

Eastern Michigan University
College of Education
Policy and Procedures on the Use of
Human Subjects in Student Research

It is the policy of Eastern Michigan University's College of Education to respect and safeguard the rights and welfare of all individuals who are involved in its activities, especially where human beings may be participating as subjects in research, experimental procedures in instruction, or other related activities. To this end, a Human Subjects Review Committee (HSRC) has been established to review all student research involving human subjects. It is the policy of the University to comply with the regulations of the United States Department of Health and Human Services for the Protection of Human Research Subjects (Part 46 of Title 45 of the Code of Federal Regulations, as amended). The COE HSRC is subordinate to, and derives its authority from, the University-level HSRC.

The COE HSRC is responsible for developing and enforcing policies and procedures applicable to student research wherein human beings may be at minimal risk, or greater, as a consequence of participating in an investigation or experimental procedure.

Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Administration of the Policy

The Board of Regents of Eastern Michigan University delegates responsibility for the implementation and administration of this Policy to the Provost and Vice President for Academic Affairs. The Provost is responsible for appointing the members of the HSRC and giving them direction. The Provost is also responsible for promulgating the procedures to be used in the implementation of this Policy.

Authority of the Human Subjects Review Committee

The HSRC of the College of Education shall review and have authority to exempt, approve, require modifications in, or disapprove all student research activities covered by the Human Subjects Review Policy. It may review proposed research at convened meetings at which a majority of the members of the Committee are present, or it may use an expedited review procedure if the research involves no more than minimal risk or if it is reviewing minor changes in previously approved research during the period in which approval is authorized.

If, during an expedited review, any member of the review group determines that there is greater than minimal risk, the proposal shall be referred to the full HSRC first, and, if necessary, to the University HSRC for consideration.

The COE HSRC shall conduct continuing review of research covered by the Policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research itself. The Committee shall have the authority to suspend or terminate approval of research that is not being conducted as approved, or in accordance with the Policy or that has produced unexpected serious harm to subjects. In cases where the Committee rejects the proposed study, notification will be sent promptly to the investigator, appropriate institutional officials and funding agency, if applicable, along with a statement of the reasons for the disapproval. The Committee may also recommend that the University impose sanctions upon any investigator who does not conform to this Policy.

Research covered by this Policy that has been approved by the HSRC may be subject to further appropriate review and approval or disapproval by officials of the University. However, those officials cannot approve the research unless it has also been approved by the Committee.

Procedural Timetable:

1. Proposal must be submitted to COE HSRC administrative co-chair:
c/o Dr. Michael Bretting
310 Porter Bldg
Ypsilanti, MI 48197
2. Human Subjects proposals will be reviewed on a continuous basis, from September through July.
3. Applicants will be notified within three weeks regarding the status of their proposal.
4. If necessary, full committee review of a proposal with “minimal risk” will take place during the next month.

Applicability of the Policy

The Human Subjects review process applies to all student research¹ involving the use of human subjects:

- Theses;
- Funded or unfunded;
- Participated in, or directed by, any faculty, staff or student at Eastern Michigan University;
- Done on the property of, or using the facilities of, Eastern Michigan University, or;
- Using University personnel or students as subjects.

All student research and theses using human subjects must, prior to the commencement of research, and using procedures promulgated by the HSRC, submit research applications for review by the Committee. Securing prior approval for data collection for the research study is the responsibility of the principal investigator (P.I.) or similarly designated person who has

¹ "Research" is defined in this policy to mean a systematic investigation designed to develop or contribute to generalizable knowledge.

responsibility for leading the project.² **Acquiring prior approval to collect data for the research is mandatory.** Decisions about whether research is **exempt** from the policy must be made by the COE HSRC, not by the P.I.

Notification of Decisions

The HSRC sends written notification to the Principal Investigator regarding HSRC decisions, conditions, and requirements. Researchers are also informed of the reasons for the disapproval of an investigation and given an opportunity to respond. Information regarding the status of an application submitted for HSRC review cannot be provided over the telephone.

Responsibilities of the Principal Investigator

The principal investigator is responsible for:

1. The compliance of all co-investigators, student investigators, and research associates with the HSRC decisions, conditions, and requirements
2. Reporting to the HSRC on any changes to the research protocol (e.g., research design of the study, recruitment procedures)
3. Reporting to the HSRC chair any unanticipated adverse reactions or unanticipated events associated with the conduct of this research
4. Seeking clarification and advice from the HSRC regarding ethical aspects of the research

The Informed Consent Document

A critical piece of the HSRC application is the Informed Consent Document. Following the guidelines below will greatly improve your chances of receiving approval from the HSRC. Remember, an effective informed consent document provides a succinct but complete explanation of the research project in a language appropriate for the targeted subject population.

Consent Forms for Children.

Parent /Guardian Consent is required for any Human Subjects Research involving Minors.

Children's *assent* is also required and a separate consent form must be submitted that is written in clear, understandable, and developmentally appropriate language so that children understand what they are *assenting* to in terms of a research project.

The following age-appropriate guidelines should be followed:

Young Children (under six) and Children who cannot read

Oral protocol must be read to the children in the presence of a neutral adult observer who will sign the protocol as a witness

Children and Adolescents 6-18

² "Principal Investigator" is defined in this policy as the faculty sponsor, supervisor, or thesis/dissertation advisor, **NOT** as the student.

Consent Form must be written to the appropriate developmental/grade level of the child/Adolescent. Language must be carefully chosen so that children are not confused by unfamiliar terminology. Children will sign a consent form that is separate from the parent consent form. Basic guarantees of anonymity and confidentiality must be included with assurance of no penalty for withdrawal or non-participation.

Instructions for administering the consent document

1. Pass out two forms – one for subjects to sign and return to you and one for them to keep for their records.
2. Read the form aloud as the subjects read it to themselves.
3. After reading it aloud, summarize what is stated on the form(s).
4. Allow ample time for subjects to ask questions.
5. Schedule a break to allow subjects time to consider whether they want to participate or not.

Components of the Consent Document

Beginning:

- Who is doing the research.
- The nature, purpose, and duration of the research.
- The uses to be made of the data.

Middle:

- The methods to be employed.
- The hazards, inconveniences, and risks the subjects will undergo, if any.
- The availability of compensation and treatment, if injured.
- The benefits that might be expected, if any.
- Disclosure of alternate procedures the subject may choose if the research is therapeutically related.
- The voluntary conditions of participation.

End:

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- The fact that the subject is at liberty to withdraw his/her consent prior to the data collection, or discontinue participation in the research at any time, without prejudice.
- An offer to answer any questions as well as instructions on whom to contact should questions arise later.
- A place for the date of signing and for the signatures of the subject and researcher.

APPLICATION INFORMATION AND PROCEDURES

1. An application (including the 400 word synopsis) for HSRC approval should stand on its own, without attached thesis or grant proposal. The information should be complete yet succinct, so that committee members unfamiliar with the proposed research are able to

evaluate potential risks to subjects, recruitment procedures, potential benefits, and the process of obtaining informed consent.

2. Researchers collaborating with other organizations (e.g., schools, hospitals, etc.) must obtain copies of the organization's agreement to participate in the study and (if applicable) their review board approval.
3. Once a project is approved and data collection begins, any unanticipated problems or changes in research protocol must be reported to the HSRC immediately.
4. The term of approval for an application is 365 days. Afterwards, researchers must reapply for HSRC review.

Exceptions to above policy:

1. Classroom activities which use human subjects if the purpose of the activity is purely pedagogical, and the results are intended solely for use within the classroom setting and do not involve any dissemination of results.
2. Any data collected for administrative, pedagogical, or clinical purposes involving human subjects, conducted by undergraduate or graduate students as part of a course assignment, where the results are intended solely for the classroom setting and do not involve dissemination of results.
3. Data collection done solely for administrative, pedagogical, or clinical purposes is not intended to contribute to generalizable knowledge and does not constitute research as defined on page 2. However, a researcher may subsequently wish to utilize data collected for administrative purposes or in the course of teaching or clinical treatment. In that case, the resulting study would be "research," and the researcher must seek HSRC approval for the use of such data.

Cooperative Research

In the event that research covered by this Policy is headed by a project director or co-director from another institution, the researcher must submit to the HSRC the statement of approval from the project director's home institution. The HSRC will accept the statement of approval if:

- A. The policy guidelines of another domestic HSRC are certified as meeting at least the U.S. Federal regulations, and
- B. The other HSRC approves the research and provides certification of such.

Independent Research

Research involving the use of human subjects, which is conducted independently of the University, is not covered by this Policy. However, to consider research as independent, the

investigator cannot use his/her affiliation with the University, nor any University facilities, nor any University resources in conducting the research, nor conduct the research under University auspices.

Ethical Standards for Research Involving Human Subjects

The decision to undertake research rests upon a considered judgment by the individual investigator. Having made the decision to conduct research, the investigator considers alternative directions in which research energies and resources might be invested. On the basis of this consideration, the investigator carries out the investigation with respect and concern for the dignity and welfare of the people who participate and with cognizance of federal and state regulations, University policy and professional standards governing the conduct of research with human participants.

In order to approve research covered by this Policy, the HSRC shall determine that, prior to any data collection involving human subjects, all of the following requirements are satisfied:

1. Risks to the subjects are minimized:
 - A. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
 - B. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable³ considering the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative. The written informed consent statement shall be in language which is understandable to the subject or his/her representative and shall include a statement about a subject's right to withdraw from a study at any time without prejudice.
5. Informed consent must be appropriately documented.
6. Where appropriate, the research plan makes adequate provision to protect the privacy of subjects and to maintain the confidentiality of data.
7. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who

³ "Equitable" is defined in this policy to mean that there is no discrimination in the selection of subjects and no over selection of vulnerable subjects.

are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Categories of Review

EXEMPT FROM REVIEW

This category applies to research that is exempt from applicable federal regulations; however, EMU still requires review by the HSRC. Therefore, investigators may not determine the status of their own research.

EXEMPTION CATEGORIES

Projects that involve no element of research are exempt from review by the Human Subjects Committee. 46.120(a) Projects in which the only involvement of human subjects will be in one or more of the following do not require review by the Human Subjects Committee unless the project involves research which includes a subject population, such as prisoners, for which a Subpart of Part 46, Title 45 of the Code of Federal Regulations provides special protection. 46.101(b)

- I. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - A. Research on regular and special education instructional strategies;
 - B. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 46.101(b1)
- II. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects. 46.101(b2)
- III. Research involving survey or interview procedures, *except* where:
 - A. The subject population includes children.
 - B. Responses are recorded in such a manner that subjects can be identified AND
 1. If the subject's responses became known, they could place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability
 2. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol. 46.101(b3)
- IV. Research involving survey or interview procedures when the respondents are elected or appointed public officials or candidates for public office. 46.101 (b4)
- V. Research involving the observation of public behavior *except* where responses are recorded in a manner that subjects can be identified, AND

- A. If the subject's responses became known, they could place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability.
 - B. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
 - C. If the subject populations include children and the investigator participates in the activities being observed. 46. 101(b5)
- VI. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified. 46.101(b6)

DEFINITIONS

HUMAN SUBJECT: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

RESEARCH: A systematic investigation designed to develop or contribute to generalizable knowledge.

If the application has been adequately completed, the exemption process typically requires a period of 14 days following receipt of the application by the HSRC office.

It is at the final discretion of the HSRC chair to have a project reviewed under a different category.

EXPEDITED REVIEW

The student researcher will complete the “Request for Approval Involving Human Subjects” application.

Expedited review consists of a subcommittee of two committee members chosen by the HSRC chair. The recommendations of the subcommittee are then submitted to the full committee for consideration at its next meeting.

Expedited review is not intended to avoid the policies of EMU or the requirements of the Code of Federal Regulations (45 CFR 46). Expedited review may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented

so that risks related to the invasion of privacy and breach of confidentiality are no greater than minimal.

The following categories of research are eligible for expedited review regardless of the age of the subjects:

1. Clinical studies of drugs and medical devices only when:
 - a. Research on drugs for which an investigational new drug application is not required
 - b. Research on medical devices for which (I) an investigational device exemption application is not required or (II) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. From healthy, nonpregnant adults weighing at least 110 pounds with the total volume collected not exceeding 450 ml in an 8-week period and collection occurring no more frequently than twice per week
 - b. From other adults and children, considering the age, weight, and health of the subject, the collection procedure, the volume of blood to be collected, and the frequency with which it will be collected not exceeding the lesser of 50 ml or 3 ml/kg in an 8-week period and collection occurring no more frequently than twice per week
3. Prospective collection of biological specimens for research purposes by noninvasive means, such as:
 - a. Hair and nail clippings in a nondisfiguring manner
 - b. Deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction
 - c. Permanent teeth if routine patient care indicates a need for extraction
 - d. Excrete and external secretions (including sweat)
 - e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue
 - f. Placenta removed at delivery
 - g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
 - h. supra- or sub gingival dental plaque and calculus, provided that the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
 - i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
 - j. Sputum collected after saline mist nebulization
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves, such as:
 - a. Physical sensors that are applied to either the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
 - b. Weighing or testing of sensory acuity

- c. Magnetic resonance imaging
 - d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
 - e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing were appropriate given the age, weight, and health of the individual
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis) in a confidential manner
 6. Collection of data from voice, video, digital, or image recordings made for research purposes
 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or confidential research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
 8. Continuing review of research previously approved by the convened HSRC as follows:
 - a. Where (i) the research is permanently closed to the enrollment of new subjects, (ii) all subjects have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of subjects
 - b. Where no subjects have been enrolled and no additional risks have been identified
 - c. Where the remaining research activities are limited to data analysis
 9. Continuing review of research, not conducted under an investigative new drug application or investigational device exemption where categories (2) through (8) do not apply but the HSRC has determined and documented at a convened meeting that the research involves no more than minimal risk and no additional risks have been identified
 10. Minor changes in previously approved research
 11. Research on dietary supplements or drugs for which a prescription is not required
 12. Other categories added to this list by the Department of Health Services at the NIH

HSRC members participating in expedited review can either approve the research as expedited or refer it for full committee review. At the following full committee meeting the HSRC Chair shall inform members of research applications that were approved as expedited. Any board member may request that a research project be re-reviewed by the full board. Members shall then vote on the request with a majority deciding the issue. The expedited review process (i.e., subcommittee review) typically requires a period of approximately two weeks, provided the application is complete and no revisions are required.

FULL BOARD REVIEW

All proposals that fail to meet the criteria for an expedited review will be addressed by a full committee review.

1. Research scheduled for full committee review shall be distributed to the HSRC office two weeks before the meeting date to allow adequate time for committee members to read the proposal. Requests for further information from investigators shall be made prior to the meeting. Investigators are invited and strongly urged to attend. At convened meetings of the committee, proposals are approved, approved with revisions, or disapproved.
2. At times a proposal may be distributed to a consultant or expert to advise the committee in its review of a proposal.
3. A quorum, constituted by a majority of HSRC members, is required to convene a full committee meeting.
4. A proposal can be approved after receiving the approval of the majority of those members present at the convened meeting.
5. The HSRC at a minimum will conduct annual reviews of approved research. It is the responsibility of the researchers to inform the HSRC of any changes in research design or adverse events, and to request annual renewal of HSRC approval, if necessary.

Level 3 reviews usually require a minimum of one month (not including revisions).

Bibliography

1. 45 CFR 46. Office for Protection from Research Risks, Department of Health Services National Institutes of Health, *Title 45 Code of Federal Regulations 46*, June 18, 1991.
2. *The Belmont Report*. Office for Protection from Research Risks, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.
3. Grundner, T.M. (1986). *Informed Consent: A Tutorial*. Owings Mills, MD: National Health Publishing.
4. Dansky, J, and Denise Tanguay Hoyer. *The EMU Policy and Procedures for the Use of Humans as Research Subjects, Guidelines for Faculty*.

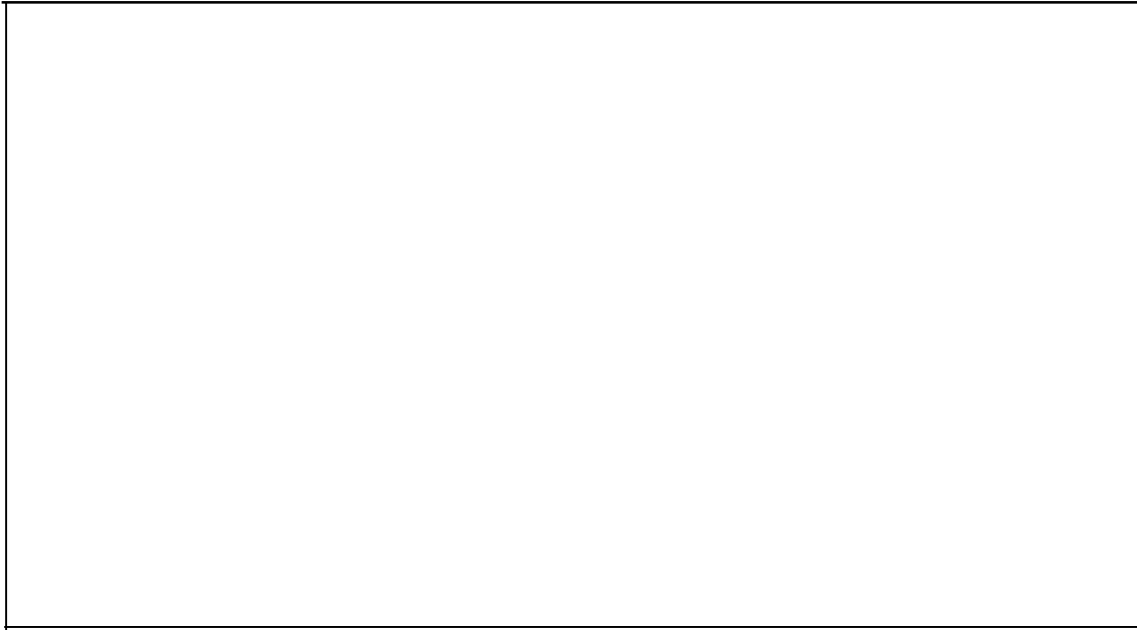
V. Confidentiality

- A. To what extent is the information confidential and to what extent are provisions made so that subjects' confidentiality is protected?

- B. What are the procedures for handling and storing all data so that the confidentiality of the subjects is protected (particular attention should be given to the use of photographs, video, and audio recordings)?

- C. By what means will the results of the research be disseminated? How will the subjects be informed of the results? Will the confidentiality of subjects or organizations be protected in the dissemination?

VI. Describe any anticipated benefits to subjects from participation in this research.



VII. Please describe instrumentation and protocol to be used.

