

necessary to be able to submit their individual level phenotypic and genotypic data to the NIH GWAS data repository. You may also contact your Program Official to inquire about the availability of supplemental funds to share the GWAS data if such funds are not available in the original project budget.

Does my sharing plan affect funding decisions?

While the GWAS sharing plan will not affect merit ratings, NIH institute staff are expected to evaluate your plan and may take it into consideration when developing funding plans. Institute staff may also evaluate progress with GWAS data sharing during the annual review of non-competing continuation applications (progress reports).

Web Links and Resources

NIH GWAS Page:

<http://grants.nih.gov/grants/gwas/index.htm>

dbGaP:

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

NIH Grants Policy Statement:

http://grants.nih.gov/grants/policy/nihgps_2003/index.htm

NIH Intellectual Property Policy Page:

<http://grants.nih.gov/grants/intellproperty.htm>

NIH Sharing Policies website:

<http://sharing.nih.gov>

Comments or Questions?

Please e-mail GWAS@mail.nih.gov.

Glossary

GWAS: Genome-wide Association Study.

For purposes of the policy, a genetic association study in which the density of genetic markers and the extent of linkage disequilibrium is sufficient to capture a large proportion of the common variation in the human genome in the population under study, and the number of specimens genotyped provides sufficient power to detect variants of modest effect.

DAC: Data Access Committee.

Committees established by NIH funding institutes (ICs) that are charged with approving access to the GWAS data deposited in the NIH GWAS data repository. The DAC will review requests and determine that access is only for research uses that are consistent with the participants' informed consent and that the recipient agrees to comply with the terms of the Data Use Certification (see below).

DUC: Data Use Certification.

This document specifies the terms and conditions under which a requestor is given access to GWAS data in the NIH GWAS data repository.

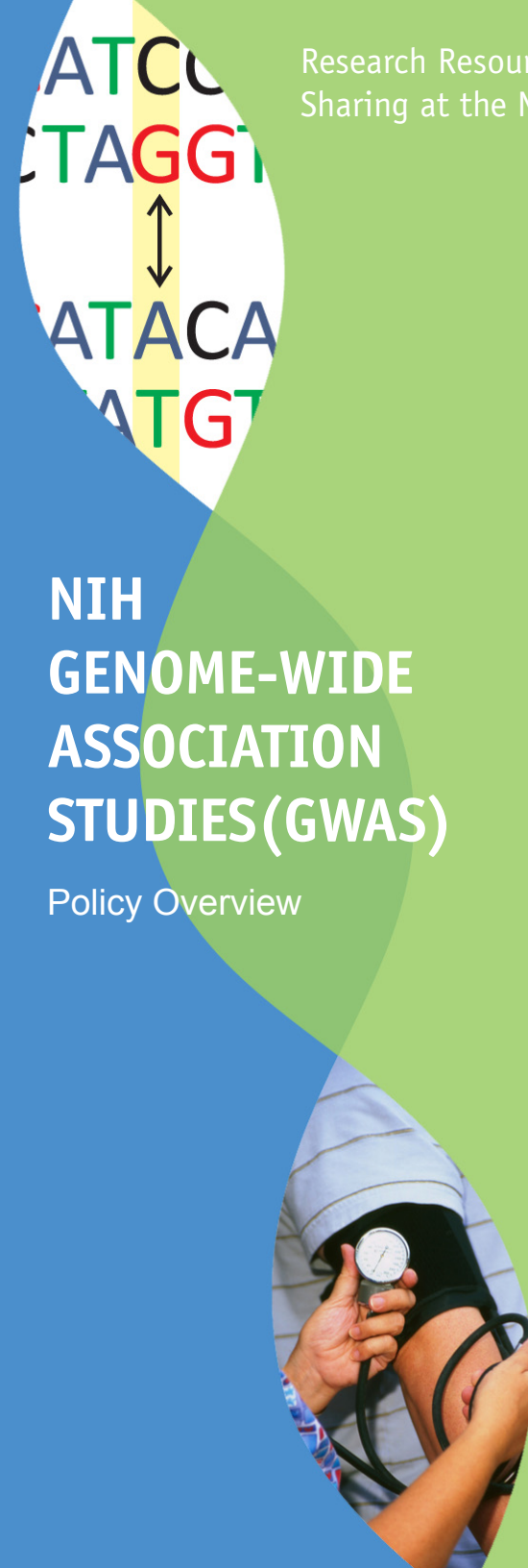
dbGaP: Database of Genotype and Phenotype.

A database developed by the National Center for Biotechnology Information (a division of the National Library of Medicine) to archive and distribute the results of studies that have investigated the interaction of genotype and phenotype. dbGaP currently serves as the NIH GWAS data repository.

Research Resource
Sharing at the NIH

NIH GENOME-WIDE ASSOCIATION STUDIES (GWAS)

Policy Overview



NIH Policy on Genome-wide Association Studies (GWAS)

Background

As part of its mission to discover new knowledge that will lead to better health for the public, the National Institutes of Health (NIH) is interested in advancing the use of genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease. Research studies and clinical trials making use of high-throughput genotyping and large-scale genetic analyses have increased rapidly in recent years with the completion of the Human Genome Project and the International HapMap (<http://www.hapmap.org/>). After public consultation, (<http://grants.nih.gov/grants/gwas/index.htm>), the NIH announced the final policy for the sharing of data obtained through NIH-supported or conducted GWAS (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>). The NIH believes the full value of GWAS to the public can be realized only if the genotype and phenotype datasets are made available as rapidly as possible to a wide range of scientific investigators. Rapid and broad data access is particularly important for GWAS because of the significant resources they require, the challenges entailed in analyzing large datasets, the extraordinary opportunities they afford for making comparisons across multiple studies, and the subsequent potential for improvements in public health.

Does this apply to me?

If you are a principal investigator planning to submit a competing grant application or contract proposal that includes a genome-wide association study for the January 25, 2008 receipt date or thereafter **or** you are an intramural NIH investigator

of a genome-wide association research project approved on or after January 25, 2008, then your study is subject to this policy. The policy applies to the following grant mechanisms:

Research project grants (Rs);

- Program projects (Ps) and SCORs (Ss);
- Cooperative research mechanisms (Us);
- Individual career development awards (Ks) that include a research component;
- S mechanisms that include a research component; and
- All other mechanisms that include a research component.

What should I do if I'm planning a genome-wide association study?

Extramural investigators submitting GWAS applications

When you are preparing your GWAS grant application or contract proposal, you are expected to develop a sharing plan for your data that is consistent with the GWAS policy. The sharing plan should include data submission to the NIH GWAS data repository. At the very least the data submission should include:

- Descriptive information about your study;
- Coded genotypic and phenotypic data that meet the criteria described in the policy;
- Institutional Certification approving of the submission to the NIH, in accord with the published policy (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>)

The study description and data submission plans should be included in the Resource Sharing Plan(s) section of the Research Plan of the SF 424 or PHS 398. Your sharing plan should address the ability to obtain institutional certification for data submission, as

this certification is required as part of data submission to the NIH GWAS data repository. In those instances where you are unable to submit your data (due to informed consent issues, local laws and limitations, concerns about harms to individuals and groups, or other limitations), you should describe why sharing is not possible. If you are preparing a proposal in response to a specific Funding Opportunity Announcement (FOA) or Request for Proposals (RFP), you will also have to address any additional requirements related to GWAS data sharing and access in those particular solicitations. You should consult with the named scientific contact (FOAs) or contract officer (RFPs) in such cases.

NIH employees conducting GWAS studies

Each IC will have a designated individual who will be the responsible IC official for reviewing research at NIH involving GWAS data. As soon as you know that you might be involved in research that includes GWAS data, you should contact your Scientific Director for guidance.

How will my GWAS application be reviewed?

GWAS applications will be evaluated using the same review criteria applied to non-GWAS applications. Reviewers will be asked to examine and comment on your proposed GWAS sharing plan. Reviewer comments will be included as an administrative note in your summary statement. However, GWAS sharing plans will not affect the merit rating of your application.

Are resources available for sharing?

You may request funds in your application to cover costs associated with sharing GWAS data. For example, funds may be requested to obtain additional consent from study participants if