

MISSOURI WESTERN STATE UNIVERSITY  
Institutional Review Committee for the Protection of Human Subjects  
GENERAL INFORMATION ABOUT IRBS AND MWSU'S CUHSR

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General Information

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The role of the human subjects Institutional Review Board (IRB) is to protect the welfare and rights of human subjects in research projects. In part, the IRB's job is to ensure that human subjects do not experience undue risks to their physical and/or psychological well-being. The IRB must ensure that the subject (or the subject's legal representative) is legally and mentally able to provide informed consent, and is free from undue coercion. The IRB also must ensure that the subject's rights are respected, including the right to reasonable information about (a) the nature of the study, (b) the personal and societal risks and benefits of the study, (c) confidentiality and accessibility of the subject's personal data, and (d) the possibility of terminating participation and/or withdrawing all personal data from the study. These obligations of the researcher and institution and these rights of the subjects are, in part, spelled out in federal, state and, possibly, local laws. In addition, each institution may have its own regulations and procedures to which each research project must conform. At MWSU, the human subjects IRB is the Committee on the Use of Human Subjects in Research (CUHSR). Projects requiring human subjects must also be approved by the department chair (or comparable person). Finally, researchers who wish to present or publish their results must be aware that many professional societies, journals, and governmental and private granting agencies, have procedural and ethical requirements that typically include strict IRB review and additional requirements (e.g., institutional signatures on ethical guidelines; a letter signed by all co-authors accompanying the submission).

The issues of the welfare, rights and responsibilities of human subjects may seem straightforward. However, the realities of many research designs create large gray areas of interpretation. For example, if subjects know the purpose of a study, this knowledge may substantially alter their behavior, often in complex and unknown ways. This means that complete informed consent will make the study invalid for assessing typical unobserved behavior. Therefore, the researcher, the IRB and other responsible parties must make a subjective decision concerning how much information about the nature of study can be revealed to a subject to meet the researcher's ethical obligations without significantly impairing the study's usefulness. If no acceptable compromise can be found, the study must be disallowed.

PRINCIPLES, RULES, AND REGULATIONS GOVERNING  
THE USE OF HUMAN SUBJECTS IN RESEARCH  
AT MISSOURI WESTERN STATE UNIVERSITY

*1. Introduction and Background*

When human beings are used as subjects in research projects, safeguards must be established to protect their health, well-being, and rights. Under the policies established by the Department of Health and Human Services (HHS), this protection was extended to all human subjects regardless of the nature of the research being performed. This protection required that Institutional Review Boards (IRB) at colleges and universities be established to review and act on all research proposals involving human subjects from review by Institutional Review Boards. The most recent revision is Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 46, Revised June 18, 1991 printed in the OPRR Reports of NIH, PHS, and HHS and simultaneously in the Federal Register.

*2. Research Exempt from Review by the Missouri Western State University Institutional Review*

### *Board (CUHSR)*

Certain types of research need not be reviewed by the CUHSR; categories of exempt research are described below. If you believe that your research falls into one of the exempt categories, you must request a verification of exemption from the CUHSR. See Application Materials -- Requesting Exemptions.

**Note on Research Involving Children:** Research involving children falls in a special category -- the exemptions below may not apply. Survey research and interview procedures involving children are not exempt. Researchers involving children in their projects are urged to contact the CUHSR for a copy of the Federal Rules and Regulations (Federal Register, Vol. 48, No. 46, Tuesday March 8, 1983) governing the use of the children. Unless otherwise required by the Chair of CUHSR, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from full CUHSR review:

**Category 1. Common Educational Practices:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instruction strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Category 2. Educational Testing:** Research involving the use of educational tests (cognitive diagnostic, aptitude, achievement), survey procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subject; (ii) and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

**Category 3. Survey and Observation:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures or observation of public behavior that is not exempt under Category 2, is exempt if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) requires(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**Category 4. Data Collection and Study:** Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked.

**Category 5. Public Service Programs:** Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs or their procedures or alternatives.

**Category 6. Taste and Food Quality:** Taste and food quality evaluation and consumer acceptance studies if safe or wholesome foods without additives are consumed.

### *3. Research Requiring Review by the Missouri Western State University Institutional Review Board*

The federal government defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

The following types of research (unless exempted in Section 2) **must** be approved by the Missouri Western State University Institutional Review Board before initiation of the research.

- a. Research proposals submitted to extramural funding agencies
- b. Research published in, or intended for publication in, non-teaching journals
- c. Research designed and conducted by students for a research course (e.g. independent study, PED451 Research in Health and Exercise Science, BIO495 Individual Research in Biology, PSY480 Independent Research) if the research

falls under the federal definition of research

d. Dissertations

*4. Requirements of Informed Consent*

Generally, investigators may not involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Under certain circumstances, informed consent may be waived (see next page). Normally, however, the basic elements of informed consent shall include the following:

Usual Requirements for Informed Consent

- a. A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, an identification of any procedures which are experimental;
- b. A description of any reasonably foreseeable risk or discomfort to the subject;
- c. A description of any benefits to the subjects or to others which may be reasonably expected from the research;
- d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- f. If more than minimal risk is involved, an explanation must be provided as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained;
- g. An explanation of whom to contact for answers to pertinent questions about the research subject's rights, and whom to contact in the events of a research-related injury to the subject; and
- h. A statement that participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and that the subject may discontinue participation at any time without penalty or loss of benefits (except loss of extra credit for failure to participate).

More Stringent Requirements for Informed Consent

Where appropriate, the following elements of informed consent must also be included:

- a. A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable;
- b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- c. Any additional costs to the subject that may result from participation in the research;
- d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- e. A statement that significant new findings developed during the research may relate to the subject's willingness to continue participation will be provided to the subject; and
- f. The approximate number of subjects involved in the study.

Waiving Informed Consent

The CUHSR has the authority to approve a consent procedure which does not include or which alters some or all of the previously mentioned elements of informed consent or waive the requirements for informed consent if, either:

- a. 1) The research involves no more than minimal risk;

- 2) The waiver or alteration does not adversely affect the rights and welfare of the subjects;
  - 3) The research could not practically be carried out without the waiver or alteration;
- and
- 4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

OR

- b. 1) The research is to be conducted by or subject to the approval of state or local government officials, and is designed to study or evaluate
  - i. public benefit or service programs;
  - ii. procedures for obtaining benefits or services under these programs, or
  - iii. possible changes in or alternatives to these programs or procedures;

OR

- 2) The research could not practically be carried out without the waiver or alteration.

#### *5. Documentation of Informed Consent*

Informed consent shall be documented by the use of a written consent form approved by CUHSR and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

#### *6. Procedure for Committee Review*

It is the responsibility of the investigator (faculty member, administrator, or student) using human beings in a covered research project to submit the appropriate application materials for Committee review according to the following guidelines.

- a. Obtain the Application Materials from the Chair of the CUHSR.
  - b. Submit all completed forms to the Chairperson of the Committee on the Use of Human Subjects in Research. Submit seven copies of all materials to permit distribution to individual members of the Committee.
  - c. Written response concerning Committee action and/or approval forms will be sent to the applicant within one week following final action by the Committee.
  - d. The Committee reserves the right to consult with experts. If expert review of a proposal is deemed necessary by the Committee, a substantial delay in Committee action should be anticipated.
  - e. In the event that a project is denied approval by the Committee, the applicant will be notified in writing of the reasons for disapproval and will be given the opportunity to respond in person or in writing.
  - f. All research projects that have been approved by the Committee may be subject to further review or disapproval by appropriate officials of the College. Projects that have been disapproved by the Committee may not be subsequently approved by any officials of the College.
  - g. Major changes in the research design and/or procedures following Committee approval must be resubmitted to the Committee as an amended proposal. In addition, progress reports must be submitted at least annually and more often if so specified by the Committee.
  - h. Approval of a project does not remove the investigator's legal responsibility for the project. The researcher is expected to retain signed individual informed consent forms for a period of five years. The Committee's approval of a project constitutes only a statement by the MWSU Committee that it believes the rights of human beings will be adequately protected.
  - i. A statement describing the methods and procedures used to protect human beings and insure confidentiality for an exempt, yet sensitive project using human subjects, should be filed with the chairperson of the Committee on the Use of Human Subjects in Research. This statement must be signed by the researcher, faculty advisor (if the researcher is a student), and the Department Chairperson.
  - j. In cooperative research with researchers at other institutions, proposals should be submitted to the Chair of the CUHSR at both institutions.
- Questions concerning application procedures and guidelines should be referred to the Chair of the CUHSR or to the Office of the Vice President for Academic and Student Affairs.

### *7. Criteria for Approval*

The CUHSR reviews and has the authority to approve, require modification in (to receive approval) or disapprove all research activities covered by HHS guidelines.

In order to approve a research project the CUHSR shall determine that all of the following requirements are satisfied:

- a. Risks to the subjects are minimized.
- b. Risks to the subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and to the importance of the knowledge that may be reasonably expected to result.
- c. Selection of subjects is equitable.
- d. In most cases, informed consent will be sought from each prospective subject or the subject's legally authorized representative (see next page for more information).
- e. Informed consent will be appropriately documented.
- f. Where appropriate, the research plan makes adequate provisions for monitoring the data collected to insure the safety of subjects.
- g. Where appropriate, adequate provisions protect privacy of subjects and maintain the confidentiality of data.
- h. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

The CUHSR shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the CUHSR's requirements or that has been associated with unexpected serious harm to subjects.

CUHSR regulations require that research involving any level of deception be followed by an appropriate debriefing of all subjects. Debriefing procedures should be specified in the CUHSR application form.