What are the ethical issues involved in research?

Many beginning researchers are discouraged by what appears to be arbitrary roadblocks set up by Institutional Review Boards (IRBs). IRBs exist for one reason and one reason only and that is to protect the rights of the human research subjects. The history of research has numerous examples in which the rights of subjects were disregarded. Ethical principles guide the IRBs in their attempt to honor the rights of subjects and avoid the mistakes of the past. There are five basic principles considered. The principle of nonmaleficence is to do no harm, the principle of beneficence is to maximize the possible benefits with minimal exposure to risks, the principle of autonomy that is supports the individual’s right to self-determination, justice that the burden and benefits of research participation are equally distributed, and the right to privacy or confidentiality that insures information gained from research is not attributable to an individual. On the surface these principles would appear easy to follow, but this is not the case. The IRB must use procedures to insure that the principles are followed.

1. Principles of nonmaleficence and beneficence

   In the Belmont Report, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research presents the two general rules that operationalize these principles as actions that: (1) do not harm and (2) maximize possible benefits and minimize possible harms. When no therapeutic benefit can result from participation in research, volunteers should be exposed to risks that are minimized to greatest extent possible.

   [http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm) (Belmont Report)

   [http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e1](http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e1) (Risk/benefit analysis)

2) Principle of respect for persons (autonomy).

   This principle requires that research participants are allowed to act autonomously and to express their right of self determination. These principals are operational through the process of informed consent, which involves providing research participants with all relevant information about the study, the risks and benefits involved (in clear and simple language), and ensuring that the information is understood. The agreement to participate must be voluntary, free from elements of coercion or undue inducement to participate.

   [http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e2](http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e2) (informed consent)
3.) The principle of justice.

IRBs are responsible to insure that the risks and benefits of research are equitably distributed. Researchers must take care when dealing with vulnerable populations such as children, patients, and prisoners. There should be no possibility of a participant feeling coerced to participate.

http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e3 (selection of subjects equitably)

4.) The principle of confidentiality.

IRBs should review research involving the collection of data on sensitive subjects such as sexual activity or identity, mental health, or the use of illicit drugs or alcohol. Subjects participating in such studies, which may include these or other sensitive topics, should be made aware of the risks to which they are exposed. In addition, researchers should protect students from any research risks to the greatest extent possible. In a small sample any demographic data collected along with the study information can pose the risk of identifying the participant. For example if there is only one Asian male in your sample on suicide and you collect demographic information, you will know who answered these questions. You must design a study to eliminate such a risk. Procedures must be in place to protect the identity of the participants.

http://www.hhs.gov/ohrp/irb/irb_chapter3.htm#e4 (privacy and confidentiality)

Some researchers believe that since they are doing survey research, there is no way need for an IRB review. Human subjects research includes survey research, outcomes research, epidemiological research, behavioral research, psychological research, oral histories, and clinical trials. (http://ors.bsd.uchicago.edu/HS/FAQ.html#DefineIRB).

Some studies may be exempt from full IRB review, but an IRB committee, not an individual needs to make such a determination. Often times researcher can overlook and underestimate a risk.

Any research paper should include human subjects protection. At a minimum the research should discuss the potential risks and benefits of the subjects’ participation, the system for maintaining privacy and confidentiality, and the procedure for obtaining informed consent. Evidence of IRB exemption or approval should be included.
Additional Web Resources on the ethics of research

http://www.hhs.gov/ohrp/
Office for Human Research Protections

http://ohsr.od.nih.gov/cbt/cbt.html
Computer based training for researchers

http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
Office for Human Subjects Protection Guidebook

http://www.hhs.gov/ohrp/irb/irb_chapter3.htm
Basic IRB review

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
Federal Regulations

http://www.nih.gov/sigs/bioethics/IRB.html
Bioethics resources on the web

http://ohsr.od.nih.gov/info/info.html
Office of Human Subjects Research Information sheets and forms

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

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