A Primer for Human Subjects Research

Berklee College of Music Institutional Review Board
Special Requirements for Research Involving Human Subjects

When a student, faculty or staff member of Berklee College of Music undertakes any research project as part of their relationship to the college, that research may require review by the college’s Institutional Review Board (IRB).

Some examples of human subjects research that might require IRB review include, but are not limited to:

• a student project that involves surveying or interviewing other students
• a faculty research project that involves testing subjects’ hearing
• an administrative survey of staff members
What is meant by *human subjects research*?

Per the US federal guidelines:

- **Research** means a systematic investigation, including research development, testing, or evaluation, designed to develop or contribute to generalizable knowledge.

- A **human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:
  - Data through intervention or interaction with the individual, or
  - Identifiable private information.

The Belmont Report

• Released in 1978
• Motivated in large part by the injustices of the Holocaust and the Tuskegee Syphilis Study

The Belmont Report suggested that three ethical principles should drive all research conducted upon human subjects:

1. Respect for Persons
2. Beneficence
3. Justice
Respect for Persons

Individuals are autonomous agents
- Autonomy must be acknowledged, therefore clear and accurate information should be provided. This is the basis for informed consent.
- Autonomy must be respected. Human subjects have the right to withdraw from research at any time.

Some individuals have diminished autonomy
- Children
- Those with mental illness or disability
- Those in circumstances which restrict liberty (e.g. incarcerated persons, students, employees)

Individuals with diminished autonomy can still be human subjects, but require enhanced considerations regarding informed consent and self-determination of participation
Beneficence

Do no harm

No research result is valuable enough to justify the deliberate harm to a person.

Maximize possible benefits

All research, but most especially research that makes use of human subjects, should contribute to generalizable knowledge. The distribution of the benefits from research should be shared with the greatest number possible.

Minimize possible risks

Every effort should be made to eliminate or control the unavoidable discomfort of some research procedures (e.g. when a needle stick is required). This includes the emotional discomfort that could result from interactions with researchers.
Justice

Benefits
Research is inherently a problem-solving endeavor. Whose problem is being solved?

Burden
Being a research subject often entails some discomfort or inconvenience. Are the burdens distributed fairly?

Balance – Equity versus Equality
Will those that bare the inconvenience or discomfort of research also share in the rewards?
The Plan into Action

The ideas of the Belmont Report were codified into law as 45 CFR 46 subpart A, often referred to as “the Common Rule.” This is a section of the United States Code of Federal Regulations.

45 CFR 46 gives the Department of Health and Human Services (DHHS), through the Office for Human Research Protections (OHRP), the authority to regulate and oversee human subjects research that is carried out or supported by federal agencies.
What does 45 CFR 46 do?

The relevant sections of the Code of Federal Regulations (45 CFR 46) outline the standards for IRB review of human subjects research, as well as the administrative practices of the IRB.

While the code states that the regulations apply to federally supported or funded research, in order for any institution to be eligible to receive federal funding for human subjects research, it is necessary to have consistent practices in place that meet the federal requirements. For this reason most schools and colleges apply the regulations to all human subject research activity.

The regulations outline which types of human subject research activity require full or expedited IRB review, and which types may be exempt from review. Only the IRB makes the determination of which category an activity falls into. The regulations also define special situations that require particular concern, such as research with children, pregnant women, and incarcerated persons.
Links to More Information

(links to html page; there is also a link on the page to download a PDF of the regulation)

NIH Human Subjects training module for researchers:
http://phrp.nihtraining.com/users/login.php

The Belmont Report:
http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html