Human Subjects Research
[From: http://www.webguru.neu.edu/professionalism/research-integrity/human-subjects-research]

If your research project involves the use of human beings as research subjects then your project must be designed skillfully to protect the health and well-being of your human subjects and it must be reviewed by your institution before you begin your experimental work. The review system we use today in conducting research involving human subjects is the direct outcome of the 1976 Belmont Report which identified three basic principles

- Respect for persons
- Beneficence; and
- Justice

as foundational to the ethical conduct of research involving people as subjects. Making these judgments, the Committee determined that the conduct of studies using human subjects must therefore address certain requirements:

- informed consent – the human subject must be competent to consent and informed concerning what will happen to them so that they can, if they choose to, (voluntary) consent;
- systematic assessment of risks and benefits; and
- equitable selection of subjects both socially and individually.

A good example of the importance of our review system is provided by a now classic study designed by Dr. Wendell Johnson, a well known and highly regarded speech pathologist ((2001). *Boston Globe*. June 12, p. A20. "Secret Experiment Created Stutterers.") In the late 1930's Dr. Johnson, ironically himself a chronic stutterer, hypothesized that stuttering arose not from genetic predisposition but from environmental conditioning. Children at a small private orphanage were separated into two groups – a control group, who received positive reinforcement, and the experimental group, who were harangued about their speech. The majority of the latter group became chronic stutterers. While the study findings eventually led to the development of a theory that has helped many children overcome childhood stuttering, it unwittingly condemned many uninformed, vulnerable study participants to a life of pain and suffering with a serious speech impediment. If you wish to learn more about this incident, often referred to as the Tutor Study, here is a link to a thoughtful web-based resource that discusses the case as well as a number of other questionable human subjects studies:

- N. Johnson. (2002) "Retroactive Ethical Judgments and Human Subjects Research: The 1939 Tudor Study in Context" Avail. URL: http://www.uiowa.edu/~cyberlaw/writing/CUNY1213.html

If your research project will involve studying people (observation, survey, medical records, blood or tissue samples, etc.) whether the work is funded or unfunded, then you will need to submit your research protocol for approval to the Institutional Review Board (IRB) before you can begin work to determine whether or not your work adequately addresses these important

issues. This is a federal requirement mandated by the United States Department of Health & Human Services' Office for Human Research Protections (HSS - OHRP) intended to protect the safety and rights of the human subjects involved in federally funded research studies.

First, you should obtain a written copy of your institution's human subjects policies and procedures and make sure that you understand them. You will likely be required to complete some form of training. Many institutions require anyone involved in human subjects research to complete the online National Institutes of Health (NIH) course entitled "Protecting Human Research Participants" which is available at URL: http://phrp.nihtraining.com/users/login.php (note: you will be required to register online in order to access the course materials). Next, you will need to file an application for study approval through your local IRB (see below). Once your application is approved, you can begin your study.

Typical IRB Application

Although the details may vary somewhat from institution to institution, an application for IRB approval usually requires the following information:

- Goals and objectives of the research study;
- Description of the methods including any written materials that will be used to recruit human subjects to the study. Note that special considerations may come into play if you plan to use minors, prisoners, incompetent patients, or other vulnerable populations as research subjects. Important issues include a discussion of any criteria that will be used either to include or exclude potential subjects such as age, gender, race or ethnicity;
- Thoughtful analysis of the potential risks and discomforts that might arise from participation in the study. This is particularly important when working with vulnerable populations such as younger children or mentally-disabled persons. Be sure to clearly describe the special safeguards that you will use in order to protect the rights and safety of vulnerable human subjects. These risks should be weighed against the potential benefits that are anticipated to result from the study and you should be prepared to demonstrate that your work will not harm your subjects or that it mill minimize the possible harm and maximize the possible benefits;
- Identification of the experimental procedures, including examples of all forms, scripts, etc. that will be used to obtain and demonstrate informed consent; and
- Discussion of the research methods that you will use to acquire your human subjects' data and to safeguard it (privacy).

Expedited Review

If you are carrying out certain types of research which are generally viewed as posing a minimal risk to participants, the IRB may carry out an expedited review of your application. Examples of the types of research that fall into this category include:

- Data collection via survey, interview, focus group, etc. for educational or psychological research; and

- Non-invasive biological specimen collection of for example, excreta, saliva, skin cells, hair or fur, etc.

Useful Advice

- It usually takes time for the IRB to review and approve applications. Depending on the number and nature of human subjects research studies at your institution, the review board may meet very infrequently, e.g., monthly. Call and find out what the IRB meeting schedule is at your institution and make appropriate allowance for this in designing your research plan.
- If you make any changes to your research protocol after obtaining approval, you should notify the IRB board of the changes you would like to make and wait for their approval before implementing them.
- If your study will be carried out over several years, you will need to renew your IRB approval at least once each year.
- Performing research on human subjects without obtaining IRB approval is illegal and can jeopardize your institution's ability to secure federal funding in support of its research programs. Also, note that research protocols cannot be approved retroactively. You must secure written approval for your study from the local IRB before you begin your project.