HUMAN SUBJECTS PROTECTION IN RESEARCH

Frequently Asked Questions

1. WHY SHOULD I BE CONCERNED ABOUT A BOUT THE PROTECTION OF HUMAN SUBJECTS?

It is the ethical thing to do, and it is mandated by Federal Regulations, 45 CFR 46.

2. WHAT ETHICAL PRINCIPLES GUIDE THE PROTECTION OF HUMAN SUBJECTS?

Three basic principles of ethics particularly relevant to the protection of human subjects in biomedical, social and behavioral research are articulated in *The Belmont Report:*

(a) Respect for Persons: recognition of the personal dignity and autonomy of human research subjects and the need for special protections of subjects with diminished autonomy, such as children, or prisoners;

(b) Beneficence: obligation to protect subjects from harm by maximizing anticipated benefits and minimizing possible risks;

(c) Justice: fairness in the distribution of benefits and burdens of research.

3. WHAT ARE THE MAJOR REQUIREMENTS OF 45 CFR 46?

The regulations require institutions conducting research involving human subjects to establish Institutional Review Boards (IRBs). IRBs review research (biomedical, social or behavioral) prospectively from the viewpoint of protecting the rights and safeguarding the welfare of human research subjects.

4. HOW DOES THE IRB PROTECT THE RIGHTS AND WELFARE OF HUMAN RESEARCH SUBJECTS?

The IRB prospectively reviews all research involving human subjects using the following criteria: (a) the design of the study is consistent with sound scientific principles and ethical norms; (b) the protocol meets the NIH FWA criteria necessary for approval; (c) the necessary elements of informed consent have been fulfilled; and (d) additional appropriate safe guards have been provided if potentially vulnerable subjects (e.g., children, prisoners, and fetuses) are to be studied.

In addition, the IRB conducts continuing review of each approved protocol at least annually. The IRB may modify, suspend or terminate approval of research that has been associated with serious harm to subjects, or is not being conducted in accordance with the IRB's decisions, stipulations or requirements. Committee membership is diverse with expertise in the sciences, ethics, and other non-scientific areas, thereby fostering a comprehensive approach to the protection of human subjects.

5. WHAT ACTIVITIES QUALIFY AS HUMAN SUBJECTS RESEARCH?

Simply stated, "any systematic attempt to collect information and gain generalizable knowledge about humans" would qualify. Federal Regulations 45 CFR 46 define research as "a systematic investigation, including research development, testing, evaluation, designed to develop or contribute to generalizable knowledge", and they define human subject as "a living individual, about whom the investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

6. DOES MSU HAVE AN IRB?

Yes, Morgan State University has an IRB. The IRB Administrator is Dr. Edet Isuk; he can be reached at x4340. The current IRB chairperson is Dr. Benjamin Welsh; he can be reached at x3748.

7. DOES MSU's IRB HAVE A FEDERAL WIDE ASSURANCE NUMBER (FWA)?

Yes, all IRB's registered with the NIH Office for Human Research Protections (OHRP) must obtain an approved assurance number. MSU's assurance number is **FWA 00003318**

8. HOW DO I KNOW IF MY STUDY NEEDS TO BE REVIEWED BY THE IRB?

Most studies conducted by MSU faculty, students or administrators will need to be reviewed by the IRB if human subjects or participants are involved. This provides protection for the participants, the researcher and the institution. If you are not sure, contact the IRB Administrator (Dr. Isuk).

9. WHAT MATERIALS DO I NEED TO SUBMIT TO THE IRB?

Submit your packet to the IRB administrator including the following:

(a) Completed and signed "Human Subjects Application Form";
(b) Project summary;
(c) Research protocol;
(d) Informed consent form; assent form; debriefing form
(e) Questionnaires, interview questions, tests, recruitment flyers, etc.

10. HOW LONG DOES THE APPROVAL PROCESS TAKE?

The IRB generally meets monthly and applications must be submitted to the IRB administrator at least THREE weeks prior to the monthly meeting. Late applications will be reviewed in the subsequent meeting. IRB meeting dates and the corresponding deadlines for submitting applications during the academic year are published on the OSPR website. Please call x4340 if you need a hard copy of the schedule.

11. WHERE CAN I GET MORE TRAINING ON PROTECTING HUMAN RESEARCH PARTICIPANTS?

MSU subscribes to the on-line CITI Training Program through which investigators can receive not only human subjects protection training, regardless of discipline, but also training broadly in responsible conduct of research (RCR). The web address is:

http://www.citiprogram.org

Also, the NIH Office of Extramural Research offers a free web-based training course that satisfies the NIH requirement that all investigators provide documentation of having received human subjects protection training. The web address is:

http://phrp.nihtraining.com

12. I HAVE MORE QUESTIONS THAT HAVE NOT BEEN ANSWERED HERE. WHAT SHOULD I DO?

Contact the IRB Administrator, Dr. Edet Isuk at x4340, irb.research@morgan.edu