GAIN Data Access Experience

Emily L. Harris, PhD, MPH
Chair, GAIN Data Access Committee
Epidemiologist, Office of Population Genomics

GAIN Analysis Workshop II
October 18, 2007

GAIN Design & Overview

Data Collection

Submission & Management of Data

Distribution & Secondary Use of Data

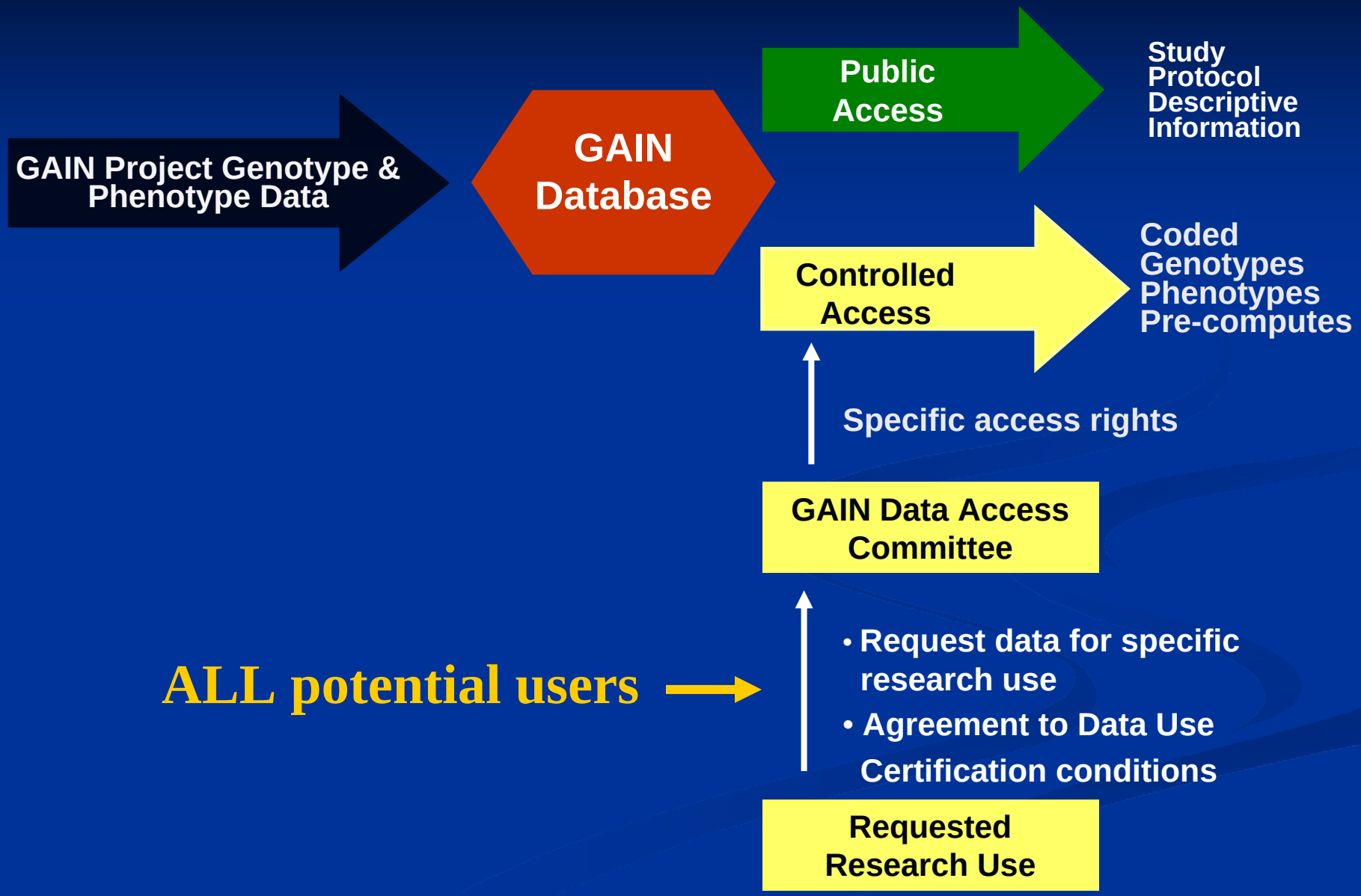
Research Participants

Submitting Investigators

GAIN Database

Recipient Investigators

GAIN Data Access Overview



Request & Review Process

- PI completes Data Access Request (DAR)
- Institutional signing official (SO) approves DAR
- DAR posted in dbGaP for GAIN DAC review
- Staff reviews DAR and clarifies any issues
- DAC reviews DAR and makes decision to approve or disapprove
- DAC Chair records decision in dbGaP, which notifies PI and SO of decision

dbGaP Home - Microsoft Internet Explorer

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Address http://www.ncbi.nlm.nih.gov/sites/entrez?db=gap

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All Databases PubMed Nucleotide Protein Genome Structure

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Security Procedures
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Publications
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Other Services

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Clinical Queries

Browse dbGaP

By Studies | By Diseases | Advanced Search

Study	Embargo Release	Variables
Collaborative Association Study of Psoriasis	July 30, 2008	-
Framingham SHARe	October 1, 2008	13183
Genotyping the 270 HapMap samples for GAIN by Broad		-
Genotyping the 270 HapMap samples for GAIN by Perlegen		-
International Multi-Center ADHD Genetics Project	March 26, 2008	438
LEAPS		-
Linking Genome-Wide Association Study of Schizophrenia	August 1, 2008	-
Major Depression: Stage 1 Genomewide Association in Population-Based Samples	July 9, 2008	228
NEI Age-Related Eye Disease Study (AREDS)	June 11, 2007	174
NINDS Parkinson's Disease	October 12, 2007	109
NINDS Parkinsonism Study	October 12, 2007	43

Collaborative Association Study of Psoriasis

Accession: phs000019.v1.p1

Description

The goal of this collaborative study is to combine the resources and expertise of three groups with long-standing studies of psoriasis gene
in order to identify new genetic susceptibility factors for psoriasis, a common inflammatory skin disease that affects over 4 million America

CASP - Collaborative Association Study of Psoriasis

GAIN The Genetic Association Information Network

National Institute of Arthritis and Musculoskeletal and Skin Diseases

- Participants: 2956
- Type: Case-control

Individual-Level Data

- **Use restrictions**
  - **Consent Groups**

    General Research Use (GRU)
    - May be used for any genetic studies.
    - This consent group does not require IRB approval.
    - Participant set: 1678

    Autoimmune Disease Only (ADO)
    - Limited to genetic studies of autoimmune disease.
    - This consent group does not require IRB approval.
    - Participant set: 1224

- Estimated Availability October 30, 2007. Apply here for controlled access to individual level data when available.
- Embargo Release Date: July 30, 2008

Publicly Available Data (Public ftp)

- Estimated Availability October 30, 2007

dbGaP Authorized Access is the management portal for individual-level data.

Authorized users can use this site to submit a data access request, manage access requests, and download approved data sets.

Log in to the Authorized access system.

Help

In order to apply for authorized access to dbGaP studies you must have one of the following accounts:

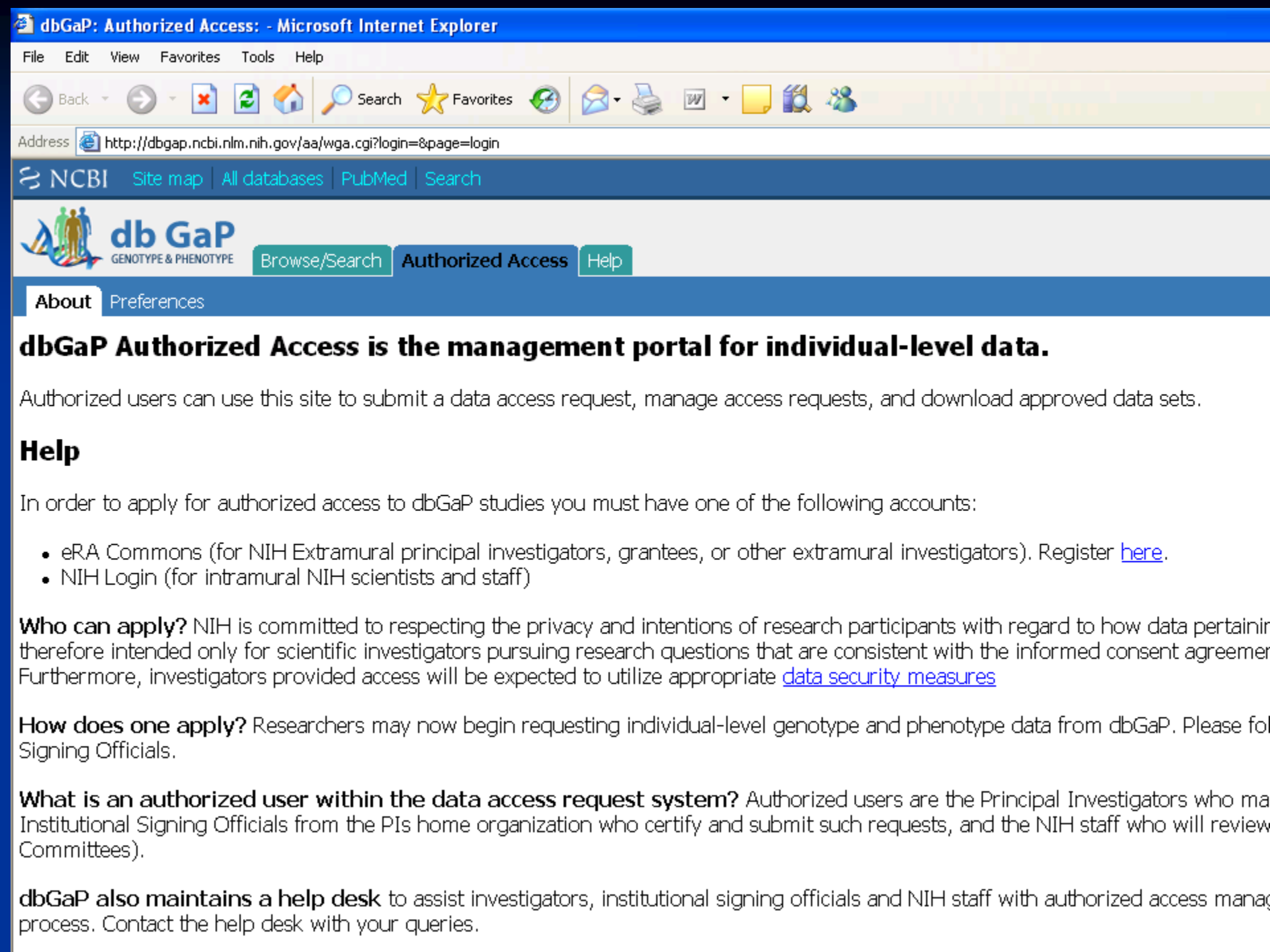
- eRA Commons (for NIH Extramural principal investigators, grantees, or other extramural investigators). Register here.
- NIH Login (for intramural NIH scientists and staff)

Who can apply? NIH is committed to respecting the privacy and intentions of research participants with regard to how data pertaining to their individual information is used. Data access is therefore intended only for scientific investigators pursuing research questions that are consistent with the informed consent agreements provided by individual research participants. Furthermore, investigators provided access will be expected to utilize appropriate data security measures

How does one apply? Researchers may now begin requesting individual-level genotype and phenotype data from dbGaP. Please follow request procedures for Principal Investigators and Signing Officials.

What is an authorized user within the data access request system? Authorized users are the Principal Investigators who may request data sets for specific research uses, the Institutional Signing Officials from the PIs home organization who certify and submit such requests, and the NIH staff who will review and process requests (e.g., members of the Data Access Committees).

dbGaP also maintains a help desk to assist investigators, institutional signing officials and NIH staff with authorized access management, and answer any questions related to the application process. Contact the help desk with your queries.


dbGaP: Authorized Access: - Microsoft Internet Explorer
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Address http://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?login=&page=login
NCBI Site map | All databases | PubMed | Search
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Authorized Access
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About
Preferences
dbGaP Authorized Access is the management portal for individual-level data.
Authorized users can use this site to submit a data access request, manage access requests, and download approved data sets.
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Online Registration - Microsoft Internet Explorer

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Address https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp;

Electronic Research Administration

eRA Commons

Sponsored by National Institutes of Health

Version 2.11.2.2

Home Links eRA Partners Help

Online Registration

Only Signing Officials can register their institutions with the NIH. Follow these directions to register your institution.

1. Complete the online Institution Registration Form and click Submit. A screen appears with information about NIH registration and the institution data entered in the Registration form.

2. Print the registration page, make any corrections and affix your signature as designated.

3. Fax the registration page to the number at the top of the page.

   NIH will validate the information your institution submitted for approval and send a verification email to the Signing Official (SO).

4. Reply to the verification e-mail.

   Upon receipt of the verification email, the NIH sets up your institution account, and sends an email to the SO with a link to a page showing their NIH institution name and associated information.

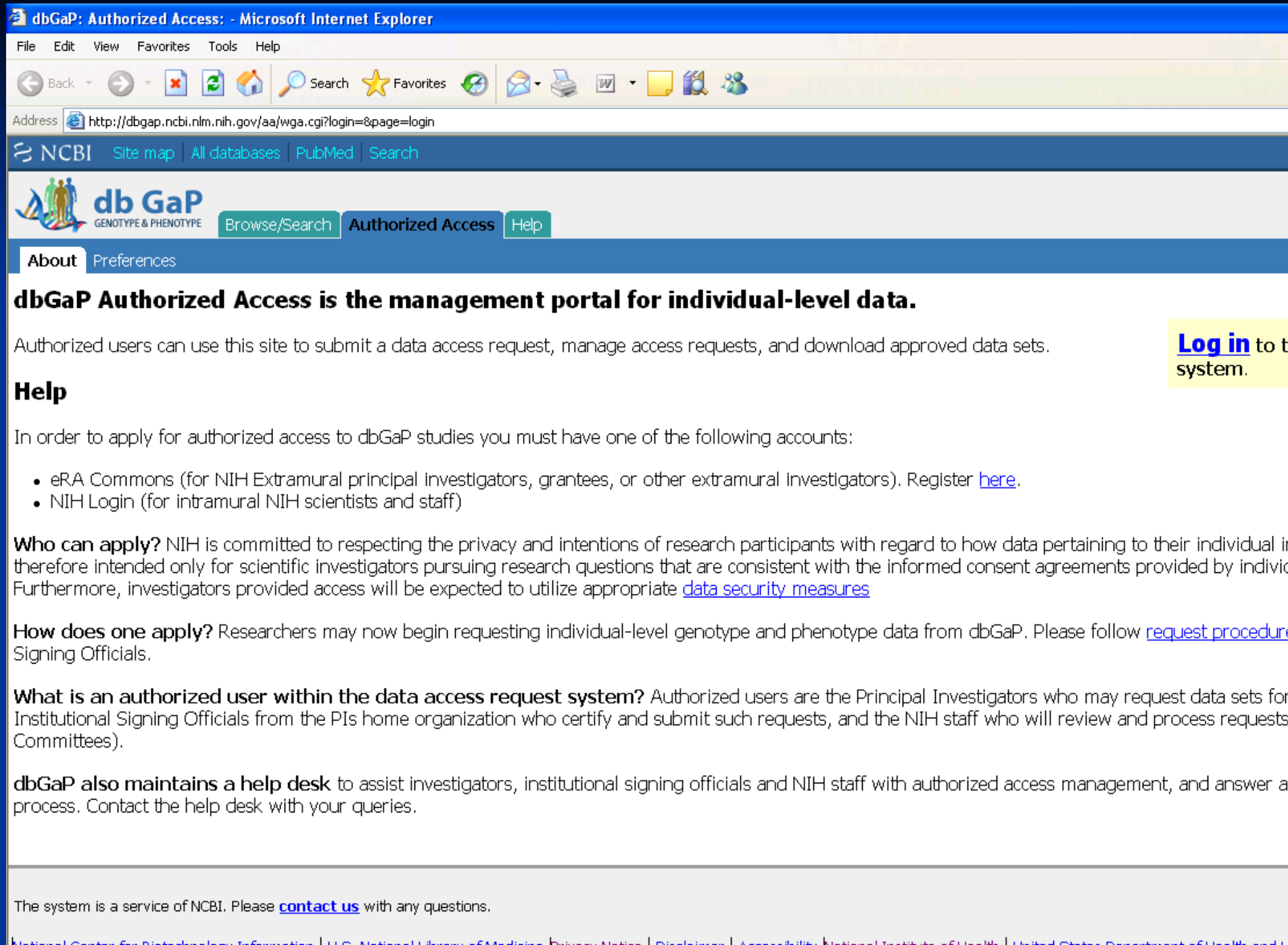
5. Verify that all information is correct.

6. Send confirmation response to this information and proceed.

7. Receive email notification of registered SO account (userid/password) from the NIH.

8. Create and maintain additional accounts for your institution staff.

Register Now


dbGaP: Authorized Access: - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?login=&page=login
NCBI Site map | All databases | PubMed | Search
db GaP
GENOTYPE & PHENOTYPE
Browse/Search
Authorized Access
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About
Preferences
dbGaP Authorized Access is the management portal for individual-level data.
Authorized users can use this site to submit a data access request, manage access requests, and download approved data sets.
Log in to th
system.
Help
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Committees).
dbGaP also maintains a help desk to assist investigators, institutional signing officials and NIH staff with authorized access management, and answer ar
process. Contact the help desk with your queries.
The system is a service of NCBI. Please contact us with any questions.

Genotype and Phenotype Data Now Available from the NCBI dbGaP Database

Request Process Involves New Procedures for Principal Investigators and Signing Officials

Researchers may now begin requesting individual-level genotype and phenotype data from dbGaP, the database of Genotype and Phenotype. The database, which was developed and is operated by the National Library of Medicine's National Center for Biotechnology Information (NCBI), archives and distributes data from studies that have investigated the relationship between phenotype and genotype, such as genome-wide association studies (GWAS).

dbGaP provides for two levels of access: open (available to anyone with no restrictions), and controlled (requiring preauthorization). NCBI launched the database in December 2006 with the open-access data on two studies; the open-access section allows users to view study documents, such as protocols, as well as summaries of the genotype and phenotype data. The controlled-access portion of the database is just now coming online; with authorization, it provides for downloads of individual-level genotype and phenotype data that have been de-identified (i.e., no personal identifiers, such as name, etc.).

Beginning on or around May 24, researchers may request access to the individual-level data from several studies: the Age-Related Eye Diseases Study (AREDS) on macular degeneration and cataracts, the National Institute of Neurological Disorders and Stroke Parkinsonism Study, and six studies conducted under the Genetic Association Information Network (GAIN). The data from AREDS, the Parkinsonism Study, and a GAIN study on an attention deficit hyperactivity disorder are expected to be available for download around June 9. Data from the other five GAIN studies will be rolled out over the next six months as they become available. Additionally, there will be many other studies added to dbGaP in the future, including the Framingham SHARe Study, which is associating genotype data with phenotype information collected in the landmark Framingham Heart Study.

The data request process

In order to request access to any of the individual-level datasets within the Controlled Access portions of the database, the Principal Investigator (PI) and the Signing Official (SO) at the

Data Access Request

Uses SF 424 (R&R) electronic submission form

- Authentication through eRA Commons login.
- Completed through web-based request process developed by NCBI.
- Requires research use statement, and request for access to a specific dataset(s).
- Requires investigator & institutional signing official to sign assurance that GAIN policies will be followed.
  - Agreement to terms of use (DUC) through the submission of access request.
  - Includes assurance that the home institution has considered participant protection issues (if any) and agrees that the research can go forward.

dbGaP Data Access Request

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

2. DATE SUBMITTED	Applicant Identifier
3. DATE RECEIVED BY STATE	State Application Identifier
4. Federal	

1. * TYPE OF SUBMISSION

☐ Pre-application ☐ Application
☐ Changed/Corrected Application

5. APPLICANT INFORMATION *** Organizational DUNS:**

* Legal Name:
Department: Division:
* Street1: Street2:
* City: County: * State: * ZIP Code:
* Country:

Person to be contacted on matters involving this application
Prefix: * First Name: Middle Name:
* Phone Number: Fax Number:

6. * EMPLOYER IDENTIFICATION *(EIN) or (TIN)*:

Research Plan

Provide below a brief Research Use Statement for the requested dataset(s), as well as a non-technical summary of this statement. The Research Use Statement will be reviewed by all NIH programs with data covered by the access request. Each program will compare this statement against the *Limitations of Use* for the respective dataset(s), which reflect the informed consent provided by the the individuals that participated in the original study.

When access is approved, the Research Use Statement and non-technical summary will be included on the dbGaP website to describe your research project to the public.

Please enter your Research Use Statement in the area below.

Research & Related Senior/Key Person Profile

List of other Independent Collaborating Investigators at the same organization. Complete this list with only Co-PIs at your organization. Any collaborators at different organizations must complete separate requests per institution. By submitting an individul's name on the form below, requestors and Institutional Signing Officials affirm that the co-PIs have read and agreed to the terms and statements within the Data Use Certification.

INVESTIGATOR 1

Prefix: First Name: Middle Name: Last Name: Suffix:
Position/Title:
Phone Number: Fax Number: Email:

INVESTIGATOR 2

Genetic Association Information Network (GAIN)
Data Use Certification

Version date 14May2007

Introduction and Statement of Policy

The Genetic Association Information Network (GAIN) is a public–private partnership formed with the goal of identifying genetic variants that contribute to diseases of major public health importance by catalyzing genome-wide association analyses on samples from existing studies that include large numbers of affected and unaffected individuals. GAIN is founded on the principle that scientific progress will be most efficient and innovative if data are readily available to all investigators in the research community. Contributing Study Investigators who provide phenotype data and DNA samples from participants to a GAIN Project have committed to this principle and their professional investments and intellectual contributions will be fundamental to the ultimate success of GAIN.

GAIN Project Datasets (genotype-phenotype datasets along with pre-computed calculations of the datasets themselves) to be distributed under this certification process will be coded; the GAIN Database will not receive personal identifying information. However, due to the extensive phenotype and genotype data included, GAIN Project Datasets will be provided to investigators who, along with their institutions, have certified their agreement with the requirements and terms of access detailed below. It is the intent of the GAIN Steering Committee that Approved Users of GAIN Project Datasets should recognize the limitations imposed by the original informed consent agreements of Contributing Studies as listed on the GAIN Database.

Terms of Access

1. Requesting Investigator ("Requestor")

The Requestor has reviewed and understands the guiding principles for responsible research use and data handling of the genotype and phenotype data included within Gain Project Datasets as described in the on-line material provided through the GAIN website.

2. Research Use

The Requestor agrees that he/she shall use the GAIN Project Dataset solely in connection with the research project described in the Data Access Request, which includes the project title, the Requestor's name and institution, the names of any independent collaborators and their institutions, a 1-2 paragraph description of the research objectives and design, and a brief analysis plan (Research Plan Attachment). New uses of these data outside those described

above will require submission of a new application; substantive modifications to the research project will require submission of an amendment to this application. The Requestor further agrees that he/she shall use the GAIN Project Dataset(s) only in accordance with the

Request & Review Process

- PI completes Data Access Request (DAR)
- Institutional signing official (SO) approves DAR
- DAR posted in dbGaP for GAIN DAC review
- Staff reviews DAR and clarifies any issues
- DAC reviews DAR and makes decision to approve or disapprove
- DAC Chair records decision in dbGaP, which notifies PI and SO of decision

Primary Considerations

- Data Access Request complete and consistent with requirements
- Proposed research use consistent with any data use limitations
- Any potential unanticipated group harms considered

Data Access Committee Membership

Regular	Emily Harris (Chair)	NHGRI
	Christine Grady	NIH Clinical Center
	Thomas Lehner	NIMH
	Catherine McKeon	NIDDK
	Joel Moss	NHLBI
	Bradley Ozenberger	NHGRI
	William Sharrock	NIAMS
	Vaurice Starks	NCI
Ex-officio	Teri Manolio	NHGRI
	Laura Lyman Rodriguez	NHGRI
Staff	Lisa McNeil	NHGRI
	Erin Ramos	NHGRI

Search for Susceptibility Genes for Diabetic Nephropathy in Type 1 Diabetes

Accession: phs000018.v1.p1

Description

Genetics of Kidneys in Diabetes (GoKinD) study is an initiative aimed at identifying susceptibility genes for diabetic nephropathy in type 1 diabetes. A large number of individuals with type 1 diabetes were screened to identify two subsets, one with clear-cut kidney disease and another with normal renal status despite long-term diabetes. Those who met additional entry criteria and consented to participate were enrolled. When possible, both parents were also enrolled to form family trios. Altogether, GoKinD includes 3043 participants comprising 931 cases, 944 singletons, 268 pairs of parents of cases, and 316 pairs of parents of control. Accessible as a GAIN database are 905 of the cases, 890 of the controls, 10 pairs of parents of cases and 10 pairs of parents of controls. The other parents and the remaining cases and controls are available by a separate application process through NIDDK. Interested investigators may request the DNA collection and corresponding clinical data for GoKinD participants using the instructions and application form available at http://www.gokind.org/access or by contacting the Juvenile Diabetes Research Foundation.

GAIN The Genetic Association Information Network

GoKinD

- Participants: 1825
- Type: Case-control

Individual-Level Data

- **Use restrictions**
  - **Consent Group**

    Type 1 diabetes and its complications (Diabetic complications only, DCO)
    - Limited to genetic research on type 1 diabetes and its complications. Complications include nephropathy, cardiovascular disease, retinopathy, neuropathy, and mortality. Phenotypes related to diabetes and its complications, such as body mass index, blood pressure, lipids, and hemoglobin A1c, may also be studied.
    - This consent group does not require IRB approval.
    - Participant set: 1825

- Data Use Certification Requirements (DUC)
  Apply here for controlled access to individual level data
- Embargo Release Date: July 16, 2008

Publicly Available Data (Public ftp)

- Connect to ftp site

Inclusion/Exclusion Criteria

Inclusion criteria

Probands for this data collection must have type 1 diabetes and either presence or absence of diabetic nephropathy according to the following definitions:

Type 1 diabetes is diagnosed if:
- Subject had diabetes diagnosed before age 31
- Treatment with insulin was instituted within one year of diagnosis

Search Within This Study
Search for: Go

Associated Variables
Search for Susceptibility Genes for Diabetic Nephropathy in Type 1 Diabetes
Sociodemography and Administration
Affection Status
Physical Observations
Laboratory Tests

Associated Documents
Search for Susceptibility Genes for Diabetic Nephropathy in Type 1 Diabetes
Questionnaires
Support Documents

- Centers for disease Control and Prevention, Atlanta, GA, USA.
- University of Minnesota, Minneapolis, MN, USA.
- Juvenile Diabetes Research Foundation, New York, NY, USA.

Authorized Data Access Requests

1. **Requestor:** BARMADA, MAHMUD
   Affiliation: UNIVERSITY OF PITTSBURGH AT PITTSBURGH
   Project: Control Comparisons
   Date project was started: 2007-08-24
   Show project summaries

2. **Requestor:** Bull, Shelley
   Affiliation: MT SINAI HOSP-SAMUEL LUNENFELD RES INST
   Project: Genome-wide association of common alleles wirh long-term diabetic complications
   Date project was started: 2007-08-15
   Show project summaries

3. **Requestor:** COX, NANCY
   Affiliation: UNIVERSITY OF CHICAGO
   Project: Genetic Studies of Diabetic Complications
   Date project was started: 2007-07-25
   Show project summaries

4. **Requestor:** Friddle, Carl
   Affiliation: LEXICON PHARMACEUTICALS, INC.
   Project: SNP Association of Candidate Genes for Type 1 Diabetes and Obesity
   Date project was started: 2007-07-02
   Show project summaries

5. **Requestor:** HIRSCHHORN, JOEL
   Affiliation: Massachusetts Institute of Technology
   Project: Genetics of Diabetic Complications
   Date project was started: 2007-08-30
   Show project summaries

6. **Requestor:** HOH, JOSEPHINE
   Affiliation: YALE UNIVERSITY
   Project: Gene-gene and gene-environmental interactions in complex human traits
   Date project was started: 2007-07-18
   Show project summaries

7. **Requestor:** Koller, Daphne
   Affiliation: STANFORD UNIVERSITY
   Project: Probabilistic Models for Individual Variation in Human Genotype Data
   Date project was started: 2007-08-09
   Show project summaries

Authorized Data Access Requests

1. **Requestor:** BARMADA, MAHMUD
   Affiliation: UNIVERSITY OF PITTSBURGH AT PITTSBURGH
   Project: Control Comparisons
   Date project was started: 2007-08-24
   Show project summaries

2. **Requestor:** Bull, Shelley
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   - **Public Summary:** Type 1 diabetes mellitus is a major health problem affecting millions of people worldwide. Despite extensive attempts at clinical management of type 1 diabetes, many patients will develop long-term complications including eye, kidney, nerve, and heart disease. Using a combination of laboratory and statistical analyses, we aim to identify the genes that contribute to the differences in risk of diabetic complications by studying DNA samples provided by a study of diabetic nephropathy, GoKinD, (an 'extreme case' 'extremecontrol' study). We will use clinical data and appropriate risk factors from the GoKinD study. We will test about 550,000 common variations in the genome across the whole of the genome for association with retinal and renal complications of type 1 diabetes. In addition, the same variations will be tested for association with risk factors for cardiovascular disease, intermediate measures of atherosclerosis and clinical neuropathy. Through this initiative, we will provide insights into the basic genetic mechanisms that underlie the long-term complications of type 1 diabetes. The information obtained will assist caregivers of individuals with type 1 diabetes predict the risk of developing specific diabetic complications, and may change treatment strategies, therapeutics, and prognosis for people with type 1 diabetes.
   - **Technical Summary:** Type 1 diabetes mellitus is a major health problem affecting millions of people worldwide. Despite extensive attempts at clinical management of type 1 diabetes, many patients will develop long-term complications including retinopathy, nephropathy, neuropathy and cardiovascular disease. Using a combination of laboratory and statistical analyses, we aim to identify the genes that contribute to the differences in risk of diabetic complications by studying DNA samples provided by a study of diabetic nephropathy, GoKinD, (an 'extreme case' 'extreme-control' study). We will use clinical data and appropriate risk factors from the GoKinD study. We will test about 500,000 common variations in the genome across the whole of the genome for association with retinal and renal complications of type 1 diabetes, as well as CNV's. In addition, the same variations will be tested for association with risk factors for cardiovascular disease, intermediate measures of atherosclerosis and clinical neuropathy. Through this initiative, we will provide insights into the basic genetic mechanisms that underlie the long-term complications of type 1 diabetes. The information obtained will assist caregivers of individuals with type 1 diabetes predict the risk of developing specific diabetic complications, and may change treatment strategies, therapeutics, and prognosis for people with type 1 diabetes.

3. **Requestor:** COX, NANCY
   Affiliation: UNIVERSITY OF CHICAGO
   Project: Genetic Studies of Diabetic Complications
   Date project was started: 2007-07-25
   Hide project summaries
   - **Public Summary:** A variety of the complications of diabetes have been shown to have a genetic component. Thus, we believe that identification and characterization of genetic factors influencing the risk of developing complications of diabetes would have great potential value for developing therapies to reduce, postpone or (ideally) eliminate such compications. We propose to conduct genome-wide association studies on case and control samples (cases with diabetes and complications and controls with diabetes but without complications) to identify genetic risk factors for complications of diabetes, including diabetic kidney disease, retinopathy, and cardiovascular disease. In addition, we are interested in learning more about the genetic risk factors for type 1 diabetes and autoimmune diseases (often more common in family members of an individual diagnosed with an autoimmune disease such as type 1 diabetes), and whether any of those genetic risk factors are also associated with risk of complications.
   - **Technical Summary:** We propose to use genotype and phenotype data that will enable us to identify and characterize genetic risk factors for diabetic complications, including but not necessarily limited to diabetic kidney disease, retinopathy, and cardiovascular disease, as well as risk factors for type 1 diabetes and other autoimmune diseases. We will conduct both case/control studies on unrelated individuals and family-based studies using trio data and will utilize data on both Americans of European descent and African Americans. We had already received permission to use the GoKiND phenotype data and DNA through application to GoKiND and NIDDK, as well as funding for the analyses of these data through DK077489, and are now making formal application to GAIN for the GoKiND samples, as well as other data sets that may be used to enable us to study the genetic basis of type 1 diabetes and other autoimmune disorders. These studies may allow us to identify genes with pleiotropic effects on both primary susceptibility to disease and risk of complications. As GoKiND samples all have type 1 diabetes, we would propose to utilize all other available European and African American samples that can be used as cases or controls for studies on type 1 diabetes and autoimmune disease, or with respect to diabetic complications, such as eye disease. Unfortunately, it seems that I am unable to assess an application that allows me to list more than 4 University of Chicago investigators on this project. I don't know what to do but add them

Data Access Activity

Through August 2007

GAIN/institutional affiliation of requestors

Type of requestor	Total Number	Number Domestic	Number Foreign
GAIN PI or collaborator	*5*	*3*	*2*
Not a GAIN PI or collaborator, from:	*15*	*14*	*1*
Academic institution	8	8	0
Pharmaceutical or biotechnology company	4	4	0
Other non-Federal research institution	2	1	1
Federal agency (e.g., NIH)	1	1	0

Time to decision for Data Access Requests

Step	Number of requests	Days elapsed (median, range)
Investigator submission to institutional approval	24	3, 0-17
Institutional approval to DAC decision	22	14, 9-34
Overall (investigator submission to DAC decision)	22	20, 9-38

Downloading Data

Dataset	Number of Approved Users	Number who have downloaded the dataset
ADHD	13	9

ADHD	Download activity for 9 dbGaP users with data (13 currently approved for ADHD)									
Component type	1	2	3	4	5	6	7	8	9	Total number of files for component
Genotype-calls-filtered	2	3	1	10	3	4			1	10
Genotype-calls-unfiltered	3			12		1	1			12
Genotype-intensities				78				78		78
Genotype-qc	1	1		1	1	1		1		1
Genotype-scatterplots				3						3
Linkage-disequilibrium				1						2
Phenotype-individual-traits	7	7	2	7	7	7		7		7
Use-contents	2	2	2	2	2	2	2	2	2	2
Use-restrictions	1	1	1	1	1	1	1	1	1	1

Challenges

- Request process
  - Questions about signing official approval process
  - Technical problems with dbGaP
  - Questions about data/data file
  - Questions about IRB review/approval
- Review process
  - Understanding the DAC's role in the overall process, and developing review procedures and material
  - Reviewing methodologic research
  - Considering potential group harms

Acknowledgments

- GAIN Data Access Committee members
- NCBI colleagues
- NHGRI colleagues
- Other NIH colleagues
- FNIH colleagues
- ACD Working Group (oversight group)
- GAIN Principal Investigators and collaborators
- GAIN dataset requestors and signing officials