



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Board Structure and Responsibilities

Board Structure and Responsibilities

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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 the board structure and responsibilities.

2.0 Scope

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

3.0 Policy/Procedure

The purpose of the Institutional Review Board is to assure that the rights and welfare of human research volunteers are adequately protected in research being conducted in conjunction with the University of Missouri and its affiliates.

The principles which govern the IRB in assuring that the rights and welfare of subjects are protected are those principles embodied in the regulations, the Belmont Report, and the Federal Wide Assurance.

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The Board also reviews proposed research for compliance with all applicable federal, state and local laws. This policy does not affect any state or local laws or regulations (including trial law passed by the official governing body of an American Indian or Alaska Native Tribe) that may otherwise be applicable and that provide additional protections for human subjects.

To accomplish this purpose, a group deliberation process is used to review and approve protocols and related materials (i.e. informed consent document, investigator brochures, recruitment materials, test article information, etc.) to determine if the criteria for IRB approval of research have been met (45 CFR 46.111, 21 CFR 56.111, 38 CFR 16.111).

Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB.

In order to fulfill IRB review requirements, the IRB shall have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

HIPAA Waivers/Alterations

To use or disclose protected health information without authorization by a research participant, a covered entity must obtain documented waiver/alteration approval from an IRB or HIPAA Privacy Board in accordance with 45 CFR 164.512(i)(1)(i). The MU IRB will review and approve requests for HIPAA waivers/alterations when all three regulatory criteria to approve a waiver of authorization are satisfied. If a waiver/alteration cannot be approved, the covered entity must require a written authorization that satisfies the requirements of 45 CFR 164.508 prior to allowing the use and disclosure of protected health information for research purposes.

IRB determinations will be documented within the applicable reviewer checklists outlining HIPAA waiver/alteration requirements and in the minutes (if applicable). The signature of the chair or other IRB member, as designated by the chair, is documented within eCompliance. eCompliance follows 21 CFR 11 for a closed system, and each user in eCompliance is authorized and authenticated. Only authorized individuals can use the system and electronically sign a record. HIPAA waivers and alterations are logged within eCompliance using a date/time stamp.

IRB Membership

1. 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 (professional competence), and the diversity of its members, including 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. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and procedures) 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

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a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration will be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

2. For FDA regulated clinical trials only, 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.
3. 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.
4. Each IRB has at least one member who represents the perspective of research participants.
5. 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.
6. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB.
7. 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.
8. The committee may include individuals associated with Harry S Truman Memorial Veterans Hospital See “Truman VA Hospital Human Subject Research – Special Considerations” policy for VA specific information.

Rosters

The IRB prepares and maintains a current list of the IRB members identified by:

1. Names;
2. Earned Degrees;
3. Representative capacities in terms of the vulnerable populations, if any, each member is knowledgeable about or experience in working with;
4. Scientific/Non-Scientific status;
5. Affiliation Status (whether the member or an immediate family member of the member is affiliated with the University of Missouri-Columbia);
6. Indications of experience such as board certifications or licenses sufficient to describe each member’s chief anticipated contributions to IRB deliberations;
7. Employment or other relationship between each IRB member and the University of Missouri-Columbia, for example full-time employees, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;
8. Alternate Members; and

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9. The primary members or class of primary members for whom each alternate member could substitute

The IRB membership roster is confidential. If a sponsor or other entity requests the roster, in lieu of a roster, investigators may contact the HRPP/IRB office for a copy of the IRB Federalwide assurance letter. It is also available on the HRPP/IRB website.

Member Appointments

1. Potential new members are identified by recommendation from deans and department heads in answer to solicitations for new members. The Institutional Official (IO) appoints new members. Routinely, appointments of the voting members will become effective at the beginning of the academic year (August 1), but special arrangements are allowed to ensure full board coverage throughout the year, including summer months. A primary reviewer member is appointed to a one-year term, with an annual review and feedback process in place to evaluate service on the board for additional terms. The Director will work in conjunction with the Institutional Official and Chairs to make these determinations on an individual basis. A secondary reviewer member is appointed to a one-year term, which can be renewed annually for an indefinite time.
2. Under the direction of The Office of Research, the Director is responsible for the distribution of renewal or service completion letters to Board members at the end 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.
3. 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 functions related to outside entities are prohibited from serving as members on the IRB and carrying out day-to-day operations of the review process.

General IRB Member Responsibilities

1. Concerned about human rights and ethical issues and stays well informed in the changing regulations relevant to the use of human subjects in research.
2. Fulfill all training requirements
3. Maintain confidentiality of Board discussions and all materials submitted for review.
4. 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.

Chair/Co-Chair Responsibilities

1. Qualifications for the IRB Chair/Co-Chair are:
 - a. A respected, active member of the faculty from an academic units

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- b. A qualified member of the IRB or has prior experience in research
2. Responsibilities of the Chair/Co-Chair include, but are not limited to:
 - a. The Chair/Co-Chair of the IRB has overall responsibility of the board.
 - b. Review Board policies and procedures
 - c. Resolve controversial substantive or procedural matters
 - d. Assist in the education of investigators and board members
 - e. Conduct Board meetings
 - f. Review and act on requests for emergency use of a test article/compassionate use
 - g. Signatory for all approval letters, termination letters and other Board correspondence
 - h. The IRB Chair/Co-Chair will designate which IRB members are qualified to perform an Expedited review.

Vice-Chair Responsibilities

1. Qualifications for the IRB Vice-Chair are:
 - a. A respected, active member of the faculty from an academic unit
 - b. A qualified member of the IRB or has prior experience in research
2. Responsibilities of the Vice-Chair include, but are not limited to:
 - a. Review Board policies and procedures
 - b. Resolve controversial substantive or procedural matters
 - c. Assist in the education of investigators and board members
 - d. Review and act on project amendment and continuing review requests
 - e. Review and act on requests for emergency use of a test article/compassionate use in the absence of the Chair/Co-Chair
 - f. The Vice-Chair serves as Chair when the Chair/Co-Chair is unable to fulfill their duties.

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 Chairs. Eligible primary reviewers will be noted on the roster and may be classified as either full board members or alternates.

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

1. Attend the majority of 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

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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.

Secondary Reviewers

A secondary reviewer represents the perspective of research participants. Secondary reviewers are appointed to a one-year term with an annual review and feedback process in place to evaluate service on the board for additional terms.

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 the majority of board meetings
5. Review meeting material prior to Board meetings
6. Apply regulatory criteria for approval and vote on recommended action to proposal

Alternate Members

1. Federal regulations allow organizations to appoint an alternate(s) to substitute for an IRB member(s) who is unable to attend an IRB meeting so that IRB business may move forward in a timely manner. Alternates are appointed by the same process and for the same length of time as primary members.
2. IRB alternates may replace a full board member at scheduled board meetings. In addition they will review expedited applications or other submissions to the IRB as needed.
3. An alternate may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Alternates and full board members have equal responsibilities in terms of required education, service and time commitments, and participation.
4. The IRB roster identifies the full board member(s) for whom each alternate may substitute. Minimally, alternates and full board members are paired by scientific “class,” as physician scientists (when applicable), other scientists, and non-scientists. The IRB roster will identify the member(s) for whom each alternate can substitute.

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5. When an alternate substitutes for a full board member, the alternate receives and reviews the same materials that the full board member received (or would have received), and IRB minutes document that an alternate replaced a full board member.

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 a 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.

The IRB also utilizes consultants to fulfill required additional reviews as outlined in the Initial Review SOP. These consultants are utilized during the review of the IRB submission and are asked to complete a reviewer checklist in eCompliance to document their acceptance of the protocol to ensure institutional requirements are met.

Board Member and Staff Evaluations

The Director of Human Subjects Research Protections Program evaluates IRB members, chairs (including vice-chairs) and staff at least annually and provides feedback to them based on the assessment. The number of chairs and members will be determined annually by the Director and the IO based upon the changing research needs of the research environment taking into account volume, risk, and type of research activities in addition to the need for diversity with respect to demographic as well as professional background.

1. IRB Members (This includes all member types, including the unaffiliated member(s)): The following are taken into consideration during the evaluation:
 - a. monitoring file reviews for completeness and accuracy;
 - b. knowledge, education and experience;
 - c. *attendance at the majority of board meetings;
 - d. availability to review research activities in a timely manner.
2. IRB Chair/Co-Chair/Vice-Chair: The following are taken into consideration during the evaluation:
 - a. *attendance at the majority of board meetings;
 - b. knowledge, education and experience;
 - c. availability to serve as reviewers on any matter requested by the Director.
3. HRPP/IRB Staff: The Associate Vice Chancellor for Research evaluates the Director of Human Subjects Research Protections Program annually per MU

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guidelines. The Director performs an annual evaluation of HRPP/IRB staff per MU performance evaluation guidelines. The evaluations are based on MU job duties and functions.

*Attendance (in person or virtual) at meetings is reviewed on an ongoing basis. If attendance is an issue, it would be addressed prior to the annual evaluation. If the attendance at the majority of the meetings is not possible for a board member due to scheduling conflicts, illness, or other reasons, their continued role on the board will be re-evaluated and communicated in writing.

Board Education

IRB Chair/Co-Chair/Vice-Chairs and members are offered ongoing educational activities designed to contribute to the improvement of their qualifications and expertise. Ongoing board education related to regulatory or institutional changes, internal processes, or basic refresher items are shared with board members and available within the board member educational folders in the eCompliance system.

1. New Members:
 - a. 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.
 - b. Mentors are assigned as needed.
 - c. New members are required to complete a CITI module and maintain updated certification every three years.
2. Current Members:
 - a. All current IRB members are provided with ongoing education, updates, and other information necessary to contribute to the improvement of their qualifications and expertise.
 - b. Every chair and board member is required to recertify CITI IRB member training every three years.

If educational requirements are not fulfilled, the HRPP/IRB 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.

HRPP/IRB Staff Education

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

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2. Current Staff:

- a. HRPP/IRB staff are provided with ongoing education, updates, and other information necessary to contribute to the improvement of their qualifications and expertise.
- b. HRPP/IRB staff are encouraged to explore opportunities for certification specific to human subjects research protections and research compliance. If certification is obtained, staff are responsible to maintain active certification and research and communicate with the Director ongoing requirements.
- c. All HRPP/IRB staff are encouraged to engage in research specific meetings provided by the institution and to explore virtual and in-person meeting opportunities related to human subjects research protections.
- d. If educational requirements/expectations are not fulfilled, during the annual evaluation of HRPP/IRB staff or more frequently, the Director will address each situation individually to discuss educational expectations.

Board Policy Maintenance:

To ensure the rights and welfare of human subjects of research will be overseen and protected in a uniform manner, the HRPP/IRB has developed Standard Operating Procedures (SOP). The SOPs reflect applicable federal regulations and guidance and also policies and procedures of the University of Missouri – Columbia. SOPs provide the framework for the ethical and scientifically sound conduct of human research, regardless of changes in personnel. Written procedures are in place to ensure the highest quality and integrity of the review and oversight of research involving human subjects and for adequate documentation of such oversight.

Review, Revision, Approval of SOPs

Policies will be reviewed by the HRPP/IRB Office every three years or sooner as necessary. The review will consist of determining the policies accurately describe the procedures as they are enacted in compliance with all applicable federal, state, local and institutional regulations.

All new or revised SOPs require review and approval by the Institutional Official in the Office of Research. Documentation of review and approval is by signature of the responsible and authorized individuals.

Policy Dissemination and Training

When new or revised SOPs are approved, the approved SOPs will be added to the policies section of the HRPP/IRB website.

Changes to federal regulations, guidelines or research practice, as well as the policies and procedures of the University of Missouri and the IRB may require a new SOP or a revision to a previously issued SOP. Any new information, identified by the HRPP/IRB (through the

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Food and Drug Administration website, Office of Human Research Protections website, or from any other source as identified) as being pertinent to the protection of research participants, will be disseminated via the HRPP/IRB List-Serve.

Educational training and information on each revised policy and/or procedure will be provided to all IRB members and HRPP/IRB staff. Evidence of training will be documented and filed with the HRPP/IRB office.

Forms, Templates, and Checklists

As a complement to the SOPs and a tool to aid in compliance with the procedures as outlined in the SOPs, various forms, templates and checklists have been developed by the HRPP/IRB office and are available to investigators, IRB members, HRPP/IRB staff, and others through the HRPP/IRB website and/or eCompliance.

These materials will be reviewed by the HRPP/IRB at the same interval as the SOPs and changes will be made accordingly.

References:

Combined Policies January 21, 2019:

Board Purpose and Function

Approval Dates: January 22, 2001; December 1, 2006; June 10, 2010; July 1, 2011; July 2, 2014; March 1, 2015; July 1, 2015; June 8, 2017; May 3, 2018

IRB Membership

Approval Dates: September 1, 2004; November 11, 2005; December 13, 2005; December 1, 2006; June 10, 2010; August 12, 2010; July 1, 2011; March 1, 2015; July 1, 2015; June 8, 2017; May 2, 2018

Maintenance

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