McPherson College Behavioral Science Institutional Review Board (IRB) Guidelines

For Faculty/Student Research

Spring, 2023

The Institutional Review Board is charged with the responsibility to review research studies and ensure that the well-being of research participants is appropriately safeguarded. Responsibility for ethical conduct rests with all parties involved in the review, oversight, or conduct of research involving human or animal subjects. Parties include the Assistant Provost, Deans, Associate Deans, Division Chairs, faculty, staff, students, and members of the IRB.

Authority

The IRB has the authority to approve, require modifications to (in order to secure approval), or disapprove all research activities involving human or animal subjects; to suspend or terminate approval of research not being conducted in accordance with IRB requirements; and to observe or have a third party observe the consent process and the conduct of the research. IRB policies are drafted by the IRB chairs or designees, and approved by a majority of members present at a convened IRB meeting at which a quorum is present.

Composition

The IRB is a specially constituted review body established or designated by an entity to protect the welfare of human and animal subjects recruited to participate in biomedical or behavioral research. Membership consists of at least five members. At least four should be faculty members – the others may be non-faculty staff members, or individuals not otherwise associated with McPherson College. IRB members are selected by nomination by existing committee members, and may accept or decline the position. Appointments are for 12 months of service and are for a period of 3 years. No more than one-half of the committee membership should change each year.

IRB Chair: Directs the proceedings of the IRB committees, providing expertise and leadership in a wide range of areas related to IRB functions. The chair is appointed by the Assistant Provost.

IRB Vice-Chair: Assists the Chair as needed, performs duties delegated by the Chair, and serves in the absence of the Chair. The vice chair is elected by committee membership.

Responsibilities

Responsibilities of the Assistant Provost:

The Assistant Provost is responsible for setting the level of the institutional culture of compliance, for instilling respect for human and animal subjects, and for ensuring effective institution-wide communication and guidance on human and animal participant research. In addition, the Assistant Provost is responsible for the creation of the budget and resource allocation necessary to ensure that there are sufficient resources, space, and staff to support the IRB's review and record-keeping obligations. The Assistant Provost must ensure respect for the authority of the IRB and its decisions, and must ensure that the IRB is free from inappropriate influence.

Specific responsibilities of the Assistant Provost include:

- Oversee the educational instruction and training for IRB committee members, investigators, and research and administrative personnel
- Oversee the ongoing evaluation of the performance of committee members
- Serve as liaison between the College community and the public at large on issues related to the protection of human and animal subjects
- Oversee the development and presentation of the College-wide educational programs and online training related to research compliance
- Ensure compliance with pertinent laws and IRB policies in conjunction with the Compliance Officer

Responsibilities of the IRB Chair:

- Understand regulations and guidelines governing the protection of human and animal subjects
- Work closely with the IRB committee members to ensure that requirements are consistently applied in the review process and that work of the committee is accomplished in an effective and timely manner
- Pre-review or assign a designee to review each application to determine if a full board review is necessary
- Review or assign application review to committee members with topic expertise and no conflict of interest
- Consolidate and effectively communicate IRB committee comments and concerns back to the primary investigator in writing within two weeks of review
- Serve as signatory authority for documentation requiring IRB approval
- Provide leadership to the IRB, participate in training and orienting of new committee members, and provide input on related policies, procedures, and educational materials governing the protection of human and animal subjects
- Chair committee meetings, ensure that the agenda is completed, and review and edit minutes

- Answer questions and complaints from PIs, participants, or community members, and direct issues to the appropriate resource
- Ensure that committee members who have potential conflict of interest for a given project are recused during discussions of that project
- Serve as a resource to researchers who are planning or conducting research involving human or animal subjects
- Report changes in composition of IRB committee membership and submit annual report to the Assistant Provost

Responsibilities of the IRB Member:

- Conduct reviews as assigned by the IRB chair in time to present findings at the regular convened IRB meeting for approval process
- Attend IRB meetings, review minutes, and provide feedback of the application review in a timely manner
- Notify the IRB chair when absences are necessary to determine whether alternate members must be present on their behalf
- Maintain the integrity of the IRB review process, declare conflict of interest, and recuse themselves from board discussions or deliberations when necessary
- Avoid discussing IRB applications with investigators outside of convened IRB meetings
- Propose and review new policies and procedures
- Comply with pertinent laws and IRB policies

Responsibilities of the Principle Investigator:

Principle investigator (PI) refers to the person primarily responsible for designing and conducting a research study, and may refer to either students or faculty. PIs are required to understand the responsibilities associated with conducting research involving human and animal subjects. Investigators must comply with federal regulations, state and local laws, and institutional policies. They are responsible for training staff and for conducting the research. Ultimately, they are responsible for the safety of the human and animal subjects participating in the study.

Specific responsibilities of PIs include:

- Provide IRB with complete and up-to-date research application at least two (2) weeks prior to scheduled committee meetings. IRB meetings are scheduled monthly August through May. Meeting dates and submission deadlines are posted prior to the start of each academic year.
- Develop a research proposal that is (a) scientifically valid, (b) consistent with sound research design, and (c) poses minimal risks to human and animal participants
- Conduct research studies without deviation from the IRB-approved application, except in circumstances of direct threat of harm to any subject

- Inform IRB of any updates or modifications to the application; secure IRB approval of any application changes prior to implementation except when a delay in implementation would place subjects at risk
- Engage in recruitment practices that are fair and non-coercive
- Ensure that no subjects are recruited and no data is collected prior to IRB approval
- Submit progress reports as directed to IRB in a timely fashion for continued review or study closure
- Personally conduct the study or supervise study conduct by sub-investigators
- Assure that all sub-investigators are adequately trained not only to perform the assigned study procedures, but also to protect human and animal subjects
- Store and handle research data in accordance with regulations on privacy and confidentiality

What Study Plans Must be Reviewed?

Not all research studies must go through an IRB review process. The following section provides definitions and guidelines for determining when projects do and do not require IRB review and approval. Please note that while the IRB is open to completing non-required review of study plans for the purpose of student learning, these applications will be considered lesser priority than required applications, and may be turned away at any time dependent on application volume.

Definition of "research":

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. To be considered a systematic investigation, the concept of a research study ordinarily:

- Attempts to answer a research question (a hypothesis)
- Is methodologically driven (data/information are collected in an organized/consistent way), and
- Conclusions are drawn from the results

Developing or contributing to generalizable knowledge often means the activity includes the following concepts:

- The information gained contributes to a theoretical framework of established knowledge
- Results are intended to be generalized to a larger population beyond the site of data collection or population studied
- The primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study, and
- The results are intended to be replicated in other settings

This definition may include qualitative and quantitative research studies, surveys, case studies, experiments, interventions, analysis of specimens, demographic and epidemiological research, oral histories, secondary analysis of documents and records, and other methods associated with biomedical, behavioral, and social sciences.

Definition of "human subjects"

A human subject is defined as a living individual about whom an investigator conducting research: (a) Obtains information or biospecimens through interaction or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (b) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

To meet the definition above, the following must apply:

- The subjects are currently alive
- The information to be collected is about the subjects (e.g. personal information about the individuals), AND
- Information or biospecimens are collected by an intervention (physical procedures and manipulations of the subject or the subject's environment for research purposes) or an interaction (communication or interpersonal contact between investigator and subject) AND the investigator uses, studies, or analyzes the information or biospecimens OR
- The investigator obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens

As an example, the following do NOT meet the definition of human subjects:

- Analysis of data about people who are deceased
- Secondary analysis of anonymous data
- Interviews with "key informants" about topics other than themselves

Definition of "animal subjects"

All projects involving the use of live vertebrate animals for research, training, wildlife studies, experimentation, agricultural studies, biological testing, and related purposes must have IRB approval. Studies that involve unobtrusive observation of animals in their natural habitats do not require oversight. If the study has a potential to cause harm or materially alter the behavior of the animals, then IRB approval is required – this includes observational or wildlife studies where animals will be captured and released for purposes such as tagging or body measurements.

Additionally, research involving invertebrate animals that are cephalopods, endangered, classified as dangerous, non-native, or that require state or federal permits for possession also requires IRB approval.

The Application Process

Guidelines for Submission

IRB applications must be approved prior to recruitment of subjects or collection of data. IRB Committee meetings are scheduled monthly from August to May. All applications will be screened by IRB members to ensure that appropriate forms and required attachments are complete. Information, forms, policies and procedures, and a check-list for complete applications are posted on Bulldog Connect. Completed applications will be sent to the chair/vice-chair or designated primary reviewer to determine review status (exempt, expedited, or full review) and distribution to selected secondary reviewers if required. Incomplete applications will be returned to the PI for completion and may or may not be reviewed during the review cycle.

If the primary reviewer has questions about the proposal, the reviewer should contact the PI in an attempt to resolve the issues. Other IRB members should express their concerns to the primary reviewer. An approval letter will be electronically sent to the PI from the committee.

The Review Process

All members will be sent applications and other materials for review approximately one week prior to scheduled meetings. Members are expected to review all materials prior to meeting. The IRB meets in executive session. The Chair may permit persons not affiliated with the IRB to attend meetings upon request. Investigators and/or their collaborators are not permitted to be present at IRB meetings during deliberations on their research; however, the IRB may decide to invite investigators to the meetings to answer questions about their research.

The IRB reviews a proposal first by assessing the risks and benefits of research participation. After determining that the research benefit outweighs the risks involved, the IRB proceeds to the consent process to ensure that potential subjects are fully aware of the risks and benefits, and that they participate in the project voluntarily. The IRB will also determine whether or not the scientific questions addressed in the protocol have adequate merit to justify the involvement of human or animal subjects. After reviewing all materials, the IRB may opt to approve, table, or reject the application. The IRB may require revisions in the protocol before approval – after revision, the IRB reviews the project again to determine whether its concerns have been adequately addressed. All IRB actions are communicated in writing to the investigator by IRB members.

No IRB member may participate in the review or vote on any initial or continuing application, revision, or other matter involving research in which he or she has a conflict of interest. A conflict of interest occurs when an IRB member is the PI, faculty mentor/advisor, or member of a project on any research being reviewed by the IRB or when the member has a financial interest in the research under consideration. Members shall recuse themselves from discussions at IRB meetings of an application or other matter in

which they have a conflict of interest; this is recorded in the minutes. Members may provide information requested by the IRB prior to or after formal deliberations. The Chair recuses him- or herself from reviewing applications for expedited review and revisions or continuations when a conflict of interest is present, and may appoint another IRB member to act as chair during the review of such applications or research activities; this is noted in forms indicating the IRB's actions.

All IRB members should avoid any form of a conflict of interest that would compromise their ability to make a fair, impartial, and ethical decision on any IRB matter and should excuse themselves from decision-making in such instances.

Research conducted by students: The responsibility of the faculty sponsor

Senior theses, independent study projects, and other similar projects must be submitted independently to the IRB by the student-researcher. Faculty sponsors must instruct students on the ethical conduct of research and help them prepare the application for IRB approval.

Students should:

- Understand the elements of informed consent
- Develop a readable consent form
- Plan appropriate recruitment strategies for identifying potential subjects
- Establish and maintain strict guidelines for protecting anonymity or confidentiality
- Allow sufficient time for IRB review and completion of the project

To ensure the College's guidelines will be followed, the faculty sponsor is required to sign the student's application for IRB approval. After IRB approval, faculty sponsors must take an active role in ensuring that projects are conducted in accordance with the IRB's requirements.

Research conducted in college courses

Many research methods courses require students to complete projects as a means of teaching research methods and skills. The IRB does not require student projects conducted in research methods courses to be reviewed if the purpose of these projects is educational in nature and will not be published or used in future research. However, a project initially conducted to learn research methods may yield data that the student subsequently wishes to use to contribute to knowledge. In order to use these data for research purposes, students must either: (a) demonstrate that individuals provided informed consent for the project at the time, through procedures approved by the instructor; or (b) obtain consent from the individuals to use previously collected information according to procedures approved by the IRB (i.e. an application for exemption, expedited review, or full review).

Student projects in courses are subject to IRB review if they are designed at least partially to provide data for research and publication purposes. For example, instructors may enlist students to assist in data collection or analysis for their own research or may design seminars in which a goal is for students to collaborate in research that will be submitted for publication. These projects constitute research and must be submitted to the IRB for approval.

Research conducted at another institution

Prior to participation in a research project at another institution, researchers must obtain approval of the project by the IRB at McPherson College and all relevant institutions. For example, a researcher engaged in research at Wichita State University must secure approval from the IRBs at both institutions. Changes in protocol or consent forms required by the IRB at the other institution must be brought to the attention of the IRB at McPherson College.

Research conducted at McPherson College by researchers from other institutions

Outside PIs must submit an application for IRB approval when the following conditions are met: (a) McPherson College facilities and resources will be used; (b) McPherson College faculty/officials are actively engaged in or actively cooperate with or encourage participation in the research; or (c) McPherson College officials, faculty, staff, or students intend to use the findings of results of these studies for their own purposes. McPherson College faculty and/or officials asked by investigators from other institutions for cooperation in their research are not under the purview of the IRB (i.e. department chairs asked to assist in distribution of surveys to faculty or students).

Types of IRB Review

There are three types of IRB review. Investigators should use the descriptions that follow to determine which level of review is appropriate and check with the IRB chair or a member of the IRB if questions remain. Note that both exemptions and expedited review apply only to research that poses no more than minimal risk to subjects, meaning 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.

Exempt research status

Exempt research is low risk and falls into one of six categories defined by the federal government. Review of exempt applications is overseen by the IRB chair/vice-chair and do not require full committee review. Exempt categories include:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
2. Research involving the use of educational tests, surveys, or questionnaires, provided that human subjects cannot be identified and that responses by the subjects will not place them at risk of liability or be damaging to financial standing or reputation.
3. Research involving the use of educational tests or observations of public behavior that is not exempt under the previous category if the human subjects are elected or appointed public officials or candidates for public office, or the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the PI in such a manner than subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads in order to review public service programs; procedures for obtaining benefits under those programs; possible changes to those programs; or possible changes in methods or levels of payment for benefits under those programs.
6. Taste and food quality evaluation and consumer acceptance studies.

Expedited review

Expedited review is permitted when the research involves no more than minimal risk and when the study procedures fall into one or more of the seven categories defined by the federal government. Expedited review must be approved prior to recruitment of subjects or collection of data, and may require full committee review. Initial review by the IRB chair/vice-chair and a designated committee member will determine the need for full committee review. Expedited categories include:

1. Risks to subjects are minimized (a) by using procedures which are consistent with sound research design and which 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. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research, and should not consider possible long-range effects of applying knowledge gained in the research.
3. Selection of subjects is equitable. In making this assessment, the IRB takes into account the purposes of the research and the setting in which the research will be conducted, and is particularly cognizant of the special problems of research involving vulnerable populations

(e.g. children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provision for monitoring the data collection to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards must be included in the study to protect the rights and welfare of these subjects.

Full committee review

Any research involving human or animal subjects that does not fall into an Exempt or Expedited category must be reviewed by the full IRB committee. Full review is required when the study poses greater than minimal risk or when an external granting agency requires full review. Full review categories include:

- Research that involves greater than minimal risk
- Non-exempt research that involves vulnerable populations
- Research that involves experimental drugs or devices
- Research that involves invasive procedures
- Research that involves deception

Survey research that involves sensitive questions or information about sexual practices, illegal behavior, or diagnosable mental disorder(s) is subject to full review in keeping with federal guidelines. Additionally, any survey or interview that is likely to be stressful for the subject requires full committee review – the primary reviewer will make this determination.

After review, the IRB will act on the application.

Approval of IRB Applications

After a full discussion, the IRB may take one of the following actions by majority vote:

Approval

The IRB may approve the project as submitted without any changes for a maximum period of 12 months. Projects that involve risks that require closer ongoing monitoring may be approved for any period of less than 12 months at the discretion of the IRB; this decision is determined in the course of discussion of the proposal and is part of the motion to approve the project. Any specific findings, such as those needed for approval of research with prisoners or for waivers of signed consent, should also be documented in the minutes. Motions to approve a proposal may include a finding that the research involves no more than minimal risk, making it eligible for expedited review.

Minor Revisions Required

The IRB committee may approve a project contingent upon specific, minor modifications that require simple concurrence by the PI. Once the IRB chair receives the revised version of the proposal with changes, it will be routed to the member designated in the minutes (typically the primary reviewer) who will compare the modifications received with the actions requested by the IRB. A memo detailing and locating the changes in the proposal should accompany the submission. If the modifications are in compliance with the IRB directives, the chair will approve the project for the period of time specified by the IRB.

Defer Pending Resubmission

If the IRB deems that the proposal and/or informed consent as submitted require substantial revisions, or if unanswered questions remain, it will require the investigator to resubmit the application and attachments with all of the changes required and/or questions resolved, as detailed in an action letter sent to the investigator. In some cases, the IRB chair may request one or more IRB members (typically the primary reviewer) to assist the investigator in resubmitting the application. If no IRB member has been designated, the investigator is urged to consult with the chair to receive assistance in the preparation of the revision. A revised version with the required changes incorporated will be reconsidered at the next committee meeting following resubmission.

Disapprove

The IRB may disapprove a project if it has determined that the human or animal subjects are at a greater risk than the benefits to be accrued. This action is taken only after all negotiations with the investigator have failed to result in a resolution of the pertinent ethical issues. The IRB will notify the PI, the chair of the investigator's department (or equivalent), and the VPAA. Notification will include a complete

rationale for the disapproval. Upon disapproval, the PI has the option to revise and resubmit the project to reduce the risks to the subjects.

Letters for projects approved contingently or deferred will include a list of any changes required or suggested by the committee. In addition, after final approval, a letter of approval will be sent to the PI.

Amending Applications

When PIs must change the study procedures, including recruitment activities and protocols, from those initially approved, a letter indicating amendment to the study must be submitted to the IRB for approval prior to initiation of these changes. Exempt studies may not require approval of amendments unless the PI determines that the changes would not fit the study as exempt status.

Minor modifications for previously approved studies may be reviewed via expedited review. A minor modification is defined as a change that would not materially affect an assessment of the risks and benefits of the study, or that does not substantially change the specific aims or design of the study. If the proposed change is eligible for expedited review, it will be sent to the IRB chair or designee for review. The IRB chair may not disapprove a requested modification via expedited review. Examples of changes that may receive expedited review include:

- Changes to advertisements
- Significant reduction in the number of study participants
- Deletion/addition of question(s) in a survey

Modifications of any study document (IRB application, protocol, consent document, recruitment materials, etc.) require submission of an updated copy of the proposed revised document with changes clearly identified.

Greater-than-minor modifications proposed for previously approved studies must be reviewed and approved (during the period for which approval was authorized) by the full board of the IRB before the changes can be implemented. A major modification is defined as any change which materially affects the assessment of the risks and benefits of the study, or that substantially changes the specific aims or design of the study. Examples of greater-than-minor changes include:

- Newly-discovered risks of the study drugs or procedures
- Previously omitted or changed items that affect the level of risk
- An increase in the number of study subjects
- A change in procedure that affects the level of risk or the inclusion/exclusion criteria

Decisions and requirements for modifications by the IRB will be promptly conveyed to PIs in writing. Written notification of any decision to disapprove an amendment to a study will be accompanied by the reasons for the disapproval and an opportunity for the PI to respond. Responses are due within 30 calendar days of the date of written notice to the PI unless otherwise specified.

Continuing Review of Approved Studies

Approval for all studies expires at maximum 12 months after the initial approval date (the IRB meeting minutes and the initial approval letter will indicate the time frame of approval), unless the PI submits for continuing review. Continuing review is required for all studies still actively enrolling subjects, providing study treatment to subjects, or collecting data from enrolled subjects.

In order to provide timely review and approval of each study, the PI shall submit required documentation no less than 2 weekss prior to the IRB meeting preceding the study expiration date. The PI is responsible for being aware of upcoming expiration dates in order to submit continuing review materials in a timely manner.

Information required for continuing review includes:

- Number of subjects enrolled, screened, and withdrawn (with reasons for withdrawal). Note that any participant who signs an informed consent document is considered to be enrolled in the project, even if they later withdraw.
- A status report on the progress of the research and interim findings
- Any information, including from recent literature relevant to the study, which might affect the possible benefits or risks to the subjects
- A summary of any incidents of the following: adverse events, unanticipated problems involving the research, and/or complaints about the research since the last IRB review
- Verification that informed consent was obtained from all subjects, that all subjects received a signed copy of the informed consent document, and that all signed consent forms are on file (unless requirements were waived by the IRB)
- Summary of any previously unreported amendments or modifications to the research since the last review
- An updated complete protocol (if changes have been made)
- Any other information which may be relevant to making a determination regarding the potential risks, benefits, or scientific merit of the study.

Failure to provide continuing review information

If a PI has failed to provide continuing review information to the IRB, or the IRB has not reviewed and approved the research study by the approval expiration date specified, all research activity, including enrollment, data collection, and analysis, shall stop unless the IRB finds that it is in the best interest of

individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.

PIs may submit continuing review materials to the IRB within 30 calendar days after the approval expiration date for continuing review; however, research activity must be halted until the review has been completed and approved. Exceptions to the 30-day deadline will be made by the IRB chair on a case-by-case basis. Any investigator who wishes to reinstate a research protocol after this point must re-submit the project as a new application.