UCLA OHRPP
Office of the Human Research Protection Program

Guidance and Procedure: Genetics Research (last updated April 14, 2009)

Introduction

Genetic research is of critical importance to behavioral science and medical research. From a human subjects protection perspective, confidentiality, disclosure of results and informed consent are some of the most significant issues. The UCLA Human Research Protection Program is currently revising the overall guidance for genetics research. In the interim, this document provides information regarding these matters. In addition to the information below, please refer to *OHRPP Guidance and Procedures: Determining When Collection or Use of Data and Specimens for Research Requires IRB Review*.

Confidentiality

If the genetic data will be stored with direct identifiers or codes, adequate security measures must be taken to assure confidentiality and minimize risks to subjects that could result from inadvertent disclosure, such as adverse consequences for an individuals' financial or social standing, insurability, or employability. If the area of study is particularly sensitive, a Certificate of Confidentiality should be obtained to provide additional protections against forced disclosure. The measures used to protect the security of the data should be described in the IRB application.

Disclosure of Results

The results of genotyping may only be disclosed to research participants when the results are likely to have clinical and therapeutic relevance, and the tests will be performed by a Clinical Laboratory Improvement Amendments (CLIA) approved lab. In most cases, the results should be relayed to study participants by a licensed study physician or a licensed genetic counselor. Information about disclosure of results should be described in the IRB application.

Exceptions to these conditions will be considered by the IRB on a case by case basis.

Informed Consent & HIPAA Authorization

Informed Consent: All informed consent requirements outlined in OHRPP Guidance : Obtaining and Documenting Informed Consent Process should be followed for genetic research. In addition, the consent form should include the following:

- Whether the samples may be used for future research, and if so, the nature of the research, whether the samples will be coded or identified, and with whom the samples/information will be shared.
- A statement that the specimens may be used in research that may result in new discoveries and that the donor-subjects do not retain any property rights to their materials. Thus, they would not receive any financial benefits from these discoveries.
- If the samples are obtained or used in the course of clinical care, the requirements of the Health Insurance Portability & Accountability Act (HIPAA) for Authorizations apply to the study. See the OHRPP Guideline for HIPAA requirements.

References

Genome-Wide Association Studies (GWAS).

Genetic Information Nondiscrimination Act of 2008: Information for Researchers and Health Care Professionals (DHHS)

Genetic information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards. (OHRP)