Protecting people who participate in research

CITI Training Study Guide

Genetic Research in Human Populations

Varieties and Benefits of Genetics Research

- Genotyping can assess the risk of disease, determine paternity or predict individuals' vulnerability to certain environments or substances.
- Pharmacogenomics studies how inherited variations in genes dictate drug response, and explores how to predict an individual's response to a drug.
- Knowledge about an individual patient's genetic make-up can influence the treatments, drugs, and doses physicians choose for that patient.
- An anticipated benefit of pharmacogenomics includes the development of more powerful drugs.

Obligations for disclosure

- **Genetics investigators must tell potential participants:**
  - **which entities and persons will have access to the data;**
  - **whether information obtained from research will be placed in a patient's medical record;**
  - **risks of others having access to their genetic information;**
  - **how genetic information can violate the privacy of family members, by revealing something about them to the subject and/or researchers;**
  - **that it may not be possible to completely "anonymize" genetic information.**

IRBs should ensure that informed consent for genetics research includes:

- Purpose of the research, in lay language;
- how specimens will be stored and who will have access to them or the information they contain
- whether subjects will be re-contacted later with information about study findings or their individual results
- whether the genetic information will have a code that can be linked to a subject's identity;
- whether researchers will use specimens to develop commercial products, and who benefits;
- whether researchers plan to conduct future testing of collected samples;
- whether samples may be used for other studies, including those that may have a different focus.

Research on stored biological samples

Retrospective research may be conducted without consent of the individuals who donated the material if:

- Identification of the subjects can be prevented;
- IRB approves the waiver of consent

IRBs may want to require consent if the study cohort is small, the health condition is stigmatizing, and/or there are concerns about maintaining confidentiality.

Priority for IRB Review of Genetic Research

The most pressing ethical issue for an IRB to address is the potential effects of research findings on family members who have not given consent to participate in the research.