UNIVERSITY OF CENTRAL MISSOURI
IRB PROCEDURES
Document Revised September 11, 2006

Organizational Structure
The university’s Institutional Review Board (IRB) is the Human Subjects Review Committee (referred to as “the committee” in the remainder of this document). The Human Subjects Protection Program includes the committee, the Institutional Compliance Official, and clerical support. The Human Subjects Protection Program reports to the Assistant Provost for Research.

Committee Meetings
The committee meets approximately every two weeks during the academic year. In the summer the committee will meet when necessary contingent on committee availability.

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. Materials should include the appropriate review form and any other documents used as part of the research protocol, such as consent and assent forms, surveys, tests, interview guides, and advertisements. All materials are to be submitted to the Human Subjects Protection Program. Upon receipt of proposals the Human Subjects Protection Program will copy all materials submitted and distribute copies of such materials to all committee members; the Human Subjects Protection Program will include a memo containing the name of the researcher, the title of the research project and the date of the scheduled meeting when these projects will be reviewed.

Upon completion of the review of research protocols, the Human Subjects Protection Program will notify the researcher in writing of the status of his/her research project. In the case of research by students, the Human Subjects Protection Program will notify in writing both the student and the faculty member supervising the student’s research.

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
- Date of meeting when the research project was approved or disapproved
- 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 Project Status Form must be completed and returned to the Human Subjects Protection Program.
Procedures for Conducting Initial Review of Research
In accordance with HHS regulations at 45 CFR 46.108(b), initial and continuing reviews of research in the Full Review category must be conducted by the committee at convened meetings at which a majority of the members of the committee are present, including at least one member whose primary concerns are in non-scientific areas and one member who is not a member of the research institution. A quorum will consist of a majority of the committee membership provided that the majority consists of the two aforementioned members. The committee may select to have an alternate external member. Should the quorum fail during a meeting (e.g., loss of a majority through departure of members with conflicting interests or early departures, or absence of either a non-scientist member or non-institutional member) the committee may not take further actions or votes unless the quorum can be restored. If the proposed research project involves expertise beyond the expertise of the committee, the committee may call for external consultants to assist. 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 or vice-chair for review. Major revisions must be referred back to the full committee for consideration.

Research protocols for which the investigator has requested Expedited Review or for which a Request for Exemption has been submitted will be reviewed by a subcommittee comprised of two voting members of the committee. The subcommittee may recommend approval, request revisions and/or more information, or may refer the protocol for Full Review. When revisions and/or more information are requested, they will be reviewed by the chair or vice chair of the committee, who may then approve the project.

For any proposal that is part of a grant or contract, the Institutional Compliance Official will review the entire grant proposal or contract to determine whether all research involving human subjects is submitted for appropriate review.

Additional Procedures for Reviewing Research Involving Prisoners
In accordance with subpart C of 45 CFR 46, initial and continuing reviews of research involving prisoners must meet the following requirements. The IRB must include a prisoner representative with the appropriate background and experience to represent the perspective of prisoners (45 CFR 46.304). The IRB must determine that the proposed research is in a permissible category under 45 CFR 46.306.

Procedures for Conducting Continuing Review of Research
The Human Subjects Protection Program will maintain a database of all research projects conducted by faculty, students and staff. The database will contain a field for the date the research project must be reviewed and the Human Subjects Protection Program will inform the researcher in writing at least 30 days prior to the date the approval will expire. The researcher must complete and submit the Project Status Form. In addition, to request renewal the investigator must submit the appropriate materials for review, including the Full Review or Expedited Review form,
**Recording of Minutes**

The minutes of all committee meetings will document all activities that take place during the meeting, including the following:

(a) List of everyone attending the meeting, categorized appropriately (primary member, alternate member, non-voting member, guest). List of absent members.

(b) Separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened committee. Include a short summary of the protocol being discussed. Also include a description of any controverted issues and how the issues were resolved.

(c) The vote on all committee actions including the number of members voting for, against, and abstaining. Indicate the motion (approve, disapprove, require modifications). In order to document the continued existence of a quorum, the committee will record votes in the minutes using the following format. For example, if there are 15 members: Total:=15; Vote: for-14, Opposed-0, Abstained-1. Also indicate any members who recused themselves due to a conflict of interest, and indicate the nature of the conflict.

(d) Indication of whether it is a continuing or initial review.

(e) If informed consent is waived, documentation that the requirements under 45 CFR 46.116c or d are satisfied. If a signed consent document is waived, documentation that the requirements under 45 CFR 46.117c are satisfied.

(f) For research involving children, documentation that the research satisfies the requirements under subpart D of 45 CFR 46; specifically that the research is no more than minimal risk (45 CFR 46.404) or that, if it is greater than minimal risk that there are direct benefits to the participants that justify the risks (45 CFR 46.405) or that the research is likely to yield generalizable knowledge about the subject’s disorder or condition (45 CFR 46.406) or that the research provides an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407). In addition, the committee will document that the research includes appropriate procedures for obtaining parental permission and assent from the subjects according to 45 CFR 46.408. If the research includes children who are wards of the state, the committee will document that the requirements of 45 CFR 46.409 are satisfied.

(g) For research involving prisoners, documentation that the research satisfies the requirements of subpart C of 45 CFR 46; specifically that the committee includes a prisoner representative with the appropriate background and experience to represent the perspective of prisoners (45 CFR 46.304) and that the proposed research is in a permissible category under 45 CFR 46.306.

(h) For research involving pregnant women, documentation that the research satisfies the requirements of subpart B of 45 CFR 46; specifically that the research satisfies the requirements listed under 45 CFR 46.204 or 45 CFR 46.207.

**Conflicts of Interest**

As per HHS regulations at 45 CFR 46.107(e), except when requested by the IRB to be present to provide information, IRB members will remove themselves from the meeting room when the IRB reviews research in which they have a conflicting interest, and such should be noted in the IRB meeting minutes.
Procedures for Determining Which Projects Require More than Annual Review
During the initial review of all Full Review research projects the IRB will determine if a research project requires more than annual review by determining whether the research project involves more than minimal risk and/or whether the research project involves protected subjects. If a determination is made that the research project requires more than annual review, the IRB will determine the next review date. The Human Subjects Protection Program will also include the date of the next review in the database of research projects and notify the researcher in writing at least thirty days prior to the review date that the research project is being reviewed and any action required by the researcher. The IRB will review the research project at a convened IRB meeting. Upon completion of the review, the Human Subjects Protection Program will inform the researcher in writing of the status of the review and any actions or findings of the review consistent with the Procedures for Reporting Finding and Actions to Investigators and the Institution.

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

Procedures for Reporting to Committee for Proposed Changes to Committee-Approved Research
All letters of approval from the committee will contain a statement that the researcher must inform the committee in writing of any proposed changes to a research project that has received committee approval and that such proposed changes to the research project cannot be implemented until the researcher receives committee approval in writing authorizing the proposed changes. Any investigator who wishes to make changes in a previously approved study must submit a request for amendment in the form of a memo addressed to the chair of the committee. The request must include revised versions of any materials in which revisions are requested, such as consent forms and surveys. A request for amendment will be reviewed by the chair or the vice-chair of the committee.

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 by phone to the Human Subjects Protection Program (660 543-4621) and in writing as soon as possible. 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 Project Status Form which specifically documents all adverse events.

Procedures for Reporting Findings and Actions to Investigators and the Institution
The Human Subjects Protection Program, upon being informed of the status of the continuing review, 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.

**Procedures for Reporting by the Institutional Compliance Official**

The Institutional Compliance Official is responsible for reporting any unanticipated problems involving risks to subjects or others; any serious or continuing noncompliance with 45 CFR Part 36 or the requirements or determinations of the IRB; and any suspension or termination of IRB approval. The Institutional Compliance Official is responsible for reporting any such events to the following parties: the IRB, the Assistant Provost for Research and Dean of The Graduate School, 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.

**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.

**Range of Possible Actions by the IRB in Response to Serious or Continuing Noncompliance**

In the event of serious or continuing noncompliance, the IRB will examine the record of noncompliance and take appropriate action, which could range from requiring appropriate educational activities 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.
Relationships with other IRB’s at Institutions
IRB Authorization Agreement

In the event that a UCM researcher has received approval from the UCM Human Subjects Review Committee and that researcher leaves UCM, on a temporary or permanent basis, then, in order to continue the approved research project, the researcher must submit an approved IRB Authorization Agreement from the appropriate institution. Prior to continuing or commencing the research project the IRB Authorization Agreement must be signed by the appropriate institutional representatives. This document must be kept on file at both institutions and provided to OHRP upon request.

In the event that a researcher from another institution comes to UCM and is going to commence or continue to conduct research on human subjects, that researcher must either have the research approved by the institution departed from or the research must be approved by the UCM Human Subjects Review Committee. In the former case the researcher must submit an approved IRB Authorization Agreement from the appropriate institution. Prior to continuing or commencing the research project the IRB Authorization Agreement must be signed by the appropriate institutional representatives. This document must be kept on file at both institutions and provided to OHRP upon request. In the later case, the researcher must follow the standard procedures for conducting research on human subjects at UCM.

This authorized agreement is governed by the date of the original Institutional Review Board approval period.
IRB Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution A):

IRB Registration # ___________    Federalwide Assurance (FWA) # ____________

Name of Institution Relying on the Designated IRB (Institution B):

__________________________________________________________

OHRP Federalwide Assurance (FWA) #:

The Officials signing below agree that ______________________ may rely on the designated IRB for review and continuing oversight of its human subject research described below: (check one)

(___) This agreement applies to all human subject research covered by Institution B’s FWA.

(___) This agreement is limited to the following protocol(s):

Name of Research Project: ____________________________________________________________

IRB Protocol Numbers for both institutions:   # / ______  # ________

Name of Principal Investigator:
Sponsor of Funding Agency:  Award Number, if any:  
(___) Other (describe):

The review and continuing oversight performed by the designated IRB will meet the human subjects protection requirements of Institution B’s OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting it findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with IRB’s determinations and with the terms of its OHRP-approved Assurance. This document must be kept on file at both institutions and provided to OHRP upon request.

Signatures:
Authorized Official of (A):  Authorized Official of (B):

___________________        _______ ____________________         _________
(signature)           (date)   (signature)       (date)

Beginning Date   Ending Date

___________________   ____________________