Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

IRB Membership

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Associate Vice Chancellor for Research

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1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting IRB membership requirements.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

I. IRB Membership

A. Each IRB has at least five members, with varying backgrounds to promote a complete and adequate review of research activities commonly conducted by the institution. Each IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, each IRB is able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Each IRB will include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration will be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

B. The IRB is not composed entirely of men or entirely of women. No selection is made to the IRB on the basis of gender. The IRB is not composed entirely of members of one profession.

C. Each IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

D. Each IRB has at least one member who represents the perspective of research participants.

E. Each IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

F. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

G. When prisoner research is submitted for review, at least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity and the majority of the members of the IRB will have no association with the prison involved in the research.

H. In order to meet the needs of some of the affiliated institutions as required, each committee will include individuals associated with Harry S Truman Memorial Veterans Hospital (two individuals per each IRB reviewing biomedical research as required by VA regulations) appointed by the VAMC Director for a three year term.

See "VA Hospital – Special Considerations" policy for VA membership requirements.

II. Rosters

A. IRB Rosters include:
   a. Names
   b. Earned Degrees
   c. Representative capacities in terms of the vulnerable populations, if any, each member is knowledgeable about or experienced in working with
   d. Scientific/nonscientific status
   e. Affiliation status (whether the member or an immediate family member of the member is affiliated with the University of Missouri-Columbia)
   f. Indications of experience sufficient to describe each IRB member's chief anticipated contributions
   g. Employment or other relationship between each IRB member and the University of Missouri-Columbia
   h. Alternate members (if any)
   i. The primary members or class of primary members for whom each alternate member could substitute (if any alternates)

III. Member Appointments

A. Potential new members are identified by recommendation from deans and department heads in answer to solicitations for new members. The Associate Vice Chancellor for Research appoints new members. Routinely, appointments of the voting members will become effective at the end of the academic year (May 1). The member is appointed to a one-year term, which can be renewed for up to three years consecutively as a full-board member and indefinitely as an alternate member.
B. Under the direction of The Office of Research, the Director is responsible for the distribution of renewal or service completion letters to Board members in April of each year. The content of these letters will be based on time of service and evaluation of performance. IRB staff will review IRB composition for compliance with regulatory and organizational requirements. An update of membership changes to the fully registered IRB will be compiled and submitted online to The Office for Human Research Protection as needed but at least annually.
C. The IRB review process shall be free of conflict of interest so that the IRB member's obligation to protect participants or ensure the integrity of the review process is not compromised by competing business interests. Therefore, individuals who are responsible for business development are prohibited from serving as members on the IRB.

IV. General IRB Member Responsibilities

A. Concerned about human rights and ethical issues and stays well informed in the changing regulations relevant to the use of human subjects in research
B. Fulfill all training requirements
C. Maintain confidentiality of Board discussions and all materials submitted for review
D. Will not 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.

V. Chair Responsibilities

The Chair of the IRB has overall responsibility of the board.

A. Qualifications for the IRB Chair are:
   1. A respected, active member of the faculty from one of the schools
   2. A qualified member of the IRB or has prior experience in research

B. Responsibilities of the Chair include, but are not limited to:
   1. Review Board policies and procedures
   2. Resolve controversial substantive or procedural matters
   3. Assist in the education of investigators and board members
   4. Conduct Board meetings
   5. Review and act on requests for emergency use of a test article/compassionate use
   6. Signatory for all approval letters, termination letters and other Board correspondence
   7. The IRB chair will designate which IRB members are qualified to perform an Expedited review.

VI. Vice-Chair Responsibilities

The Vice-Chair serves as Chair when the Chair is unable to fulfill their duties.

A. Qualifications for the IRB Vice-Chair are:
   1. A respected, active member of the faculty from one of the schools
   2. A qualified member of the IRB or has prior experience in research

B. Responsibilities of the Vice-Chair include, but are not limited to:
   1. Review Board policies and procedures
   2. Resolve controversial substantive or procedural matters
   3.
   4. Assist in the education of investigators and board members
   5. Review and act on project amendment requests
   6. Review and act on requests for emergency use of a test article/compassionate use in the absence of the Chair

VII. Primary Reviewers

A primary reviewer must demonstrate a consistent and comprehensive pattern of review of assigned protocols and demonstrate a dedication to the protection of human subjects with their actions and comments before being considered for eligibility, to be determined by the Chair. Eligible primary reviewers will be noted on the roster.

Responsibilities of the primary reviewer include, but are not limited to:

1. Attend board meetings
2. Review meeting material prior to Board meetings
3. Apply regulatory criteria for approval and vote on recommended action to proposal
4. Serve as primary reviewer on assigned submitted proposals and prepare overview to present to the Board and recommendation of action to be taken
5. Determine whether proposal information is sufficient to allow knowledgeable vote (if not, determine if necessary to contact investigator or request review by outside consultant)
6. Evaluate submitted consent for appropriateness
7. Assist in maintaining quorum, leaving only for emergencies
8. Review and act on requests for amendments and reports of unanticipated problems
9. Review and act on compliance issues that require board action
10. Expedited reviews are conducted by experienced reviewers, either those with previous IRB experience or those who have participated in additional training and demonstrated an appropriate competency in applying criteria and protecting human subjects.

VIII. Secondary/Lay Reviewers

A secondary reviewer represents the perspective of research participants.

Responsibilities of the secondary reviewer include, but are not limited to:

1. Serve as consent reviewer on assigned submitted proposals and prepare list of any consent concerns to discuss at the Board meeting
2. Determine if informed consent is adequate to allow knowledgeable vote (if not, determine if necessary to contact investigator or request review by outside consultant)
3. Assist in maintaining quorum, leaving only for emergencies
4. Attend board meetings
5. Review meeting material prior to Board meetings
6. Apply regulatory criteria for approval and vote on recommended action to proposal

IX. Alternate Members

Appointed alternates are included on the membership lists on file at the OHRP. Alternate IRB members replace regular IRB members who are unable to attend

convened meetings. Appropriately trained alternate members who demonstrate an appropriate competency in applying criteria and protecting human subjects may be asked to review expedited projects. Alternate members have qualifications comparable to the applicable regular member and may be alternates for more than one IRB member.

X. Consultants

If the IRB staff determines that there is not at least one person on each IRB with the necessary expertise, they will invite individuals with competence in that area (and with no conflicts of interest) to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. The consultant will review the project and provide their opinions and comments in a written report. The consultant will be required to conduct an in-depth review of the protocol.

The consultant's findings will be presented to the Board for consideration either in person by the consultant or by the Chair of the IRB. The written report will be included in the board packet and available to all members. These individuals will provide consultation but will not participate in or observe the vote. Information provided by the consultant is documented in a written report included in the board packet and in the minutes of the meeting.

XI. Evaluations

The Director of Human Research Protections evaluates IRB members, chairs and staff at least annually and provides feedback to them based on the assessment.

a. IRB Members: The following are taken into consideration during the evaluation:
    i. monitoring file reviews for completeness and accuracy
    ii. knowledge, education and experience
    iii. attendance at meetings
    iv. availability to review research activities in a timely manner.
b. IRB Chairs: The following are taken into consideration during the evaluation:
    i. attendance at meetings
    ii. knowledge, education and experience
    iii. availability to serve as reviewers on any matter requested by the Director.
c. IRB Staff: The Associate Vice Chancellor for Research evaluates the Director of Human Research Protections annually using the University of Missouri performance evaluation tools. The Director of Human Research Protections performs an annual evaluation of IRB staff using the University of Missouri performance evaluation tools. The evaluations are based on MU job duties and functions.

XII. Board Education

IRB Chairs and members are offered ongoing educational activities designed to contribute to the improvement of their qualifications and expertise.

a. New Members:
    i. Every new member receives an initial orientation, including eCompliance navigational training, access to reviewer checklists, review of IRB policies, and other educational materials such as CITI modules for board members.
    ii. Mentors are assigned as needed.
    iii. New members are required to complete a CITI module and maintain updated certification every three years.

b. Current Members:
    i. All current IRB members are provided with ongoing education, updates, and other information necessary to contribute to the improvement of their qualifications and expertise.
    ii. Every chair and board member is required to recertify CITI IRB member training every three years.
    iii. If educational requirements are not fulfilled, the HRPP Director will meet the board member(s) to discuss the requirements of serving on the IRB and whether the recertification can be achieved in a reasonable amount of time. If educational requirements cannot be met in a reasonable timeframe, the board member will be dismissed from serving on the IRB.

XIII. IRB Staff Education

a. New Staff:
    i. All new staff receive a comprehensive training of all IRB requirements and review processes. Each new staff member is mentored by one or more seasoned IRB staff members.
    ii. All new staff are required to complete the basic CITI training within three months of hire.

b. Current Staff:
    i. IRB staff are provided with ongoing education, updates, and other information necessary to contribute to the improvement of their qualifications and expertise.
    ii. IRB staff are encouraged to prepare for and take the Certification of IRB Professionals (CIP) exam after three years of hire. CIP designated staff members serve as mentors to staff preparing for the exam.
    iii. CIP designated staff are expected to maintain active certification by obtaining the necessary continuing education requirements.

iv. All IRB staff are encouraged to attend PRIMR, AAHRPP and other conferences and meetings covering human subject research protections.
v. If educational requirements/expectations are not fulfilled, during the annual evaluation of IRB staff or more frequently, the Director will address each situation individually to discuss educational expectations.

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