

What is GWAS?

Genetic association studies explore the connection between specific genes, known as genotype information, and their outward expression, known as phenotype information. Genome-wide association studies (GWAS) rely on newly available research tools and technologies to rapidly and cost-effectively analyze genetic differences between people with specific illnesses, such as diabetes or heart disease, compared to healthy individuals. The differences facilitate the identification of genetic risk factors for the development or progression of disease. Several NIH institutes recently launched, or are planning, GWAS initiatives with the expectation that the results will accelerate the development of better diagnostic tools and the design of new, safe and highly effective treatments.

Why a NIH GWAS Repository?

- **Improve Health** – Sharing genome-based research, including both genotypic and phenotypic information, with a broad number of scientists, will enable medical science to better understand the health needs of the public and facilitate development of new technologies and approaches for the prevention, diagnosis and treatment of disease.
- **Maximize Public Investment** – Providing centralized access significantly increases the availability of data for researchers, which is predicted to accelerate the discovery of associations between genetic data and disease while reducing research costs.

What is the proposed GWAS Policy?

The proposed GWAS Policy calls for investigators funded by the National Institutes of Health (NIH) for GWAS 1) to submit de-identified genetic (genotypic and phenotypic) data to a centralized NIH repository; and, 2) to submit documentation that describes how the investigators will protect privacy and confidentiality of research participants.

Data Management

The proposed policy defines how investigators may submit and request access to GWAS data for research purposes. Investigators using GWAS data from the NIH database will continue to ensure the privacy and confidentiality of the individuals that participated in the original genetic association studies.

Publication

The NIH proposes that investigators who submit GWAS data to the repository should be given time to analyze and publish their results before additional investigators would be permitted to submit manuscripts for publication using those data. Secondary investigators will be asked to acknowledge the submitting investigator(s) in all publications utilizing GWAS data.

Intellectual Property

In the proposed policy, NIH would encourage patents for downstream discoveries that would be necessary to develop products to meet public health needs, while discouraging obtaining a patent for early, pre-competitive information that may impede future research.

How can the public contribute to the development of the policy?

The NIH believes that the public should be engaged in discussions on the varied and complex interests related to the submission of, and access to, GWAS data. Wide and rapid access to GWAS data may have implications for participants in studies, as well as their families and communities, investigators, institutions, and/or industry.

Comments

The NIH is soliciting comments on the proposed policy via the NIH web site at <http://grants.nih.gov/grants/gwas/index.htm> or via email at gwas@nih.gov.

A Town Hall Meeting is planned for December 14, 2006.