

To: Institute and Center (I/C) Directors, Extramural Program Management Committee (EPMC), I/C Scientific Directors

From: Michael Gottesman, NIH Deputy Director for Intramural Research
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Date: February 6, 2008

Re: NIH Staff Requirements:
Requesting Access to Data in the NIH GWAS Data Repository

The purpose of this memo is to define requirements for NIH Intramural and Extramural Staff who request approval to access data in the centralized repository for NIH Genome-Wide Association Studies (GWAS) data, currently the database for Genotypes and Phenotypes (dbGaP).

EFFECTIVE DATE: The date of this memo.

BACKGROUND

On August 28, 2007, NIH released a new policy focused on sharing data from GWAS (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>). A genome-wide association study is defined as a study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. The new policy applies to competing grant applications and proposals for contracts that include GWAS and are submitted to the NIH for the January 25, 2008 and subsequent receipt dates. The policy also applies to NIH intramural projects that include GWAS and are approved on or after January 25, 2008.

Investigators and institutions seeking data from the NIH GWAS data repository will be asked to submit a Data Access Request (DAR), as well as a Data Use Certification (DUC) agreement. At the NIH, the DAR and the DUC agreement will be co-signed by the investigator and a designated I/C official (see below). Access to the genotype and phenotype datasets submitted and stored in the NIH GWAS data repository will be provided for research purposes through an NIH Data Access Committee (DAC).

POLICY FOR NIH STAFF REQUESTING ACCESS TO GWAS DATA

An NIH Intramural or Extramural Staff member must obtain one-time permission from his/her Supervisor, Scientific Director or Division Director (or other senior I/C official), and I/C Director to request access to GWAS data. Once permission is obtained, the Staff member will be able to access the DAR system within dbGaP and submit DARs for specific GWAS datasets. As required by the GWAS policy, a DAR initiated by a staff investigator will be sent through the dbGaP system to the designated I/C official for approval and co-signature prior to final submission to the appropriate DAC(s).

If an individual moves to another I/C, a new, one-time permission from the Director of the new I/C must be obtained.

If access to GWAS data is permitted, the Staff member must agree to follow the terms of use for the dataset(s) outlined in the DUC agreement.

Permission to access central GWAS repositories may be granted to:

- NIH intramural investigators who are also Principal Investigators (tenure-track investigators, senior investigators, adjunct investigators, senior scientists and senior clinicians); and
- Extramural scientific Staff who
 - serve as the designated program official for normal stewardship of grants, have no substantial involvement or collaboration with the grantee, and need to access individual level data for audit and program monitoring activities for data obtained by the PI from GWAS;

- have substantial involvement in cooperative agreements or contracts, or are involved in research activities with respect to such data that are beyond normal stewardship roles; or
- seek to obtain the use of data for their own research that is not covered by an extramural award.

IMPLEMENTATION GUIDANCE

Two levels of approval are required for NIH Staff to obtain access to data in the NIH GWAS data repository:

1. Permission from the I/C Director and other supervisors, using the “**NIH Staff Request for Permission to Access GWAS Data**” form (see attachment for form and instructions).

- A Principal Investigator in the Intramural Research Program must be given permission by his/her supervisor, I/C Scientific Director, *and* I/C Director (who may delegate the authority to approve this request to the Scientific Director).
- An Extramural Staff member must be given permission by his/her supervisor, Division Director (or other senior I/C official), *and* I/C Director in accordance with NIH policies regarding the conduct of research by extramural staff.

To meet these conditions for GWAS, the I/C Director may:

- Assume responsibility for establishing an oversight procedure for uses of the GWAS data by that Extramural Staff member, OR
- Have the Extramural Staff member affiliate with an intramural laboratory for accessing GWAS data.

In making a decision between these two options, the I/C Director should consider whether any Conflict of Interest would be created by Extramural Staff affiliation with an intramural laboratory, and establish appropriate procedures for managing any potential Conflict of Interest.

In addition, the designated I/C official authorized to sign institutional certifications, as part of the DAR process for Extramural or Intramural Staff, must consider whether any Conflict of Interest would be created by access to the data set requested, and establish appropriate procedures for managing any potential Conflict of Interest.

2. Data Access Request Approval. NIH Staff who have been given permission by the I/C Director to access GWAS data then must follow the GWAS procedures and submit a DAR for each proposed research use of GWAS data, using the web-based request process on dbGaP. Each DAR will be submitted for a specific dataset and will include the proposed uses for that data, as well as agreement to specific terms of use within a DUC agreement. Once a DAR is completed by NIH Staff it will be routed electronically through dbGaP to the designated I/C official for approval and co-signature, as is required for all GWAS data requestors by the GWAS policy. After I/C approval and re-submission to dbGaP, the request will be routed electronically to the appropriate DAC for review. Information on the process for requesting data from dbGaP is provided at this site:

<http://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?login=&page=login>.

These NIH Staff requirements for access to GWAS Data will be included in the NIH training for implementing the GWAS policy; see Staff Training Opportunities at

<http://odoerdb2.od.nih.gov/oer/training/training.htm>.

CONTACTS: Any questions or comments should be referred to GWAS@nih.gov.