EASTERN MICHIGAN UNIVERSITY
Human Subjects Review Committee
Administrative Policy and Procedures
(Revised April 2017)
ADMINISTRATIVE PROCEDURES

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) and, when applicable, the Food and Drug Administration (Parts 50, 56, 312, and 812 of Title 21 of the Code of Federal Regulations).

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[1] 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.

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 or their designee is responsible for appointing the members of the University Human Subjects Review Committee and giving them direction. The Provost or their designee 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

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

[1] Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102 (j))

a quorum of the members of the Committee are present, it may use an expedited review procedure if the research involves no more than minimal risk and meets one or more of the categories outlined in OHRP guidance document https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html or if it is reviewing minor changes that do not constitute an increase in risk in previously approved research during the period in which approval is authorized, or it may determine that research is exempt from federal regulatory requirements.

If during an expedited review any of the designated reviewers determines that there is greater than minimal risk, the proposal shall be referred to the full Committee for consideration. The UHSRC would be given at least 10 business days when University classes are in session to review the document(s) and discuss the protocol at their next monthly meeting.

The UHSRC shall conduct continuing review of research requiring review at a convened meeting at intervals appropriate to the degree of risk, but not less frequently than once per calendar year. Projects requiring review more often than annually will be those in which the UHSRC determines that there is greater than minimal risk of physical or psychological harm *and* the likelihood of physical or psychological harm is high, or if any member of the research team has demonstrated significant or continuing non-compliance on the current or on previous research projects. Unless the UHSRC determines otherwise and documents the basis for such a determination, continuing review of research is not required for research eligible for expedited review in accordance with 45 CFR 46.110; research reviewed by the UHSRC in accordance with the limited IRB review described in 45 CFR 46.104 (d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8); research that has progressed to the point that it involves only data analysis, including analysis of identifiable private information or identifiable specimens, and/or accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. The UHSRC shall have authority to observe or have a third party observe the consent process and the research itself. The UHSRC 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 UHSRC 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 UHSRC may also recommend that the University impose sanctions upon any investigator who does not conform to this Policy, however any sanctions imposed on an investigator remain under the purview of the Provost or their designee.

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 UHSRC has also approved it.

C. Applicability of the Policy

The Human Subjects review process applies to all research[2] involving the use of human

[2] Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. For the purposes of

subjects for one or more of the following criteria:

1. Whether funded or unfunded

2. Initiated, conducted, 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

All faculty, staff, and students must, prior to the commencement of research, using procedures promulgated by the University Human Subjects Review Committee, submit research proposals for review by the UHSRC. 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, the principal investigator shall be responsible for having the research reviewed in accordance with this policy.

Undergraduate students are prohibited from conducting research in which there would be greater than minimal risk to human subjects. The student could assist on a study conducted by a faculty member and the faculty member would seek UHSRC approval.

E. Course-Related Activities

Course-related activities that use human subjects do not require UHSRC review if the purpose of the activity is purely pedagogical and the results are intended solely for use within the classroom setting. If the results will be presented outside of the classroom (e.g., Undergraduate Symposium, Graduate Research Conference, professional conferences, journal articles, etc.), then UHSRC approval must be obtained prior to presentation.

F. Cooperative Research

In the event that a research project's principal investigator is from another institution, the University Human Subjects Review Committee may cede review to the other institution. The EMU Principal Investigator must complete an Institutional Authorization Agreement Form for review by the Institutional Official.

If the Principal Investigator of a collaborative research project is a faculty or staff member of

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this policy, scholarly and journalistic activities (e.g., oral history, class projects, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected are not considered research.

Eastern Michigan University, the Principal Investigator must submit an Institutional Authorization Agreement Form in addition to the UHSRC *Request for Human Subjects Approval* form. The Eastern Michigan University Human Subjects Review Committee must review the project in accordance with this policy.

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 their 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 but is not limited to 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 identifiable Protected Health Information is to be collected or maintained by one of the departments or organizations that constitute EMU's HIPAA-covered hybrid entity, then the data are subject to HIPAA regulation.

I. Use of Technology (online data collection)

Researchers who use online data collection must explain in their protocol security precautions, data storage procedures, and data confidentiality protections 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

Research in which all activities fall into one or more Exempt categories as described in 45 CFR 46.104 will be reviewed according to the Exempt Review Procedures (see Appendix A).

Program Review

Data collected for the purpose of evaluation, review, and improvement of EMU academic and extra-curricular programs does not meet the federal definition of Research and will

be designated as Not Human Subject Research *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 neither contribute to nor develop generalizable results do not need to be sent to the EMU UHSRC.

Studies in which EMU is not Engaged

Human subjects research that is otherwise non-exempt does not require UHSRC review if it is determined that EMU is not engaged in the research, in accordance with the guidelines set forth by the U.S. Department of Health and Human Services Office for Human Research Protections (DHHS OHRP, 2008). In brief, EMU would not be considered "engaged" in a research study that might be conducted on campus, using EMU students, staff, property, or facilities, if:

1. EMU employee or agents perform commercial or other services for non-EMU investigators provided that **all** of the following conditions also are met:
    a. the services performed do not merit professional recognition or publication privileges;
    b. the services performed are typically performed by those EMU employees or agents for non-research purposes; and
    c. the EMU employees or agents do not administer any study intervention being tested or evaluated under the protocol.
    d. when appropriate, investigators from an institution engaged in the research retain responsibility for:
        i. overseeing protocol-related activities; and
        ii. ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.

2. EMU employees or agents are involved only to the extent that they
    a. inform prospective subjects about the availability of the research;
    b. provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB-approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators;
    c. provide prospective subjects with information about contacting investigators for information or enrollment; and/or
    d. seek or obtain the prospective subjects' permission for investigators to contact them.
    e. An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to investigators.

3. EMU permits the use of their facilities for intervention or interaction with subjects by investigators from another institution. Examples would be if EMU allows investigators from another institution to conduct or distribute a research survey in the classroom; or EMU

permits investigators from another institution to recruit research subjects on campus.

K. Limited UHSRC Review

Limited UHSRC review will be conducted as required by 45 CFR 46.104(d)(2)(iii), (d)(3)(i), (d)(7), and (d)(8).

1. Limited UHSRC review for the storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use where broad consent is required will consist of the following determinations:

    a. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements in 45 CFR 46.116(d) of these procedures; AND

    b. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 45 CFR 46.117; AND

    c. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2. Limited UHSRC review for research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior when the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained; for research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording if the subject prospectively agrees to the intervention and information collection and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained; and for secondary research involving the use of identifiable private information or identifiable biospecimens for which broad consent is required when broad consent has been obtained and documented:

    a. The research to be conducted is within the scope of the broad consent; AND

    b. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

L. 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, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Selection of subjects is equitable[3] 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, in accordance with, and to the extent required by, 45 CFR 46.116. 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 or appropriately waived in accordance with 45 CFR 46.117.

6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of research subjects.

7. Where appropriate, the research plan makes adequate provision to protect the privacy of subjects and to maintain the confidentiality of data.

8. For purposes of conducting the limited IRB review required by 45 CFR 46.104(d)(7), the determinations in paragraphs 1-7 of this section need not be made. The following determinations shall be made instead:

    a. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of 45 CFR 46.116(a)(1)-(4), (a)(6), and (d);

    b. Broad consent is appropriately documented or waiver of documentation is appropriate, and in accordance with 45 CFR 46.117; AND

[3] The term "equitable" is defined to mean that there is no discrimination in the selection of subject populations and no over-selection of vulnerable subjects.

c. If there is a change made for research purposes to the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe 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.

For FDA-regulated research involving the use of an investigational medical device, the Committee will also make a significant risk (SR) device determination, a non-significant risk (NSR) device determination, or an exempt determination. In order to be classified as a SR device, the investigational device must meet at least one of the following criteria:

1. It is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
2. It is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
3. It is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
4. It otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

If the investigational medical device does not meet at least one of the four SR criteria, it will be classified as a NSR device. Research using medical devices will be determined exempt from FDA regulation in accordance with 21 CFR 812.2(b) and (c).

Research ethics and responsible conduct of research training is provided from the Office of Research Compliance website.

ADMINISTRATIVE PROCEDURES

A. Membership

1. The University Human Subjects Review Committee (hereafter UHSRC) shall be composed of a minimum of seven voting members.
   a. No fewer than five members shall be selected from the ranks of the faculty. At least one person from each of the colleges shall be selected.
   b. At least one person, such as a, 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. At least one person who is not otherwise affiliated with the institution or a part of the immediate family of one who is affiliated.

d. The Research Compliance Officer will serve as an Alternate member of the UHSRC. The Research Compliance Officer will not be permitted to vote at meetings except as a proxy if and only if required to maintain quorum.

2. The Associate Provost and Associate Vice President for Graduate Studies and Research will approve new UHSRC members. Prospective members from the faculty must be nominated by the Faculty Senate.
   a. 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.
   b. 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.
   c. 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 online training provided by the Collaborative Institutional Training Initiative (CITI). 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 Chair and Research Compliance Officer will be responsible for communicating with committee members about training options and monitoring adherence to this policy. Members who do not complete such training or, for whatever reasons, are unable to provide informed reviews that address pertinent human subjects issues may be removed from the committee by the Chair.

B. Term of Service

1. The term of service on UHSRC shall be three years.

2. All new appointments shall become effective at the beginning of either the Fall or Winter semester, at the discretion of the Associate Provost and Associate Vice President for Graduate Studies and Research.

3. 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 Institutional Official. Additionally, if reviews indicate a lack of comprehension about important human subjects' considerations, the member may be removed and replaced by the Institutional Official.

C. Officers of the UHSRC

1. There shall be one Chairperson for the UHSRC: a faculty member of the UHSRC who shall serve as executive and signature authority for the Committee.

2. There shall be a Vice-Chairperson for the UHSRC: a faculty member of the UHSRC who shall serve as a secondary executive and signatory authority for the Committee. The Vice-Chair shall take on primary executive and signatory duties at the request of the 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 two weeks 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. To be considered for review, investigators must submit a completed UHSRC Request for Approval application. All applicable supplemental documents that also must be submitted and reviewed include:
    - Consent forms and scripts/assent forms and scripts/information sheets
    - Recruitment and screening materials
    - Questionnaires, surveys, interview questions, and other assessments or measures
    - A brief research protocol as described in the UHSRC Request for Approval application
    - Evidence of completion of online human subject protection training

3. UHSRC Review

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. 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 Chair or Research Compliance Officer will also notify the Associate Provost and Associate Vice President for Graduate Studies and Research of any proposed research activity that has been disapproved.

Requirement for Review of Research by the UHSRC at Convened Meetings: Projects that are greater than "minimal risk" must undergo **Full Board review** at a convened meeting. The UHSRC may also review at a convened meeting studies that are deemed not greater than minimal risk at its discretion. Each project will be reviewed and voted upon separately to ensure that members with a conflicting interest related to a particular study do not participate in the continuing review of that study, except to provide information requested by the UHSRC. Materials to be reviewed by the Full Board must be provided to UHSRC members at least two weeks prior to the date of the convened meeting. Full Board meetings will be scheduled for September through April, inclusive. During summer months (May, June, July, August), a convened meeting may take place if necessary due to imminent funding and if quorum can be obtained.

Approval of research is by a majority vote of the quorum as described in 45 CFR 46.108(b). Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored. The date of initial approval for projects discussed at convened meetings is the meeting date, unless approval is granted with conditions and the UHSRC decides that one member of the UHSRC can review the Principal Investigator response in lieu of the committee. Under this scenario, further review by the UHSRC at a subsequent convened meeting is not necessary for the initial approval to become effective; the effective date of the initial approval is the date on which the UHSRC Chair (or any other individual(s) designated by the UHSRC) has reviewed and accepted as satisfactory all changes to the protocol or informed consent documents, or any other responsive materials, required by the UHSRC from the investigator.

Expedited studies do not require approval at a convened meeting. Expedited reviews are conducted by at least one (usually two) members of the UHSRC. The Expedited reviewers will send their reviews to the Office of Research Compliance, who will then notify the UHSRC Chair or Vice-Chair. After reviews are received, the UHSRC Chair, Vice-Chair, or a UHSRC member who has been designated by the Chair may issue approval through a letter; the approval date is the date that the letter is sent. Reports of all Expedited approvals will be reported to the UHSRC at convened meetings.

An expedited review may be conducted for research in which all research activities can be described by at least one of the categories delineated by the Office of Human Research Protection and involving no more than minimal risk, minor changes in research previously approved at a convened meeting during the period for which approval is authorized, or research for which limited IRB review is a condition of exemption. Classified research cannot be approved under Expedited review. Principal investigators of expedited studies will be contacted three years post approval to determine if the study is ongoing or if it can be closed.

Expedited reviewers will review applications in accordance with regulations and guidelines specified in 45 CFR 46 and all other application federal, state, local, and institutional regulations and policies. Expedited reviewers can approve, approve with conditions, or defer a study. Expedited reviewers cannot disapprove a study. If Expedited reviewers decide that a study should be disapproved, they must recommend it for Full Board review.

3. Continuing Review of Research Projects

UHSRC approval for research approved at a convened meeting or for expedited research in which the need for continuing review has been appropriately documented lasts up to, and no longer than, one year in accordance with 45 CFR 46.109(e). Continuing review must be conducted before the expiration date of the previous UHSRC approval, even if the research activity began some time after the UHSRC approval date. Continuing review must be conducted according to criteria outlined in 45 CFR 46.111. Continuing review will be conducted at a convened meeting unless one of the following situations applies:

1. Continuing review of a study approved under Expedited review;

2. Continuing review of research previously approved by the convened UHSRC as follows:
    a. Where the research is
        i. 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; OR
    b. Where no subjects have ever been enrolled and no additional risks have been identified; OR
    c. Where the remaining research activities are limited to data analysis

3. Continuing review of research, not conducted under an Investigational New Drug application or an Investigational Device Exemption where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risks and no additional risks have been identified.

Principal Investigators who require continuing review must submit the Continuing Review form. Annual reviews may be processed using the Continuing Review 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. If, at the time of annual review, the only remaining activities are analysis of de-identified data and manuscript preparation, the study can be administratively closed. The UHSRC will maintain all study documentation for five years post-closure.

Research projects deemed to be Expedited at the time of initial review do not require continuing review, unless otherwise determined and documented. When continuing review of research is conducted under an Expedited review procedure, the review must be conducted by the UHSRC Chair or one or more of the UHSRC Chair designees. The date of continuation approval for Expedited projects is the date on which the approval email/letter is sent to the Principal Investigator.

Three years post-approval, principal investigators of Expedited research not otherwise determined to require continuing review will be contacted for a progress report on their research. If the research has concluded to the point where the only remaining activities are analysis of de-identified data and manuscript preparation, the study will be administratively closed. The USHRC will maintain all study documentation for five years post-closure.

No UHSRC member may participate in the initial or continuing review of research in which the member has a conflicting interest, except to provide information requested by the UHSRC.

Research on non-exempt, non-expedited (i.e., Full Board) studies undergoing continuing review will be evaluated and discussed at a convened meeting. The Continuing Review form and supporting documentation will be distributed to the Committee at least two weeks prior to the meeting. Each project will be reviewed and voted upon separately to ensure that members with a conflicting interest related to a particular study do not participate in the continuing review of that study, except to provide information requested by the UHSRC. The meeting minutes will reflect any conflicts of interest and the outcome of the vote on each continuing review. The date of continuation approval for projects discussed at convened meetings is the meeting date, unless approval is granted with conditions. Under this scenario, further review by the UHSRC at a subsequent convened meeting is not necessary for the continuation approval to become effective; the effective date of the approval is the date on which the UHSRC Chair (or any other individual(s) designated by the UHSRC) has reviewed and accepted as satisfactory all changes to the protocol or informed consent documents, or any other responsive materials, required by the UHSRC from the investigator.

If the Principal Investigator does not submit for continuing review prior to lapse of UHSRC approval, the Research Compliance Officer or their designee will send a notice to the Principal Investigator that UHSRC approval has lapsed, the Principal Investigator must submit a Continuing Review form as soon as possible, and all study activity must cease until approval has been granted again. If the UHSRC does not receive a Continuing Review form within 60 days of the expiration date, the study will be administratively closed.

4. Event Reporting

   a. Adverse Event Reporting
   An adverse event is defined as any negative outcome experienced by the subject that has taken place during the course of a research project. Note that the adverse event does not necessarily have to be *caused by* research participation Adverse events must be reported to the UHSRC at continuing review.

   b. Serious Adverse Events, Unanticipated Problems, and Deviations
   Serious Adverse Events (SAE) are serious negative outcomes experienced by a subject and include death, life-threatening outcomes, hospitalizations (initial or prolonged), disability or permanent damage, congenital anomaly/birth defect, required intervention to prevent permanent impairment or damage (as in with a device), or other important medical or psychological events. Unanticipated Problems (UP) are any events that are unexpected, related or possibly related to the research, and may increase risk to subjects or others. Deviations are all instances where the UHSRC-approved protocol has not been followed, whether intentionally or unintentionally.

   SAEs, UPs, and Deviations must be reported to the UHSRC soon as possible, but no later than 24 hours after the PI learned of the event (see Event Report form). In the event of a SAE, the Research Compliance Officer will appropriately notify University General Counsel. If the research is being funded by an external agency, the principal investigator must also report the event to the Director of the Office of Research Development and Administration, whose responsibility it is to inform the agency in conformance with agency rules or regulations.

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

5. Protocol Changes
   Principal investigators are responsible for notifying the UHSRC when there are changes to their research protocol. The *Modification to Research Protocol* form must be submitted to request any change to the research protocol. All study documents requiring modifications must also be altered with changes highlighted or otherwise tracked and submitted with the modification request form. All changes, whether major or minor,

must be accompanied by a modified protocol (with changes highlighted or otherwise tracked) and all modified supplemental documents (with changes highlighted or otherwise tracked).
Approval of all changes must be obtained in advance of implementation.

All modifications to non-exempt research that do not increase risk to subjects will be reviewed via expedited procedures by the UHSRC Chair, Vice-Chair, or their designees. If the change increases the risk to subjects so that it no longer meets the "not greater than minimal risk" threshold, the changes will be reviewed at a convened meeting. All changes are subject to the criteria outlined in 45 CFR 46.111, 46.116, and 46.117.

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 Chair or their designee shall immediately notify the investigators, the Research Compliance Officer, and the Associate Provost/AVP for Research in writing that the research must cease until approval can be obtained. The principal investigator must also submit an event report to the UHSRC for review. If the noncompliance persists, the Research Compliance Officer will file a misconduct allegation with the Academic Integrity Committee when appropriate.

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, where new information indicates an increase in the level of risk to subjects, or in instances of serious and/or continuing non-compliance. 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 PI, the dean, the department head/school director, the Research Compliance Officer, the Associate Provost/AVP for Research, the Provost, the Office of Human Research Protection, and if the study is funded, the Director of the Office of Research Development and the funding agency. 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. Informed Consent

No investigator may involve a human being as a subject in research covered by these procedures 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 for Full Board and Expedited research, and these records must be maintained for a minimum of three years past 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.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or representative in understanding the reasons why one might or might not want to participate in the research. Informed consent must present information in sufficient detail and must be organized and presented in a way that facilitates understanding. 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 or where further information may be obtained;

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. One of the following statements about any research that involves collection of identifiable private information or identifiable biospecimens:
   a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent, if this might be a possibility; OR
   b. A statement that the subject's information or biospecimens collected as a part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional elements of informed consent that may be included in the consent form when applicable but are not required:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the representative's consent;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

6. The approximate number of subjects involved in the study;

7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

9. For research involving biospecimens, whether the research will (if known) to might include whole genome sequencing.

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) may be obtained as an alternative to the required elements of consent. If the subject or representative is asked to provide broad consent, the following information shall be provided:

1. A description of any reasonably foreseeable risks or discomforts to the subject;

2. A description of any benefits to the subject or to others that may reasonably be expected;

3. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

4. 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 the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

5. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

6. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the idenfiable private information or identifiable biospecimens;

7. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be infinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be infinite);

8. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed about the details of any specific research studies that might be conducted using the subject's data, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

9. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject;

10. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subjects' identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm;

11. If applicable, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; and

12. If applicable, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing

The UHSRC may waive the requirement to obtain informed consent or may approve a consent procedure that omits some or alters some or all of the elements of informed consent above provided that the following requirements are satisfied and documented:

1. The research involves no more than minimal risk to the subjects; and

2. The research could not practicably be carried out without the requested waiver or alteration; and

3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and

4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; AND

5. Whenever appropriate, the subjects or representatives will be provided with additional pertinent information after participation.

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, the UHSRC cannot waive consent for the storage, maintenance, or secondary use of the identifiable private information or identifiable biospecimens. The UHSRC may not omit or alter any of the above requirements if a broad consent procedure is used.

A waiver of <u>signed</u> informed consent may be requested for non-FDA regulated research 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; or

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; OR

3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no

more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

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.

The UHSRC may approve a research proposal in which an investigator will obtain information or biospecimens for the purposes of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative; OR

2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

For each clinical trial conducted or supported by a federal department or agency, one UHSRC-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conduting the trial on a publicly available Federal Web site that is established as a repository for such informed consent forms. The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by protocol. If the federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available, such department or agency may permit or require redactions.

G. Record Keeping

The UHSRC shall maintain records of all reviews, correspondences related to reviews, decisions, and other UHSRC activities. 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, including the rationale for conducting continuing review of research that otherwise would not require continuing review according to 45 CFR 46.109(f)(1);

4. Copies of all correspondence between the UHSRC and the investigators;

5. A list of UHSRC members as required by 45 CFR 46.108(a)(2);

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) 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; (d) ensuring prompt reporting to the UHSRC, Institutional Official, department or agency head, and the Office for Human Research Protections or Secretary of Health and Human Services of unanticipated problems involving risks to subjects or others; any serious or continuing noncompliance with these procedures or the requirements or determinations of the UHSRC; and any suspension or termination of UHSRC approval;

7. Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(c)(5);

8. The rationale for an expedited reviewer's determination under 45 CFR 46.110(b)(1)(i) that research appearing on the expedited review list described in 45 CFR 46.110(a) is more than minimal risk; and

9. Documentation specifying the responsibilities that EMU will undertake to ensure compliance with OHRP policy as described in 45 CFR 46.103.

Conclusion. The intent of EMU policy and related review procedures is to assure the 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).