

# Children's Hospital Institutional Review Board

## Information Sheet

### Genetic Studies

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Federal guidelines strongly advise IRBs to consider specific issues when reviewing clinical genetic research, and to alert investigators that these issues need to be addressed in the IRB application. For IRB review purposes, the guidelines divide genetic research into four categories:

1. Pedigree studies
2. Positional cloning studies, including databanks
3. DNA diagnostic studies and test development
4. Gene therapy.

Unlike the risks presented by biomedical research, the primary risks of the first three categories of genetic research are risks of social and psychological harm rather than risks of physical injury. Genetic studies may be limited to a collection of family histories or blood draws, but those that generate information about subjects' personal health risks can provoke anxiety and confusion, damage familial relationships and compromise subjects' insurability and employment opportunities.

There may be different concerns for each of the four categories of genetic research. All the following points are not relevant to each study, but they are relevant to all research involving human subjects, not only "genetic" studies. Although the Children's IRB application addresses each of these points in general terms, researchers proposing genetic studies may wish to provide more detailed information by answering the following questions.

1. Into which of the four categories named above does the research fall?
2. When children are directly involved, with blood draws, biopsies or interviews for example, will they benefit directly from participating in the project?
3. When extended family members are involved:
  - How will they be contacted and recruited in a way that does not unduly influence or coerce them to participate?
  - Are there confidentiality issues involved and how will they be handled? Extended family may not know an individual is sick or has a specific condition, for example.
  - Which measures can be taken to minimize family pressure on children in the extended family to participate?
4. What information will families receive?
  - At what point in the research?

- What is the meaning of the information? Are there diagnostic, predictive or reproductive implications?
  - How will interim or inconclusive results be reported?
  - Will individuals be given the opportunity **not** to receive information about themselves?
5. Are there psychological risks like anxiety or confusion associated with the research or receiving the results? If so:
- How will the information be given to families in a way that will minimize the risks?
  - Will genetic counseling be available?
  - How will data be collected from and conveyed to children who are directly involved in the research in a way that minimizes self-doubt and anxiety?
6. Are there social risks like jeopardy to insurability or employability, or damage to familial relationships, associated with the research or the results being known? If so:
- How will the research data be protected from third parties, such as employers and insurance companies?
  - When extended family members are to be studied, will methods be in place to protect individuals from unauthorized disclosure of medical or personal information to other family members?
7. Is there a possibility that the results will include incidental findings such as paternity, or information about diseases or conditions other than those being studied? If so, how will the information be handled?
8. Will research findings be disclosed to the patient's physician for clinical use?
9. How will data and samples will be handled:
- After the project has been completed?
  - If a subject wishes to withdraw from a genetic study after it has begun?
  - If either the current investigator or another investigator wishes to use the research data or samples from the project for other research purposes?

The consent form should address the issues raised above as they relate to the protocol, including:

- The type of information that will be provided and when
- The implications of the findings
- Psychological and social risks
- Which support services are available
- Methods to ensure confidentiality
- The possibility of incidental findings
- The future uses of stored data and samples.