

FAC Appendix 13. Guidelines for IRB

McPherson College Institutional Review Board Guidelines for Research

Purpose of the Institutional Review Board (IRB)

The Institutional Review Board is charged with the responsibility of reviewing research studies and ensuring that the well-being of both researchers and research participants is appropriately safeguarded.

Application Process

What study plans must be reviewed?

Not all research studies must go through the full review process. Review is not required for research using historical documents or pre-collected data. Some research can be approved by means of an expedited review process. Research dealing with sensitive topics, using innovative methodology, using human or animal subjects, or involving vulnerable subjects is required to go through the full review process.

What is the nature of the review?

There are two types of review.

1. Full Review by all members of IRB. Full review is required for all research involving greater than minimal risk to subjects. In addition, full review is required for all research involving vulnerable or "captive" subjects. Examples of vulnerable populations would include children, the elderly, or psychiatric patients. Examples of captive subjects would include animals, prisoners, and students in a classroom setting. The following is required in the application process when a full review is warranted:

- A. Risks to subjects are fully explained, have been minimized as much as possible, and are reasonable in relation to anticipated benefits, if any, to subjects; and the proposal explains how the study adds to the body of knowledge.
 - B. In the case of animals, the scientific purpose of the research is sufficient to justify the use of animals.
 - C. Procedures are in place to assure the proper care and humane treatment of animals (if more humane alternative procedures are available, the Review Board should require that they be used).
 - D. Informed consent of human subjects will be appropriately documented.
 - E. Selection of subjects is justified and follows the good practice of the discipline.
 - F. Informed consent will be sought from each potential human subject or that subject's legal guardian. Informed consent will be documented. The documentation and data should be maintained by the department for a period of one year.
 - G. The proposal has a provision for monitoring data collected to ensure safety of the subjects.
 - H. Adequate provisions to protect the confidentiality or anonymity of subject's identity are in place.
 - I. Adequate provisions for maintaining the confidentiality of data are in place.
2. Expedited review by the chair and one member of the committee. Expedited review is provided for research that involves no more than minimal risk to subjects or for review of minor changes in previously approved research projects. Expedited review can be requested when the risks are minimal, selection of subjects is in accordance with good practice as identified by the profession, informed consent of humans will be obtained and will be appropriately documented, and safeguards are in place to maintain the confidentiality or anonymity of

subjects.

Who does the review?

Each Institutional Review Board will be composed of 3-5 persons appointed by the college. For each proposal, the board must include one person trained in the methodology to be used, and one member must be from outside the discipline. The faculty project advisor may not sit on the board.

Steps of the review process.

1. The student researcher contacts the chair of the committee to pick up the research proposal application.
2. The student researcher prepares the application and schedules an appointment with the review board. In general, the committee should receive the application one week prior to the meeting.
3. The student researcher and the faculty project advisor meet with the board. The student researcher is asked to provide a brief overview of the project. Members of the board may ask questions of the researcher or the advisor.
4. The IRB will respond in writing to the student researcher and the faculty project advisor within one week hours of the meeting.

Decisions of the Institutional Review Board.

The IRB can reach one of three conclusions in relation to a research project application. These decisions are:

1. Full Approval.
Members of the board approve the project as presented without stipulations.
2. Conditional Approval.
The proposal is approved with stipulations that is, members of IRB approve the project contingent upon the recommended changes. Should a problem or problems be identified, the board may award only conditional

approval contingent upon specific ethical or methodological changes identified by the board. If changes are deemed important but not essential to the proposal, the researcher need submit only a corrected proposal to the chair of the committee, who may approve the revised proposal. Should the changes be deemed important and significant, the chair of the board may approve the revised proposal after consultation with the whole committee.

3. Project Denial.

Should the members of IRB determine that there are serious ethical or methodological problems with a proposal, it can refuse to approve the project. Should a project be denied, the researcher and the faculty advisor will be informed of the reasons for denial. Should the board conditionally approve a proposal or deny a proposal, the student researcher can request an additional meeting with the board for reconsideration.

MCPHERSON COLLEGE APPLICATION FOR PROJECT/PROPOSAL APPROVAL Institutional Review Board (IRB)

Name of Student or Faculty Researcher(s):

Name of Faculty Project Advisor:

Date of application _____

Title of Project/Proposal:

Funding Agency (if applicable):

Decision of the Institutional Review Board:

Date of decision: _____

_____ Full Approval _____ Conditional Approval.

Reasons for conditional approval:

_____ Project Denied.

Reasons for denial:

Institutional Review Board Application Check List

_____ Completed and Signed Application Form

_____ Copy of Research Proposal

_____ Consent Form and Cover Letter (if applicable)

_____ Copy of Instruments/Questionnaires

_____ Copy of Protocol (if needed)

_____ Letter of Approval of Outside Agency (should data be collected external to the college)

Institutional Review Board Reviewer's Evaluation Sheet

Project/Proposal Title:

Student Researcher:

Type of Review: _____ full review _____ expedited review

Consent Form: _____ approve without correction _____ approve with correction _____ not approved; needs to be re-written and re-submitted _____ not applicable

Methodology/: _____ approve without correction

Procedures _____ approve with correction _____ not approved; needs to be re-written and re-submitted

Instruments/ _____ approve without correction

Questionnaires _____ approve with correction _____ not approved; needs to be re-written and re-submitted _____ not applicable

Risks to Subjects: _____ no risk to subjects (Human or _____ minimal risks Animal) _____ risks more than minimal;

appropriate safeguards in place _____ risks more than minimal;
appropriate safeguards not in place

Other Problems with Proposal:

Recommendation:

_____ full approval

_____ conditional approval

_____ project denial

Reasons for Conditional Approval:

Reasons for Denial:

Meeting Date:

Reviewer's Signature (Approved by EPC on 12/09/08)