

**Policy Number: 37**

**Title: Genetics Research**

**Date of Last Revision: July 27, 2007**

## **I. Introduction**

Human genetic research involves the study of inherited human traits. Much of this research is aimed at identifying the molecular cause of specific health problems, developing methods of identifying those genetic mutations, and improving the treatments for patients with genetic diseases. The ethical and regulatory challenges raised by genetic research include, information sharing with and the implications of research findings on the subject, as well as family members, issues of confidentiality, testing, availability or lack of availability of proven clinical interventions, and the appropriate methods for providing genetic information to subjects.

In addition to the criteria outlined in [OPRS/IRB Policy 19: IRB Review Requirements](#), IRB review of genetics research must include consideration of the following issues.

## **II. Risks of Participating in Genetics Research**

- A. In addition to physical risks, potential risks to research subjects in genetics research may include risks of breach of confidentiality of test results, risks of emotional distress such as anxiety or guilt, risks of genetic testing, including false positives or false negatives, and effects of the knowledge that one has a disease-related gene that might alter one's life course, reproductive decisions, employability or insurability.
1. IRBs consider such risks when assessing the risk/benefit ratio of proposed genetic research and evaluate whether the protocol incorporates sufficient safeguards to minimize these risks.
  2. Investigators are asked to describe these potential risks in lay language in the consent form for the subjects. IRBs review the consent forms to ensure that subjects are informed of all potential risks.
- B. Genetic research may also reveal misattribution of parentage. In studies which may yield such data, investigators are asked to provide an ethical justification for providing attribution of parentage to the subjects or family (when applicable) as well as a plan for managing and/or disclosing this information. IRBs evaluate this plan for its appropriateness within the context of the study and given the subject population.

- C. Genetic research may further yield results which may pose risks of stigmatization and/or discrimination or psychosocial risks to the participant's family, ethnic community or to isolated populations.
1. IRBs consider such risks when assessing the risk/benefit ratio of proposed genetic research and evaluate whether the protocol incorporates sufficient safeguards to minimize these risks.
  2. Investigators and IRBs ensure that subjects are adequately informed of such risks by ensuring that the risks are described in lay language in the consent form.

### **III. Genetic Sub-studies**

Protocols in which genetic testing/analysis is not a necessary or integral part of the overall research study should give participants the option to decline participation in the genetic sub-study. The approved protocol should include a mechanism for tracking subject choices in order to ensure adherence to and respect for subjects' decisions.

### **IV. Involvement of Family Members**

- A. Policies and procedures regarding recruitment methods and tools must be followed if an investigator plans to recruit relatives of the proband. Please refer to [OPRS/IRB Policy 30: Recruitment Methods and Tools](#) for details.
- B. If an investigator intends to obtain identifiable private information about the proband's family members, the family members may be considered human research subjects as defined above. . In such instances, IRBs consider the necessity and/or appropriateness of a consent process for secondary subjects. Please refer to policies and procedures regarding special subject populations and informed consent for details.
1. Investigators are asked to indicate in their application whether proband subjects' consent to contact family members is obtained. IRBs consider whether proband subjects' consent to contact family members should be a requirement on a case-by-case basis.

### **V. Disclosure of Results**

- A. Risks of research participation include the disclosure of genetic test results that lack clinical utility or validity. Investigators are required to indicate whether results of genetic tests will be provided to the participants, and to provide an ethical and scientific justification for either decision. The IRBs will determine if the decision to disclose such results is appropriate. IRBs will consider the following when making this determination:

1. Clinical relevance and implications of the genetic test results
2. Quality of genetic test results
  - a. Clinical Laboratory Improvement Amendments of 1988 [CLIA] are applicable to a “laboratory... for the... examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings.”
  - b. Test results that will be used as the basis for clinical decision-making should be performed in a CLIA certified laboratory. If test results relevant to subject’s clinical care are conducted at a non-CLIA certified lab, UCLA IRBs will require that the tests be verified using a validated test at a CLIA certified laboratory prior to the use of such results for diagnosis, prevention or treatment.
  - c. Research results from tests conducted at non-CLIA certified labs should not be shared with the subjects and should not be used for clinical decision-making. The UCLA IRB will consider requests to share non-CLIA certified results with subjects on a case-by-case basis.
- B. If the protocol allows for the disclosure of research results to subjects, the informed consent process and document should provide subjects with the option of receiving the genetic test results, such as initialing boxes in the signature block. For subjects who choose to be informed of their results, the protocol should outline the procedures which will be implemented to minimize the risks associated with such disclosure and to preserve the confidentiality of the results. The IRBs will determine whether the risks are accurately reflected in the protocol and the consent document, and whether sufficient procedures are in place to minimize these risks.
- C. If a protocol allows for the disclosure of genetic test results, the protocol should outline how such a disclosure will be managed. UCLA IRBs consider the following when reviewing the adequacy of such a plan:
  1. Appropriateness of the methods by which subjects will be informed of their results
  2. Qualifications of the individuals who will disclose the results to the subjects, including the training and experience of the individual in discussing and counseling in the social, psychological and other non-physical risks of such information
  3. Whether counseling will be offered and, if so, qualifications of the individuals who will provide counseling and the party responsible for the cost of counseling

## **VI. Disposition of Samples**

- A. Investigators inform subjects in the informed consent form whether their samples will be used exclusively for the purposes of the research under consideration, or if samples may be used for future research.
  - 1. Information describing the nature and purpose of the research provided to the subjects in the informed consent document should be as specific as possible. As such, if samples will be stored and/or shared for future research, all requirements outlined in the policies and procedures regarding research involving the use of human specimens must be followed.

## **VII. Informed Consent & HIPAA Authorization**

- A. All informed consent requirements outlined in the policies and procedures regarding informed consent apply to informed consent process and documentation for genetics research. Please refer to [ORPS/IRB Policy 29: Informed Consent Process and Documentation](#) for details.
- B. All requirements outlined in Health Insurance Portability & Accountability Act apply to research involving human specimens and genetic research that fall within HIPAA jurisdiction. Please refer to [OPRS/IRB Policy 49: HIPAA](#) for details.

### **References:**

Clinical Laboratory Improvement Amendments of 1988