Are you planning to conduct a Genome-Wide Association (GWAS) study?

Genome-Wide Association Studies (GWAS) *

A GWAS study is 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. Whole genome information, when combined with clinical and other phenotype data, offers the potential for:

- increased understanding of basic biological processes affecting human health,
- improvement in the prediction of disease and patient care, and
- ultimately the realization of the promise of personalized medicine.

The NIH Policy for Genome Wide Association Studies (GWAS) applies to protocols for which the NIH will cover the cost of the GWAS analysis via a grant or contract that was submitted for NIH funding after January 25, 2008. Competing GWAS applications to NIH must include a GWAS data sharing plan as part of the research plan or outline why such data sharing is not appropriate.

Data Sharing Plan
The data sharing plan of the research plan (grant application) should include:

- Documentation that the data submission is consistent with applicable federal and Mississippi laws and institutional policies
- The appropriate research uses of the data and any specific research exclusions as outlined in the informed consent document
- *If samples have not yet been collected* the informed consent document should include information regarding the data sharing. The informed consent must be clear that DNA will undergo genome-wide analysis and that genotype and phenotype will be shared for research purposes with investigators who submit proposals to the GWAS data repository. (The IRB-HSR consent form template contains suggested language for use).
- *If samples have already been collected* the IRB must review the informed consent documents which were signed by participants to confirm whether or not the initial consent under which genetic materials were obtained is consistent with the submission of data to the GWAS data repository and the sharing as outlined in the GWAS policy.
    - The IRB may determine that the original consent is not inconsistent with the submission of data to the GWAS data repository and provide certification as documentation.

- The IRB may determine that the original consent is not consistent with submission of data to the GWAS data repository and may request re-consent of participants.
- The IRB may determine that the original consent is not consistent with submission of data to the GWAS data repository and determine that it cannot verify that the criteria outlined in the GWAS policy have been met for submission of data to the GWAS data repository and therefore, such submission is not appropriate.

Institutional Certification

All submissions to the NIH GWAS **D**ata**b**ase of **G**enotypes **a**nd **P**hentotypes (dbGaP) of data should be accompanied by a certification by the responsible Institutional Official(s) of the submitting institution that they approve submission to the NIH GWAS data repository.

The certification should assure that:

- The proposed data submission is consistent with applicable federal and Mississippi laws and regulations, as well as institutional policies;
- The research uses of the data and the uses that are specifically excluded by the informed consent documents are described;
- The proposal provides that the identities of research participants will not be disclosed to the NIH GWAS data repository; and
- The institution's IRB and Privacy Board have reviewed the relevant aspects of the proposal and verified that
  - The proposed submission of data to the general NIH GWAS data repository for subsequent sharing for research purposes as described in the NIH Policy is not inconsistent with the informed consent of study participants from whom the data were obtained;
  - The investigator's plan for de-identifying datasets is consistent with the NIH "Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies"
  - Based on the characteristics of the subject population and the data involved in the primary study, and within the limits of its knowledge of the future potential uses and users of the data, it has considered the risks to individuals, their families, and groups or populations associated with the proposed submission of the data to the general NIH GWAS data repository. The IRB/Privacy Board understand that assessment of risks associated with specific future secondary uses will be performed by NIH's Data Access Committees, and,
  - To the extent applicable, the genotype and phenotype data proposed to be submitted were collected/will be collected in a manner consistent with 45 C.F.R. Part 46.

The IRB will review the grant application when submitted to the IRB. If a GWAS certification is requested, the IRB will work with the Office of the Associate Vice Chancellor for Research to determine the applicability of the certification. If certification is given, it will be sent to the PI of the Grant Proposal.

Privacy Protections
Due to the potentially sensitive nature of the data, steps must be taken to protect the privacy of the individual data.

- De-identification or Coding of Data: Before data are submitted to the NIH GWAS dbGaP, submitting investigators will be expected to de-identify the data per HIPAA regulations or assign a random, unique code to the data to protect participants' privacy and confidentiality. The key to the code will remain at UMMC and will never be shared with GWAS. This information must be stipulated in the protocol.

Withdrawal of Individual Consent
The NIH GWAS data repository has developed policies with regard to removal of individual data records if consent is withdrawn. Submitting investigators and their institutions may request removal of coded data on individual participants from the data repository in the event that a research participant withdraws consent. However, data that have already been distributed for approved research use will not be able to be retrieved.

Prospective use of Data from the GWAS Repository by UMMC Investigators
UMMC Investigators choosing to request data from the GWAS data repository must have confirmation from the UMMC IRB that the research meets the qualifications of research that does not involve human participants.

Additional Information
Additional information may be found on the NIH GWAS website, http://grants.nih.gov/grants/gwas

- National Institute of Health (NIH) Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)
- GWAS NIH Points to Consider for IRB's and Institutions in their Review of Data Submission Plans for Institutional Certification.
- GWAS Tips for Informed Consent for Genomic Research

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