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

d Z µ v] À Œ •] ğ Ş [r Ž 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 ^ Œ À] • XIRB 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

- 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(e), no IRB may have a member ‰ ŒŠ]]‰ Š]v Š Z /Z [•]v]Š of any project in which the P ŒÀ] A 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

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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

2. ENDORSEMENT. 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
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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

- 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 changes 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.

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