GENOME-WIDE ASSOCIATION STUDIES (GWAS) SHARING PLAN

BACKGROUND

The NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence human health and disease. For the purposes of this policy, a genome-wide association study is defined as “any 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.”

GWAS SHARING PLAN REQUIREMENTS

An investigator or offeror undertaking GWAS research is required to provide a GWAS sharing plan for the data to be generated by the GWAS study or studies proposed in the grant application or contract proposal. When the applicant/offeror is unable to submit GWAS data (due to informed consent issues, local laws and limitations, concerns about harms to individuals and groups, or other limitations), the applicant must describe why sharing (in part or in full) is not possible. The sharing plan should include details about the submission of relevant data to the NIH GWAS data repository. Overall, the sharing plan should include:

- Descriptive information about the study or studies to be performed.
- Details about the coded genotypic/phenotypic data, study populations, and study documents that will be included.
- A timeline of sharing.
- Institutional certification approving the investigator’s submission of the data to the NIH. This certification is required as part of data submission to the NIH GWAS data repository.

Additionally, the applicant/offeror must address any special requirements related to GWAS data sharing and access that maybe present in the Funding Opportunity Announcement.

International Collaborations and Foreign Grants/Contracts

If the US institution is the primary grantee or offeror, then the domestic institution is responsible for its sub-grantee or subcontract arrangements and is expected to ensure that this policy is adequately addressed in the application.

GWAS Sharing Plan Evaluation for Grants

The reviewer will address whether the application’s GWAS sharing plan is “Acceptable” or “Unacceptable,” if applicable. The reviewer should not include an assessment of the plan in the determination of the application’s Overall Impact/Priority score. If the plan is deemed “Unacceptable,” a brief explanation of why it was unacceptable should be provided.
However, some special initiatives may contain additional requirements related to GWAS data sharing; in these cases, the adequacy of the GWAS sharing plan may be an additional review criterion, and the reviewers would then factor an evaluation of the plan into the overall evaluation of scientific merit, i.e. the Overall Impact/Priority score.

**GWAS Sharing Plan Evaluation for Contracts**

The reviewer will address whether the proposal’s GWAS sharing plan is “Acceptable” or “Unacceptable,” if applicable. The reviewers should not include an assessment of the plan in the determination of whether the overall proposal is “Acceptable” or “Unacceptable.” If the plan is deemed “Unacceptable,” a brief explanation of why it was unacceptable should be provided.

However, some Requests for Proposal or Broad Agency Announcements may contain special requirements related to GWAS data sharing; in these cases, the adequacy of the GWAS sharing plan may be factored into the score of the respective Technical Evaluation Criteria and into whether the proposal is “Acceptable” or “Unacceptable.”

For more information, see the following NIH web sites:
