

***EASTERN MICHIGAN UNIVERSITY***  
***Human Subjects Review Committee***  
***Administrative Policy and Procedures***  
*(Revised June 2008)*

**ADMINISTRATIVE POLICY**

It is the policy of Eastern Michigan University 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 University Human Subjects Review Committee has been established to review all 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, Office for Human Research Protections (Part 46 of Title 45 of the Code of Federal Regulations, as amended).

The University Human Subjects Review Committee (UHSRC) is responsible for developing and enforcing policies and procedures applicable to research wherein human beings may be at minimal risk<sup>1</sup> or greater as a consequence of participating in an investigation or experimental procedure.

Note that research using secondary data on human subjects must be reviewed by the UHSRC. In cases where an investigator begins a project for non-research purposes (e.g., a experiment done in the context of a class assignment), and then realizes that he or she might like to disseminate findings, the project must also be reviewed by the UHSRC. It is the investigator's responsibility to seek UHSRC approval whenever considering dissemination of such findings beyond the classroom. When there is a question about whether an activity constitutes human subject research that is subject to UHSRC review, EMU requires that a qualified person (i.e., College or University-level HSRC member) *other than the investigator or research team* verify and document that the activity qualifies for exemption from IRB review.

**A. Implementation of the Policy**

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

**B. Authority of the University Human Subjects Review Committee**

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<sup>1</sup> Minimal risk means that the risk of harm anticipated in the proposed research is not greater, considering probability and magnitude, than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The University Human Subjects Review Committee shall review and have authority to exempt, approve, require modifications in, or disapprove all research activities covered by the Human Subjects policy. It shall 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 expedited review group determines that there is greater than minimal risk, the proposal shall be referred to the full Committee for consideration. The UHSRC would be given 10 business days when University classes are in session to review the document(s) and discuss the protocol at their next meeting, which is typically the second week of the month.

The UHSRC may establish college-level committees to review student research, using procedures approved by the UHSRC, when the volume, type or timing of research in a particular college necessitates it, and when students initiate the research. In such instances the student's faculty advisor shall be considered the Principal Investigator and shall be responsible for obtaining UHSRC approval and for enforcing any conditions of such approval.

The University Human Subjects Review Committee shall conduct continuing review of research covered by the Policy at intervals appropriate to the degree of risk, but not less frequently than once per calendar 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 in accordance with the Policy or that has produced unexpected serious harm to subjects. In cases where the Committee disapproves of research, notification will promptly be sent 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 the Policy that has been approved by the University Human Subjects Review Committee may be subject to further appropriate review and approval or disapproval by officials of the University. However, those officials cannot approve the research unless the committee has also approved it.

### **C. Applicability of the Policy**

The Human Subjects review process applies to all research<sup>2</sup> involving the use of human subjects for one or more of the following criteria:

1. Whether funded or unfunded

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<sup>2</sup> "Research" is defined in this policy to mean a systematic investigation designed to develop or contribute to generalizable knowledge

2. Participated in, or directed by, any faculty, staff or students at Eastern Michigan University
3. Done on the property of, or using the facilities of, Eastern Michigan University
4. Using university personnel or students as subjects

All faculty and staff must, prior to the commencement of research, using procedures promulgated by the University Human Subjects Review Committee, submit research proposals for review by the Committee. Securing prior approval for research is the responsibility of the project director, principal investigator or similarly designated person who has responsibility for leading the project.

#### **D. Student Research**

In the case of research involving human subjects that is conducted by undergraduate or graduate students as part of a course assignment or thesis project, the instructor of the class or project investigator shall be responsible for having the research reviewed by a college-level Human Subjects Review Committee whose responsibility is to review such research, using the Guidelines approved by the University Human Subjects Review Committee and attached as Appendix A (Review of Student Research with Human Subjects: Guidelines for College-Level Committees, page 13). The University-level committee (UHSRC) reviews all doctoral research.

Undergraduate students are prohibited from conducting research in which there would be greater than minimal risk to human subjects.

#### **E. Course-Related Activities**

Course-related activities that use human subjects are exempt from review if the purpose of the activity is purely pedagogical and the results are intended solely for use within the classroom setting (see Appendix A for further discussion).

#### **F. Cooperative Research**

In the event that a research project's director or co-director is from another institution, the University Human Subjects Review Committee may accept a statement of approval from the Human Subjects Review Committee at the project director's home institution in lieu of review by the EMU Committee when and only when:

1. The policy guidelines of another domestic Human Subjects Review Committee are certified as meeting at least the U.S. federal regulations

2. The other Human Subjects Review Committee certifies that it has approved the research

If the project director of a collaborative research project is a faculty or staff member of Eastern Michigan University, the Eastern Michigan University Human Subjects Review Committee must review the project.

### **G. Independent Research**

Research involving the use of human subjects that is conducted independent 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, any University facilities, nor other University resources in the conduct of the research, nor may the research be pursued under University auspices in any way.

### **H. Use of Secondary Data**

Research projects proposing to analyze secondary data fall under this policy and therefore require UHSRC approval. The term “secondary data” includes all forms of clinical records, medical charts, correctional institution records, personnel or human resource records, financial records, or records from educational institutions. Prior consent for medical treatment, psychological counseling, or other informed consent for treatment or service is neither a substitute for nor an *a priori* equivalent to UHSRC review. If information is to be obtained from medical records, the UHSRC *HIPAA Summary Form* must be completed, in addition to the *Request for Human Subjects Approval*.

### **I. Use of Technology (online data collection)**

Researchers who use online data collection must explain in their protocol security precautions, data storage procedures, and anonymity issues relative to safeguarding sample identity.

If data are collected manually and subsequently converted to an electronic/digital format for storing and analysis, the researcher needs to explain in the protocol safeguards to protect data through such measures as encryption, password protection, de-identifying the data, deletion of file, etc.

### **J. Exempt Activities**

As described in the Code of Federal Regulations (Title 45, Part 46, Protection of Human Subjects, Subpart A), research activities in which the only involvement of human subjects will be in one or more of the following categories may be

determined through the expedited review process of the University Human Subjects Review Committee to be exempt from this policy and accompanying procedures.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects;  
AND
  - b. 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.

**NOTE:** This exemption does not apply to research involving children, unless the investigator is a non-participant observer of behavior.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Criterion 2, above, if:
  - a. The human subjects are elected or appointed public officials or candidates for public office; OR
  - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the 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 subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
  - a. Public benefit or service programs;
  - b. Procedures for obtaining benefits or services under those programs;
  - c. Possible changes in or alternatives to those programs or procedures; or
  - d. Possible changes in methods or levels of payment for benefits or services under those programs.
  
6. Taste and food quality evaluation and consumer acceptance studies, if:
  - a. Wholesome foods without additives are consumed, or
  - b. A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

#### **Exempt Research -- Program Review**

1. **Federal Regulations Exemptions.** Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine: 1) Public benefit or service programs; 2) Procedures for obtaining benefits or services under those programs; 3) Possible changes in or alternatives to those programs or procedures; or 4) Possible changes in methods or levels of payment for benefits or services under those programs.
  
2. **EMU Program Review Data.** Data collected for the purpose of evaluation, review, and improvement of EMU academic and extra-curricular programs is exempt from review under the federal regulations exemptions listed above *unless* these data are collected: a) for use beyond program review, and/or b) for publication beyond the review process for EMU programs administered by EMU, by its associated accrediting agencies, and by other related educational bodies. Program Review proposals that meet the criteria for exemption from review do not need to be sent to the EMU UHSRC.

#### **K. 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 University Human Subjects Review Committee shall determine that all of the following requirements are satisfied:

1. Risks to the subjects are minimized.
  - a. By using procedures that are consistent with sound research design and that 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, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable<sup>3</sup> 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 that 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 will 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 are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

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<sup>3</sup> The term "equitable" is defined to mean that there is no discrimination in the selection of subjects and no over-selection of vulnerable subjects.

## ADMINISTRATIVE PROCEDURES

### A. Membership

1. The University Human Subjects Review Committee (hereafter UHSRC) shall be composed of a minimum of thirteen voting members.
  - a. No fewer than eleven members shall be selected from the ranks of the faculty. At least one person from each of the colleges shall be selected including an additional member from each doctoral program.
  - b. At least one person, such as a medical doctor, lawyer, ethicist, or member of the clergy, shall be from professions or vocations that are in a non-scientific area. This person may be a member of the faculty if he or she meets the vocational requirement.
  - c. A representative appointed by the Associate Provost and Associate Vice President (AVP) for Research will serve as the Administrative Co-Chair.
  - d. At least one person who is not otherwise affiliated with the institution or a part of the immediate family of one who is affiliated.
  - e. During the spring and summer terms the UHSRC will function as a committee of the whole with a minimum of 6 members needed to conduct business.
  
2. The Provost and Vice President for Academic Affairs shall Approve UHSRC membership, based on the recommendation of the Associate Provost and AVP for Research and UHSRC Co-Chairs.
  - a. Candidates for faculty positions on the UHSRC shall be selected by the Co-Chairs from the lists of names recommended by the academic Deans in consultation with their constituent departments/schools and programs.
  - b. The selection of faculty to serve on UHSRC shall take into account such factors as the prospective member's experience and expertise in matters that fall within the purview of the UHSRC, the degree to which the faculty member's discipline involves research likely to be in the domain of the UHSRC, and representation from among the colleges.
  - c. The following additional criteria should be considered in selecting UHSRC membership.
    - i. The UHSRC shall be sufficiently qualified through the experience and expertise of its members, and the gender, professional, racial and cultural diversity of the members' background to assure its sensitivity to such issues as community attitudes, and to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
    - ii. The UHSRC shall possess the professional competence necessary to review specific research activities.
    - iii. In order to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice, the UHSRC shall include persons knowledgeable in these areas.
  
  - d. There shall annually be public notice of vacancies on the UHSRC.

3. The UHSRC may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond that available on the UHSRC. These individuals may not vote with the UHSRC.
4. No member of the UHSRC may participate in the committee's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the UHSRC.
5. New members of the UHSRC, within the first semester of their appointments, shall obtain training in the protection of Human Research Subjects by completing a certification program or equivalent training. Because the availability and suitability of these programs may vary over time, appropriate training options for meeting this expectation will be delineated and periodically revised by the UHSRC. If new members have received training prior to joining the Committee, the nature and extent of such training will be taken into consideration, and the training requirement may be waived or reduced. The UHSRC Co-Chairs will be responsible for communicating with committee members about training options and monitoring adherence to this policy.

## **B. Term of Service**

1. With the exception noted in B.2, the term of service on UHSRC shall be three years.
2. Appointments to the UHSRC during its initial year shall be for staggered terms of service as follows:
  - One-third of the appointments for a one-year term
  - One-third of the appointments for a two-year term
  - One-third of the appointments for a three-year term
3. All new appointments shall become effective at the beginning of the academic year.
4. Members who do not fulfill the training requirement in human subjects protection, who do not return protocol review documents in a timely fashion, or who do not regularly attend the Committee meetings will be removed and replaced by the Co-chairs if there is the consensus of the UHSRC.

## **C. Officers of the UHSRC**

1. There shall be two co-chairpersons for the UHSRC: an appointee of the Associate Provost and AVP for Research and a faculty member of the UHSRC who shall share as executive and signature authority for the Committee.
2. The faculty co-chairperson shall be selected in consultation with the members and the administrative co-chair, and his/her appointment by the Provost shall be confirmed or disconfirmed at the first meeting of each academic year by the members of the committee. At the end of a maximum of four contiguous years of service, a faculty co-

chair shall step down for a minimum of two years before being eligible to serve again as co-chair.

#### **D. Voting**

Except when an expedited review procedure is used, the UHSRC shall review proposed research at meetings at which a majority of the members of the UHSRC are present, including at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it must receive the approval of a majority of those members present at the meeting. All documents that require consideration for a vote at the meeting of the full committee shall be distributed at least one week in advance of the meeting.

#### **E. Research Approval and Oversight**

1. Only research approved by the means set forth in this document shall be considered authorized.
2. Notification of UHSRC Action

The UHSRC shall notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of the modifications required to secure UHSRC approval of it. If the UHSRC decides to disapprove a research activity, it shall include in its notification a statement of the reasons for its decision and shall give the investigators an opportunity to respond to the Committee in person or in writing. The co-chairs will also notify the Provost and the Associate Provost/AVP for Research of any proposal that has been disapproved.

3. Continuing Review of Research Projects

The Federal Office for Human Research Protections (OHRP) requires that “an IRB shall conduct continuing review . . . at intervals appropriate to the degree of risk, but not less than once per year.” OHRP interprets “not less than once per year” review to mean on or before the one-year anniversary date of the previous IRB review, even if the research activity began some time after the IRB approval date. Continuing review must be substantive and meaningful. Review will be processed by one of the UHSRC co-chairs unless concerns arise or study protocols have major changes and expedited or full-board review becomes required.

To comply with federal policy, the EMU HSRC has prepared a *Continuation Form* that should be completed annually. Annual reviews may be processed using the *Continuation Form* for two years after the initial review (i.e., a total of three years of research activity). If a project is being renewed for a fourth year of data collection, it should be submitted

using the full *Request for Human Subjects Approval* form, including all attachments listed on the last page of that form.

The annual *Continuation Form* is not required for research projects deemed to be exempt at the time of initial review.

If a project is not continuing beyond the one-year approval period, the protocol can be closed by completing and submitting the *Closure Form* to the UHSRC. A protocol can be closed when all research activities including participant/subject recruitment, enrollment, intervention, interaction, and follow-up have been completed. PI may continue data analysis and dissemination of findings. Documents are retained by the UHSRC for three years post study closure.

#### 4. Adverse Event Reporting

If an adverse event occurs during a research project that has been approved by the EMU-UHSRC, it is the responsibility of the project investigator to report this event to the co-chairs of the UHSRC as soon as possible, but no later than 24 hours after the PI learned of the event (see *Adverse Event Report* form). The UHSRC Co-Chairs are responsible for immediately sending a copy of this report to the University's attorney.

An adverse event is defined as any experience that has taken place during the course of a research project, which, in the opinion of the investigators, was harmful to a subject participating in the research, increased the risks of harm in the research, or had an unfavorable impact on the risk/benefit ratio. Note that the investigator does not necessarily have to feel that an adverse event was *caused by* research participation in order for it to merit reporting to the UHSRC.

All adverse events must be reported to the UHSRC within 24 hours of the PI's knowledge of the adverse event, using the *Adverse Event Report* form. If the research is being funded by an external agency, the project investigator must also report the adverse event to the head of the Office of Research Development, whose responsibility it is to inform the agency in conformance with agency rules or regulations. Upon approval by the UHSRC committee, a newly dated version of a protocol change for approved research above minimal risk shall be provided for UHSRC files.

The UHSRC will review the *Adverse Event Report* and determine what actions might be necessary to protect human subjects and continue the study, if risks can be adequately managed. The UHSRC may halt the research or take other appropriate action as necessary.

Subsequent to an *Adverse Event Report*, for studies that continue to involve more than minimal risk and/or a high risk/potential benefit ratio, the UHSRC may require additional oversight such as:

- a. a six-month review or a review at the completion of 20% (not less than five participants) of the sampling based upon the type and level of risk. (The length of this oversight period shall be documented. Two members of the UHSRC shall serve as the primary reviewers with a full report to be voted upon by the full committee.)
- b. direct or third-party observation of the consent process or aspects of the research protocol
- c. committee review of a protocol summary and status report on the progress of the research, including:
  - i. the number of subjects recruited
  - ii. a summary of adverse events and any unanticipated problems involving risks to subjects or others
  - iii. a summary of subject withdrawal from the research or complaints about the research since the last UHSRC review
  - iv. a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review
  - v. any relevant multi-center trial reports
  - vi. other relevant information, especially information about risks associated with the research
  - vii. a copy of the current informed consent document and any newly proposed consent document.

## 5. Protocol Changes

Project investigators are responsible for notifying the UHSRC when there are changes to their research protocol. For minor changes, use the *Minor Modification to Research Protocol* form. Minor modifications would include items such as the addition or deletion of researchers or research partners, change in source of sample but type of source is the same (e.g., different high school), change in contact information on informed consent, minor changes to the language of the survey instrument or interview questions, etc. When the changes address sample composition to include special populations or when data collection procedures change, use the *Request for Human Subjects Approval* form checking the modification section.

Upon approval by the UHSRC, a dated version of a protocol change for approved research shall be provided for the UHSRC files. This approval must be obtained in advance of implementation, except in those cases in which an immediate change is made in response to an adverse event or new information that demonstrates an unnecessarily high risk to subjects. In these cases, the co-chairs of the UHSRC must be notified immediately of the change, and reasons for it, and an application for approval shall be submitted with documentation of the appropriateness of the change. (As stated in E.7, it is within the purview of the co-chairs to halt the research if they deem it necessary, prior to implementation of a protocol change.)

## 6. Ongoing Research Not Approved by the UHSRC

Research otherwise falling under the purview of the UHSRC but that has not been approved by the UHSRC shall not be conducted at the University or under its auspices. When such research becomes known to the committee, the UHSRC co-chairs shall immediately notify the investigators, the Associate Provost/AVP for Research, the Provost and Vice President for Academic Affairs and the University Attorney in writing that if the research is not halted, the Provost and the Vice President for Academic Affairs shall notify the investigator and University's attorney of the continuing infraction of the University Policy and shall specify the disciplinary actions that the University has at its disposal. Should the research not be halted, the Provost shall take appropriate action in consultation with the University's attorney to resolve the matter.

## 7. Suspension or Termination of Research

The UHSRC shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the UHSRC's requirements, that has resulted in unexpected serious harm to subjects, or where new information indicates an increase in the level of risk to subjects. Any suspension or termination of approval shall include a statement of the reasons for the UHSRC's action and shall be reported promptly to the investigator, the Associate Provost/AVP for Research and the Provost. Should compliance with a notice of suspension or termination not occur immediately, the Provost will take appropriate action in consultation with the University's attorney to resolve the matter.

## **F. Expedited Review**

1. An expedited review may be conducted for research involving no more than minimal risk. (See Appendix A of this document for the definition of "minimal risk.")
2. An expedited review is conducted two members of the UHSRC selected by the administrative co-chair.
3. When a proposal goes to expedited reviewer(s), notice of such shall be disseminated to all members of the UHSRC. In addition, full details of the project being reviewed shall be available for examination by all UHSRC members. Any UHSRC member may call for a full review, which will then be held in accordance with the procedures contained in this document.
4. If one or both of the expedited reviewers recommend disapproval, the research proposal must be given a full review in accord with the guidelines set forth in this document.

## **G. College-Level Review Committees**

The UHSRC will grant authority to college-level permanent committees to conduct review of minimal-risk student research. Such college-level committees will be approved when the following conditions are met:

1. The college-level committee is composed of at least two faculty who are thoroughly conversant with all guidelines and procedures of the UHSRC (committee composition should meet the protocol volume of the college)
2. The UHSRC will be notified of the chairs and current membership of the college-level committees

Committees will annually report their activities to the UHSRC.

## **H. Informed Consent**

No investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the appropriate informed consent of the subject or the subject's legally authorized representative. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language at an appropriate understandable level 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. Copies of the UHSRC-approved informed consent form with approval and expiration dates must be used by the investigator to obtain consent, and these records must be maintained throughout the life of the project.

In conducting research with children, procedures must be in place for obtaining both the informed consent of the parent or legal guardian and the assent of the child, obtained in a developmentally appropriate fashion. Ideally, parents will provide written informed consent, but in some cases, it may be permissible to request a "passive consent" process, wherein parents are asked to provide written refusal if they do not want their child to participate, but need to do nothing if they are agreeable to the child participating. Typically, approval for passive consent would only be granted in cases where the research involved minimal risk and there is no practical way to obtain written informed consent.

In seeking informed consent, the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purpose of the research and expected duration of the subject's participation, a description of the

- procedures to be followed, identification of any procedures that are experimental, that may result in public dissemination;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
  3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
  4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject;
  5. A statement describing the extent to which confidentiality of records identifying the subject will be maintained and how participant confidentiality will be maintained in the dissemination of results;
  6. For research involving more than minimal risk, information must be made available regarding medical treatments, counseling or other personal assistance that will be provided should personal injuries or problems occur;
  7. A list of contacts who can answer pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related physical or psychological injury to the subject;
  8. A statement that participation is voluntary, 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;
  9. Statements of significant new findings developed during the course of the research that may relate to the subjects' willingness to continue participation will be provided to all subjects.

A waiver of signed informed consent may be requested if either of the following two conditions apply.

1. The only record linking the subject and the research would be the consent document AND the principal risk is potential harm resulting from a breach of confidentiality
2. The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

Regardless of whether informed consent is obtained on a signed document or more informally, the above delimited elements of informed consent must be in place.

## **I. Record Keeping**

The UHSRC shall maintain a file of records. These shall be retained for at least three years after the completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the University at reasonable times and in a reasonable manner. These records shall include:

1. Copies of all research proposal reviews, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of adverse events;
2. Minutes of UHSRC meetings, which shall be in sufficient detail to show attendance at the meetings, actions taken by the UHSRC, the vote on these actions including (the number of members voting for, against, and abstaining) the basis for requiring changes in or disapproving research, and a written summary of the discussion of controversial issues and their resolution;
3. Records of continuing review activities;
4. Copies of all correspondence between the UHSRC and the investigators;
5. A list of UHSRC members as required by federal guidelines;
6. Written procedures which the UHSRC will follow for (a) conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (b) determining which projects require review more often than annually and which projects need verification from sources other than investigators that no material changes have occurred since previous UHSRC review; (c) reporting changes that have occurred since previous UHSRC review; (d) ensuring prompt reporting to the UHSRC of proposed changes in research activity, and for ensuring that changes in approved research, during the period for which approval has already been given, may not be initiated without UHSRC review and approval except where necessary to eliminate apparent immediate hazards to the subjects; and (e) ensuring prompt reporting to the Secretary of Health and Human Services of unanticipated problems involving risks to subjects or others.

## **J. Institutional Support**

The Division of Academic Affairs shall provide administrative and financial support for the operation of the UHSRC, including support for faculty training.

## APPENDIX A

### Review of Student Research with Human Subjects: Guidelines for College-Level Committees

College-level review committees are formed to conduct expedited reviews of student research and course-related activities that are covered by the University Human Subjects Review Committee's policies. Any application may be submitted to the UHSRC; however, student applications are typically submitted to the appropriate college committee.

In order to assure that faculty liability is protected by the University, the University Human Subjects Review Committee (UHSRC) must explicitly sanction these college-level committees. College-level committees report only to the UHSRC, not to each other. As part of the establishment of a sanctioned committee, guidelines are developed that outline a review process that parallels that of the UHSRC and follows the ethical guidelines stated in the UHSRC's policy document. These guidelines are to be seen as complementary to practice dictated by the professional ethics of a given discipline.

1. **Establishing an Approved Committee.** To establish a sanctioned committee, a college must apply to the UHSRC for approval. The application must include a statement of need (including an estimate of the number of applications that would be reviewed by the committee each year) and the names(s) of potential committee members who have served on the UHSRC. Prior to approval, all members of a committee must participate in an orientation program conducted by the UHSRC.
2. **Composition and Meetings.** College committees have a minimum of two faculty members. One member of each committee should be a member of the University HSRC (or have previously served on the UHSRC). The chairperson of each committee is responsible for keeping records of proposals reviewed and serves as a liaison to the UHSRC. (See Section 11 regarding record keeping). Research applications are reviewed independently by at least two members of the appropriate committee (in a manner parallel to the UHSRC's expedited review process.) However, if any member of the committee recommends disapproval or believes that the proposed research may put participants at more than minimal risk, the entire committee must meet to review the proposal. If after the committee meeting any member of the committee believes that a proposal puts participants at more than minimal risk, the proposal may be forwarded to the UHSRC with a recommendation for either Expedited or Full Review, or it must be rejected by the committee. (See Section 5 for a definition of "minimal risk.")
3. **Procedures and Forms.** The policies and procedures of the UHSRC serve as the policies and procedures of all college-level review committees. The forms used by investigators to apply for approval, as well as the reviewers' response forms, are the same as forms used by the UHSRC. For a committee to remain viable, applicants shall be notified within a three-week timeframe of the status of their request for approval.

4. **Scope and Enforcement.** The University HSRC policy document states that the UHSRC's review process applies to *all research involving the use of human subjects*, including:
- (a) Research that is funded or unfunded
  - (b) Research that is pursued by any individual while in his/her role as a faculty member, staff, or student at EMU
  - (c) Research done on the property of EMU, or using the facilities of EMU
  - (d) Research using university personnel or students as subjects, *except for data collection that will be used exclusively for internal EMU administrative purposes*

Research that has not been approved by the UHSRC or one of its approved college-level committees may not be conducted at the University or under its auspices. All faculty and staff research, as well as dissertation research, must be reviewed by the University HSRC; the circumstances under which course-related activities and student research do, and do not, require committee review are discussed in items 6, 7, and 8 below. For additional information concerning the research approval and oversight functions of the UHSRC, as well as information concerning the enforcement of HSRC policies and procedures, see the University policy and procedure documents which are appended to these guidelines and available on the Office of Research Development (ORD) website, Federal Compliance section --

[http://www.ord.emich.edu/federal/federal\\_comp\\_subdir/humansubjects/human.html](http://www.ord.emich.edu/federal/federal_comp_subdir/humansubjects/human.html)

5. **Minimal Risk.** A pivotal issue in the review process is whether or not the proposed research might place subjects at more than minimal risk. There is no simple, objective criterion that can be applied in all such judgments. The university's policy document on human subjects research states that "minimal risk means that the risks of harm anticipated by 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." This definition acknowledges that most people's daily lives include challenges and stresses. In practice, the kinds of experiences that "most people" have on a "typical" day are considered minimal risk; exposing subjects to the kinds of physical or psychological stresses that make some of our days rather painful or disturbing are judged to involve more than minimal risk, despite the fact that such experiences may not always cause lasting harm. It is possible that research involving more than minimal risk may be approved; *however, all research involving more than minimal risk to participants must be reviewed by the UHSRC.* If there is uncertainty about whether the research involves more than minimal risk, an application for approval may either be sent directly to the UHSRC, or it may first be submitted to a college-level committee for a judgment regarding the level of risk involved.

**Example from Business: Minimal Risk:** An interview in which a student asks a manager to describe her job, her largest challenges in her job, and the effect of her long hours on her home life.

**More than Minimal Risk:** Students interview a manager about her feelings of competency on the job, her relationship with her boss, the likelihood that she will leave her job due to

stress and dissatisfaction, the dynamics of her last performance appraisal, her appraisal of her boss's competency, and the effects on her marriage of her work life.

**Example from Health and Human Services: Minimal Risk:** Graduate nursing students frequently survey practicing nurses about the activities they perform related to the identified taxonomy of nursing interventions.

**More than Minimal Risk:** The purpose of a graduate nursing study could be to study the effectiveness of various cardiac rehabilitation interventions in patients with heart disease (e.g., post-coronary artery bypass surgery or post-heart attack). This might involve a supervised exercise program. There is a possibility that subjects could demonstrate a cardiac dysrhythmia or another heart attack.

6. **Course-Related Student Research Requiring Review.** When undergraduate or graduate students conduct research involving human subjects as part of a thesis project or analogous independent, formal research project, it is subject to the same ethical standards, review, and procedures as faculty research. Supervising faculty members are responsible for having this research reviewed by a college-level HSR committee, or by the UHSRC. Specifically, those student research projects that always require review when using human subjects include, but are not limited to:
  - (a) Student independent studies that are formal research projects using human subjects, and
  - (b) Undergraduate or master's theses using human subjects

**College-level HSR committees may not review dissertation research involving human subjects.** Like faculty research, dissertations must be reviewed by the UHSRC.

**Please Note: Decisions about whether a project is exempt from review or about their level of risk are to be made by the appropriate review committee, not by the supervising faculty member.**

7. **Course-Related Activities That Must Be Reviewed.** Course assignments that result in a set of independent formal research projects that will be, or are intended to be, disseminated to a community broader than those enrolled in the course must be reviewed by the appropriate committee.
8. **Course-Related Activities Not Requiring Review.** All course-related student activities **may** be reviewed; however, most course-related student activities do not require review. Course assignments involving human participants do not require review if these assignments meet either of the following criteria (and are not included as student research as described in section 6 above):
  - (a) The results of the assignment are intended solely for use within the classroom setting
  - (b) A practicum experience in educational settings, including health care facilities, is supervised by appropriately licensed practitioners.

Course assignments that meet either of the above criteria are exempt from review; however, like all human subjects research, faculty should be sure that these projects and other assignments involving human participants meet university and professional guidelines involving voluntary participation, informed consent, and confidentiality. When an instructor believes that course-related activities involving human participants might fail to meet these criteria for exemption, it is the faculty member's responsibility to have that activity reviewed by the appropriate review committee. If the activity involves more than minimal risk to participants, the University HSRC must review the activity. (**Please note:** If subsequently either student or faculty member wishes to analyze further the course assignment data and prepare it for dissemination, the research must be reviewed by the appropriate committee.)

9. **Faculty Assessment of Classroom Instruction.** Classroom assessment techniques (CATs) are procedures for obtaining information from students for the purpose of improving classroom instruction. CATs are designed to extend information typically obtained from examinations and/or course products (e.g., papers). These extensions of instruction include assessing academic skills and intellectual development, students' self-awareness as learners and their learning skills, and students' reactions to teachers and teaching methods, course materials, activities and assignments. Because the purpose is instructional improvement rather than individual student evaluation, data collection is typically anonymous. Such anonymous data, collected for purposes of improving instruction, should not put students at more than minimal risk and thus does not typically require human subjects review. (**Please note:** If a faculty member or other individual intends to disseminate the results of his/her assessment research, then as with all faculty research, the project must be reviewed by the UHSRC).
10. **Confidentiality and Informed Consent.** Two concerns central to the evaluation of virtually all student and faculty research proposals are confidentiality and informed consent. To be approved, an application for review must provide a thorough description of the steps that will be taken (a) to maintain confidentiality of the data and (b) to obtain the legally effective informed consent of all participants or their legally authorized representatives, with special attention given to the protection of children and other vulnerable groups. All of the University's human subjects review committees follow the guidelines stated in the University's policy and procedures in assessing the adequacy of measures proposed to achieve confidentiality and informed consent. The guidelines pertaining to confidentiality and informed consent include numerous provisions (but which are not likely to be familiar to students). Therefore, these guidelines and the statement of ethical standards from the University's policy document are appended to this statement of college-level committee guidelines. Because supervising faculty are responsible for having student research reviewed, these faculty are urged to ensure that student researchers become familiar with this document and its appendices.
11. **Record Keeping and Liability.** The chair of each review committee is responsible for maintaining records of all reviewed research and serving as a liaison to the UHSRC. Once a college-level committee approves or disapproves a proposal, copies of the reviewer forms and the committee letter to the investigator notifying him/her of the status of the proposal must be forwarded to the Associate Dean of the College. One or more UHSRC members,

whose findings will be reported back to the UHSRC, will review these files each year. At the end of each academic year, the chairperson of a college-level committee must submit a report of committee activities to the UHSRC. This report includes a list of applications evaluated by his or her committee, with the names of the principal investigators, faculty supervisors, project titles, and an indication of the decision made about each application. The annual report also includes the names of individuals who served on the committee for the prior year, as well as the names of those who will serve the following year. Complete records of the review process for each application are kept by the college for at least three years and are available for review by the UHSRC upon request.

Whenever an application is reviewed, a written statement of approval, conditional approval, or rejection is provided to the applicant. Students are provided with this written feedback when the application involves a thesis or other independent research project. In situations where a faculty member submits a single application for a course assignment that is the same (or very similar) for several students, the written feedback is given to the faculty member, who is encouraged to share it with participating students.

**Conclusion.** The intent of EMU policy and related review procedures is to assure the elimination or minimization of research-related risks to human beings and to provide for informed and voluntary participation by subjects, while complying, as an institution, with Federal regulations. The goal of the review process is to work with faculty and students to promote research that protects all participants, including the investigators. When investigators conduct or supervise research that has been approved by the UHSRC or one of its sanctioned review committees, their personal liability is limited in the same way that it is when one is teaching in the classroom (or conducting other activities associated with the terms and conditions of his or her employment).