

TO: Deans, Directors, Department Chairs and Administrative Officers

The National Institutes of Health recently released a Genome-Wide Association Studies (GWAS) data sharing policy. This policy applies to all NIH supported or conducted “studies of genetic variation across the 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.” Investigators who receive NIH support to conduct GWAS are expected to submit descriptive information about their studies in an open access portion of the data repository, and to submit coded de-identified data into a secure portion of the data repository. See: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>.

In response to concerns about the possibility that data may be used in ways that might potentially harm research subjects, the NIH has indicated that a variety of data security and oversight measures will be put into place. The August 28, 2007, notice and policy also indicate that:

- Data should be submitted to the GWAS repository without identifiable information and using a random, unique code.
- Keys to the code should be held by the submitting institution and should not be submitted to the NIH.
- Individual-level genotype and phenotype data will be redacted from disclosures made in response to requests for data under the federal Freedom of Information Act to protect against unreasonable invasions of personal privacy.
- The NIH will develop guidance for IRBs to use in considering studies proposing **submission of data** to the GWAS repository. Although some or most of the research to be conducted using data **from** the GWAS repository will not constitute human subjects research, please note that the collection and sharing of data to be added to the GWAS repository may be human subjects research requiring UCLA IRB review and approval. Please see [OPRS/IRB Policy 3: Human Subjects Research Determinations](#) for more information.
- **Submission of data** to the GWAS repository is to be accompanied by a written certification indicating that the identity of individual research subjects will not be disclosed to the GWAS data repository. At UCLA these certifications are to be co-signed by the investigator and the Director or Assistant Director of the campus Office for the Protection of Research Subjects (OPRS).

- Institutions and investigators seeking ***access to data*** from the GWAS data repository for research use must include a data use certification. This certification should indicate that the data will be used only for the approved research, will not be shared or sold, will be treated confidentially; and that appropriate data security protections will be put into place. At UCLA these certifications are to be co-signed by the Investigator, and an Office of Contract and Grant Administration (OCGA) Contract and Grant Officer.

The NIH encourages investigators conducting GWAS to consider obtaining Certificates of Confidentiality to protect against the possibility of compelled disclosure of identifiers by the investigator's institution in response to record requests. At UCLA, applications for Certificates of Confidentiality are handled through OPRS. For instructions on submitting these applications, see <http://www.oprs.ucla.edu/human/documents/pdf/CoC%20instructions.pdf>. I suggest that all investigators conducting Genome-Wide Association Studies follow this advice.

Questions about applying for a Certificate of Confidentiality should be addressed to Kip Kantelo kkantelo@oprs.ucla.edu or Alison Orkin aorkin@oprs.ucla.edu at x55344, in the Office for Protection of Research Subjects. Questions about the NIH policy should be addressed to Ann Pollack, Assistant Vice Chancellor – Research at x40387 or apollack@research.ucla.edu.

Sincerely,

Roberto Peccei
Vice Chancellor for Research