

# Protecting Human Research Participants: An Introduction and Summary

## *To whom does human subjects review apply?*

Any living person about whom a researcher obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Note, too: If you use an already existing data base, you will need to verify the original informed consent specifically permits the present use of those data. Researchers can not assume such consent was given unless they can document it. It is also desirable to include a letter from the original researcher authorizing your use of their collected data. However, some data sets are 'fair use information. Census data is such a data set. Consent forms and letters are not needed in such instances.

## *In what types of research?*

Any where bodily materials (cells, blood, hair, nail clippings, etc - even if you did not originally collect these materials); residual diagnostic specimens (even if they would otherwise have been discarded) or private information that can be readily identified with individuals (even if the information was not specifically collected for the study in question).

## *Why is it important?*

Research is necessary to improve practice and services. Yet it must also be done in a manner that protects and promotes the safety and well being of human participants in research, adheres to the ethical values and principles underlying research, is both ethical and scientifically valid, and addresses concerns of the general public about the responsible conduct of research.

Abuses of research such as Nazi experimentation on prisoners led to the establishment of ethical principles to protect the interests of research participants. These principles are still vital and important today. They can be found in the Belmont Report

[<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>] the United States government's Department of Health and Human Services (HHS) regulations for Protection of Human Research Subjects (45 CFR 46, as amended), Protecting Human Research Participants [<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>]

## *Who's responsible? Researchers are ultimately responsible for their work.*

Agencies such as the National Institutes of Health (NIH) provide policies and guidelines concerning participant protections for research. Funding agencies and other sponsors such as educational institutions are responsible by ensuring that grantees, faculty and students adhere to the federal regulations. Scientific peer review groups, institutional review boards review research and oversee human participant protections at different stages in the research process. Through all these steps, the researcher has responsibility to know the regulations and to take several steps to insure their work adheres to the policies and procedures.

## *USE OF HUMAN SUBJECTS: BASIC REQUIREMENTS AND PROCEDURES*

Strict federal regulations (45 CFR 46) and NESAs policy govern the use of human subjects to protect their welfare, ensure their safety, and to ensure that documented informed consent is obtained when necessary (see 45 CFR 46)

The following is taken from the Belmont Report, the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

The expression "basic ethical principles" refers to general judgments that serve as a justification for the ethical prescriptions and evaluations of human actions. Three basic principles are particularly relevant to the ethics of research involving human subjects: the principles of respect for persons, beneficence and justice. Prior to initiating any research involving human subjects, the investigator should carefully consider these ethical principles and the applicability of each to the proposed research.

I. Respect for Persons -This principle is based on two ethical considerations. First, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The Belmont reports describes an autonomous person is one "capable of deliberation about personal goals and of acting under the direction of such deliberation". To respect autonomy would include respect for a person's opinions and choices, and the freedom to act as one chooses (as long as that action is not harmful to others). Human subjects should enter into research voluntarily and with adequate information. Persons with diminished autonomy, who are less capable of self-determination, should be protected.

II. Beneficence -The investigator should also take active measures to secure the well-being of human subjects. Two general rules of beneficence are 1) do no harm and 2) maximize possible benefits. Any possible risk to human subjects should be carefully weighed against possible benefits to the individuals and to the advancement of knowledge.

III. Justice -In research involving human subjects the benefits should at least equal risks to the subjects and, preferably, outweigh the risks. Investigators should especially be careful in the selection of research subjects to be sure that no group of participants are consistently selected for or omitted from the opportunity to participate in research.

It is the view of the New England School of Acupuncture that the principles elucidated in the Belmont Report are fully consistent with its values and ethical positions.

1. APPROVAL: All projects that use human subjects (including use of data or material from living individuals) in ALL research or experiments, OR as the object of projects or surveys, must be approved in advance by the NESAs Institutional Review Board (IRB), or be found exempt from IRB oversight by an authorized person.

2. IRB APPROVAL: Human subject welfare oversight is managed by IRB Chair. An application forms package is available from Dr. Marcel, or the materials may be downloaded from the Web at <http://www.NESA.edu>. Further guidance regarding procedures is available there.

The IRB meets every 2 months to ensure timely review of projects requiring full review. Some projects qualify for an expedited review (about 2 weeks). IRB approval is good for no longer than 1 year from the date of approval. Before this period expires, renewed approval must be sought from the IRB.

3. EXEMPTION: The IRB Chair has been appointed to determine what projects meet the criteria for exemption from IRB oversight. This determination is based on a completed Exemption Request Form, a project summary, consent form and instruments. A form is available from Dr. Marcel for the Principal Investigator to make an initial assessment of the project, and to apply for exemption.

4. STUDENTS may be Principal Investigators only of exempt projects. A NESAs employee must be the responsible Principal Investigator of all non-exempt projects.

5. CLASS PROJECTS present special problems, especially if the instructor intends to collect the data for his/her own research/publication use. It is necessary to seek advance exemption or IRB approval for such projects. A single exemption may be sought for a group of projects to be conducted by a class. If projects are to be designed by class members, the students may read the Belmont Report (see below), complete an Exemption Request Form for each project and apply to IRB Chair. Non-exempt class projects must be approved in advance by the IRB in the usual way.

6. KNOWLEDGE OF REGULATIONS: Principal Investigators of IRB-approved projects are required to be familiar with the Belmont Report, the OHRP regulations, and NESAs Assurance with OHRP regarding human subjects, particularly page 9, investigator responsibilities. All researchers conducting research involving human subjects with NIH funds must receive training on the protection of human subjects, ([http://ohsr.od.nih.gov/extramural/extramural\\_training.html](http://ohsr.od.nih.gov/extramural/extramural_training.html) ). Principal Investigators of exempt projects are also required to comply with the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report), including securing documented Informed Consent.

7. DOCUMENTATION OF INFORMED CONSENT is required to be kept on file by the investigator for 6 years after the end of the study. If the investigator leaves the NESAs, the records should be turned over to the IRB Chair.

IRB forms, the Belmont Report, the regulations governing research with humans, and other relevant materials are available from the IRB chair or on the OHRP Web site at:

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>

Please contact the IRB Chair, Barbara B. Marcel, [bmarcel@NESAs.edu](mailto:bmarcel@NESAs.edu), 617-926-1788, ext 121.