

Guidelines for Human Subjects Research Miami University

I. Introduction

To assure the protection of human subjects and to comply with Federal law, Miami University requires that prior to contacting potential study participants; all research projects involving human subjects must be reviewed and approved by the Institutional Review Board for Human Subjects Research (IRB). The IRB has the responsibility for protecting the rights and welfare of human subjects in research.

Miami University has a Federal wide Assurance (FWA) with the Office for Human Research Protections (OHRP) in the Department of Health and Human Services. This agreement assures that all human subjects research conducted under the auspices of Miami University will comply with Title 45, Code 46 (Common Rule) of the federal regulations. The Miami University IRB also adheres to other federal, state, local and institutional guidelines as applicable on the responsible conduct of research.

Institutional Review Board (IRB)

The Institutional Review Board for Human Subjects Research (IRB) for Miami University has the responsibility to oversee procedures for carrying out the University's commitment to protect human subjects in research. This oversight includes both internal and externally funded research. The IRB is authorized to approve, require modifications in (to secure approval), or disapprove all research activities using human subjects covered by this policy.

The IRB has two designated subcommittees: (a) the Psychology Subcommittee of the IRB (Departmental Review Board) and (b) International Research Subcommittee. Both subcommittees have delegated responsibility for expedited review and have members who are full-board members of the IRB. Research protocols in the area of psychology may be submitted to the chairperson of the Psychology subcommittee (DRB) and all international research protocols should be submitted to the OARS for review by the International Research Subcommittee.

II. What Is Human Subjects Research?

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

Research is defined as a systematic investigation, inquiry or analysis-including critical analysis or inquiry-that is designed to develop or contribute to generalizable knowledge. This definition also expands to include if the results of your work are to be published, presented or shared externally.

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

III. Do I have to submit an IRB application?

This policy applies to all activities which, in whole or in part, involve research with human subjects if:

- (a) The research is sponsored by Miami University, or
- (b) The research is conducted by or under the direction of faculty, staff, or students of Miami University in connection with their institutional responsibilities, or
- (c) The research is conducted by or under the direction of faculty, staff or students of Miami University using any property or facility of the University, or
- (d) The research involves the use of Miami University's nonpublic information to identify or contact human research subjects or prospective subjects.

Graduate and undergraduate student research projects which meet the definition of research and are intended for dissemination beyond the classroom are covered by this policy. Student projects designed to provide research training which are not intended for dissemination beyond the classroom are not treated as research projects under this policy (*Refer to Standard Operating Procedure 11.7 for further details*).

IV. Required Ethics Training on Human Subjects Research

All researchers who interact with human subjects to collect data must complete a required educational program on the ethics and procedures for the use of human subjects in research before the Institutional Review Board may approve a proposal. The Miami University required training is CITI. Information on the training is as follows:

Who Should Complete Ethics Training?

The CITI on-line training course must be completed by the principal investigator (PI), co-principal investigators, and other key personnel who are responsible for the design and/or conduct of the study. The requirement applies to subcontractors, consultants, individual fellowship applicants, study coordinators, and persons who conduct invasive procedures, or conduct health or opinion surveys or interviews. Research assistants including graduate and undergraduate students who are collecting data from human subjects including providing explanations or answering questions about the research or data gathering instruments are also required to complete the training program.

Individuals providing technical services only such as setting up a room, handing out and collecting survey instruments without providing explanations or answering questions about the research or data-gathering instruments, typing data into a data base, transcribing audiotapes, or reviewing videotapes to code behavior, are not covered by this requirement; however, they should receive instruction on maintaining privacy and confidentiality of data.

Researchers are required to complete a two-part training requirement. The first component is the CITI on-line ethics training. The second component is the one hour practicum session. Both components are described below:

1) CITI On-Line Training Requirement (<http://www.citiprogram.org>)

A vital component of all human subjects ethics training are the ethical principles regarding all research involving humans as subjects. These principles have been set forth in the report published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." Some of these principles include respect for persons, beneficence (including minimization of risks and maximization of benefits), and justice. This report

is addressed in the CITI on-line training and may also be accessed at the following site:

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

2) One Hour Practicum Session

As of August 24, 2006 only Principal Investigators and Faculty Advisors will be required to attend the 1 hour practicum session since the practicum's focus is on the IRB application development and submission process.

Individuals who are working as part of the research project, but will not be responsible in any way for the development and submission of the IRB application are no longer required to attend this session. However, these individuals must still complete the CITI Basic Course.

V. Submitting an IRB Application for Review

Researchers who propose to conduct research involving human subjects shall prepare and submit an Application for Approval of Research Involving Human Subjects to the IRB or to the DRB. Applications must be approved prior to any subject recruitment or contact with subjects. Researchers must complete the required education program on research ethics for human subjects research prior to approval of an application (see section IV).

The objective of committee review is to ensure that the rights and welfare of the subjects are adequately protected and that all activities involving human subjects are in compliance with University policies and Federal regulations to assure that:

- (a) Selection of research subjects is equitable
- (b) Informed consent is obtained and documented where appropriate
- (c) Risks to subjects are minimized
- (d) Risks are reasonable in relation to anticipated benefits to subjects and others
- (e) Privacy and confidentiality are protected
- (f) Data handling and safety monitoring provisions are adequate
- (g) Vulnerable subjects are provided special safeguards against undue influence or coercion to participate in the research

Types of Protocol Review

A. New Protocol Review -- All new research projects involving human subjects shall be reviewed by the IRB or the DRB prior to beginning the project. For initial review by the IRB, investigators

shall submit a signed original and three copies of an Application for Approval of Research Involving Human Subjects, including the cover page, research description and supporting materials as specified in the Instructions for Completing an Application for New Protocol Review. If the protocol is referred to the full IRB for review by the initial reviewers, the investigator will be contacted to submit additional copies of the protocol with any requested changes.

B. Revisions to an Approved Protocol -- Any changes in an approved protocol, including subject population, study location, procedures, or project personnel must be reviewed and approved by the IRB prior to initiating changes. Investigators shall submit a signed original and three copies of a new Application Cover Page, a description of the proposed changes, and the revised protocol that incorporates the proposed changes.

C. Continuing Project Review -- All research involving human subjects must be re-reviewed periodically, at least every twelve months or more frequently as specified in the original approval notification. This applies to studies for which data are continuing to be collected or for which research data are being maintained with personal identifiers that can be linked to individual subject responses. For review of continuing projects, investigators shall submit a signed original and three copies of an Application for Approval of Research Involving Human Subjects including a status report and supporting materials as specified in the Instructions for Completing an Application for Continuing Project Review. Research projects are not eligible for continuing review if the project's approval has expired. A new protocol application needs to be filed in this situation.

VI. Researchers' Responsibilities for Responsible Conduct of Research

Researchers shall obtain approval for proposed human subjects research prior to recruiting subjects or collecting data from subjects. This applies to preliminary and pilot studies which are developing or testing instruments and procedures, as well as the full study.

Researchers shall explain to subjects, prior to their decision about whether or not to participate, the objectives of the research, the procedures to be followed and the potential risks and benefits. Researchers shall not use individuals as subjects unless satisfied that they, and/or others legally

responsible for their well-being, fully understand the consequence of participation and freely consent to participate in the research. The IRB may waive these requirements for written informed consent only when persuaded that the research cannot otherwise be done, that its potential value outweighs the indignity to the subject, and that the subject runs no further risk or harm in participating. Researchers shall seek consent from subjects to participate only under circumstances that provide the prospective subject sufficient opportunity to consider and decide freely whether or not to participate. Subjects shall be given a copy of the informed consent materials to keep.

Researchers shall make clear to subjects that participation is voluntary and that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw shall be allowed to do so promptly and without penalty or loss of benefits to which the subject is otherwise entitled. Any payment to subjects must be reasonable and prorated with partial payment in the event subjects discontinue participation during the course of the study.

Researchers shall respect the privacy of subjects. They shall protect confidential information given them, advising subjects in advance of any limits upon their ability to ensure that the information will remain confidential.

Researchers shall obtain approval from the IRB or DRB prior to making any changes in the research procedures. This approval shall be done in a timely manner.

Student Researchers

- A. Student Research Projects designed to add to generalizable knowledge through dissemination of results in publications or presentations beyond the classroom are covered by this policy on human subjects research. Faculty members who assign or supervise research conducted by students are responsible for ensuring that the proposed research is reviewed and conducted in accordance with University policy and the student is qualified to safeguard adequately the well-being of the subjects.
- B. Class Projects designed to provide hands-on experience or research training to students are not treated as research projects in this policy and do not require formal IRB or DRB review. Projects in

this category are expected to be confined to the specific class and end at the termination of that class. If it is anticipated that the research project will be used in other classes or published or presented beyond the classroom, the project should be submitted to the IRB for review. Faculty members who assign research learning experiences are responsible for assuring that people used in such projects are treated ethically. Faculty members must provide information to students on University policies and guidelines on human subjects research and develop class procedures in a manner that protects the privacy, dignity, and welfare of participants. **If you are planning to conduct student or course-related research as part of your work, please refer to SOP 11.7 for further guidance.**

Research Subjects Under Age 18

Consent from parent(s) or legal guardian(s) is required for children under age 18. College students who are under age 18 must have parental or guardian consent to participate as research subjects. In addition to parental or guardian consent, children should also be asked for their assent to participate in the research project in language appropriate to the subject's age and maturity.

Surveys, interview procedures, or participant observations are not eligible for exempt status when persons under age 18 are involved as subjects. **If you are planning to conduct research in a public or private educational setting with students, please refer to Standard Operating Procedure 11.6 for guidance on this type of research.**

If you have any further questions about the IRB application materials, training requirements, review procedure or other issues, please contact the Office for the Advancement of Research and Scholarship at 529-3734 or email us at (humansubjects@muohio.edu).