Volume II
Human Subjects Research:
Institutional Review Board (IRB)

Chapter 1: Summary and Purpose of the Institutional Review Board (IRB)

1.1 Purpose

The purpose of the Institutional Review Board (IRB) is to review, approve, disapprove or request revisions to research protocols submitted by UCM researchers, while ensuring the rights and welfare of human subjects, according to federal regulations for research. Federal, state, and university regulations require that all research conducted by UCM researchers be approved prior to the start of research

1.2 Regulations Governing Human Subjects Administration

University of Central Missouri, through the Office of Sponsored Programs and Research Integrity, is responsible for ensuring that the institution is compliant with regulations set by the Office for Human Research Protections (OHRP) and adhere to the principles in the Belmont Report. The IRB adheres to 45 CFR 46 federal regulations concerning human subjects research.

Chapter 2: Institutional Review Board (IRB) Operations

2.1 Organizational Structure

The university's IRB is also referred to as the Human Subjects Review Committee. The IRB includes the committee, the Institutional Official (IO), the Research Compliance Officer, and clerical support. The IRB reports to the Vice Provost of Academic Programs and Services. UCM'S IRB website can be found at https://www.ucmo.edu/offices/sponsored-programs-and-research-integrity/human-subjects-irb/index.php.

2.1.1 IRB Membership

- Members will be chosen from varying backgrounds to assure complete and adequate review of activities commonly conducted by the University. Committee membership should reflect diversity and be in accordance with 45 CFR 46, 107.
- At least one faculty member must come from a scientific area; at least one must come from a non-scientific area; and at least one must be knowledgeable about specific protected categories.
- One community representative member who is not an officer, employee or agent, or otherwise associated with the University of Central Missouri, apart from this committee membership is nominated by the chairperson and appointed by the IO. An alternate community representative may also be appointed.
- The Research Compliance officer (ex officio and non-voting).

- A student member is nominated by the chairperson and appointed by the IO.
- Faculty members who have previously served on the committee may volunteer for terms as alternate members.

2.1.2 Committee Meetings

The committee meets approximately every two weeks during the academic year. During the summer, the IRB will meet at least once. The IRB may meet more than once in the summer to review additional protocols and conduct business. Meeting dates are posted on the website.

2.1.3 Conflicts of Interest

As per HHS regulations at 45 CFR 46.107(d), no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

2.1.4 Requirements for IRB Approval

In conducting the initial review of proposed research, the committee must receive information in sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111.

The IRB must determine that the risks to human subjects are minimized. Investigators should minimize risk by using sound research design and not exposing subjects to unnecessary risk. 45 CFR 46.111.(a)1

The IRB must ensure that the ratio of risks to benefits is appropriate and safe with respect to the welfare of human subjects. 45 CFR 46.111.(a)2. The IRB must ensure that selection of subjects is fair and equitable. The IRB should take into consideration the research design, purpose of the research, and special populations the research may target. 45 CFR 46.111.(a)3. The IRB must determine that informed consent will be documented and obtained in compliance with 45 CFR 46.116 and 45 CFR 46.117, 45 CFR 46.111.(a)4. The IRB must ensure that there are appropriate protections for collected data, confidentiality of data, and privacy of subjects. 45 CFR 46.111.(a)6 and 45 CFR 46.111(a)7. The IRB must verify that additional protections are prepared for vulnerable populations such as, but not limited to, pregnant women, prisoners, and children. 45 CFR 46.111(b). Materials should include the appropriate review form and any other documents used as part of the research protocol, such as consent and/or assent forms, surveys, tests, interview guides, and advertisements.

Per federal regulations, the letter sent to the researcher will include the following:

- Date letter was written
- Name of researcher (and in cases of student researcher, the name of the faculty member supervising the research)
- Title of research project
- In the case of disapproval, the reasons why the research project was not approved
- A statement indicating that the researcher must use the committee-approved consent form, which will contain an approval stamp
- A statement that the researcher must report in writing any adverse event immediately and that the research is to be stopped immediately unless stopping the research will cause more harm than continuing the research
- A statement indicating the length of approval (one year or less)
- A statement that the researcher must inform the committee in writing of any adverse events, any change in the nature or status of the risks involved in participating in the research project and any change in the committee-approved research project and that the proposed changes cannot be implemented until the researcher receives committee approval in writing
- A statement containing the deadline by which the Final/Renewal Report must be completed and returned to the IRB.

2.1.5 Responsible Conduct of Research Training (RCR)

A Responsible Conduct of Research training requirement applies to all new proposals submitted for review. This training requirement is through the Collaborative Institutional Training Initiative Web-based Training Program (CITI Program). There is no cost to the participates as the subscription is paid by OSPRI. The following are instructions to logon to CITI for the first time:

1. User should be instructed to go to www.citiprogram.org to register for CITI online training. Once there, they simply click on "New Users Register Here". Select your organization affiliation: you can use the drop-down list and type in University of Central Missouri.
2. Enter your name as you would like it to appear on your completion report received at the end of the course.
3. Ensure you use an email address that you can access to complete the registration process.
4. Set up user name & password and chose a security question – put this information somewhere you can find later.
5. Demographic information is voluntary. Use the blue information question marks for more information on specific categories.

6. CEU's are available to RN students. Otherwise answer no to the question.
7. Each institution determines the fields listed on this page and what information is required or optional.
8. This enrolls you in CITI Program courses. These questions are set up based on the institutional specific courses. Please read each question carefully to ensure you are enrolled in the correct course.

After going through registration process you should be ready and setup as a CITI Learner. Please contact https://support.citiprogram.org/s/contactsupport in case of any questions.

These programs are composed of several modules. Completion of the Responsible Conduct for Research (RCR) Module is required. Additional modules may be required by the IRB depending on the nature of your protocol. Refresher courses are required every three years.
Note: IRB approval of research protocols will be delayed, pending the researcher's completion of CITI training.

Chapter 3: Institutional Review Board Procedures

3.1 Procedures for Conducting Initial Review of Research

In accordance with HHS regulations at 45 CFR 46.108(b), initial and continuing review of research in the Full Review category must be conducted by the committee at convened meetings and voted on by a quorum. A Full Review protocol involves one or more of the following; more than minimal risk to participants, special populations, and IRB uncertainty regarding the safety of the research design. The committee may approve the project; disapprove the project, or request revisions and/or more information. Minor revisions, such as requesting a specific change to a consent form, may be referred to the chair, vice chair, or other designee for review. Major revisions must be referred to the full committee for consideration. The IRB must require information in the informed consent to be compliant with 45 CFR 46.116. When the IRB deems it necessary for the protection of the human subject, additional information may be requested to be included in the informed consent 45 CFR 46.109(b). The IRB must require documentation of the informed consent or waive the informed consent requirement in compliance with 45 CFR 46.117, 45 CFR 46.109(c). Lower risk research projects may be reviewed via exempt or expedited means. These projects are reviewed by designated reviewers on the IRB. Approvals, revisions, and disapprovals must be communicated via writing by the IRB to the Office of Sponsored Programs and Research Integrity and the primary investigator. Investigators whose protocol is disapproved must receive written notification and the basis of disapproval and be given an opportunity to respond. 45 CFR 46.109(d). IRB approved protocols may be reviewed and/or disapproved by the Institution. The

Institution may approve a protocol only if the IRB has approved the protocol under review. 45 CFR 46.112

3.1.1 Procedures for Reviewing Protected Populations

Research involving pregnant women, neonates, fetuses, children, or prisoners must meet additional requirements. The IRB shall consider the additional parameters defined in 45 CFR 46., when reviewing a research protocol.

3.1.2 Procedures for Reporting to Committee for Proposed Changes to Committee-Approved Research (Amendment)

Researchers may request amendments to approved projects. They may not enact their proposed changes until they have received IRB approval.

3.1.3 Procedures for Conducting Continuing Review of Research (Renewal)

Expedited and Full projects are mandated to be either reviewed or closed once per year. However, the IRB may review any project, in any category, at any interval they deem necessary.

3.1.4 Procedure for Research Conducted by Students- Faculty Advisor's Responsibilities

Faculty Advisors are required on all student research. They are to assist students throughout the research process, by reviewing application, overseeing research, assisting with the resolution of any problems or concerns encountered during research, ensuring that UCM's IRB is notified of any adverse events, and guiding students through the research process.

3.1.5 Class Project Exemption

Class projects are exempt from IRB approval unless the project will be presented or published outside of the classroom and must meet the following parameters.

3.1.5a Recommended parameters for Class Projects:

1. NO MINORS The project cannot include minors or any other vulnerable populations like pregnant women, prisoners, those who lack the capacity to consent, non-English speaking individuals etc.
    a. Exception Projects conducted in established or commonly accepted educational settings, involving normal educational practices, such as: work on regular and special education instructional strategies, or work on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods.

2. NO MORE THAN MINIMAL RISK "Minimal risk" is the probability and magnitude of harm that is normally encountered in the daily lives of healthy individuals. This also precludes the study of any illegal activities or the collection of private information that could put the participants at risk through a breach of confidentiality.
3. NO DECEPTION The class project cannot include any deception. Individuals must be fully informed and given the opportunity to voluntarily consent to participation.
4. NO PUBLICATION Data from class projects approved under this exemption cannot be used for publication or for thesis/ dissertation research.
5. NO VIDEOTAPING Audio taping is allowed only if the recording is erased upon transcription or no later than the end of the semester.

If a class project does not fall within the above parameters, the researcher may submit an IRB application that will go through the regular review and approval process.

(Modified from: University of Georgia, Office of the Vice President for Research, Guidelines for Researchers http://www.ovpr.uga.edu/hso/guidelines.html#15

3.1.6 Procedures for Determining Which Projects Need Verification from Sources other than the Investigators that no Material Changes Have Occurred Since the Previous Committee Review

During the initial review of all Full Review research projects the committee will determine if a research project requires verification from sources external to the committee under the following conditions:

- Researcher has history of noncompliance
- Committee informed of possible noncompliance
- Proposed research project involves more than minimal risk
- Proposed research project involves protected subjects
- 45 CFR 46.103(b)(4)

3.1.7 IRB Collaboration with Other Institutions (external)

In the event a UCM researcher is working with someone outside the campus they may need to submit an external IRB application and obtain approval before conducting the research according to 45 CFR 46.114. This also applies to research conducted by UCM affiliated researchers in foreign countries.

3.1.8 Requirements for Research Conducted at UCM by Non UCM Researchers

UCM collaborates with IRB's from other institutions. UCM requires:

1. The researcher must establish a UCM faculty contact to help implementation of the research in accordance with UCM policies.
2. A letter of approval, the original application form and all associated documents provided to the UCM IRB from the institution assuming responsibility for monitoring compliance with all applicable regulations.
3. The researcher must use the consent form submitted when enrolling participants for this research.
4. Please note that the researcher is required to notify the UCM committee in writing of any changes in the research project and that the researcher may not implement changes without prior approval of the UCM IRB committee. The researcher must also notify the committee in writing of any change in the nature or the status of the risks of participants in the research project.
5. Should any adverse events occur in the course of the research (such as harm to a research participant) the researcher must notify the UCM IRB in writing immediately. In the case of any adverse event, the researcher is required to stop the research immediately unless stopping the research would cause more harm to the participants than continuing with it.

At the conclusion of the project, the researcher will need to submit a completed Final/Renewal Report to this office. The researcher must also submit the Final/Renewal Report if the researcher wishes to continue the research project beyond its initial expiration date.

All institutions involved in the research are responsible for the protection and welfare of human subjects. 45 CFR 46.114

3.1.9 Procedure for Research Involving Exercise

For exercise risk management address blood and body fluid protection, ACSM risk stratification and ParQ form, and reference to emergency response policies as indicated.

3.1.10 Procedure for Gaining Permission to Conduct Research off Campus

The IRB requires a statement indicating that the researcher has permission to collect data at an off-campus location, including the off-campus entity name and the entity authorized representative's name and title. This statement may be in the form of an email on letterhead or from the site's official e-mail.

3.1.11 Research Undertaken Without the Intention of Involving Human Subjects

If research that was initially intended to be conducted without human subjects later involves human subjects, the investigator must report this to the IRB and wait for the IRB's approval before implementing the research. 45 CFR 46.119

3.2 Procedures for Reporting Adverse Events or Research Misconduct

3.2.1 Definitions

3.2.1.a Research Misconduct

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting results. Investigations of research misconduct must find: that there is a significant departure from accepted practices of the relevant research community; the misconduct is committed intentionally; and the allegation must be proven by evidence.
42 CFR 93.103(a-d) and 42 CFR 93.104(a-c)

3.2.1.b Adverse Events

Adverse events are defined as events, foreseen or unforeseen, that bring harm to human subjects and/or increase the risk of harm to human subjects.

3.2.2 Procedures for Reporting to Committee about Adverse Events

All letters from the committee approving a research project will contain a statement that the researcher must report any adverse event immediately to the Human Subjects Protection Program. The research is to be stopped immediately unless stopping the research will cause more harm than continuing the research. In addition, every researcher must submit a Final/Renewal Report which specifically documents all adverse events.

3.2.3 Procedures for Reporting Findings and Actions to Investigators and the Institution

The IRB will inform the researcher in writing of the review status of the research project. The letter will include the following:

- Date letter was written
- Name of research (and in cases of student researchers, the name of the faculty member supervising the research)
- Title of research project being reviewed
- Date of meeting when the research project was reviewed

- A statement outlining any findings or actions identified by the IRB
- A statement outlining any action that the researcher must perform if such actions were identified by the IRB
- A statement indicating that the researcher must continue to use the IRB approved consent form, which will contain an IRB approval stamp
- A statement indicating the approval period is only good for one year or less
- A statement that the researcher must inform the IRB in writing of any adverse events, any change in the nature or status of the risks involved in participating in the research project and any change in the IRB approved research project and that the proposed changes cannot be implemented until the researcher receives IRB approval in writing
- A statement that the researcher must report any adverse event immediately and that the research is to be stopped immediately unless stopping the research will cause more harm than continuing the research.

3.2.4 Procedures for Reporting by the Research Compliance Officer

The Research Compliance Officer is responsible for reporting any unanticipated problems involving risks to subjects or others; any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and any suspension or termination of IRB approval. The Research Compliance Officer is responsible for reporting any such events to the following parties: the IRB, Vice Provost of Academic Programs and Services, the Provost and Vice President for Academic Affairs, the appropriate college dean, any agency or department which is funding the research; and OHRP. Such reporting will take place no more than five business days after a determination has been made that one of the events described above has occurred.

3.3 Institutional Review Board Responses

3.3.1 Actions by the IRB in Response to Unanticipated Problems

In the event of unanticipated problems involving risks to the subjects or others, the IRB will evaluate the nature of the problems and decide on appropriate action, which could range from temporarily suspending the research project to terminating approval for the project and requiring the investigator(s) and appropriate institutional officials to resolve the problems.

3.3.2 IRB Response to Serious or Continuing Noncompliance

Guidelines for the procedure for the investigation of allegations of scholarly or scientific misconduct are outlined in the Ethics in Research Document found in

the Faculty Guide Section IV. The IRB may informally gather and process information to evaluate the nature of the IRB problem for the purpose of determining if the criteria for a human subject's violation has been met. If serious or continuing noncompliance is determined, the IRB will examine the record of noncompliance and take appropriate action. The IRB may suspend or terminate protocols that do not comply with federal regulations or when unexpected adverse events occur in the research process, affecting the safety of participants. Any suspension or termination will be quickly reported to investigators, institutions officials, and the department chair and contain the rationale for IRB action. 45 CFR 46.113

3.3.3 Range of Possible Actions

Appropriate action could range from requiring appropriate educational training to recommending official reprimand of the investigator(s), listing the investigator(s) as ineligible to conduct research with human subjects at UCM, or recommending termination of employment.

3.4 Informed Consent

UCM provides consent/assent templates for primary investigators. Templates follow federal regulations. 45 CFR 46.116. Consent is required for all research involving human subjects. Subjects who are 18 years of age or older must complete a consent form. Parents/legal guardians of subjects younger than 18 years must complete a consent form for their child to participate.

Assent must be obtained from all subjects under the age of 18 years. Consent for studies conducted over the internet must meet the same requirements as face to face consent. 45 CFR 46.116. All consent/assent forms must be compliant with 45 CFR 46.116

3.5 Record Keeping Requirements

The IRB shall maintain applications and modification forms submitted for review; minutes of meetings, including records of attendance; activities of the IRB and deliberations, records of proposed activities, and proposed significant changes, including whether the IRB approval was given or withheld; records of semiannual reports and recommendations; and

- Record Retention– The IRB shall retain records relating to proposed activities and significant changes in ongoing activities reviewed and approved by the IRB for the duration of the activity and three years after the end of the activity. Such records include, but are not limited to, records of applications, modifications, minutes of IRB meetings, and records of investigations of noncompliance related to an approved protocol.