Special Issues in Conducting Human Genetic Research

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Description

A module covering the ethical issues that arise in conducting human genetic research. Issues of disclosure and informed consent, are among those discussed.

Body

Background and Module Content

One of the most striking features of basic scientific research in biomedicine today is the ubiquity of genomic tools and genetic strategies. Across the spectrum of disciplines from molecular biology to epidemiology, investigators are increasingly turning to the human genome for clues to the physiological and pathological processes that concern them. Much of this "gene hunting" research takes the form of bench science, using human chromosomes acquired from "immortalized" cell lines long since separated from their human sources. In that context, it is easy for basic scientists to overlook the fact that this research is still a form of research with human subjects. In fact, human subjects are involved in these studies in a way that was largely unanticipated by our research regulations: they are involved as entire families and as entire populations, rather than as isolated individuals.

As new research teams take up gene hunting, an increasing number of investigators and institutional review boards are finding that both the federal research regulations and the research ethics literature are virtually silent on the key issues that genetic families and populations studies raise. If anything, the prevailing standards seem to assume that cohorts of biomedical research subjects usually consist of strangers, rather than people who live together as family members or group members. At the same time, a bewildering variety of homegrown practices and policies have evolved within the genetic research community to cope with these challenges. While local approaches to specific problems are often defended passionately by their advocates, almost all have their critics as well. As gene hunting protocols multiply within biomedicine, the need for wider discussion and fuller training with respect to these issues is increasing.

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Method and Scenarios

Distribution of scenarios to the students and faculty. *All of the following scenarios are based on real events.*

- Responding to a Request for Information
- Recruiting Relatives of a Proband with a Stigmatizing Condition
- Disclosing Preliminary Results to Research Subjects
- Negotiating Research Practices with Local Communities
- Using Shared Tissues Samples for Genetic Research
- Recontacting Old Research Subjects with New Clinical Findings
- A Question of Host Factors in Side Effects of Medication

Panel discussion based on those scenarios and questions and any others that students or faculty wish to add.

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Readings

- Explanation of Federal Regulations (45CFR46) on research with human subjects, Part I and Part II.
- Reading Questions for the Federal Regulations on research with human subjects.

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Objectives

Discussing the ethical merits of different approaches to the key issues that arise in human genetics research can be like discussing politics, in that research practices are often based on firmly held, and therefore potentially divisive, personal views. Today, with increased stakes at issue in human genetic research, laboratory leaders often need to do a more explicit job of negotiating the social contract in their unit lives than their supervisors ever did during their training. This module is designed to:

- provide a laboratory with structured activities to help articulate, develop, and communicate the terms of those basic expectations.
- clarify and strengthen norms for the responsible conduct of human genetic research.
- aid in the development of new norms as changing conditions of human genetic research require.
- increase the capacity of the group to respond as a moral community to problems that arise within it and to prevent misunderstandings

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Bibliography (for further reading)

1. *Protecting Human Research Subjects: Institutional Review Board Guidebook.* (OPPR, Bethesda, Maryland, 1993). Office of Protection from Research Risk, DHHS, "Human Genetic Research," Chapter H. This guidebook was intended as an interpretation of how the regulations on human subjects apply to genetic research. But now it is under discussion. Many of the key issues listed in this module are addressed in this commentary.
2. "ASHG Report: Statement on Informed Consent for Genetic Research," American Society of Human Genetics, *American Journal of Human Genetics* 59:471-474, 1996.
3. For more information please consult the In-depth Annotated Bibliography

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Relevant Web Resources

1. UNESCO Declaration United Nations Educational, Scientific and Cultural Organization (UNESCO). 1997. *Universal Declaration on the Human Genome and Human Rights.* New York: UNESCO.
2. National Information Resource on Ethics and Human Genetics Within this Georgetown site, 22,000 volumes and 130,000 cataloged articles that deal with issues in molecular biology and human genetics with extensive links and database access.

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Resource Type

Educational Activity Description

Topics

Informed Consent
Human Subjects Research
Institutional Review Boards
Privacy and Surveillance
Confidentiality

Discipline(s)