

Approved by IRB Executive Committee: January 14, 2009
Supersedes Document Dated: December 1, 2005, May 1, 2005

POLICY

The University of Utah IRB requires that special consideration be given during the review of studies involving genetic research and information, given the potential predictive power of some genetic information, the familial nature of some genetic research and information, and the potential risks associated with genetic information.

The IRB requires investigators to provide a plan to ensure the privacy and confidentiality of participants, minimize the risks associated with genetic research, and provide adequate disclosure of genetic results that may be clinically relevant to the participant.

The IRB guidelines regarding genetic research are posted on the IRB website.

PROCEDURES

1. Procedure for Review of Genetic Research

- 1.1. Investigators must submit all information and documents required by the IRB for genetic research in the new study application.
- 1.2. The IRB reviews the proposed research, informed consent documents, and additional information, when applicable, to determine whether:
 - 1.2.1. The plan to ensure the privacy and confidentiality of participants is adequate;
 - 1.2.2. The risks associated with genetic research are minimized;
 - 1.2.3. The plan to disclose clinically relevant genetic results to the participant is adequate.

2. Procedures for Review of Gene Transfer Research

- 2.1. Investigators must submit all information and documents required by the IRB for gene transfer research in the new study application. This information must include the following:
 - 2.1.1. delivery methods
 - 2.1.2. target population
 - 2.1.3. required follow-up
- 2.2. The assigned IRB reviewer(s) may contact a qualified member of the University of Utah Biosafety Committee and external consultants, as necessary, to provide independent guidance to the IRB.
- 2.3. Research involving gene transfer to human subjects may be reviewed and approved by the National Institutes of Health Recombinant DNA Advisory Committee prior to IRB approval. Monitoring must be adequate and a DSMB is required.