding suggestions for improving the data access process in general. Information provided in the progress updates helps NIH evaluate program activities and may be considered by the NIH GDS governance committees as part of NIH's effort to provide ongoing stewardship of data sharing activities subject to the NIH GDS Policy.

12. Non-Endorsement, Indemnification

The Requester and Approved Users acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of controlled-access data obtained through the attached DAR, the NIH and Submitting Investigator(s) do not and cannot warrant the results that may be obtained by using any data included therein. NIH and all contributors to these datasets disclaim all warranties as to performance or fitness of the data for any particular purpose.

No indemnification for any loss, claim, damage, or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement, except that NIH, as an agency of the United States, may be liable only to the extent provided under the Federal Tort Claims Act, 28 USC 2671 et seq.

13. Termination and Data Destruction

Upon Project Close-out, the Requester and Approved Users agree to destroy all copies, versions, and Data Derivatives of the dataset(s) retrieved from NIH-designated controlled-access databases, on both local servers and hardware, and if cloud computing was used, delete the data and cloud images from cloud computing provider storage, virtual and physical machines, databases, and random access archives, in accord with the NIH Security Best Practices for Controlled-Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy. However, the Requester may retain these data as necessary to comply with any institutional policies (e.g., scientific data retention policy), law, and scientific transparency expectations for disseminated research results, and/or journal policies. A Requester who retains data for any of these purposes continues to be a steward of the data and is responsible for the management of the retained data in accordance with the NIH Security Best Practices for Controlled-Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy, and any institutional policies. Any retained data may only be used by the PI and Requester to support the findings (e.g., validation) resulting from the research described in the DAR that was submitted by the Requester and approved by NIH. The data may not be used to answer any additional research questions, even if they are within the scope of the approved Data Access Request, unless the Requester submits a new DAR and is approved by NIH to conduct the additional research. If a Requester retains data for any of these purposes, the relevant portions of Terms 4, 5, 6, 7, 8, and 12 remain in effect after termination of this Data Use Certification Agreement. These terms remain in effect until the data is destroyed.

14. DEFINITIONS

Approved User: A user approved by the relevant Data Access Committee(s) to access one or more datasets for a specified period of time and only for the purposes outlined in the Principal Investigator (PI)'s approved Research Use Statement. The Information Technology (IT) Director indicated on the Data Access Request, as well as any staff members and trainees under the direct supervision of the PI are also Approved Users and must abide by the terms laid out in the Data Use Certification Agreement.

Collaborator: An individual who is not under the direct supervision of the PI (e.g., not a member of the PI's laboratory) who assists with the PI's research project involving controlled-access data subject to the NIH GDS Policy. Internal collaborators are employees of the Requester and work at the same location/campus as the PI. External collaborators are not employees of the Requester and/or do not work at the same location as the PI, and consequently must be independently approved to access controlled-access data subject to the NIH GDS Policy.

Cloud Computing: The National Institute for Standards and Technology defines cloud computing as a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. For more information see NIST Special Publication 800-145.

Cloud Service Provider (CSP): A company or institution that offers some component of cloud computing to other businesses or individual, typically Infrastructure as a Service (IaaS), Software as a Service (SaaS) or Platform as a Service (PaaS), as defined by the National Institute of Standards and Technology. For more information see NIST Special Publication 800-145.

Data Access Request (DAR): A request submitted to a Data Access Committee for a specific "consent group" specifying the data to which access is sought, the planned research use, and the names of collaborators and the IT Director. The DAR is signed by the PI requesting the data and her/his Institutional Signing Official. Requester Collaborators and project team members on a request must be from the same organization.

Data Derivative: Data derived from controlled-access datasets obtained from NIH-designated data repositories. Examples of derived data include imputed datasets and single nucleotide polymorphisms.

Data Use Certification (DUC) Agreement: An agreement between the Approved User, the Requester, and NIH regarding the terms associated with access of controlled-access datasets subject to the NIH GDS Policy and the expectations for use of these datasets.

Genomic Data User Code of Conduct: Key principles and practices agreed to by all research investigators requesting access to controlled-access data subject to the NIH GDS Policy. The elements within the Genomic Data User Code of Conduct reflect the terms of access in the Data Use Certification Agreement. Failure to abide by the Genomic Code of Conduct may result in revocation of an investigator's access to any and all approved datasets.

Information Technology (IT) Director: An Approved User who is generally a senior IT official of the Requester with the necessary expertise and authority to affirm the IT capacities at the Requester. The IT Director is expected to have the authority and capacity to ensure that the NIH Security Best Practices for Controlled-Access Data Subject to the NIH GDS Policy and the Requester's IT security requirements and policies are followed by all of the Requester's Approved Users.

Institutional Certification: Certification by the Submitting Institution that delineates, among other items, the appropriate research uses of the data and the uses that are specifically excluded by the relevant informed consent documents. Further information may be found here.

Institutional Signing Official: The label, "Signing Official," is used in conjunction with the NIH eRA Commons and refers to the individual that has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the institution, but is typically located in its Office of Sponsored Research or equivalent. The Signing Official for the Requester reviews Data Access Request, Project Renewal, and Project Close-out applications submitted by Principal Investigators and legally binds the Requester to agree to adhere to the terms described in this Agreement if the application is submitted to NIH. The Institutional Signing Official for the Submitting Institution enters into the Institutional Certification and signs on behalf of the Submitting Investigator(s) who has submitted data.

Principal Investigator (PI): The investigator who prepares Data Access Requests (DARs), Project Renewals, and Project close-outs. The Principal Investigator plays a lead role in ensuring that management and use of controlled-access data remains consistent with the terms in the Data Use

Certification Agreement. To be able to submit a DAR, a Principal Investigator must be designated as such by their institution in eRA Commons *and* be a permanent employee of their institution at a level equivalent to a tenure-track professor or senior scientist with responsibilities that most likely include laboratory administration and oversight.

Private Cloud System (PCS): A cloud infrastructure provisioned for exclusive use by a single organization comprising multiple consumers (e.g., business units). It may be owned, managed, and operated by the Requester, a third party, or some combination of them, and it may exist on or off premises.

Progress Update: Information included with the annual Data Access Request (DAR) renewal or Close-out summarizing the analysis of controlled-access datasets obtained through the DAR and any publications and presentations derived from the work.

Project Close-out: Termination of a research project that used controlled-access data from an NIH-designated data repository (e.g., dbGaP) and confirmation of data destruction when the research is completed and/or discontinued. The project close-out process is completed in the dbGaP Authorized Access System.

Project Renewal: Renewal of a PI's access to controlled-access datasets for a previously-approved project.

Requester: The home institution or organization of the Approved User that applies to dbGaP for access to controlled-access data subject to the NIH GDS Policy.

Submitting Institution: An organization who submitted a genomic dataset to an NIH-designated data repository (e.g., dbGaP).

Submitting Investigator: An investigator who submitted a genomic dataset to an NIH designated data repository (e.g., dbGaP).

Study specific DUC addendum

phs000209 : MESA Cohort

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical

Consent Group # : 1

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through the NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity and perceptions of racial/ethnic identity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in MESA.

Name : Health/Medical/Biomedical (NPU)

Consent Group # : 2

Abbreviation : HMB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

Data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through the NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity and perceptions of racial/ethnic identity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in MESA.

phs001120 : ELLIPSE Prostate Cancer Meta-Analysis and Genotyping

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NCI DAC

Important Contacts : NCIDAC@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : Meta-Analysis: Funding for the meta-analysis provided by NIH grant U19CA148537.

de novo Genotyping: We would like to acknowledge the NCRN nurses and Consultants for their work in the UKGPCS study. We thank all the patients who took part in this study. This work was supported by Cancer Research UK (grant numbers C5047/A7357, C1287/A10118, C1287/A5260, C5047/A3354, C5047/A10692, C16913/A6135 and C16913/A6835). We would also like to thank the following for funding support: Prostate Research Campaign UK (now Prostate Cancer UK), The Institute of Cancer Research and The Everyman Campaign, The National Cancer Research Network UK, The National Cancer Research Institute (NCRI) UK. We are grateful for support of NIHR funding to the NIHR Biomedical Research Centre at The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust.
The MEC was supported by NIH grants CA63464, CA54281 and CA098758.

Name : Disease-Specific (Prostate Cancer, MDS)

Consent Group # : 1

Abbreviation : DS-PC-MDS

Data Use Limitation : Use of the data must be related to Prostate Cancer.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Health/Medical/Biomedical (PUB)

Consent Group # : 3

Abbreviation : HMB-PUB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.

Name : Disease-Specific (Cancer, PUB)

Consent Group # : 2

Abbreviation : DS-CA-PUB

Data Use Limitation : Use of the data must be related to Cancer.
Requestor agrees to make results of studies using the data available to the larger scientific community.

General methods development research is NOT permitted.

Name : Disease-Specific (Prostate Cancer)

Consent Group # : 4

Abbreviation : DS-PC

Data Use Limitation : Use of the data must be related to Prostate Cancer.

General methods development research is NOT permitted.

phs001644 : NHLBI TOPMed - NHGRI CCDG: The BioMe Biobank at Mount Sinai

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

Acknowledgement Statement : The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements. In addition, please include: "The Mount Sinai BioMe Biobank is supported by The Andrea and Charles Bronfman Philanthropies."

Name : Health/Medical/Biomedical (NPU)

Consent Group # : 1

Abbreviation : HMB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

phs000289 : GENEVA GWAS of Venous Thrombosis

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : Funding support for the GWAS of Venous Thrombosis study was provided through the NIH Genes, Environment and Health Initiative [GEI] (U01HG004735). The GWAS of Venous Thrombosis study is one of the genome-wide association studies funded as part of the Gene Environment Association Studies (GENEVA) under GEI. Assistance with phenotype harmonization and genotype cleaning, as well as with general study coordination, was provided by the GENEVA Coordinating Center (U01 HG004446). Assistance with data cleaning was provided by the National Center for Biotechnology Information. Funding support for genotyping, which was performed at the Johns Hopkins University Center for Inherited Disease Research, was provided by the NIH GEI (U01HG004438) and the NIH contract "High throughput genotyping for studying the genetic contributions to human disease(HHSN268200782096C). The datasets used for the analyses described in this manuscript were obtained from dbGaP at http://www.ncbi.nlm.nih.gov/sites/entrez?db=gap through dbGaP accession number phs000289.

Name : General Research Use

Consent Group # : 1
Abbreviation : GRU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs000888 : eMERGE Network Imputed GWAS for 41 Phenotypes

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical
Consent Group # : 1
Abbreviation : HMB
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

These data will be used only for health related research, including research to improve methods for health related research.

Name : Disease-Specific (Dementia)
Consent Group # : 2
Abbreviation : DS-DEM
Data Use Limitation : Use of the data must be related to Dementia.

Use of the data must be related to health research on dementia or other adult conditions related to the aging process. This includes research to improve methods for conducting research that could be applied to dementia or other adult conditions related to the aging process. For example, studies of conditions like cataract, diabetes, and psoriasis might be appropriate, while conditions like attention deficit hyperactivity disorder (ADHD) and neuroblastoma might not be appropriate. Studies of conditions that are common in both children and the elderly, such as schizophrenia or depression, would not be appropriate if they focused on children or young adults. Studies focused primarily on pediatric populations are not permitted.

Name : Health/Medical/Biomedical - Genetic Studies Only-No Insurance Companies
Consent Group # : 3
Abbreviation : HM-B-GSO-NIC
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data is limited to genetic studies only. No permitted use: Insurance Companies

Name : Health/Medical/Biomedical (GSO)
Consent Group # : 4
Abbreviation : HMB-GSO
Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

Investigators must state in the Data Use Request their intention to publish or otherwise broadly share any findings from his or her study with the scientific community.

Name : General Research Use
Consent Group # : 5
Abbreviation : GRU
Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

Name : Disease-Specific (Childhood Diseases)
Consent Group # : 6
Abbreviation : DS-CHILDD
Data Use Limitation : Use of the data must be related to Childhood Diseases.

Approved use for studies of the genetic and environmental factors that contribute to childhood health, development and disease

phs000200 : Women's Health Initiative

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

All requestors and data users must provide a local Institutional Review Board (IRB) letter from their respective institution approving conduct of the proposed research project. Only full or expedited approvals will be accepted. There are two consent groups for this study: a) Health/Medical/Biomedical IRB, and b) Health/Medical/Biomedical IRB for use by not-for-profit organizations only.

IC Specific Access Term : Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were primarily dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree not to use the data to infer tribal status or affiliation.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

All requestors and data users must provide a local Institutional Review Board (IRB) letter from their respective institution approving conduct of the proposed research project. Only full or expedited approvals will be accepted.

Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were primarily dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree not to use the data to infer tribal status or affiliation.

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

All requestors and data users must provide a local Institutional Review Board (IRB) letter from their respective institution approving conduct of the proposed research project. Only full or expedited approvals will be accepted.

Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were primarily dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree not to use the data to infer tribal status or affiliation.

phs000810 : Hispanic Community Health Study / Study of Latinos (HCHS/SOL)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : 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 these data to conduct non-genetic research is prohibited. The data may not be used to investigate individual participant genotypes for the purpose of identifying study participants. Investigation of relatedness among individuals, and of genomic composition in terms of genetic ancestry, may be used as tools to detect and characterize genetic risk factors for health-related traits. However, publications based on HCHS/SOL data may not provide specific pedigree structures, results concerning sensitive issues such as non-paternity, or in any way compromise the anonymity of study participants (either directly or indirectly). Publication of genetic associations with traits should focus on specific genetic variants rather than overall genetic ancestry profiles. [Please note Advisory Board Guidance: "Users acknowledge that tribal status or affiliation of American Indian participants should not be inferred since they are self-identified, urban dwelling, and are not representative of the diverse American Indian population across the United States."] Publications may not report results that could be considered as stigmatizing to an individual or group. Data use must be consistent with the HCHS/SOL informed consent, which is limited to the following two groups: a) Health/Medical/Biomedical (HMB) and b) Health/Medical/Biomedical Non-Profit Use Only (HMB-NPU).

Acknowledgement Statement : link

Name : Health/Medical/Biomedical

Consent Group # : 2

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

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 these data to conduct non-genetic research is prohibited. The data may not be used to investigate individual participant genotypes for the purpose of identifying study participants. Investigation of relatedness among individuals, and of genomic composition in terms of genetic ancestry, may be used as tools to detect and characterize genetic risk factors for health-related traits. However, publications based on HCHS/SOL data may not provide specific pedigree structures, results concerning sensitive issues such as non-paternity, or in any way compromise the anonymity of study participants (either directly or indirectly). Publication of genetic associations with traits should focus on specific genetic variants rather than overall genetic ancestry profiles. Publications may not report results that could be considered as stigmatizing to an individual or group. Data use must be consistent with the HCHS/SOL informed consent, which is limited to the following two groups: a) Health/Medical/Biomedical (HMB) and b) Health/Medical/Biomedical Non-Profit Use Only (HMB-NPU). The NHLBI will keep all Data Use Certifications, and all approved studies utilizing HCHS/SOL dbGaP data will be listed on the dbGaP website.

Name : Health/Medical/Biomedical (NPU)

Consent Group # : 1

Abbreviation : HMB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

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 these data to conduct non-genetic research is prohibited. The data may not be used to investigate individual participant genotypes for the purpose of identifying study participants. Investigation of relatedness among individuals, and of genomic composition in terms of genetic ancestry, may be used as tools to detect and characterize genetic risk factors for health-related traits. However, publications based on HCHS/SOL data may not provide specific pedigree structures, results concerning sensitive issues such as non-paternity, or in any way compromise the anonymity of study participants (either directly or indirectly). Publication of genetic associations with traits should focus on specific genetic variants rather than overall genetic ancestry profiles. Publications may not report results that could be considered as stigmatizing to an individual or group. Data use must be consistent with the HCHS/SOL informed consent, which is limited to the following two groups: a) Health/Medical/Biomedical (HMB) and b) Health/Medical/Biomedical Non-Profit Use Only (HMB-NPU). The NHLBI will keep all Data Use Certifications, and all approved studies utilizing HCHS/SOL dbGaP data will be listed on the dbGaP website.

phs000286 : The Jackson Heart Study (JHS)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) :	National Heart, Lung, and Blood Institute DAC
Important Contacts :	nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov
	In the event of a data management incident, within 24 hours, please contact emails above.
	Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.
IC Specific Access Term :	Data users will be required to obtain IRB approval for their projects from their respective institutions. Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution. There are four consent groups for JHS: 1) Health/Medical/Biomedical; 2) Non-profit Health/Medical/Biomedical; 3) Focus Diseases only, limiting analysis to the study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only; and 4) Non-profit Focus Diseases only.
Acknowledgement Statement :	link
Name :	Health/Medical/Biomedical (IRB, NPU)
Consent Group # :	1
Abbreviation :	HMB-IRB-NPU
Data Use Limitation :	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor must provide documentation of local IRB approval. Use of the data is limited to not-for-profit organizations. Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted). This JHS consent group allows for health/medical/biomedical research by investigators employed by non-profit organizations only.
Name :	Disease-Specific (Focused Disease Only, IRB, NPU)
Consent Group # :	2
Abbreviation :	DS-FDO-IRB-NPU
Data Use Limitation :	Use of the data must be related to Focused Disease Only. Requestor must provide documentation of local IRB approval. Use of the data is limited to not-for-profit organizations. Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted). This JHS consent group allows for study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only. Use of these data to study other diseases (e.g. cancer, schizophrenia) is NOT allowed under the current consent. This consent group allows for use by investigators employed by non-profit organizations only.
Name :	Health/Medical/Biomedical (IRB)
Consent Group # :	3
Abbreviation :	HMB-IRB
Data Use Limitation :	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins

or ancestry.
Requestor must provide documentation of local IRB approval.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

This JHS consent group allows for health/medical/biomedical research.

Name : Disease-Specific (Focused Disease Only, IRB)

Consent Group # : 4

Abbreviation : DS-FDO-IRB

Data Use Limitation : Use of the data must be related to Focused Disease Only.
Requestor must provide documentation of local IRB approval.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

This JHS consent group allows for study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only. Use of these data to study other diseases (e.g. cancer, schizophrenia) is NOT allowed under the current consent.

phs000294 : Myocardial Infarction Genetics Consortium (MIGen)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : INSTRUCTIONS: This study has not provided a suggested acknowledgement statement. However, Approved Users are expected to acknowledge the Submitting Investigator(s) who submitted data from the original study to an NIH-designated data repository, the primary funding organization that supported the Submitting Investigator(s), and the NIH-designated data repository (e.g., dbGaP). The acknowledgment statement should include the dbGaP accession number to the specific version of the dataset(s) analyzed.

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : This dataset has no restrictions on use.

phs001093 : UK South Asian T2D-GENES Exome Sequencing Study

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NIDDK Central Repository GWAS Data Access Committee

Important Contacts : niddk-dac@mail.nih.gov; niddk-dac@mail.nih.gov ; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : The UK South Asian T2D-GENES Exome Sequencing Study was conducted by the UK South Asian T2D-GENES Exome Sequencing Study Investigators and supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The data from the UK South Asian T2D-GENES Exome Sequencing Study reported here were supplied by the Broad Institute and Imperial College London. This manuscript was not prepared in

collaboration with Investigators of the UK South Asian T2D-GENES Exome Sequencing Study study and does not necessarily reflect the opinions or views of the UK South Asian T2D-GENES Exome Sequencing Study , or the NIDDK.

Name : Disease-Specific (Type 2 Diabetes, IRB, RD)

Consent Group # : 1

Abbreviation : DS-T2D-IRB-RD

Data Use Limitation : Use of the data must be related to Type 2 Diabetes and related disorders.
Requestor must provide documentation of local IRB approval.

phs000779 : Ontario Familial Colon Cancer Registry Single Nucleotide Polymorphisms and CpG methylation (OFCCR SNP-CpG)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : OFCCR is a member of the Colon Cancer Family Registry (CCFR). Funding sources for the OFCCR SNP-CpG dataset include grants from the National Cancer Institute, Genome Canada, the Ontario Research Fund (GL2 competition) and the Ontario Ministry of Research and Innovation.

Name : Disease-Specific (Cancer, IRB)

Consent Group # : 1

Abbreviation : DS-CA-IRB

Data Use Limitation : Use of the data must be related to Cancer.
Requestor must provide documentation of local IRB approval.
The Requestor must provide documentation of local IRB approval.
The Requestor must get Colon Cancer family Registries or mount Sinai Hospital (Toronto) Research Ethics Boards approval. See http://coloncfr.org/collaboration

phs001584 : eMERGE Network Phase III: HRC Imputed Array Data

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : None.

Acknowledgement Statement : Cincinnati Childrens Hospital Medical Center (CCHMC) Acknowledgement Text: CCHMC is a participating pediatric institution for Phase III of the eMERGE network, a national consortium selected to expand best practices and knowledge in effective implementation of genomic medicine to pursue a broad-based program sufficiently large to define health outcomes associated with rare variants in ~100 clinically relevant genes. CCHMC Principal Investigators (PIs) have contributed sequencing data generated from the following cohorts: (1) Better Outcomes for Children (BOfC). Since January, 2011, the Cincinnati Biobank has managed the sample repository developed through the BOfC protocol (PI: John Harley), an institution-wide broad based consent project to utilize remnant clinical samples for biomedical research from participants consented at registration. This project is made possible by institutional resources. To date, over 261,000 participants have consented to BOfC and DNA samples are stored from more than 84,000 unique patients. Through an IRB approved protocol led by Dr. Bahram Namjou (2015-7778), 2,800 samples were selected for sequencing on the eMERGE sequencing panel representing >15 primary phenotypes including Arrhythmia, Asthma, Cardiomyopathy, Chronic kidney disease, Ehlers-Danlos Syndrome, Hyperlipidemia, Autistic behavior, and Tuberous Sclerosis 1. This project is made possible by the support of U01HG008666 (PI: John Harley). (2) Return of eMERGE III Genomic Results. Through an IRB approved protocol led by Dr. Melanie Myers (2016-3361), 200 adolescent patients and their parents were consented to examine (1) their choices about results to be returned on the eMERGE sequencing panel, (2) their responses to learning negative genetic test results, and (3) the parents responses after learning their childrens positive results. All 200 participants provided blood samples. Extracted DNA samples were sequenced on the eMERGE sequencing panel. Results are to be returned to participants. This project is made possible by the support of U01HG008666 (PI: John Harley). Patients of interest were identified using anthropometric measurements, clinical data and ICD codes extracted from the EPIC electronic medical record (EMR). The extraction of data from the EMR into the de-identified data warehouse, i2b2, was made possible by institutional

resources and UL1RR026314/UL1TR001425, the Cincinnati Center for Clinical and Translational Sciences and Training Grant (PI: James Heubi). Childrens Hospital of Philadelphia (CHOP) Center for Applied Genomics, The Childrens Hospital of Philadelphia Samples and associated genomic and phenotype data used in this study were provided by the Center for Applied Genomics at the Childrens Hospital of Philadelphia (CHOP). Support for genotyping was provided by an Institutional Development Award from CHOP. Support for sequencing was provided by the National Institutes of Health through an award from the National Human Genome Research Institutes Electronic Medical Records and Genomics (eMERGE) program (U01HG008684). Columbia University Samples and data used in this study were provided by the Center for Glomerular Diseases at Columbia University, the Columbia Transplant Programs, the DataBase Shared Resource at the Herbert Irving Comprehensive Cancer Center, and the Institute for Genomic Medicine at Columbia University. Funding support for the Columbia eMERGE III research study was provided by a U01 grant from the National Human Genome Research Institute (U01HG008680; PIs Chunhua Weng, PhD; George Hripcsak, MD; Ali Gharavi, MD). Geisinger Funding for the MyCode® sample and data collection was provided by grants from Commonwealth of Pennsylvania, the Clinic Research Fund of Geisinger Clinic, and the Regeneron Genetics Center. Partners Health Care (Harvard University) Samples and data used in this study were provided by the Partners Health Care Biobank (https://biobank.partners.org/). Funding support for the Partners Biobank was provided by Partners Health Care and Partners Personalized Medicine. Assistance with phenotype harmonization was provided by the eMERGE Coordinating Center (Grant number U01HG04603). Additional support was provided by the NIH, NHGRI eMERGE Network (U01HG 5U01HG008685-03). Funding support for genotyping, which was performed at the Translational Genomics Core, Partners Personalized Medicine and funded by Partners Personalized Medicine. Assistance with phenotype harmonization and genotype data cleaning was provided by the eMERGE Administrative Coordinating Center (U01HG004603) and the National Center for Biotechnology Information (NCBI). The datasets used for the analyses described in this manuscript were obtained from dbGaP at http://www.ncbi.nlm.nih.gov/gap through dbGaP accession number; phs000944.v1.p1. Kaiser Washington/University of Washington Funding support for Alzheimer's Disease Patient Registry (ADPR) and Adult Changes in Thought (ACT) study was provided by a U01 from the National Institute on Aging (Eric B. Larson, PI, U01AG006781). A gift from the 3M Corporation was used to expand the ACT cohort. DNA aliquots sufficient for GWAS from ADPR Probable AD cases, who had been enrolled in Genetic Differences in Alzheimer's Cases and Controls (Walter Kukull, PI, R01 AG007584) and obtained under that grant, were made available to eMERGE without charge. Funding support for genotyping, which was performed at Johns Hopkins University, was provided by the NIH (U01HG004438). Genome-wide association analyses were supported through a Cooperative Agreement from the National Human Genome Research Institute, U01HG004610 (Eric B. Larson, PI). Assistance with phenotype harmonization and genotype data cleaning was provided by the eMERGE Administrative Coordinating Center (U01HG004603) and the National Center for Biotechnology Information (NCBI). The datasets used for the analyses described in this manuscript were obtained from dbGaP at http://www.ncbi.nlm.nih.gov/gap through dbGaP accession number phs000234.v1.p1. Mayo Clinic Samples and associated genotype and phenotype data used in this study were provided by the Mayo Clinic. Funding support for the Mayo Clinic was provided through a cooperative agreement with the National Human Genome Research Institute (NHGRI), Grant #: UOIHG004599, UOIHG006379; and the Mayo Center for Individualized Medicine. Funding support for sequencing, which was performed at The Baylor Human Genomics Sequencing Center, was provided by the NIH. Assistance with phenotype harmonization and genotype data cleaning was provided by the eMERGE Administrative Coordinating Center and the National Center for Biotechnology Information (NCBI). Northwestern University Samples and data used in this study were obtained from patients of Northwestern Medicine, Chicago, IL, who were recruited for the eMERGE II Pharmacogenomics Study and the eMERGE III Your Genes and Your Health Study. The Pharmacogenomics Study, a supplement to the Northwestern eMERGE II Project (U01HG006388) and the Your Genes and Your Health Study (U01HG008673) were funded through the NIH, NHGRI eMERGE Network. Vanderbilt University Funding support for the Vanderbilt Genome-Electronic Records (VGER) project was provided through a cooperative agreement (U01HG008672) with the National Human Genome Research Institute (NHGRI) with additional funding from the National Institute of General Medical Sciences (NIGMS). The dataset(s) used for the analyses described were obtained from Vanderbilt University Medical Center. Assistance with phenotype harmonization and genotype data cleaning was provided by the eMERGE Administrative Coordinating Center (U01HG004603) and the National Center for Biotechnology Information (NCBI). The datasets used for the analyses described in this manuscript were obtained from dbGaP at http://www.ncbi.nlm.nih.gov/gap through dbGaP accession number phs000188.v1.p1.

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

Name : General Research Use (IRB, PUB, GSO)

Consent Group # : 2

Abbreviation : GRU-IRB-PUB-GSO

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data is limited to genetic studies only.

Name : General Research Use (IRB, NPU)

Consent Group # : 3

Abbreviation : GRU-IRB-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Name : Health/Medical/Biomedical

Consent Group # : 4

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Name : Health/Medical/Biomedical (MDS)

Consent Group # : 5

Abbreviation : HMB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Disease-Specific (Childhood Diseases)

Consent Group # : 6

Abbreviation : DS-CHILDD

Data Use Limitation : Use of the data must be related to Childhood Diseases.

Approved use for studies of the genetic and environmental factors that contribute to childhood health, development and disease.

Name : Disease-Specific (Dementia)

Consent Group # : 7

Abbreviation : DS-DEM

Data Use Limitation : Use of the data must be related to Dementia.

Use of the data must be related to health research on dementia or other adult conditions related to the aging process. This includes research to improve methods for conducting research that could be applied to dementia or other adult conditions related to the aging process. For example, studies of conditions like cataract, diabetes, and psoriasis might be appropriate, while conditions like attention deficit hyperactivity disorder (ADHD) and neuroblastoma might not be appropriate. Studies of conditions that are common in both children and the elderly, such as schizophrenia or depression, would not be appropriate if they focused on children and young adults. Studies focused primarily on pediatric populations are not permitted.

Name : Health/Medical/Biomedical (PUB, GSO)

Consent Group # : 8

Abbreviation : HMB-PUB-GSO

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data is limited to genetic studies only.

Name : General Research Use (IRB, PUB)

Consent Group # : 9

Abbreviation : GRU-IRB-PUB

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.
Requestor agrees to make results of studies using the data available to the larger scientific community.

Name : Health/Medical/Biomedical (GSO)

Consent Group # : 10

Abbreviation : HMB-GSO

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

No permitted use: Insurance companies.

phs000812 : Characterizing Genetic Susceptibility to Breast and Prostate Cancer - BPC3

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NCI DAC

Important Contacts : NCIDAC@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

The Breast and Prostate Cancer Cohort Consortium (BPC3) genome-wide association studies of advanced prostate cancer and estrogen-receptor negative breast cancer was supported by the National Cancer Institute under cooperative agreements U01-CA98233, U01-CA98710, U01-CA98216, and U01-CA98758 and the Intramural Research Program of the National Cancer Institute, Division of Cancer Epidemiology and Genetics. The BPC3 investigators request that publications resulting from the use of these data cite their original publications, as relevant:

Schumacher FR, Berndt SI, Siddiq A, Jacobs KB, Wang Z, Lindstrom S, Stevens VL, Chen C, Mondul AM, Travis RC, Stram DO, Eeles RA, Easton DF, Giles G, Hopper JL, Neal DE, Hamdy FC, Donovan JL, Muir K, Al Olama AA, Kote-Jarai Z, Guy M, Severi G, Grönberg H, Isaacs WB, Karlsson R, Wiklund F, Xu J, Allen NE, Andriole GL, Barricarte A, Boeing H, Bueno-de-Mesquita HB, Crawford ED, Diver WR, Gonzalez CA, Gaziano JM, Giovannucci EL, Johansson M, Le Marchand L, Ma J, Sieri S, Stattin P, Stampfer MJ, Tjonneland A, Vineis P, Virtamo J, Vogel U, Weinstein SJ, Yeager M, Thun MJ, Kolonel LN, Henderson BE, Albanes D, Hayes RB, Feigelson HS, Riboli E, Hunter DJ, Chanock SJ, Haiman CA, Kraft P. Genome-wide association study identifies new prostate cancer susceptibility loci. Hum Mol Genet. 2011 Oct 1;20(19):3867-75.

Acknowledgement Statement : Siddiq A, Couch FJ, Chen GK, Lindström S, Eccles D, Millikan RC, Michailidou K, Stram DO, Beckmann L, Rhie SK, Ambrosone CB, Aittomäki K, Amiano P, Apicella C; Australian Breast Cancer Tissue Bank Investigators, Baglietto L, Bandera EV, Beckmann MW, Berg CD, Bernstein L, Blomqvist C, Brauch H, Brinton L, Bui QM, Buring JE, Buys SS, Campa D, Carpenter JE, Chasman DI, Chang-Claude J, Chen C, Clavel-Chapelon F, Cox A, Cross SS, Czene K, Deming SL, Diasio RB, Diver WR, Dunning AM, Durcan L, Ekici AB, Fasching PA; Familial Breast Cancer Study, Feigelson HS, Fejerman L, Figueroa JD, Fletcher O, Flesch-Janys D, Gaudet MM; GENICA Consortium, Gerty SM, Rodriguez-Gil JL, Giles GG, van Gils CH, Godwin AK, Graham N, Greco D, Hall P, Hankinson SE, Hartmann A, Hein R, Heinz J, Hoover RN, Hopper JL, Hu JJ, Huntsman S, Ingles SA, Irwanto A, Isaacs C, Jacobs KB, John EM, Justenhoven C, Kaaks R, Kolonel LN, Coetzee GA, Lathrop M, Le Marchand L, Lee AM, Lee IM, Lesnick T, Lichtner P, Liu J, Lund E, Makalic E, Martin NG, McLean CA, Meijers-Heijboer H, Meindl A, Miron P, Monroe KR, Montgomery GW, Müller-Myhsok B, Nickels S, Nyante SJ, Olswold C, Overvad K, Palli D, Park DJ, Palmer JR, Pathak H, Peto J, Pharoah P, Rahman N, Rivadeneira F, Schmidt DF, Schmutzler RK, Slager S, Southey MC, Stevens KN, Sinn HP, Press MF, Ross E, Riboli E, Ridker PM, Schumacher FR, Severi G, Dos Santos Silva I, Stone J, Sund M, Tapper WJ, Thun MJ, Travis RC, Turnbull C, Uitterlinden AG, Waisfisz Q, Wang X, Wang Z, Weaver J, Schulz-Wendtland R, Wilkens LR, Van Den Berg D, Zheng W, Ziegler RG, Ziv E, Nevanlinna H, Easton DF, Hunter DJ, Henderson BE, Chanock SJ, Garcia-Closas M, Kraft P, Haiman CA, Vachon CM. A meta-analysis of genome-wide association studies of breast cancer identifies two novel susceptibility loci at 6q14 and 20q11. Hum Mol Genet. 2012 Dec 15;21(24):5373-84.

Name : General Research Use (MDS)

Consent Group # : 1

Abbreviation : GRU-MDS

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Health/Medical/Biomedical (PUB, MDS)

Consent Group # : 2

Abbreviation : HMB-PUB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Cancer in all age groups, other disease in adults only and methods

Consent Group # : 4

Abbreviation : CADM

Data Use Limitation : The informed consent document signed by the study participants allows use of these data by investigators for discovery and hypothesis generation in the investigation of the genetic contributions to cancer in all age groups and other diseases in adults only, as well as development of novel analytical approaches for GWAS.

Name : Disease-Specific (Breast, Ovarian, or Endometrial Disease, MDS)

Consent Group # : 3

Abbreviation : DS-BOED-MDS

Data Use Limitation : Use of the data must be related to Breast, Ovarian, or Endometrial Disease.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs001616 : eMERGE Network Phase III Clinical Sequencing: eMERGEseq Panel

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : This phase of the eMERGE Network was initiated and funded by the NHGRI through the following grants: U01HG8657 (Kaiser Washington/University of Washington); U01HG8685 (Brigham and Womens Hospital); U01HG8672 (Vanderbilt University Medical Center); U01HG8666 (Cincinnati Childrens Hospital Medical Center); U01HG6379 (Mayo Clinic); U01HG8679 (Geisinger Clinic); U01HG8680 (Columbia University Health Sciences); U01HG8684 (Childrens Hospital of Philadelphia); U01HG8673 (Northwestern University); U01HG8701 (Vanderbilt University Medical Center serving as the Coordinating Center); U01HG8676 (Partners Healthcare/Broad Institute); and U01HG8664 (Baylor College of Medicine)

Name : Health/Medical/Biomedical (GSO)

Consent Group # : 7

Abbreviation : HMB-GSO

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

Name : General Research Use (IRB, NPU)

Consent Group # : 4

Abbreviation : GRU-IRB-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Limited from use by insurance companies.

Name : General Research Use (IRB)

Consent Group # : 3

Abbreviation : GRU-IRB

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.

Name : General Research Use (IRB, PUB, NPU)

Consent Group # : 5

Abbreviation : GRU-IRB-PUB-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data is limited to not-for-profit organizations.

Name : Health/Medical/Biomedical

Consent Group # : 6

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Name : Health/Medical/Biomedical (NPU)

Consent Group # : 8

Abbreviation : HMB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

Name : General Research Use (NPU)

Consent Group # : 9

Abbreviation : GRU-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Use of the data is limited to not-for-profit organizations.

Name : Health/Medical/Biomedical (IRB, PUB)

Consent Group # : 10

Abbreviation : HMB-IRB-PUB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Requestor agrees to make results of studies using the data available to the larger scientific community.

phs001033 : PAGE: Global Reference Panel

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Advisory Board Guidance: Users acknowledge that tribal status or affiliation of American Indian participants should not be inferred since they are self-identified, urban dwelling, and are not representative of the diverse American Indian populations across the United States.

Acknowledgement Statement : Samples and data used in this study were provided by the Stanford University Global Reference Panel data. Funding support for the Population Architecture Using Genomics and Epidemiology (PAGE) Global Reference Panel was provided through the National Human Genome Research Institute (U01 HG007417). Assistance with phenotype harmonization, SNP selection, data cleaning, meta-analyses, data management and dissemination, and general study coordination, was provided by the PAGE Coordinating Center (U01HG007419, U01HG004801 and its NHGRI ARRA supplement). The datasets used for the analyses described in this manuscript were obtained from dbGaP.

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs000951 : NHLBI TOPMed: Genetic Epidemiology of COPD (COPDGene)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There are two consent groups in COPDGene:
Disease-Specific: Use of this data is limited to studies of COPD and other smoking-related disorders. The full list of diseases or conditions for which smoking is considered to be a risk factor can be found at: www.copdgene.org/smoking-related-disorders. The institutional certification assured that data submission was compliant with, and limited to, local and federal policies, and Massachusetts state law; To the extent possible, consideration was given to individuals and groups for subsequent data sharing and are reviewed by the National Institutes of Healths Data Access Committees.
Health/Medical/Biomedical: Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Acknowledgement Statement :	The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements In addition, please include: "This research used data generated by the COPDGene study, which was supported by NIH grants U01 HL089856 and U01 HL089897. The COPDGene project is also supported by the COPD Foundation through contributions made by an Industry Advisory Board comprised of Pfizer, AstraZeneca, Boehringer Ingelheim, Novartis, and Sunovion."
Name :	Health/Medical/Biomedical
Consent Group # :	1
Abbreviation :	HMB
Data Use Limitation :	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Name :	Disease-Specific (COPD and Smoking, RD)
Consent Group # :	2
Abbreviation :	DS-CS-RD
Data Use Limitation :	Use of the data must be related to COPD and Smoking and related disorders. Use of this data is limited to studies of COPD and other smoking-related disorders. The full list of diseases or conditions for which smoking is considered to be a risk factor can be found at: www.copdgene.org/smoking-related-disorders. The institutional certification assured that data submission was compliant with, and limited to, local and federal policies, and Massachusetts state law; To the extent possible, consideration was given to individuals and groups for subsequent data sharing and are reviewed by the National Institutes of Healths Data Access Committees.

phs000280 : Atherosclerosis Risk in Communities (ARIC) Cohort

	Public Posting of Genomic Summary Results - Allowed.
NIH Data Access Committee (DAC) :	National Heart, Lung, and Blood Institute DAC
Important Contacts :	nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov
	In the event of a data management incident, within 24 hours, please contact emails above.
IC Specific Access Term :	Use of the ARIC Study data deposited in dbGaP is restricted to research on associations between phenotypes and genotypes. ARIC data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity, non-paternity, and perceptions of racial/ethnic identity. Data users will be required to obtain IRB approval for their projects from their respective institutions. Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution. Two consent groups are available for the ARIC Study: health/medical/biomedical research and cardiovascular disease research only. This Data Use Certification will be reviewed and approved by the NHLBI Data Access Committee. The NHLBI will keep all Data Use Certifications, and all approved studies utilizing ARIC dbGaP data will be listed on the dbGaP website. Annual updates regarding publications, etc. will be provided by the NHLBI to the ARIC study when and if necessary.
Acknowledgement Statement :	link
Name :	Health/Medical/Biomedical (IRB)
Consent Group # :	1
Abbreviation :	HMB-IRB
Data Use Limitation :	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor must provide documentation of local IRB approval. Use of the ARIC Study data deposited in dbGaP is restricted to research on associations between phenotypes and genotypes. ARIC data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity, non-paternity, and perceptions of racial/ethnic identity. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

This Data Use Certification will be reviewed and approved by the NHLBI Data Access Committee. The NHLBI will keep all Data Use Certifications, and all approved studies utilizing ARIC dbGaP data will be listed on the dbGaP website. Annual updates regarding publications, etc. will be provided by the NHLBI to the ARIC study when and if necessary.

Name : Disease-Specific (Cardiovascular Disease, IRB)

Consent Group # : 2

Abbreviation : DS-CVD-IRB

Data Use Limitation :

Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.

Use of the ARIC Study data deposited in dbGaP is restricted to research on associations between phenotypes and genotypes. ARIC data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity, non-paternity, and perceptions of racial/ethnic identity. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

This Data Use Certification will be reviewed and approved by the NHLBI Data Access Committee. The NHLBI will keep all Data Use Certifications, and all approved studies utilizing ARIC dbGaP data will be listed on the dbGaP website. Annual updates regarding publications, etc. will be provided by the NHLBI to the ARIC study when and if necessary.

phs000964 : NHLBI TOPMed: The Jackson Heart Study (JHS)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term :

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

There are four consent groups for JHS: 1) Health/Medical/Biomedical; 2) Non-profit Health/Medical/Biomedical; 3) Focus Diseases only, limiting analysis to the study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only; and 4) Non-profit Focus Diseases only.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 3

Abbreviation : HMB-IRB

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

There are four consent groups for JHS: 1) Health/Medical/Biomedical; 2) Non-profit Health/Medical/Biomedical; 3)

Focus Diseases only, limiting analysis to the study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only; and 4) Non-profit Focus Diseases only.

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 1

Abbreviation : HMB-IRB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

There are four consent groups for JHS: 1) Health/Medical/Biomedical; 2) Non-profit Health/Medical/Biomedical; 3) Focus Diseases only, limiting analysis to the study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only; and 4) Non-profit Focus Diseases only.

Name : Disease-Specific (Focused Disease Only, IRB)

Consent Group # : 4

Abbreviation : DS-FDO-IRB

Data Use Limitation : Use of the data must be related to Focused Disease Only.
Requestor must provide documentation of local IRB approval.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

There are four consent groups for JHS: 1) Health/Medical/Biomedical; 2) Non-profit Health/Medical/Biomedical; 3) Focus Diseases only, limiting analysis to the study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only; and 4) Non-profit Focus Diseases only.

Name : Disease-Specific (Focused Disease Only, IRB, NPU)

Consent Group # : 2

Abbreviation : DS-FDO-IRB-NPU

Data Use Limitation : Use of the data must be related to Focused Disease Only.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Jackson Heart Study (JHS) data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in Jackson Heart Study.

Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

There are four consent groups for JHS: 1) Health/Medical/Biomedical; 2) Non-profit Health/Medical/Biomedical; 3) Focus Diseases only, limiting analysis to the study of blood pressure, heart or other cardiovascular disease, obesity, diabetes, kidney disease, or lung disease and risk factors for these diseases only; and 4) Non-profit Focus Diseases only.

phs001167 : Type 2 Diabetes in African Americans, GWAS and Exome Sequencing

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NIDDK Central Repository GWAS Data Access Committee

Important Contacts : niddk-dac@mail.nih.gov; niddk-dac@mail.nih.gov ; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : The T2D-GENES Sequencing Study in African Americans was conducted by the T2D-GENES Sequencing Study in African Americans Investigators and supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The data from the T2D-GENES Sequencing Study in African Americans reported here were supplied by Wake Forest and Broad Institute. This manuscript was not prepared in collaboration with Investigators of the T2D-GENES Sequencing Study in African Americans study and does not necessarily reflect the opinions or views of the T2D-GENES Sequencing Study in African Americans study, or the NIDDK.

Name : Disease-Specific (Type 2 Diabetes, IRB, RD)

Consent Group # : 1

Abbreviation : DS-T2D-IRB-RD

Data Use Limitation : Use of the data must be related to Type 2 Diabetes and related disorders.
Requestor must provide documentation of local IRB approval.

phs000929 : High-Risk Breast Cancer GWAS

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : NCI DAC

Important Contacts : NCIDAC@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Collaborative Agreement : link

Acknowledgement Statement : link

Name : Disease-Specific (Cancer, MDS)

Consent Group # : 2

Abbreviation : DS-CA-MDS

Data Use Limitation : Use of the data must be related to Cancer.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

Name : Disease-Specific (Breast Cancer, MDS)

Consent Group # : 3

Abbreviation : DS-BRCA-MDS

Data Use Limitation : Use of the data must be related to Breast Cancer.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Disease-Specific (Breast and Ovarian cancer, GSO)

Consent Group # : 5

Abbreviation : DS-BROC-GSO

Data Use Limitation : Use of the data must be related to Breast and Ovarian cancer.
Use of the data is limited to genetic studies only.

Name : Disease-Specific (Cancer, GSO)

Consent Group # : 6

Abbreviation : DS-CA-GSO

Data Use Limitation :	Use of the data must be related to Cancer. Use of the data is limited to genetic studies only.
Name :	Cancer, Benign Neoplasms, or Hematopoietic Diseases (MDS)
Consent Group # :	4
Abbreviation :	CABNHD-MDS
Data Use Limitation :	Use the data must related to cancer, benign neoplasms, or hematopoietic diseases related to cancer or risk of cancer. Benign neoplasms and hematopoietic diseases are understood as having potential for significant morbidity in themselves, such as benign brain tumors, neuroendocrine tumors, desmoid tumors, myelodysplastic syndromes, which are reportable or potentially reportable to cancer registries. This data may also be used for general methods research (e.g. development of software or algorithms).
Name :	Disease-Specific (Breast Diseases)
Consent Group # :	8
Abbreviation :	DS-BRD
Data Use Limitation :	Use of the data must be related to Breast Diseases. General methods development research is NOT allowed.
Name :	Disease-Specific (Breast Cancer, PUB, MDS)
Consent Group # :	7
Abbreviation :	DS-BRCA-PUB-MDS
Data Use Limitation :	Use of the data must be related to Breast Cancer. Requestor agrees to make results of studies using the data available to the larger scientific community. Use of the data includes methods development research (e.g., development of software or algorithms).
Name :	Health/Medical/Biomedical (PUB)
Consent Group # :	10
Abbreviation :	HMB-PUB
Data Use Limitation :	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor agrees to make results of studies using the data available to the larger scientific community.
Name :	Disease-Specific (Cancer, PUB)
Consent Group # :	9
Abbreviation :	DS-CA-PUB
Data Use Limitation :	Use of the data must be related to Cancer. Requestor agrees to make results of studies using the data available to the larger scientific community. General methods development research is NOT permitted.

phs001238 : Genetic Epidemiology Network of Arteriopathy (GENOA)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) :	National Heart, Lung, and Blood Institute DAC
Important Contacts :	nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term :	Use of the data must be related to Arteriosclerosis and its Risk Factors. Use of the data is limited to not-for-profit organizations.
Acknowledgement Statement :	link
Name :	Disease-Specific (Arteriosclerosis and its Risk Factors, NPU)
Consent Group # :	1
Abbreviation :	DS-ASC-RF-NPU
Data Use Limitation :	Use of the data must be related to Arteriosclerosis and its Risk Factors. Use of the data is limited to not-for-profit organizations.

phs000963 : PGRN – RIKEN: Genetic Determinants of Clinical Cardiovascular Events in Patients Receiving Statins

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
May be used for genetic studies to learn about, treat, or prevent health problems.

Acknowledgement Statement : The dataset(s) used for this study were obtained from Vanderbilt University Medical Centers BioVU which is supported by institutional funding and by the Vanderbilt CTSA grant UL1 TR000445 from NCATS/NIH. This study was supported by an NIH Pharmacogenomics Research Network (PGRN) RIKEN Center for Integrative Medical Sciences (IMS) Global Alliance, and genome-wide genotyping was funded and performed by the IMS. This study was also supported by NHLBI/NIH grants U19 HL065962 and U01 HL069757.

Name : Health/Medical/Biomedical

Consent Group # : 1

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

phs000096 : GENEVA GWA mapping: Maternal Metabolism-Birth Weight Interactions

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : Funding support for the GWA mapping: Maternal Metabolism-Birth Weight Interactions study was provided through the NIH Genes, Environment and Health Initiative [GEI] (U01HG004415). The GWA mapping: Maternal Metabolism-Birth Weight Interactions study is one of the genome-wide association studies funded as part of the Gene Environment Association Studies (GENEVA) under GEI. Assistance with phenotype harmonization and genotype cleaning, as well as with general study coordination, was provided by the GENEVA Coordinating Center (U01 HG004446). Assistance with data cleaning was provided by the National Center for Biotechnology Information. Funding support for genotyping, which was performed at the Broad Institute of MIT and Harvard, was provided by the NIH GEI (U01 HG04424). The datasets used for the analyses described in this manuscript were obtained from dbGaP at http://www.ncbi.nlm.nih.gov/sites/entrez?db=gap through dbGaP accession number phs000096.v5.

Name : GWA mapping: Maternal Metabolism-Birth Weight Interactions

Consent Group # : 1

Abbreviation : T2DMBIRTHWT

Data Use Limitation : Limited to research on genes that may be important for the development of type 2 diabetes and related conditions as well as fetal growth and metabolism. Related conditions and maternal phenotypes include body mass index, blood pressure, hemoglobin A1c, and glucose and C-peptide levels. Measures of fetal growth and metabolism include birth weight, head circumference, skin-fold thickness, length, glucose and C-peptide.

phs000333 : Family Investigation of Nephropathy and Diabetes (FIND) Study

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NIDDK Central Repository GWAS Data Access Committee

Important Contacts : niddk-dac@mail.nih.gov; niddk-dac@mail.nih.gov ; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : The FIND study was conducted by the FIND Investigators and supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute for Minority Health Disparities (formerly NCMHD) and the Special Statutory Funding Program for Type 1 Diabetes Research. The data from the FIND study reported here were supplied by the FIND investigators. This manuscript was not prepared in collaboration with Investigators of the FIND study and does not necessarily reflect the opinions or views of the FIND study, or the NIDDK.

Name : diabetes, kidney disease, retinopathy and/or related diseases

Consent Group # : 1

Abbreviation : DNAR

Data Use Limitation : These data may be used only for studies related to diabetes, kidney disease, retinopathy and/or related diseases. The data may not be bought and/or sold. All reasonable efforts must be made to secure the data with adequate security controls, maintain appropriate control over the dataset, and maintain the privacy of the participants.

phs001222 : CCDG - Whole Genome Sequencing in Type 1 Diabetes (T1DGC)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : This research utilizes resources provided by the Type 1 Diabetes Genetics Consortium, a collaborative clinical study sponsored
by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Allergy and Infectious
Diseases (NIAID), National Human Genome Research Institute (NHGRI), National Institute of Child Health and Human
Development (NICHD), and JDRF and supported by U01 DK062418.

Name : Disease-Specific (Diabetes and Related Complications, IRB, NPU)

Consent Group # : 1

Abbreviation : DS-DRC-IRB-NPU

Data Use Limitation : Use of the data must be related to Diabetes and Related Complications.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

phs001286 : The Prostate, Lung, Colon, Ovary Screening Trial (PLCO)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NCI DAC

Important Contacts : NCIDAC@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : If these dataset(s) were used, please acknowledge them in all oral or written presentations, disclosures, or publication in the following manner: We thank the National Cancer Institute (NCI) for access to NCIs data collected by the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial who was funded in whole or in part with federal funds from the NCI, US National Institutes of Health (NIH). The datasets have been accessed through the NIH database for Genotypes and Phenotypes (dbGaP). The statements contained herein are solely those of the authors and do not represent or imply concurrence or endorsement by NCI.

Name : Research relating to adults diseases and methods

Consent Group # : 1

Abbreviation : CADM

Data Use Limitation : The informed consent document signed by the PLCO study participants allows use of these data by investigators for discovery and hypothesis generation in the investigation of the genetic contributions to cancer and other adult diseases as well as development of novel analytical approaches for GWAS.

phs000285 : CARDIA Cohort

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There are two consent groups for the CARDIA_Cohort studies:
1) Health/Medical/Biomedical (HMB)-IRB: Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor must provide documentation of local IRB

approval.
2) Health/Medical/Biomedical (HMB)-IRB-NPU: Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor must provide documentation of local IRB approval. Use of the data is limited to not-for-profit organizations.
For both consent groups: Data may not be used to investigate individual pedigree structures; individual participant genotypes; phenotype-only analyses; issues such as non-maternity and non-paternity; assess variables or proxies that could be considered stigmatizing to an individual or a group; or assess individual participant racial/ethnic identity. All research must be consistent with the CARDIA informed consent documents. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. population consistent with the demographic distribution in the CARDIA Study. Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions. Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Data Use Limitation : Data may not be used to investigate individual pedigree structures; individual participant genotypes; phenotype-only analyses; issues such as non-maternity and non-paternity; assess variables or proxies that could be considered stigmatizing to an individual or a group; or assess individual participant racial/ethnic identity. All research must be consistent with the CARDIA informed consent documents. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. population consistent with the demographic distribution in the CARDIA Study. Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Data Use Limitation : Data may not be used to investigate individual pedigree structures; individual participant genotypes; phenotype-only analyses; issues such as non-maternity and non-paternity; assess variables or proxies that could be considered stigmatizing to an individual or a group; or assess individual participant racial/ethnic identity. All research must be consistent with the CARDIA informed consent documents. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. population consistent with the demographic distribution in the CARDIA Study. Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

phs000147 : CGEMS Breast Cancer

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NCI DAC

Important Contacts : NCIDAC@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

When referencing the CGEMS breast cancer dataset please use the following citations:

Hunter DJ, Kraft P, Jacobs KB, Cox DG, Yeager M, Hankinson SE, Wacholder S, Wang Z, Welch R, Hutchinson A, Wang J, Yu K, Chatterjee N, Orr N, Willett WC, Colditz GA, Ziegler RG, Berg CD, Buys SS, McCarty CA, Feigelson HS, Calle EE, Thun MJ, Hayes RB, Tucker M, Gerhard DS, Fraumeni JF Jr, Hoover RN, Thomas G, Chanock SJ. A Genome-Wide Association Study Identifies Alleles in FGFR2 Associated with Risk of Sporadic Postmenopausal Breast Cancer. Nat Genet, 39(7):870-874, 2007.

Acknowledgement Statement : Haiman CA, Chen GK, Vachon CM, Canzian F, Dunning A, Millikan RC, Wang X, Ademuyiwa F, Ahmed S, Ambrosone CB, Baglietto L, Balleine R, Bandera EV, Beckmann MW, Berg CD, Bernstein L, Blomqvist C, Blot WJ, Brauch H, Buring JE, Carey LA, Carpenter JE, Chang-Claude J, Chanock SJ, Chasman DI, Clarke CL, Cox A, Cross SS, Deming SL, Diasio RB, Dimopoulos AM, Driver WR, Dünnebier T, Durcan L, Eccles D, Edlund CK, Ekici AB, Fasching PA, Feigelson HS, Flesch-Janys D, Fostira F, Försti A, Fountzilas G, Gerty SM; Gene Environment Interaction and Breast Cancer in Germany (GENICA) Consortium, Giles GG, Godwin AK, Goodfellow P, Graham N, Greco D, Hamann U, Hankinson SE, Hartmann A, Hein R, Heinz J, Holbrook A, Hoover RN, Hu JJ, Hunter DJ, Ingles SA, Irwanto A, Ivanovich J, John EM, Johnson N, Jukkola-Vuorinen A, Kaaks R, Ko YD, Kolonel LN, Konstantopoulou I, Kosma VM, Kulkarni S, Lambrechts D, Lee AM, Marchand LL, Lesnick T, Liu J, Lindstrom S, Mannermaa A, Margolin S, Martin NG, Miron P, Montgomery GW, Nevanlinna H, Nickels S, Nyante S, Olswold C, Palmer J, Pathak H, Pectasides D, Perou CM, Peto J, Pharoah PD, Pooler LC, Press MF, Pylkäs K, Rebbeck TR, Rodriguez-Gil JL, Rosenberg L, Ross E, Rüdiger T, Silva Idos S, Sawyer E, Schmidt MK, Schulz-Wendtland R, Schumacher F, Severi G, Sheng X, Signorello LB, Sinn HP, Stevens KN, Southey MC, Tapper WJ, Tomlinson I, Hogervorst FB, Wauters E, Weaver J, Wildiers H, Winqvist R, Berg DV, Wan P, Xia LY, Yannoukakos D, Zheng W, Ziegler RG, Siddiq A, Slager SL, Stram DO, Easton D, Kraft P, Henderson BE, Couch FJ. A common variant at the TERT-CLPTM1L locus is associated with estrogen receptor-negative breast cancer. Nat Genet. 2011 Oct 30;43(12):1210-4.

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : CGEMS Breast Data Use Limitations: The informed consent document signed by the CGEMS Breast Cancer Study Participants allows use of these data by investigators for discovery and hypothesis generation in the investigation of the genetic contributions to cancer and other diseases as well as development of novel analytical approaches for GWAS.

phs002018 : Center Common Disease Genomics [CCDG] - Cardiovascular: Partners Biobank

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : We gratefully acknowledge the participants and leadership team of the Partners HealthCare Biobank (https://biobank.partners.org), funding support from the NHGRI (1UM1HG008895-01), and generation of new genetic data by the performance of the sequencing by the Broad Genomics Platform.

Name : Health/Medical/Biomedical (MDS)

Consent Group # : 1

Abbreviation : HMB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs000784 : Genetic Epidemiology Network of Salt Sensitivity (GenSalt)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Use of the data must be related to High blood pressure and related cardiovascular-renal disease. Requestor must provide documentation of local IRB approval. Please note that only full or expedited IRB approvals will be accepted.

Acknowledgement Statement : We express our sincere appreciation to the Genetic Epidemiology Network of Salt Sensitivity Study participants

for their participation and cooperation in this project.

Name : Disease-Specific (High blood pressure and related cardiovascular-renal disease, IRB)

Consent Group # : 1

Abbreviation : DS-HCR-IRB

Data Use Limitation : Use of the data must be related to High blood pressure and related cardiovascular-renal disease.
Requestor must provide documentation of local IRB approval.

Please note that only full or expedited IRB approvals will be accepted.

phs000974 : NHLBI TOPMed: Genomic Activities such as Whole Genome Sequencing and Related Phenotypes in the Framingham Heart Study

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There are two consent groups for this study: HMB-IRB-MDS and HMB-IRB-NPU-MDS
For both:
Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor must provide documentation of local IRB approval. Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the Framingham data deposited in dbGaP is restricted to research on: genotype-phenotype associations; molecular phenotype (e.g., gene expression; microRNA)-phenotype associations; and proteomics/metabolomics-phenotype associations. All other phenotype-only analyses are prohibited (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC). Additionally, the Framingham data may not be used to:
Investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; or explore issues such as non-maternity or non-paternity.
Investigate topics that could be considered as stigmatizing an individual or group.
Assess outcomes that are not related to health or disease conditions (note: methodological research that will serve as a prelude to health or disease research is permitted).
Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted). It is anticipated that, at least in some cases, the FHS data will be updated with additional information and will be so identified by an appropriate version number.

In addition, for HMB-IRB-NPU-MDS, use of the data is limited to not-for-profit organizations.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical (IRB, MDS)

Consent Group # : 1

Abbreviation : HMB-IRB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the Framingham data deposited in dbGaP is restricted to research on: genotype-phenotype associations; molecular phenotype (e.g., gene expression; microRNA)-phenotype associations; and proteomics/metabolomics-phenotype associations. All other phenotype-only analyses are prohibited (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC). Additionally, the Framingham data may not be used to:

Investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; or explore issues such as non-maternity or non-paternity.
Investigate topics that could be considered as stigmatizing an individual or group.
Assess outcomes that are not related to health or disease conditions (note: methodological research that will serve as a prelude to health or disease research is permitted).

Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted). It is anticipated that, at least in some cases, the FHS data will be

updated with additional information and will be so identified by an appropriate version number.

Name : Health/Medical/Biomedical (IRB, NPU, MDS)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU-MDS

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the Framingham data deposited in dbGaP is restricted to research on: genotype-phenotype associations; molecular phenotype (e.g., gene expression; microRNA)-phenotype associations; and proteomics/metabolomics-phenotype associations. All other phenotype-only analyses are prohibited (note: investigators may request data for such phenotype-only analyses through NHLBI's BioLINCC). Additionally, the Framingham data may not be used to:

Investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; or explore issues such as non-maternity or non-paternity.
Investigate topics that could be considered as stigmatizing an individual or group.
Assess outcomes that are not related to health or disease conditions (note: methodological research that will serve as a prelude to health or disease research is permitted).

Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted). It is anticipated that, at least in some cases, the FHS data will be updated with additional information and will be so identified by an appropriate version number.

phs001143 : NHLBI TOPMed: The Genetics and Epidemiology of Asthma in Barbados

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There is one consent group for this study: GRU-IRB. Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval (please note only full or expedited approvals will be accepted).

Acknowledgement Statement :

The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements.

In addition, please include:
"The Genetics and Epidemiology of Asthma in Barbados is supported by National Institutes of Health (NIH) National Heart, Lung, Blood Institute TOPMed (R01 HL104608-S1) and: R01 AI20059, K23 HL076322, and RC2 HL101651.

Authorized access to genotype data may be obtained through accession number phs001143.
For the specific cohort descriptions and descriptions regarding the collection of phenotype data can be found at: https://topmed.nhlbi.nih.gov/group/bags-asthma.

The authors wish to give special recognition to the individual study participants who provided biological samples and or data, without their support in research none of this would be possible."

Name : General Research Use (IRB)

Consent Group # : 1

Abbreviation : GRU-IRB

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.

phs001426 : Type 1 Diabetes Genetics Consortium (T1DGC): Case-only RNA-Seq Study

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NIDDK Central Repository GWAS Data Access Committee

Important Contacts : niddk-dac@mail.nih.gov; niddk-dac@mail.nih.gov ; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : This manuscript utilizes data that were generated with resources provided by the Type 1 Diabetes Genetics Consortium, a collaborative clinical study sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Allergy and Infectious Diseases (NIAID), National Human Genome Research Institute (NHGRI), National Institute of Child Health and Human Development (NICHD), and Juvenile Diabetes Research Foundation International (JDRF). This manuscript was not prepared in collaboration with Investigators of the T1DGC study and does not necessarily reflect the opinions or views of the T1DGC study, or the study sponsors.

Name : Disease-Specific (Type 1 diabetes, its complications and other autoimmune diseases, IRB, RD)

Consent Group # : 1

Abbreviation : DS-T1DR-IRB-RD

Data Use Limitation : Use of the data must be related to Type 1 diabetes, its complications and other autoimmune diseases and related disorders.
Requestor must provide documentation of local IRB approval.

phs000086 : Diabetes Control and Complications Trial (DCCT) and Epidemiology of Diabetes Interventions and Complications Study (EDIC)

NIH Data Access Committee (DAC) : NIDDK Central Repository GWAS Data Access Committee

Important Contacts : niddk-dac@mail.nih.gov; niddk-dac@mail.nih.gov ; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : INSTRUCTIONS: This study has not provided a suggested acknowledgement statement. However, Approved Users are expected to acknowledge the Submitting Investigator(s) who submitted data from the original study to an NIH-designated data repository, the primary funding organization that supported the Submitting Investigator(s), and the NIH-designated data repository (e.g., dbGaP). The acknowledgment statement should include the dbGaP accession number to the specific version of the dataset(s) analyzed.

Name : Disease-Specific (Type 1 Diabetes, IRB)

Consent Group # : 1

Abbreviation : DS-T1D-IRB

Data Use Limitation : Use of the data must be related to Type 1 Diabetes.
Requestor must provide documentation of local IRB approval.

Name : Disease-Specific (Diabetes and Related Complications, IRB)

Consent Group # : 2

Abbreviation : DS-DRC-IRB

Data Use Limitation : Use of the data must be related to Diabetes and Related Complications.
Requestor must provide documentation of local IRB approval.

phs000007 : Framingham Cohort

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : DATA USE LIMITATION FOR FHS:
Use of the Framingham data deposited in dbGaP is restricted to research on: genotype-phenotype associations; molecular phenotype (e.g., gene expression; microRNA)-phenotype associations; and proteomics/metabolomics-phenotype associations. All other phenotype-only analyses are prohibited (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC). Additionally, the Framingham data may not be used to:
o Investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; or explore issues such as non-maternity or non-paternity.
o Investigate topics that could be considered as stigmatizing an individual or group.
o Assess outcomes that are not related to health or disease conditions (note: methodological research that will serve as a prelude to health or disease research is permitted).
Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users

will be required to obtain IRB approval for their projects from their respective institutions. Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution. It is anticipated that, at least in some cases, the FHS data will be updated with additional information and will be so identified by an appropriate version number. Data use is limited by consent groups to the following two groups: a) Health/Medical/Biomedical and related Methods and b) Health/Medical/Biomedical and related Methods for Non-Profit Use Only.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical (IRB, MDS)

Consent Group # : 1

Abbreviation : HMB-IRB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the Framingham data deposited in dbGaP is restricted to research on: genotypephenotype associations; molecular phenotype (e.g., gene expression; microRNA)-phenotype associations; and proteomics/metabolomics-phenotype associations. All other phenotype-only analyses are prohibited (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC). Additionally, the Framingham data may not be used
to:
o Investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; or explore issues such as non-maternity or non-paternity.
o Investigate topics that could be considered as stigmatizing an individual or group.
o Assess outcomes that are not related to health or disease conditions (note: methodological research that will serve as a prelude to health or disease research is permitted).
Please note that only full or expedited approvals will be accepted.

Name : Health/Medical/Biomedical (IRB, NPU, MDS)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the Framingham data deposited in dbGaP is restricted to research on: genotypephenotype associations; molecular phenotype (e.g., gene expression; microRNA)-phenotype associations; and proteomics/metabolomics-phenotype associations. All other phenotype-only analyses are prohibited (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC). Additionally, the Framingham data may not be used
to:
o Investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; or explore issues such as non-maternity or non-paternity.
o Investigate topics that could be considered as stigmatizing an individual or group.
o Assess outcomes that are not related to health or disease conditions (note: methodological research that will serve as a prelude to health or disease research is permitted).
Please note that only full or expedited approvals will be accepted.

phs001078 : Common Variant GWAS, GECCO

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : NCI DAC

Important Contacts : NCIDAC@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Data Use Limitation : Only full or expedited IRB approvals will be accepted. Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree to not use the data to infer tribal status or affiliation.

Name : Disease-Specific (Colorectal Cancer, NPU, GSO)

Consent Group # : 5

Abbreviation : DS-CC-NPU-GSO

Data Use Limitation : Use of the data must be related to Colorectal Cancer.
Use of the data is limited to not-for-profit organizations.
Use of the data is limited to genetic studies only.

Name : Health/Medical/Biomedical (PUB, NPU, MDS, GSO)

Consent Group # : 4

Abbreviation : HMB-PUB-NPU-MDS-GSO

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).
Use of the data is limited to genetic studies only.

Name : Cancer in all age groups, other diseases in adults only, and methods

Consent Group # : 3

Abbreviation : CADM

Data Use Limitation : The informed consent document signed by the study participants allows use of these data by investigators for discovery and hypothesis generation in the investigation of the genetic contributions to cancer in all age groups and other diseases in adults only, as well as development of novel analytical approaches for GWAS.

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

Name : Disease-Specific (Colorectal Cancer, MDS)

Consent Group # : 6

Abbreviation : DS-CC-MDS

Data Use Limitation : Use of the data must be related to Colorectal Cancer.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 7

Abbreviation : HMB-IRB

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Data Use Limitation : Only full or expedited IRB approvals will be accepted. Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree to not use the data to infer tribal status or affiliation.

Name : Disease-Specific (Cancer, PUB)

Consent Group # : 8

Abbreviation : DS-CA-PUB

Data Use Limitation : Use of the data must be related to Cancer.
Requestor agrees to make results of studies using the data available to the larger scientific community.

General methods development research is NOT permitted.

Name : Health/Medical/Biomedical (PUB)

Consent Group # : 9

Abbreviation : HMB-PUB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor agrees to make results of studies using the data available to the larger scientific community.

phs001217 : NHLBI TOPMed: Genetic Epidemiology Network of Salt Sensitivity (GenSalt)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Use of the data must be related to High blood pressure and related cardiovascular-renal disease. Requestor must provide documentation of local IRB approval. Please note that only full or expedited IRB approvals will be accepted.

Acknowledgement Statement : The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements. In addition please include: "This work was supported by a cooperative agreement project grant (U01HL072507, R01HL087263, and R01HL090682) from the National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, MD. Research reported in this publication was supported by the National Institute of General Medical Sciences of the National Institutes of Health under Award Number P20GM109036. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. A detailed description of the GenSalt study has been published previously (GenSalt Collaborative Research Group GenSalt: rationale, design, methods and baseline characteristics of study participants. Journal of Human Hypertension 2007; 21(8): 639-646)."

Name : Disease-Specific (High blood pressure and related cardiovascular-renal disease, IRB)

Consent Group # : 1

Abbreviation : DS-HCR-IRB

Data Use Limitation : Use of the data must be related to High blood pressure and related cardiovascular-renal disease.
Requestor must provide documentation of local IRB approval.

Please note that only full or expedited IRB approvals will be accepted.

phs000722 : Whole Exome Sequencing of Colorectal Cancer Patients from the Nurses' Health Study (NHS) and Health Professionals Follow-up Study (HPFS)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : We thank the Broad Institute for generating high-quality sequence data supported by NHGRI funds (grant # U54 HG003067) with Eric Lander as PI. The datasets used in this manuscript were obtained from dbGaP at http://www.ncbi.nlm.nih.gov/gap through dbGaP accession number phs000722. We also thank Nurses Health Study (NHS) and Health Professionals Follow-up Study (HPFS) for the samples collection.

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

Name : Disease-Specific (Men's Health)

Consent Group # : 2

Abbreviation : DS-MH

Data Use Limitation : Use of the data must be related to Men's Health.

phs001368 : NHLBI TOPMed: Trans-Omics for Precision Medicine (TOPMed) Whole Genome Sequencing Project: Cardiovascular Health Study

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term :

This study has four consent groups: (1) HMB-MDS, (2) HMB-NPU-MDS, (3) DS-CVD-MDS, and (4) DS-CVD-NPU-MDS. For all four groups, use of the data includes methods development research (e.g., development of software or algorithms).

(1) For HMB-MDS: Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

(2) For HMB-NPU-MDS: Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data is limited to not-for-profit organizations.

(3) For DS-CVD-MDS: Use of the data must be related to Cardiovascular Disease.

(4) For DS-CVD-NPU-MDS: Use of the data must be related to Cardiovascular Disease. Use of the data is limited to not-for-profit organizations.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical (NPU, MDS)

Consent Group # : 2

Abbreviation : HMB-NPU-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Health/Medical/Biomedical (MDS)

Consent Group # : 1

Abbreviation : HMB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Disease-Specific (Cardiovascular Disease, NPU, MDS)

Consent Group # : 4

Abbreviation : DS-CVD-NPU-MDS

Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Disease-Specific (Cardiovascular Disease, MDS)

Consent Group # : 3

Abbreviation : DS-CVD-MDS

Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs001395 : NHLBI TOPMed - NHGRI CCDG: Hispanic Community Health Study/Study of Latinos (HCHS/SOL)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : 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 these data to conduct non-genetic research is prohibited. The data may not be used to investigate individual participant genotypes for the purpose of identifying study participants. Investigation of relatedness among individuals, and of genomic composition in terms of genetic ancestry, may be used as tools to detect and characterize genetic risk factors for health-related traits. However, publications based on HCHS/SOL data may not provide specific pedigree structures, results concerning sensitive issues such as non-paternity, or in any way compromise the anonymity of study participants (either directly or indirectly). Publication of genetic associations with traits should focus on specific genetic variants rather than overall genetic ancestry profiles. [Please note Advisory Board Guidance: "Users acknowledge that tribal status or affiliation of American Indian participants should not be inferred since they are self-identified, urban dwelling, and are not representative of the diverse American Indian population across the United States."] Publications may not report results that could be considered as stigmatizing to an individual or group. Data use must be consistent with the HCHS/SOL informed consent, which is limited to the following two groups: a) Health/Medical/Biomedical (HMB) and b) Health/Medical/Biomedical Non-Profit Use Only (HMB-NPU).

Acknowledgement Statement : link

Name : Health/Medical/Biomedical

Consent Group # : 2

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Name : Health/Medical/Biomedical (NPU)

Consent Group # : 1

Abbreviation : HMB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

phs001624 : NHLBI TOPMed - NHGRI CCDG: The Vanderbilt University BioVU Atrial Fibrillation Genetics Study

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There is one consent group for this study: HMB-GSO.
Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

Acknowledgement Statement : The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements. In addition, please include: "Whole genome sequencing (WGS) for the Trans-Omics in Precision Medicine (TOPMed) program was supported by the National Heart, Lung and Blood Institute (NHLBI). WGS for NHLBI TOPMed: Defining time-dependent genetic and transcriptomic responses to cardiac injury among patients with arrhythmias (phs# with version extension) was performed at the Broad Institute of MIT and Harvard (UM1HG008895). This funding source was an NHLBI supplement to NHGRI's Centers for Common Disease Genomics (CCDG). Centralized read mapping and genotype calling, along with variant quality metrics and filtering were provided by the TOPMed Informatics Research Center (3R01HL-117626-02S1). Phenotype harmonization, data management, sample-identity QC, and general study coordination, were provided by the TOPMed Data Coordinating Center (3R01HL-120393-02S1). We gratefully acknowledge the studies and participants who provided biological samples and data for TOPMed. This study is part of the Centers for Common Disease Genomics (CCDG) program, a large-scale genome sequencing effort to identify rare risk and protective alleles that contribute to a range of common disease phenotypes. The CCDG program is funded by the National Human Genome Research Institute (NHGRI) and the National Heart, Lung, and Blood Institute (NHLBI). Sequencing was completed at the Human Genome Sequencing Center at Baylor College of Medicine under NHGRI grant UM1 HG008898.

Name : Health/Medical/Biomedical (GSO)

Consent Group # : 1

Abbreviation : HMB-GSO

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

phs001398 : Center for Common Disease Genomics [CCDG] - Cardiovascular: The Bangladesh Risk of Acute Vascular Events (BRAVE) Study

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : We thank the Broad Institute for generating high-quality sequence data supported by NHGRI funds (grant # UM1HG008895) with Eric Lander as PI. The datasets used in this manuscript were obtained from dbGaP at http://www.ncbi.nlm.nih.gov/gap through dbGaP accession number phs000XXX.

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs000360 : eMERGE-I Genome Wide Association Studies of Network Phenotypes

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : Sample statements for the acknowledgment of the eMERGE GWAS dataset(s) can be found at the following link: eMERGE dbGaP Acknowledgment Statements (http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/GetPdf.cgi?document_name=eMERGE_Acknowledgement.pdf). Please include all Acknowledgment Statements relevant to the dataset(s) used in your analysis.

Name : Health/Medical/Biomedical

Consent Group # : 1

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

These data will be used only for health related research, including research to improve methods for health related research.

Name : Disease-Specific (Dementia)

Consent Group # : 2

Abbreviation : DS-DEM

Data Use Limitation : Use of the data must be related to Dementia.

Use of the data must be related to health research on dementia or other adult conditions related to the aging process. This includes research to improve methods for conducting research that could be applied to dementia or other adult conditions related to the aging process. For example, studies of conditions like cataract, diabetes, and psoriasis might be appropriate, while conditions like attention deficit hyperactivity disorder (ADHD) and neuroblastoma might not be appropriate. Studies of conditions that are common in both children and the elderly, such as schizophrenia or depression, would not be appropriate if they focused on children or young adults. Studies focused primarily on pediatric populations are not permitted.

Name : Health/Medical/Biomedical - Genetic Studies Only-No Insurance Companies

Consent Group # : 3

Abbreviation : HM-B-GSO-NIC

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data is limited to genetic studies only. No permitted use: Insurance Companies

Name : Health/Medical/Biomedical (GSO)

Consent Group # : 4

Abbreviation : HMB-GSO

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to genetic studies only.

Investigators must state in the Data Use Request their intention to publish or otherwise broadly share any findings from his or her study with the scientific community.

phs000284 : NHLBI Cleveland Family Study (CFS) Candidate Gene Association Resource (CARe)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Data use is limited to academic researchers conducting research in heart, lung, blood and sleep disorders, and their risk factors, and does not include the study of population origins and ancestry. CFS data may not be used to investigate individual pedigree structures, individual participant genotypes, phenotype-only analyses or issues such as non-maternity and non-paternity. All researchers requesting CFS data will be required to obtain approval from their IRB for their proposed project using CFS data.

Acknowledgement Statement : Support for the Cleveland Family Study was provided by NHLBI grant number R01 HL46380 and NHLBI grant number R01 HL113338.

Name : Disease-Specific (Heart, Lung, Blood, and Sleep Disorders, IRB, NPU)

Consent Group # : 1

Abbreviation : DS-HLBS-IRB-NPU

Data Use Limitation : Use of the data must be related to Heart, Lung, Blood, and Sleep Disorders.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Data Use Limitation : Data use is limited to academic researchers conducting research in heart, lung, blood and sleep disorders, and their risk factors, and does not include the study of population origins and ancestry. CFS data may not be used to investigate individual pedigree structures, individual participant genotypes, phenotype-only analyses or issues such as non-maternity and non-paternity. All researchers requesting CFS data will be required to obtain approval from their IRB for their proposed project using CFS data.

phs000993 : NHLBI TOPMed: Heart and Vascular Health Study (HVH)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There are two consent groups for this study: (1) HMB-IRB-MDS and (2) DS-CVD-IRB-MDS.
(1) For HMB-IRB-MDS:
Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval (please note only full or expedited approvals will be accepted).
Use of the data includes methods development research (e.g., development of software or algorithms).

(2) For DS-CVD-IRB-MDS - Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval (please note only full or expedited approvals will be accepted).
Use of the data includes methods development research (e.g., development of software or algorithms).

The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements.

Acknowledgement Statement : In addition the acknowledgment of the Heart and Vascular Health Study should always include the statement below, along with the relevant dbGaP accession number(s):

"The research reported in this article was supported by grants HL068986, HL085251, HL095080, and HL073410 from the National Heart, Lung, and Blood Institute. This manuscript was not prepared in collaboration with Heart and Vascular Health (HVH) Study investigators, and does not necessarily reflect the opinions or views of the HVH Study or the NHLBI."

Name : Health/Medical/Biomedical (IRB, MDS)

Consent Group # : 1

Abbreviation : HMB-IRB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Disease-Specific (Cardiovascular Disease, IRB, MDS)

Consent Group # : 2

Abbreviation : DS-CVD-IRB-MDS

Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs000944 : eMERGE Phase III: Clinical Center at Partners HealthCare

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : We wish to acknowledge the Partners HealthCare BioBank of Partners HealthCare (Massachusetts General Hospital and Brigham and Womens Hospital) and the BioBank subjects who contributed samples, and genotypes to the Partners BioBank.

Name : Health/Medical/Biomedical (MDS)

Consent Group # : 1

Abbreviation : HMB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs001927 : NHLBI TOPMed: SubPopulations and InteRmediate Outcome Measures In COPD Study (SPIROMICS)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There are eight consent groups for this study:
GRU: Use of the data is limited only by the terms of the model Data Use Certification.

GRU-NPU: Use of the data is limited only by the terms of the model Data Use Certification. Use of the data is limited to not-for-profit organizations.

GRU-COL: Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide a letter of collaboration with the primary study investigator(s).

GRU-COL-NPU: Use of the data is limited only by the terms of the model Data Use Certification. Use of the data is limited to not-for-profit organizations. Requestor must provide a letter of collaboration with the primary study

investigator(s).

DS-COPD: Use of the data must be related to Chronic Obstructive Pulmonary Disease.

DS-COPD-NPU: Use of the data must be related to Chronic Obstructive Pulmonary Disease. Use of the data is limited to not-for-profit organizations.

DS-COPD-COL: Use of the data must be related to Chronic Obstructive Pulmonary Disease. Requestor must provide a letter of collaboration with the primary study investigator(s).

DS-COPD-COL-NPU: Use of the data must be related to Chronic Obstructive Pulmonary Disease. Use of the data is limited to not-for-profit organizations. Requestor must provide a letter of collaboration with the primary study investigator(s).

Acknowledgement Statement : "The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov//acknowledgements." The authors thank the SPIROMICS participants and participating physicians, investigators and staff for making this research possible. More information about the study and how to access SPIROMICS data is at www.spiromics.org. We would like to acknowledge the following current and former investigators of the SPIROMICS sites and reading centers: Neil E Alexis, MD; Wayne H Anderson, PhD; Mehrdad Arjomandi, MD; Igor Barjaktarevic, MD, PhD; R Graham Barr, MD, DrPH; Lori A Bateman, MSc; Surya P Bhatt, MD; Eugene R Bleecker, MD; Richard C Boucher, MD; Russell P Bowler, MD, PhD;; Stephanie A Christenson, MD; Alejandro P Comellas, MD; Christopher B Cooper, MD, PhD; David J Couper, PhD; Gerard J Criner, MD; Ronald G Crystal, MD; Jeffrey L Curtis, MD; Claire M Doerschuk, MD; Mark T Dransfield, MD; Brad Drummond, MD; Christine M Freeman, PhD; Craig Galban, PhD; MeiLan K Han, MD, MS; Nadia N Hansel, MD, MPH; Annette T Hastie, PhD; Eric A Hoffman, PhD; Yvonne Huang, MD; Robert J Kaner, MD; Richard E Kanner, MD; Eric C Kleerup, MD; Jerry A Krishnan, MD, PhD; Lisa M LaVange, PhD; Stephen C Lazarus, MD; Fernando J Martinez, MD, MS; Deborah A Meyers, PhD; Wendy C Moore, MD; John D Newell Jr, MD; Robert Paine, III, MD; Laura Paulin, MD, MHS; Stephen P Peters, MD, PhD; Cheryl Pirozzi, MD; Nirupama Putcha, MD, MHS; Elizabeth C Oelsner, MD, MPH; Wanda K ONeal, PhD; Victor E Ortega, MD, PhD;; Sanjeev Raman, MBBS, MD; Stephen I. Rennard, MD; Donald P Tashkin, MD;; J Michael Wells, MD; Robert A Wise, MD; and Prescott G Woodruff, MD, MPH. The project officers from the Lung Division of the National Heart, Lung, and Blood Institute were Lisa Postow, PhD, and Lisa Viviano, BSN; SPIROMICS (phs001927) was supported by contracts from the NIH/NHLBI (HHSN268200900013C, HHSN268200900014C, HHSN268200900015C, HHSN268200900016C, HHSN268200900017C, HHSN268200900018C, HHSN268200900019C, HHSN268200900020C), and a grant from the NIH/NHLBI (U01 HL137880, and supplemented by contributions made through the Foundation for the NIH and the COPD Foundation from AstraZeneca/MedImmune; Bayer; Bellerophon Therapeutics; BoehringerIngelheim Pharmaceuticals, Inc..; Chiesi Farmaceutici S.p.A.; Forest Research Institute, Inc.; GlaxoSmithKline; Grifols Therapeutics, Inc.; Ikaria, Inc.; Novartis Pharmaceuticals Corporation; Nycomed GmbH; ProterixBio; ; Regeneron Pharmaceuticals, Inc.; Sanofi; Sunovion; Takeda Pharmaceutical Company; and Theravance Biopharma and Mylan.

Couper D, LaVange LM, Han M, Barr RG, Bleecker E, Hoffman EA, Kanner R, Kleerup E, Martinez FJ, Woodruff PG, Rennard S; SPIROMICS Research Group. Design of the Subpopulations and Intermediate Outcomes in COPD Study (SPIROMICS. Thorax. 2014 May;69(5):491-4. doi: 10.1136/thoraxjnl-2013-203897. Epub 2013 Sep 12. PubMed PMID: 24029743; PubMed Central PMCID: PMC3954445.

Name : General Research Use

Consent Group # : 4

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

Name : General Research Use (NPU)

Consent Group # : 3

Abbreviation : GRU-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Use of the data is limited to not-for-profit organizations.

Name : Disease-Specific (Chronic Obstructive Pulmonary Disease)

Consent Group # : 2

Abbreviation : DS-COPD

Data Use Limitation : Use of the data must be related to Chronic Obstructive Pulmonary Disease.

Name : Disease-Specific (Chronic Obstructive Pulmonary Disease, NPU)

Consent Group # : 1

Abbreviation : DS-COPD-NPU

Data Use Limitation : Use of the data must be related to Chronic Obstructive Pulmonary Disease.
Use of the data is limited to not-for-profit organizations.

phs001293 : NHLBI TOPMed: HyperGEN - Genetics of Left Ventricular (LV) Hypertrophy

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term :

There are two consent groups for this study: (1) General Research Use with IRB (GRU-IRB) and (2) Disease Specific- Cardiovascular Disease (DS-CVD-IRB-RD).

(1) For GRU-IRB: Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval (please note only full or expedited approvals will be accepted).

(2) For DS-CVD-IRB-RD: Use of the data must be related to Cardiovascular Disease and related disorders. Requestor must provide documentation of local IRB approval (please note only full or expedited approvals will be accepted).

Acknowledgement Statement :

The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements.

In addition, please include:
"We thank the participants and investigators of the HyperGEN: Genetics of Left Ventricular Hypertrophy Study and its TOPMed supplement (R01HL055673, 3R01HL055673-18S1) for their generous contributions to this study."

Name : General Research Use (IRB)

Consent Group # : 1

Abbreviation : GRU-IRB

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval.

Name : Disease-Specific (Cardiovascular Disease, IRB, RD)

Consent Group # : 2

Abbreviation : DS-CVD-IRB-RD

Data Use Limitation : Use of the data must be related to Cardiovascular Disease and related disorders. Requestor must provide documentation of local IRB approval.

phs000180 : Type 1 Diabetes Genetics Consortium (T1DGC) GWAS

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NIDDK Central Repository GWAS Data Access Committee

Important Contacts : niddk-dac@mail.nih.gov; niddk-dac@mail.nih.gov ; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement :

For T1DGC GWAS and TaqMan data in the GRID study:
"This research utilizes resources provided by the Type 1 Diabetes Genetics Consortium (T1DGC), a collaborative clinical study sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Allergy and Infectious Diseases (NIAID), National Human Genome Research Institute (NHGRI), National Institute of Child Health and Human Development (NICHD), and the Juvenile Diabetes Research Foundation International (JDRF) and supported by U01 DK062418. The UK case series collection was additionally funded by the JDRF and Wellcome Trust and the National Institute for Health Research Cambridge Biomedical Centre, at the Cambridge Institute for Medical Research, UK (CIMR), which is in receipt of a Wellcome Trust Strategic Award (079895). The data from the T1DGC study were supplied by dbGAP. This manuscript was not prepared in collaboration with Investigators of the T1DGC study and does not necessarily reflect the opinions or views of the T1DGC study or the study sponsors."

For other T1DGC datasets:
"This research was performed under the auspices of the Type 1 Diabetes Genetics Consortium, a collaborative clinical study sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Allergy and Infectious Diseases (NIAID), National Human Genome Research Institute (NHGRI), National Institute of Child Health and Human Development (NICHD), and Juvenile Diabetes Research Foundation International (JDRF)."

Name : Disease-Specific (Type 1 diabetes, its complications and other autoimmune diseases, IRB)

Consent Group # : 1

Abbreviation : DS-T1DR-IRB

Data Use Limitation : Use of the data must be related to Type 1 diabetes, its complications and other autoimmune diseases. Requestor must provide documentation of local IRB approval.

phs000925 : PAGE: The Charles Bronfman Institute for Personalized Medicine (IPM) BioMe Biobank

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Advisory Board Guidance: Users acknowledge that tribal status or affiliation of American Indian participants should not be inferred since they are self-identified, urban dwelling, and are not representative of the diverse American Indian populations across the United States.

Acknowledgement Statement : Samples and data of The Charles Bronfman Institute for Personalized Medicine (IPM) BioMe BioBank used in this study were provided by The Charles Bronfman Institute for Personalized Medicine at the Icahn School of Medicine at Mount Sinai (New York). Phenotype data collection was supported by The Andrea and Charles Bronfman Philanthropies. Funding support for genotyping, which was performed at The Center for Inherited Disease Research (CIDR), was provided by the NIH (U01HG007417). The datasets used for the analyses described in this manuscript were obtained from dbGaP at http://www.ncbi.nlm.nih.gov/gap through dbGaP accession number [Insert accession number].

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs000297 : eMERGE Resistant Hypertension

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : Sample statements for the acknowledgment of the eMERGE GWAS dataset(s) can be found at the following link: eMERGE dbGaP Acknowledgment Statements (http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/GetPdf.cgi?document_name=eMERGE_Acknowledgement.pdf). Please include all Acknowledgment Statements relevant to the dataset(s) used in your analysis.

Name : Health Research - Group Health Seattle

Consent Group # : 1

Abbreviation : HR_GHS

Data Use Limitation : These data will be used only for health related research, including research to improve methods for health related research.

Name : Dementia or Aging - Group Health Seattle

Consent Group # : 2

Abbreviation : AGING_GHS

Data Use Limitation : Limited to health research on dementia or other adult conditions related to the aging process. This includes research to improve methods for conducting research that could be applied to dementia or other adult conditions related to the aging process. For example, studies of conditions like cataract, diabetes, and psoriasis might be appropriate, while conditions like attention deficit hyperactivity disorder (ADHD) and neuroblastoma might not be appropriate. Studies of conditions that are common in both children and the elderly, such as schizophrenia or depression, would not be appropriate if they focused on children or young adults. Studies focused primarily on pediatric populations are not permitted.

Name : Health Research - Marshfield Clinic

Consent Group # : 3

Abbreviation : HR_MC

Data Use Limitation : May be used for genetic studies to learn about, prevent, or treat health problems.
No Permitted Use: Insurance companies

Name : Health Research - Vanderbilt U

Consent Group # : 4

Abbreviation : HR_VU

Data Use Limitation : May be used for genetic studies to learn about, prevent, or treat health problems.

Name : Health Research - Mayo Clinic

Consent Group # : 5

Abbreviation : HR_MYO

Data Use Limitation : Mayo Clinic Data may only be used for genetic studies to learn about, prevent, or treat health problems.

Investigators must state in the Data Use Request their intention to publish or otherwise broadly share any findings from his or her study with the scientific community.

Name : Health Research - Northwestern U

Consent Group # : 6

Abbreviation : HR_NWU

Data Use Limitation : May be used for genetic studies to learn about, prevent, or treat health problems

No Permitted Use: Insurance companies

phs001211 : NHLBI TOPMed - NHGRI CCDG: Atherosclerosis Risk in Communities (ARIC)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There are two consent groups for this study: HMB-IRB and DS-CVD-IRB. For both consent groups, the use of the ARIC Study data deposited in dbGaP is restricted to research on associations between phenotypes and genotypes. ARIC data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as non-maternity, non-paternity, and perceptions of racial/ethnic identity. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).
This Data Use Certification will be reviewed and approved by the NHLBI Data Access Committee. The NHLBI will keep all Data Use Certifications, and all approved studies utilizing ARIC dbGaP data will be listed on the dbGaP website. Annual updates regarding publications, etc. will be provided by the NHLBI to the ARIC study when and if necessary.
1) For HMB-IRB:
Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
2) For DS-CVD-IRB:
Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Use of the ARIC Study data deposited in dbGaP is restricted to research on associations between phenotypes and genotypes. ARIC data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through NHLBIs BioLINCC); or explore issues such as

non-maternity, non-paternity, and perceptions of racial/ethnic identity. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted). One consent group is available for the ARIC Study: health/medical/biomedical research.
This Data Use Certification will be reviewed and approved by the NHLBI Data Access Committee. The NHLBI will keep all Data Use Certifications, and all approved studies utilizing ARIC dbGaP data will be listed on the dbGaP website. Annual updates regarding publications, etc. will be provided by the NHLBI to the ARIC study when and if necessary.

Name : Disease-Specific (Cardiovascular Disease, IRB)

Consent Group # : 2

Abbreviation : DS-CVD-IRB

Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.

phs000788 : Research Program on Genes, Environment and Health (RPGEH)

NIH Data Access Committee (DAC) : Joint Addiction, Aging, and Mental Health DAC

Important Contacts : JAAMH-DAC@list.nih.gov ; URGENTJAAMHDAC@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : The RPGEH Data will not be made available under this agreement to for-profit companies.
The RPGEH Data will not be made available under this agreement for analyses that have as an outcome any of the demographic and behavioral variables derived from the RPGEH Survey, including the following: Age (BirthYearCat); Gender; Race; Education (EduCat); Marital Status (MaritalCat); Year of Initial KP Membership (KPMembershipYear); Smoking (SmokingPackYearsCat, SmokingStatusCat); Physical Activity (PhysicalActivityCat); Income (IncomeCat); Self-reported Health (GeneralHealthCat); Body Mass Index (BMICat); Alcohol Consumption (AlcoholDaysPerWeekCat). Data Access Requests for the RPGEH Data under this agreement must specify that the demographic and behavioral variables listed above will be used only as covariates in analyses and will not be used as outcome variables. For example, the RPGEH Data may not be used to conduct a Genome-Wide Association Study (GWAS) of Education or Smoking Pack Years. Data Access Requests for the RPGEH Data must specify that only health conditions, as listed in the Diseases Related to Study (Mesh Terms) will be used as outcomes in analyses. Approved Users agree not to use demographic or behavioral data from the RPGEH Survey, including the variables listed above, as outcome variables in analyses. Results generated from use of the RPGEH Data shall not include any patient-identifiable data or any data that identifies a patients health care provider.

Researchers who wish to request access to other data not in dbGaP may apply for access from the Research Program on Genes, Environment and Health (RPGEH) at the Kaiser Permanente Division of Research. See the RPGEH website (https://rpgehportal.kaiser.org/Welcome.aspx) for details. A separate application and Materials and Data Transfer Agreement (MDTA) will be required to obtain access to these data.

Acknowledgement Statement : Data came from a grant, the Resource for Genetic Epidemiology Research in Adult Health and Aging (RC2 AG033067; Schaefer and Risch, PIs) awarded to the Kaiser Permanente Research Program on Genes, Environment, and Health (RPGEH) and the UCSF Institute for Human Genetics. The RPGEH was supported by grants from the Robert Wood Johnson Foundation, the Wayne and Gladys Valley Foundation, the Ellison Medical Foundation, Kaiser Permanente Northern California, and the Kaiser Permanente National and Northern California Community Benefit Programs. The RPGEH and the Resource for Genetic Epidemiology Research in Adult Health and Aging are described in the following publication, Schaefer C, et al., The Kaiser Permanente Research Program on Genes, Environment and Health: Development of a Research Resource in a Multi-Ethnic Health Plan with Electronic Medical Records, In preparation, 2013.

Acknowledgement of the Genomics of blood pressure-induced target organ damage dataset should include: "The origin of the data is described in detail in Hoffmann et al. Nat Genet. 2017 Jan;49(1):54-64. Funding support was provided by the National Institutes of Health, National Heart, Lung, and Blood Institute (NHLBI) grant R01 HL128782. We thank our collaborators who created and maintain the datasets used from KAISER and UCSF (phs000788.v1.p2). We are grateful to Kaiser Permanente members, whose participation in the research program makes this genotyping project possible."

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 1

Abbreviation : HMB-IRB-NPU

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

phs001218 : NHLBI TOPMed: Genetic Study of Atherosclerosis Risk (GeneSTAR)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Use of the NHLBI TOPMed: Genetic Studies of Atherosclerosis Risk (GeneSTAR) is limited to studies of Cardiovascular Disease. Requestor must provide documentation of local IRB approval (only full or expedited IRB approvals will be accepted). Use of the data is limited to not-for-profit organizations. Use of the data includes methods development research (e.g., development of software or algorithms).

Acknowledgement Statement : The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements. In addition please include: "This work was supported by the National Heart, Lung and Blood Institute through the PROGENI (U01 HL72518) and STAMPEED (R01 HL87698-01) consortia, and through R01-HL48157 and R01HL112064."

Name : Disease-Specific (Cardiovascular Disease, IRB, NPU, MDS)

Consent Group # : 2

Abbreviation : DS-CVD-IRB-NPU-MDS

Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs001672 : Veterans Administration (VA) Million Veteran Program (MVP) Summary Results from Omics Studies

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

Acknowledgement Statement : The authors thank Million Veteran Program (MVP) staff, researchers, and volunteers, who have contributed to MVP, and especially participants who previously served their country in the military and now generously agreed to enroll in the study. (See https://www.research.va.gov/mvp/ for more details).
The citation for MVP is Gaziano, J.M. et al. Million Veteran Program: A mega-biobank to study genetic influences on health and disease. J Clin Epidemiol 70, 214-23 (2016).
This research is based on data from the Million Veteran Program, Office of Research and Development, Veterans Health Administration, and was supported by the Veterans Administration (VA) Million Veteran Program (MVP) award #000.

Name : Health/Medical/Biomedical (MDS)

Consent Group # : 1

Abbreviation : HMB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs001612 : NHLBI TOPMed: Coronary Artery Risk Development in Young Adults (CARDIA)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : This study has two consent groups: (1) HMB-IRB, and (2) HMB-IRB-NPU.
(1) For HMB-IRB: Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor must provide documentation of local IRB approval.
(2) For HMB-IRB-NPU: Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor must provide documentation of local IRB approval. Use of the data is limited to not-for-profit organizations.
For both consent groups: Data may not be used to investigate individual pedigree structures; individual participant genotypes; phenotype-only analyses; issues such as non-maternity and non-paternity; assess variables or proxies that could be considered stigmatizing to an individual or a group; or assess individual participant racial/ethnic identity. All research must be consistent with the CARDIA informed consent documents. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. population consistent with the demographic distribution in the CARDIA Study. Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

Acknowledgement Statement : The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements. In addition, please include: "Whole genome sequencing (WGS) for the Trans-Omics in Precision Medicine (TOPMed) program was supported by the National Heart, Lung and Blood Institute (NHLBI). WGS for NHLBI TOPMed: CARDIA (Coronary Artery Risk Development in Young Adults) phs001612 was performed at the Baylor Human Genome Sequencing Center (grant/contract number). Centralized read mapping and genotype calling, along with variant quality metrics and filtering were provided by the TOPMed Informatics Research Center (3R01HL-117626-02S1). Phenotype harmonization, data management, sample-identity QC, and general study coordination, were provided by the TOPMed Data Coordinating Center (3R01HL-120393-02S1). We gratefully acknowledge the studies and participants who provided biological samples and data for TOPMed. The Coronary Artery Risk Development in Young Adults Study (CARDIA) is supported by contracts HHSN268201300025C, HHSN268201300026C, HHSN268201300027C, HHSN268201300028C, HHSN268201300029C, and HHSN268200900041C from the National Heart, Lung, and Blood Institute (NHLBI), the Intramural Research Program of the National Institute on Aging (NIA), and an intra-agency agreement between NIA and NHLBI (AG0005)."

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Data Use Limitation : Data may not be used to investigate individual pedigree structures; individual participant genotypes; phenotype-only analyses; issues such as non-maternity and non-paternity; assess variables or proxies that could be considered stigmatizing to an individual or a group; or assess individual participant racial/ethnic identity. All research must be consistent with the CARDIA informed consent documents. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. population consistent with the demographic distribution in the CARDIA Study. Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Data Use Limitation : Data may not be used to investigate individual pedigree structures; individual participant genotypes; phenotype-only analyses; issues such as non-maternity and non-paternity; assess variables or proxies that could be considered stigmatizing to an individual or a group; or assess individual participant racial/ethnic identity. All research must be consistent with the CARDIA informed consent documents. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. population consistent with the demographic distribution in the CARDIA Study. Data users are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies, and that the data are always maintained in a secured fashion. Data users will be required to obtain IRB approval for their projects from their respective institutions (please note that only full or expedited approvals will be accepted).

phs002719 : Reasons for Geographic and Racial Differences in Stroke Cardiorenal GWAS

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution.

Acknowledgement Statement : The GWAS study was supported by the National Institutes of Health (NIH) National Heart, Lung, and Blood Institute (NHLBI) grant R01HL136666. The parent REGARDS study is supported by a cooperative agreement U01 NS041588 from the National Institute of Neurological Disorders and Stroke, National Institutes of Health, U.S. Department of Health and Human Services.

For publications, written, and/or oral presentations resulting from use of this data, please cite the following information: Armstrong et al. "Genetic Contributors of Incident Stroke in 10,700 African Americans With Hypertension: A Meta-Analysis From the Genetics of Hypertension Associated Treatments and Reasons for Geographic and Racial Differences in Stroke Studies" (PMID 34992631) and 'The reasons for geographic and racial differences in stroke study: objectives and design" (PMID 15990444). The original data used for the analysis in this publication can be found in the NIH database of Genotypes and Phenotypes (dbGaP) under the accession number phs002719.v1.p1

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution.

phs000954 : NHLBI TOPMed: The Cleveland Family Study (CFS)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There is one consent group for this study: DS-HLBS-IRB-NPU (Disease-Specific Heart, Lung, Blood, and Sleep Disorders, IRB, NPU).
Use of the data must be related to Heart, Lung, Blood, and Sleep Disorders.
Requestor must provide documentation of local IRB approval (please note only full or expedited approvals will be accepted).
Use of the data is limited to not-for-profit organizations.
Data use is limited to academic researchers conducting research in heart, lung, blood and sleep disorders, and their risk factors, and does not include the study of population origins and ancestry. CFS data may not be used to investigate individual pedigree structures, individual participant genotypes, phenotype-only analyses or issues such as non-maternity and non-paternity. All researchers requesting CFS data will be required to obtain approval from their IRB for their proposed project using CFS data (please note only full or expedited approvals will be accepted).

Acknowledgement Statement : The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements.

In addition, please include:
"Support for the Cleveland Family Study was provided by NHLBI grant number R01 HL46380 and NHLBI grant number R01 HL113338."

Name : Disease-Specific (Heart, Lung, Blood, and Sleep Disorders, IRB, NPU)

Consent Group # : 1

Abbreviation : DS-HLBS-IRB-NPU

Use of the data must be related to Heart, Lung, Blood, and Sleep Disorders.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Data Use Limitation : Data use is limited to academic researchers conducting research in heart, lung, blood and sleep disorders, and their risk factors, and does not include the study of population origins and ancestry. CFS data may not be used to investigate individual pedigree structures, individual participant genotypes, phenotype-only analyses or issues such as non-maternity and non-paternity. All researchers requesting CFS data will be required to obtain approval from their IRB for their proposed project using CFS data (please note only full or expedited approvals will be accepted).

phs001166 : Type 2 Diabetes Starr County GWAS and Exome Sequencing

NIH Data Access Committee (DAC) : NIDDK Central Repository GWAS Data Access Committee

Important Contacts : niddk-dac@mail.nih.gov; niddk-dac@mail.nih.gov ; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : INSTRUCTIONS: This study has not provided a suggested acknowledgement statement. However, Approved Users are expected to acknowledge the Submitting Investigator(s) who submitted data from the original study to an NIH-designated data repository, the primary funding organization that supported the Submitting Investigator(s), and the NIH-designated data repository (e.g., dbGaP). The acknowledgment statement should include the dbGaP accession number to the specific version of the dataset(s) analyzed.

Name : General Research Use (IRB)

Consent Group # : 1

Abbreviation : GRU-IRB

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide documentation of local IRB approval.

phs001215 : NHLBI TOPMed: San Antonio Family Heart Study (SAFHS)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Use of the NHLBI TOPMed: San Antonio Family Heart Study is limited to studies of Diabetes and Heart Disease and related disorders such as aging. Full or expedited IRB approval is required for data access. Requestor agrees to make results of studies using the data available to the larger scientific community. Use of the data includes methods development research (e.g., development of software or algorithms).

Acknowledgement Statement : The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements. In addition, please include "The San Antonio Family Heart Study genetic and phenotypic data were obtained as part of several NIH funded projects including P01HL045522, R01HL113322, R01HD049051, and U01DK085524."

Name : Disease-Specific (Diabetes and Heart Disease, IRB, PUB, MDS, RD)

Consent Group # : 1

Abbreviation : DS-DHD-IRB-PUB-MDS-RD

Data Use Limitation : Use of the data must be related to Diabetes and Heart Disease and related disorders.
Requestor must provide documentation of local IRB approval.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of the data is limited to genetic studies of the specified disease and related conditions, such as phenotypes relevant for aging.

phs001483 : DRIVE Breast Cancer Whole Genome Sequencing

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NCI DAC

Important Contacts : NCIDAC@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement :	This dataset was generated by the DRIVE GAME-ON consortium (http://epi.grants.cancer.gov/gameon/) (U19 CA148065). The whole-genome sequencing data was provided from the University of Cambridge, UK, Harvard School of Public Health, University of Southern California and Vanderbilt University. The key investigators included Douglas Easton (University of Cambridge, Cambridge, UK), Christopher A. Haiman (University of Southern California, Los Angeles, CA, USA), David J Hunter (Harvard University, Boston, MA), and Wei Zheng (Vanderbilt University, Nashville, TN, USA). We would like to thank the participants and staff of the NHS and NHSII for their valuable contributions as well as the following state cancer registries for their help: AL, AZ, AR, CA, CO, CT, DE, FL, GA, ID, IL, IN, IA, KY, LA, ME, MD, MA, MI, NE, NH, NJ, NY, NC, ND, OH, OK, OR, PA, RI, SC, TN, TX, VA, WA, WY.
Name :	Disease-Specific (Cancer, PUB)
Consent Group # :	1
Abbreviation :	DS-CA-PUB
Data Use Limitation :	Use of the data must be related to Cancer. Requestor agrees to make results of studies using the data available to the larger scientific community. General methods development research is NOT allowed.
Name :	General Research Use
Consent Group # :	2
Abbreviation :	GRU
Data Use Limitation :	Use of the data is limited only by the terms of the model Data Use Certification.
Name :	Disease-Specific (Breast Diseases, MDS)
Consent Group # :	3
Abbreviation :	DS-BRD-MDS
Data Use Limitation :	Use of the data must be related to Breast Diseases. Use of the data includes methods development research (e.g., development of software or algorithms).
Name :	Disease-Specific (Breast Diseases)
Consent Group # :	4
Abbreviation :	DS-BRD
Data Use Limitation :	Use of the data must be related to Breast Diseases. General methods development research is NOT permitted.
Name :	Disease-Specific (Colorectal, ovarian, and/or breast cancer, NPU, MDS)
Consent Group # :	5
Abbreviation :	DS-COBC-NPU-MDS
Data Use Limitation :	Use of the data must be related to Colorectal, ovarian, and/or breast cancer. Use of the data is limited to not-for-profit organizations. Use of the data includes methods development research (e.g., development of software or algorithms).
Name :	Health/Medical/Biomedical (PUB)
Consent Group # :	7
Abbreviation :	HMB-PUB
Data Use Limitation :	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor agrees to make results of studies using the data available to the larger scientific community.
Name :	Health/Medical/Biomedical (PUB, NPU)
Consent Group # :	6
Abbreviation :	HMB-PUB-NPU
Data Use Limitation :	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor agrees to make results of studies using the data available to the larger scientific community. Use of the data is limited to not-for-profit organizations.

phs000091 : GENEVA Diabetes Study (NHS/HPFS)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) :	National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : Assistance with data cleaning was provided by the National Center for Biotechnology Information. Support for collection of datasets and samples was provided by the Collaborative Study on the Genetics of Alcoholism (COGA; U10 AA008401), the Collaborative Genetic Study of Nicotine Dependence (COGEND; P01 CA089392), and the Family Study of Cocaine Dependence (FSCD; R01 DA013423). Funding support for genotyping, which was performed at the Johns Hopkins University Center for Inherited Disease Research, was provided by the NIH GEI (U01HG004438), the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the NIH contract "High throughput genotyping for studying the genetic contributions to human disease" (HHSN268200782096C). The datasets used for the analyses described in this manuscript were obtained from dbGaP at http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000091.v1.p1 through dbGaP accession number phs000091.v1.p.

Name : Non-Profit Use Only

Consent Group # : 1

Abbreviation : NPU

Data Use Limitation : General research use, but not for distribution to commercial entities.

phs000018 : GoKinD: Search for Susceptibility Genes for Diabetic Nephropathy in Type 1 Diabetes

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : NIDDK Central Repository GWAS Data Access Committee

Important Contacts : niddk-dac@mail.nih.gov; niddk-dac@mail.nih.gov ; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Users registered before 8/28/14 do not need to re-register in order to be granted continued access to data. Registration on or after 8/28/14 requires IRB approval or waiver.

Acknowledgement Statement : The Genetics of Kidneys in Diabetes (GoKinD) Study was conducted by the GoKinD Investigators and supported by the Juvenile Diabetes Research Foundation, the CDC, and the Special Statutory Funding Program for Type 1 Diabetes Research administered by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The data [and samples] from the GoKinD study were supplied by the NIDDK Central Repositories. This manuscript was not prepared in collaboration with Investigators of the GoKinD study and does not necessarily reflect the opinions or views of the GoKinD study, the NIDDK Central Repositories, or the NIDDK.

Name : Disease-Specific (Type 1 Diabetes, Complications, and Related Traits, IRB)

Consent Group # : 1

Abbreviation : DS-T1DCR-IRB

Data Use Limitation : Use of the data must be related to Type 1 Diabetes, Complications, and Related Traits.
Requestor must provide documentation of local IRB approval.

Requestors requesting access before 8/28/14 do not need to re-register for access. Requestors requesting access on 8/28/14 or thereafter must complete a new registration.

phs001119 : Subpopulations and Intermediate Outcome Measures in COPD Study (SPIROMICS)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There are eight consent groups for this study:
GRU: Use of the data is limited only by the terms of the model Data Use Certification.

GRU-NPU: Use of the data is limited only by the terms of the model Data Use Certification. Use of the data is limited to not-for-profit organizations.

GRU-COL: Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide a letter of collaboration with the primary study investigator(s).

GRU-COL-NPU: Use of the data is limited only by the terms of the model Data Use Certification. Use of the data

is limited to not-for-profit organizations. Requestor must provide a letter of collaboration with the primary study investigator(s).

DS-COPD: Use of the data must be related to Chronic Obstructive Pulmonary Disease.

DS-COPD-NPU: Use of the data must be related to Chronic Obstructive Pulmonary Disease. Use of the data is limited to not-for-profit organizations.

DS-COPD-COL: Use of the data must be related to Chronic Obstructive Pulmonary Disease. Requestor must provide a letter of collaboration with the primary study investigator(s).

DS-COPD-COL-NPU: Use of the data must be related to Chronic Obstructive Pulmonary Disease. Use of the data is limited to not-for-profit organizations. Requestor must provide a letter of collaboration with the primary study investigator(s).

Acknowledgement Statement : The authors thank the SPIROMICS participants and participating physicians, investigators, study coordinators, and staff for making this research possible. More information about the study and how to access SPIROMICS data is available at www.spiromics.org. The authors would like to acknowledge the University of North Carolina at Chapel Hill BioSpecimen Processing Facility (http://bsp.web.unc.edu/) and Alexis Lab (https://www.med.unc.edu/cemalb/facultyresearch/alexislab/) for sample processing, storage, and sample disbursements.
We would like to acknowledge the following current and former investigators of the SPIROMICS sites and reading centers: Neil E Alexis, MD; Wayne H Anderson, PhD; Mehrdad Arjomandi, MD; Igor Barjaktarevic, MD, PhD; R Graham Barr, MD, DrPH; Patricia Basta, PhD; Lori A Bateman, MS; Christina Bellinger, MD; Surya P Bhatt, MD; Eugene R Bleecker, MD; Richard C Boucher, MD; Russell P Bowler, MD, PhD; Russell G Buhr, MD, PhD; Stephanie A Christenson, MD; Alejandro P Comellas, MD; Christopher B Cooper, MD, PhD; David J Couper, PhD; Gerard J Criner, MD; Ronald G Crystal, MD; Jeffrey L Curtis, MD; Claire M Doerschuk, MD; Mark T Dransfield, MD; M Bradley Drummond, MD; Christine M Freeman, PhD; Craig Galban, PhD; Katherine Gershner, DO; MeiLan K Han, MD, MS; Nadia N Hansel, MD, MPH; Annette T Hastie, PhD; Eric A Hoffman, PhD; Yvonne J Huang, MD; Robert J Kaner, MD; Richard E Kanner, MD; Mehmet Kesimer, PhD; Eric C Kleerup, MD; Jerry A Krishnan, MD, PhD; Wassim W Labaki, MD; Lisa M LaVange, PhD; Stephen C Lazarus, MD; Fernando J Martinez, MD, MS; Merry-Lynn McDonald, PhD; Deborah A Meyers, PhD; Wendy C Moore, MD; John D Newell Jr, MD; Elizabeth C Oelsner, MD, MPH; Jill Ohar, MD; Wanda K ONeal, PhD; Victor E Ortega, MD, PhD; Robert Paine, III, MD; Laura Paulin, MD, MHS; Stephen P Peters, MD, PhD; Cheryl Pirozzi, MD; Nirupama Putcha, MD, MHS; Sanjeev Raman, MBBS, MD; Stephen I Rennard, MD; Donald P Tashkin, MD; J Michael Wells, MD; Robert A Wise, MD; and Prescott G Woodruff, MD, MPH. The project officers from the Lung Division of the National Heart, Lung, and Blood Institute were Lisa Postow, PhD, and Lisa Viviano, BSN; SPIROMICS was supported by contracts from the NIH/NHLBI (HHSN268200900013C, HHSN268200900014C, HHSN268200900015C, HHSN268200900016C, HHSN268200900017C, HHSN268200900018C, HHSN268200900019C, HHSN268200900020C), grants from the NIH/NHLBI (U01 HL137880, U24 HL141762, R01 HL182622, and R01 HL144718), and supplemented by contributions made through the Foundation for the NIH and the COPD Foundation from Amgen; AstraZeneca/MedImmune; Bayer; Bellerophon Therapeutics; Boehringer-Ingelheim Pharmaceuticals, Inc.; Chiesi Farmaceutici S.p.A.; Forest Research Institute, Inc.; Genentech; GlaxoSmithKline; Grifols Therapeutics, Inc.; Ikaria, Inc.; MGC Diagnostics; Novartis Pharmaceuticals Corporation; Nycomed GmbH; Polarean; ProterixBio; Regeneron Pharmaceuticals, Inc.; Sanofi; Sunovion; Takeda Pharmaceutical Company; and Theravance Biopharma and Mylan/Viatris.

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

Name : General Research Use (NPU)

Consent Group # : 2

Abbreviation : GRU-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Use of the data is limited to not-for-profit organizations.

Name : Disease-Specific (Chronic Obstructive Pulmonary Disease)

Consent Group # : 3

Abbreviation : DS-COPD

Data Use Limitation : Use of the data must be related to Chronic Obstructive Pulmonary Disease.

Name : Disease-Specific (Chronic Obstructive Pulmonary Disease, NPU)

Consent Group # : 4

Abbreviation : DS-COPD-NPU

Data Use Limitation : Use of the data must be related to Chronic Obstructive Pulmonary Disease.
Use of the data is limited to not-for-profit organizations.

Name : General Research Use (COL)

Consent Group # : 5

Abbreviation : GRU-COL

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide a letter of collaboration with the primary study investigator(s).

Name : General Research Use (COL, NPU)

Consent Group # : 6

Abbreviation : GRU-COL-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Requestor must provide a letter of collaboration with the primary study investigator(s).
Use of the data is limited to not-for-profit organizations.

Name : Disease-Specific (Chronic Obstructive Pulmonary Disease, COL)

Consent Group # : 7

Abbreviation : DS-COPD-COL

Data Use Limitation : Use of the data must be related to Chronic Obstructive Pulmonary Disease.
Requestor must provide a letter of collaboration with the primary study investigator(s).

Name : Disease-Specific (Chronic Obstructive Pulmonary Disease, COL, NPU)

Consent Group # : 8

Abbreviation : DS-COPD-COL-NPU

Data Use Limitation : Use of the data must be related to Chronic Obstructive Pulmonary Disease.
Requestor must provide a letter of collaboration with the primary study investigator(s).
Use of the data is limited to not-for-profit organizations.

phs001345 : NHLBI TOPMed: Genetic Epidemiology Network of Arteriopathy (GENOA)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Use of the data must be related to Arteriosclerosis and its Risk Factors. Use of the data is limited to not-for-profit organizations.

Acknowledgement Statement : link

Name : Disease-Specific (Arteriosclerosis and its Risk Factors, NPU)

Consent Group # : 1

Abbreviation : DS-ASC-RF-NPU

Data Use Limitation : Use of the data must be related to Arteriosclerosis and its Risk Factors.
Use of the data is limited to not-for-profit organizations.

phs001237 : NHLBI TOPMed: Women's Health Initiative (WHI)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : All requestors and data users must provide a local Institutional Review Board (IRB) letter from their respective institution approving conduct of the proposed research project. Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution. There are two consent groups for this study: a) Health/Medical/Biomedical IRB, and b) Health/Medical/Biomedical IRB for use by not-for-profit organizations only.

Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that

could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were primarily dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree not to use the data to infer tribal status or affiliation.

Acknowledgement Statement : link

Name : Health/Medical/Biomedical (IRB)

Consent Group # : 1

Abbreviation : HMB-IRB

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.

All requestors and data users must provide a local Institutional Review Board (IRB) letter from their respective institution approving conduct of the proposed research project. Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution.

Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were primarily dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree not to use the data to infer tribal status or affiliation.

Name : Health/Medical/Biomedical (IRB, NPU)

Consent Group # : 2

Abbreviation : HMB-IRB-NPU

Data Use Limitation :

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data is limited to not-for-profit organizations.

Use of the data is limited to not-for-profit organizations.
All requestors and data users must provide a local Institutional Review Board (IRB) letter from their respective institution approving conduct of the proposed research project. Only full or expedited approvals are acceptable, and an ANNUAL IRB review is required base on the informed consents from the submitting institution.

Use of the WHI data to conduct non-genetic research is prohibited. WHI data may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, variables that could be considered as stigmatizing an individual or group, or issues such as non-maternity. Users acknowledge that American Indian participants were self-identified and were primarily dwelling in urban areas and are not representative of the diverse American Indian population across the United States. Users agree not to use the data to infer tribal status or affiliation.

phs000517 : GWAS of Breast Cancer in the Multiethnic Cohort

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : NCI DAC

Important Contacts : NCIDAC@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : The Multiethnic Cohort and the genotyping in this study were funded by grants from the National Institute of Health (CA63464, CA54281, CA098758, CA132839 and HG005922) and the Department of Defense Breast Cancer Research Program (W81XWH-08-1-0383).

Name : Disease-Specific (Cancer)

Consent Group # : 1

Abbreviation : DS-CA

Data Use Limitation :

Use of the data must be related to Cancer.

Data can NOT be used for general methods development research.

Name : General Research Use (MDS)

Consent Group # : 2

Abbreviation :	GRU-MDS
Data Use Limitation :	Use of the data is limited only by the terms of the model Data Use Certification. Use of the data includes methods development research (e.g., development of software or algorithms).
Name :	Health/Medical/Biomedical (MDS)
Consent Group # :	5
Abbreviation :	HMB-MDS
Data Use Limitation :	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data includes methods development research (e.g., development of software or algorithms).

phs001402 : NHLBI TOPMed: Whole Genome Sequencing of Venous Thromboembolism (WGS of VTE)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) :	National Heart, Lung, and Blood Institute DAC
Important Contacts :	nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov
	In the event of a data management incident, within 24 hours, please contact emails above.
IC Specific Access Term :	Use of the data is limited only by the terms of the model Data Use Certification.
Acknowledgement Statement :	The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements. In addition please include: "Funded in part by grants from the National Institutes of Health, National Heart, Lung and Blood Institute (HL66216 and HL83141) and the National Human Genome Research Institute (HG04735)."
Name :	General Research Use
Consent Group # :	1
Abbreviation :	GRU
Data Use Limitation :	Use of the data is limited only by the terms of the model Data Use Certification.

phs001416 : NHLBI TOPMed: MESA and MESA Family AA-CAC

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) :	National Heart, Lung, and Blood Institute DAC
Important Contacts :	nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov
	In the event of a data management incident, within 24 hours, please contact emails above.
IC Specific Access Term :	There are two consent groups: a) Health/Medical/Biomedical; and b) Health/Medical/Biomedical - Use by not-for-profit organizations only.
Acknowledgement Statement :	link
Name :	Health/Medical/Biomedical
Consent Group # :	1
Abbreviation :	HMB
Data Use Limitation :	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through the NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity and perceptions of racial/ethnic identity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in MESA.
Name :	Health/Medical/Biomedical (NPU)
Consent Group # :	2
Abbreviation :	HMB-NPU

Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.

Data Use Limitation : Data may not be used to investigate individual pedigree structures or individual participant genotypes for the purpose of identifying individuals or families; assess variables or proxies that could be considered as stigmatizing an individual or a group; perform phenotype-only analyses (note: investigators may request data for such phenotype-only analyses through the NHLBIs BioLINCC); or explore issues such as non-maternity and non-paternity and perceptions of racial/ethnic identity. All research must be related to the etiology and prevention of morbidity and mortality of the U.S. Population consistent with the demographic distribution in MESA.

phs000220 : PAGE: Multiethnic Cohort (MEC)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Advisory Board Guidance: Users acknowledge that tribal status or affiliation of American Indian participants should not be inferred since they are self-identified, urban dwelling, and are not representative of the diverse American Indian populations across the United States.

Acknowledgement Statement : Funding support for the PAGE Multiethnic Cohort study was provided through the National Cancer Institute (R37CA54281, R01CA6364, P01CA33619, U01CA136792, and U01CA98758) and the National Human Genome Research Institute (U01HG004802).
Assistance with phenotype harmonization, SNP selection, data cleaning, meta-analyses, data management and dissemination, and general study coordination, was provided by the PAGE Coordinating Center (U01HG004801-01).

The datasets used for the analyses described in this manuscript were obtained from dbGaP at http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000220.v1.p1.

Name : Disease-Specific (Cancer Research and Methods, PUB, MDS)

Consent Group # : 1

Abbreviation : DS-CRM-PUB-MDS

Use of the data must be related to Cancer Research and Methods.
Requestor agrees to make results of studies using the data available to the larger scientific community.
Use of the data includes methods development research (e.g., development of software or algorithms).

Data Use Limitation : Use of the data is limited to scientific research relevant to the etiology, prevention, treatment and late complications of treatment of cancer appropriate to the age group, including applications proposing analytical methods, software or other research tool development. Investigators must state in the Data Access Request their intention to publish or otherwise broadly share any finding from his/her study with the scientific community.

Name : General Research Use

Consent Group # : 2

Abbreviation : GRU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.

phs000356 : Population Architecture using Genomics and Epidemiology, summary data (PAGE-summary)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Human Genome Research Institute

Important Contacts : nhgridac@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : Funding support for "Epidemiologic Architecture for Genes Linked to Environment (EAGLE)" was provided through the National Human Genome Research Institute's Population Architecture Using Genomics and Epidemiology (PAGE) network (U01HG004798-01). The human subjects participating in the study derive from the National Health and Nutrition Examination Surveys, and these studies are supported by the Centers for Disease Control and Prevention.
Funding support for the PAGE Multiethnic Cohort study was provided through the National Cancer Institute

(R37CA54281, R01 CA63, P01CA33619, U01CA136792, and U01CA98758) and the National Human Genome Research Institute (U01HG004802).
Funding support for the Epidemiology of putative genetic variants: The Womens Health Initiative was provided through the National Human Genome Research Institute's Population Architecture Using Genomics and Epidemiology (PAGE) network (U01HG004790). The WHI program is funded by the National Heart, Lung, and Blood Institute; NIH; and U.S. Department of Health and Human Services through contracts N01WH22110, 24152, 32100-2, 32105-6, 32108-9, 32111-13, 32115, 32118-32119, 32122, 42107-26, 42129-32, and 44221.
Funding support for the Genetic Epidemiology of Causal Variants Across the Life Course (CALiCo) was provided through the National Human Genome Research Institute's Population Architecture Using Genomics and Epidemiology (PAGE) network (U01HG004803). The human subjects derive from the following studies: Atherosclerosis Risk in Communities (ARIC) Study, Coronary Artery Risk Development in Young Adults (CARDIA), and Cardiovascular Health Study (CHS).
The Atherosclerosis Risk in Communities (ARIC) Study is carried out as a collaborative study supported by National Heart, Lung, and Blood Institute contracts N01-HC-55015, N01-HC-55016, N01-HC-55018, N01-HC-55019, N01-HC-55020, N01-HC-55021, N01-HC-55022. The Coronary Artery Risk Development in Young Adults (CARDIA) study is supported by the following National Institutes of Health, National Heart, Lung and Blood Institute contracts: N01-HC-95095; N01-HC-48047; N01-HC-48048; N01-HC-48049; N01-HC-48050; N01-HC-45134; N01-HC-05187; and N01-HC-45205. The Cardiovascular Health Study (CHS) is supported by contracts N01-HC-35129, N01-HC-45133, N01-HC-75150, N01-HC-85079 through N01-HC-85086, N01 HC-15103, N01 HC-55222, and U01 HL080295 from the National Heart, Lung, and Blood Institute, with additional contribution from the National Institute of Neurological Disorders and Stroke and grant AG09556 from the National Institute of Aging
Assistance with phenotype harmonization, SNP selection, data cleaning, meta-analyses, data management and dissemination, and general study coordination, was provided by the PAGE Coordinating Center (U01HG004801-01).

The datasets used for the analyses described in this manuscript were obtained from dbGaP at phs000356.

Name : General Research Use

Consent Group # : 1

Abbreviation : GRU

Data Use Limitation : General Research Use

phs000179 : Genetic Epidemiology of COPD (COPDGene)

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : There are two consent groups in COPDGene:
Disease-Specific (COPD and Smoking): Use of the data must be related to COPD and Smoking. The full list of diseases or conditions for which smoking is considered to be a risk factor can be found at: www.copdgene.org/smoking-related-disorders.
Health/Medical/Biomedical: Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Acknowledgement Statement : This research used data generated by the COPDGene study, which was supported by NIH grants U01 HL089856 and U01 HL089897. The COPDGene project is also supported by the COPD Foundation through contributions made by an Industry Advisory Board comprised of Pfizer, AstraZeneca, Boehringer Ingelheim, Novartis, and Sunovion.

In addition, when using the GO-ESP: Lung Cohorts Exome Sequencing Project: COPDGene dataset(s), please add:
This study is part of the NHLBI Grand Opportunity Exome Sequencing Project (GO-ESP). Funding for GO-ESP was provided by NHLBI grants RC2 HL103010 (HeartGO), RC2 HL102923 (LungGO) and RC2 HL102924 (WHISP). The exome sequencing was performed through NHLBI grants RC2 HL102925 (BroadGO) and RC2 HL102926 (SeattleGO).

Name : Health/Medical/Biomedical

Consent Group # : 1

Abbreviation : HMB

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Name : Disease-Specific (COPD and Smoking)

Consent Group # : 2

Abbreviation : DS-CS

Use of the data must be related to COPD and Smoking.

Data Use Limitation : The full list of diseases or conditions for which smoking is considered to be a risk factor can be found at: www.copdgene.org/smoking-related-disorders.

phs000615 : The CIDR NINDS International Stroke Genetics Consortium Study

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Institute of Neurological Disorders and Stroke

Important Contacts : ninds-dac@mail.nih.gov; zhangr@mail.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

Acknowledgement Statement : INSTRUCTIONS: This study has not provided a suggested acknowledgement statement. However, Approved Users are expected to acknowledge the Submitting Investigator(s) who submitted data from the original study to an NIH-designated data repository, the primary funding organization that supported the Submitting Investigator(s), and the NIH-designated data repository (e.g., dbGaP). The acknowledgment statement should include the dbGaP accession number to the specific version of the dataset(s) analyzed.

Name : Disease-Specific (Stroke, NPU)

Consent Group # : 2

Abbreviation : DS-STK-NPU

Data Use Limitation : Use of the data must be related to Stroke.
Use of the data is limited to not-for-profit organizations.

Stroke Academic Research Use Only. Limited to academic research on stroke, including stroke risk factors.

Name : General Research Use (NPU)

Consent Group # : 3

Abbreviation : GRU-NPU

Data Use Limitation : Use of the data is limited only by the terms of the model Data Use Certification.
Use of the data is limited to not-for-profit organizations.

phs000956 : NHLBI TOPMed: Genetics of Cardiometabolic Health in the Amish

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : Use of these data is limited to health/medical/biomedical purposes. The data can be used only for health related research, including research to improve methods for health related research. It is not permissible to use the genetic or relationship information to attempt to identify these individuals or to link these data to other databases (e.g., the Anabaptist Genealogy Database). These data may not be used for analyses whose primary purpose is to study population origins or ancestry or for the study of inbreeding, non-paternity rates, etc. without the express approval of the Amish study PI. Requestor must provide documentation of local IRB approval (please note only full or expedited approvals will be accepted).

Acknowledgement Statement : The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements.
In addition please include:
The Amish studies upon which these data are based were supported by NIH grants R01 AG18728, U01 HL072515, R01 HL088119, R01 HL121007, and P30 DK072488. See publication: PMID: 18440328

Name : Health/Medical/Biomedical (IRB, MDS)

Consent Group # : 2

Abbreviation : HMB-IRB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

Use of these data is limited to health/medical/biomedical purposes. The data can be used only for health related

research, including research to improve methods for health related research. It is not permissible to use the genetic or relationship information to attempt to identify these individuals or to link these data to other databases (e.g., the Anabaptist Genealogy Database). These data may not be used for analyses whose primary purpose is to study population origins or ancestry or for the study of inbreeding, non-paternity rates, etc. without the express approval of the Amish study PI.

phs001412 : NHLBI TOPMed: Diabetes Heart Study (DHS) African American Coronary Artery Calcification (AA CAC)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term :

There are two consent groups for this study: (1) HMB-IRB-COL-NPU and (2) DS-DHD-COL-NPU.

(1) For HMB-IRB-COL-NPU:
Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor must provide documentation of local IRB approval (please note only full or expedited approvals will be accepted). Requestor must provide a letter of collaboration with the primary study investigator(s). Use of the data is limited to not-for-profit organizations.

(2) For DS-DHD-COL-NPU:
Use of the data is limited to Type 2 Diabetes and Cardiovascular Disease. Requestor must provide documentation of local IRB approval (please note only full or expedited approvals will be accepted). Requestor must provide a letter of collaboration with the primary study investigator(s). Use of the data is limited to not-for-profit organizations.

Acknowledgement Statement : The TOPMed acknowledgement statement can be found at: https://topmed.nhlbi.nih.gov/acknowledgements . In addition please include: "The investigators acknowledge the cooperation of our Diabetes Heart Study (DHS) and AA-DHS participants. This work was supported by NIH R01 DK071891, HL67348, HL092301 and the General Clinical Research Center of Wake Forest School of Medicine M01-RR-07122."

Name : Health/Medical/Biomedical (IRB, COL, NPU)

Consent Group # : 1

Abbreviation : HMB-IRB-COL-NPU

Data Use Limitation :
Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Requestor must provide a letter of collaboration with the primary study investigator(s).
Use of the data is limited to not-for-profit organizations.

Name : Disease-Specific (Diabetes and Heart Disease, IRB, COL, NPU)

Consent Group # : 2

Abbreviation : DS-DHD-IRB-COL-NPU

Data Use Limitation :
Use of the data must be related to Diabetes and Heart Disease.
Requestor must provide documentation of local IRB approval.
Requestor must provide a letter of collaboration with the primary study investigator(s).
Use of the data is limited to not-for-profit organizations.

Use of the data is limited to Type 2 Diabetes and Cardiovascular Disease.

phs001013 : Heart and Vascular Health Study (HVH)

Public Posting of Genomic Summary Results - Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term :

There are two consent groups for this study - Health/Medical/Biomedical (HMB-IRB-MDS) and Disease-Specific Cardiovascular (DS-CVD-IRB-MDS).

For HMB-IRB-MDS: Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Requestor must provide documentation of local IRB approval. Use of the data

includes methods development research (e.g., development of software or algorithms).

For DS-CVD-IRB-MDS - Use of the data must be related to Cardiovascular Disease. Requestor must provide documentation of local IRB approval. Use of the data includes methods development research (e.g., development of software or algorithms).

The acknowledgment of the Heart and Vascular Health Study should always include the statement below, along with the relevant dbGaP accession number(s).

Acknowledgement Statement : The research reported in this article was supported by grants HL068986, HL085251, HL095080, and HL073410 from the National Heart, Lung, and Blood Institute. This manuscript was not prepared in collaboration with Heart and Vascular Health (HVH) Study investigators, and does not necessarily reflect the opinions or views of the HVH Study or the NHLBI.

Name : Health/Medical/Biomedical (IRB, MDS)

Consent Group # : 1

Abbreviation : HMB-IRB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Disease-Specific (Cardiovascular Disease, IRB, MDS)

Consent Group # : 2

Abbreviation : DS-CVD-IRB-MDS

Data Use Limitation : Use of the data must be related to Cardiovascular Disease.
Requestor must provide documentation of local IRB approval.
Use of the data includes methods development research (e.g., development of software or algorithms).

phs000287 : Cardiovascular Health Study (CHS) Cohort

Public Posting of Genomic Summary Results - Not Allowed.

NIH Data Access Committee (DAC) : National Heart, Lung, and Blood Institute DAC

Important Contacts : nhlbigeneticdata@nhlbi.nih.gov; GDS@mail.nih.gov

In the event of a data management incident, within 24 hours, please contact emails above.

IC Specific Access Term : CHS consents allowed for use of the data by four consent groups:
1) health/medical/biomedical research, including methods development (HMB-MDS),
2) health/medical/biomedical research, including methods development, by not-for profit organizations only (HMB-NPU),
3) cardiovascular disease research, including methods development (DS-CVD-MDS), and
4) cardiovascular disease research, including methods development, by not-for-profit organizations only (DS-CVD-NPU-MDS).

Acknowledgement Statement : link

Name : Health/Medical/Biomedical (MDS)

Consent Group # : 1

Abbreviation : HMB-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Health/Medical/Biomedical (NPU, MDS)

Consent Group # : 2

Abbreviation : HMB-NPU-MDS

Data Use Limitation : Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Use of the data is limited to not-for-profit organizations.
Use of the data includes methods development research (e.g., development of software or algorithms).

Name : Disease-Specific (Cardiovascular Disease, MDS)

Consent Group # : 3

Abbreviation : DS-CVD-MDS

Data Use Limitation	:	Use of the data must be related to Cardiovascular Disease. Use of the data includes methods development research (e.g., development of software or algorithms).
Name	:	Disease-Specific (Cardiovascular Disease, NPU, MDS)
Consent Group #	:	4
Abbreviation	:	DS-CVD-NPU-MDS
Data Use Limitation	:	Use of the data must be related to Cardiovascular Disease. Use of the data is limited to not-for-profit organizations. Use of the data includes methods development research (e.g., development of software or algorithms).

IRB CONTINUING REVIEW APPROVAL

July 17, 2023

Dear Kenneth Rice:

On 7/17/2023, University of Washington IRB Committee <J> reviewed the following application:

Type of Review:	Continuing Review
Title of Study:	Polygenic Risk Methods in Diverse Populations (PRIMED) Consortium Coordinating Center
Investigator:	Kenneth Rice
STUDY ID	STUDY00014711
CR ID:	CR00007514
Funding:	Name: National Human Genome Research Institute (NHGRI), Grant Office ID: A157210, Funding Source ID: U01HG011697 Funding Title(s): "Polygenic Risk Score Diversity Consortium Coordinating Center"
IND, IDE, or HDE:	None

IRB Approval

Under FWA #00006878, the IRB renewed approval for your activity from 7/17/2023 to 7/16/2024.

- Your application qualified for expedited review ("minimal risk"; Category <5>).
- Tracking IRB approval periods and preventing a lapse is the researcher's responsibility. However, the Zipline system sends automated courtesy reminders prior to expiration of approval. If a renewal application or study closure is not received within 90 days of expiration, HSD may administratively close the study. In some circumstances, HSD may refuse to review additional submissions from the researcher until a status report is received, lapsed IRB approval may be considered continuing non-compliance, and the study may be "terminated" by the IRB.

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

ELIZABETH FALSBERG, PhD
Team Operations Lead, IRB Committee J
(phone) 206-543-0639
(email) falsberg@uw.edu

Wake Forest™
School of Medicine
1 Medical Center Boulevard
Winston-Salem, NC 27157

July 18, 2023

Kenneth M. Rice
PI, PRIMED Coordinating Center
University of Washington
Email: kenrice@uw.edu

Dear Dr. Kenneth Rice,

We are supportive of your plans to use data from the Diabetes Heart Study to facilitate the development and evaluation of Polygenic Risk Scores (PRS) in diverse ancestry populations as part of the NIH-funded Polygenic Risk Methods in Diverse Populations (PRIMED) Consortium. We understand that you are applying for TOPMed phs001412 in dbGaP as part of a coordinated PRIMED dbGaP application and provide this letter to satisfy the requirement posed by the -COL consent modifier for phs001412. We understand that these study data will be used for collaborative analyses in PRIMED, which are primarily being conducted in Consortium workspaces on the NHGRI-designated repository and cloud platform AnVIL (Analysis, Visualization, and Informatics Lab-space). Only investigators with similarly approved data access requests for this study will be able to access the data in a given Consortium workspace.

We also understand that your use of these data fall within scope of the PRIMED approved Research Use Statement—use of phenotypic and genomic data from existing datasets to generate and refine polygenic risk scores (PRS) for populations of diverse race, ethnicities, and genetic ancestry—and that participant consent and data use limitations will be respected in all cases.

In addition, we give this approval conditional on acceptance of the spirit of collaboration regarding issues of DHS study-specific findings. That is, if a novel variant(s) with an effect on one of the phenotypes is identified in DHS study-specific exploratory and/or QC-type analysis we would be informed and have the chance to discuss being able to then move forward on our own with that DHS-specific finding. Your larger cross-study group effort, which found the interesting study-specific results, would be recognized as authors, of course.

For subsequent annual renewals of this collaboration letter, I am willing to indicate renewal with an email confirmation in lieu of a new, formally signed letter.

Sincerely,

Donald W. Bowden
Professor, Biochemistry

Barry I. Freedman
Professor, Nephrology

Wake Forest™
School of Medicine
1 Medical Center Boulevard
Winston-Salem, NC 27157

August 25, 2022

Kenneth M. Rice
PI, PRIMED Coordinating Center
University of Washington
Email: kenrice@uw.edu

Dear Dr. Kenneth Rice,

We are supportive of your plans to use data from the Diabetes Heart Study to facilitate the development and evaluation of Polygenic Risk Scores (PRS) in diverse ancestry populations as part of the NIH-funded Polygenic Risk Methods in Diverse Populations (PRIMED) Consortium. We understand that you are applying for TOPMed phs001412 in dbGaP as part of a coordinated PRIMED dbGaP application and provide this letter to satisfy the requirement posed by the -COL consent modifier for phs001412. We understand that these study data will be used for collaborative analyses in PRIMED, which are primarily being conducted in Consortium workspaces on the NHGRI-designated repository and cloud platform AnVIL (Analysis, Visualization, and Informatics Lab-space). Only investigators with similarly approved data access requests for this study will be able to access the data in a given Consortium workspace.

We also understand that your use of these data fall within scope of the PRIMED approved Research Use Statement—use of phenotypic and genomic data from existing datasets to generate and refine polygenic risk scores (PRS) for populations of diverse race, ethnicities, and genetic ancestry—and that participant consent and data use limitations will be respected in all cases.

In addition, we give this approval conditional on acceptance of the spirit of collaboration regarding issues of DHS study-specific findings. That is, if a novel variant(s) with an effect on one of the phenotypes is identified in DHS study-specific exploratory and/or QC-type analysis we would be informed and have the chance to discuss being able to then move forward on our own with that DHS-specific finding. Your larger cross-study group effort, which found the interesting study-specific results, would be recognized as authors, of course.

For subsequent annual renewals of this collaboration letter, I am willing to indicate renewal with an email confirmation in lieu of a new, formally signed letter.

Sincerely,

Donald W. Bowden
Professor, Biochemistry

Barry I. Freedman
Professor, Nephrology

Printed on: 10/04/2023

PRIMED Eligibility List

The PRIMED *Eligibility List (EL)* below is the list of investigators eligible to enter into PRIMED Consortium-wide data sharing mechanisms (e.g., eligible to submit a PRIMED Coordinated dbGaP application or eligible to be an investigator signatory on the PRIMED Consortium Data Sharing Agreement, CDSA). For PRIMED Coordinated dbGaP applications, the EL doubly serves as the External Collaborators List, to be appended to PRIMED Coordinated dbGaP applications in lieu of manually inputting names and institutions for collaborator applicants from other institutions (as described in the Instructions for PRIMED Coordinated dbGaP Applications).

Date of last addition or removal: 9/27/2023

Name	Institution(s)	Study Site or Center
Sally Adebamowo	University of Maryland Baltimore	CARDINAL
Paul Auer	Medical College of Wisconsin	EPIC-PRS
Ran Barzilay	Children's Hospital of Philadelphia, University of Pennsylvania	Affiliate Member
Stephen Chanock	National Institutes of Health	PRIMED-Cancer
David Conti	University of Southern California	PRIMED-Cancer
Nancy Cox	Vanderbilt University Medical Center	D-PRISM, EPIC-PRS
LaShaunta "Tay" Glover	Duke University	Affiliate Member
Eimear Kenny	Mount Sinai	CAPE
Peter Kraft	National Institutes of Health	PRIMED-Cancer
Iftikhar Kullo	Mayo Clinic	PREVENT
Leslie Lange	University of Colorado	CAPE
Loic Le Marchand	University of Hawai'i Cancer Center	PRIMED-Cancer
Yun Li	University of North Carolina at Chapel Hill	EPIC-PRS
Alisa Manning	Broad Institute	D-PRISM, Affiliate Member
Rasika Mathias	Johns Hopkins University	EPIC-PRS
Josep Mercader	Broad Institute	D-PRISM, Affiliate Member
Pradeep Natarajan	Broad Institute	FFAIRR-PRS
Maggie Ng	Vanderbilt University Medical Center	D-PRISM
Bogdan Pasaniuc	University of California Los Angeles	CAPE
Ulrike "Riki" Peters	Fred Hutchinson Cancer Center	PRIMED-Cancer
Alexander "Alex" Reiner	Fred Hutchinson Cancer Center	EPIC-PRS

Name	Institution(s)	Study Site or Center
Kenneth "Ken" Rice	University of Washington	CC
Lori Sakoda	Kaiser Permanente	PRIMED-Cancer
Dan Schaid	Mayo Clinic	PREVENT
Bamidele Tayo	Loyola University of Chicago	CARDINAL
John Witte	Stanford University	PRIMED-Cancer
Lisa Yanek	Johns Hopkins University	EPIC-PRS