




Campus Institutional Review Board
University of Missouri-Columbia

Board Meeting Procedures
Policy Number 2876.9

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Approval Authority:

Signed 
IRB Chair

Date December 12, 2007

Institutional Approval:

Signed 
Associate Vice-Chancellor for Research

Date December 12, 2007

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1.0 Policy

The Campus Institutional Review Board (Campus IRB) convened meetings will be conducted in a manner that assures proposals are comprehensively reviewed on a cases-by-case basis in relation to the foreseeable risk and benefits afforded to subject participants. No member or consultant may review a proposal for which they have a conflicting interest.

2.0 Scope

This policy applies to all board meeting procedures being conducted under the jurisdiction of the Campus IRB at the University of Missouri-Columbia.

3.0 Purpose

The direct responsibility for assuring the safety of those enrolled in human subject research shall monitored by the Campus IRB. The board shall conduct all review activities, meetings and deliberations in a manner that will provide cogent guidance and a standard of ethical excellence to the research community.

4.0 Standard Operating Procedure

I. MEETING SCHEDULE

The Campus IRB shall tailor the meeting schedule according to the needs of the Behavioral & Social Sciences (i.e. non-medical research including, but not limited to social, behavioral, educational, ethnography, journalistic, and oral history) human subject research community. The meetings shall be conducted in accordance with procedural guidelines that will endorse an environment where deliberations can be freely conducted, without logistical constraints or conflicts that could interfere with the decision-making process. The Campus IRB meeting schedule shall be determined by the proposed research review interval, member availability, and the administrative office.

The investigator must submit their proposal by the FIRST DAY OF THE MONTH in which the board meeting is held to guarantee the matter will be placed on the month's docket. If the FIRST DAY OF THE MONTH falls on a non-business day or holiday, the deadline will be extended to the next available business day. (Example: December 30 Meeting Date = December 1 Deadline for submission). If the proposal is submitted "after" the deadline, the Campus IRB will not guarantee that the matter will be placed on the month's docket.

A. CONFLICTS OF INTEREST: All board meeting procedures shall comply with the Conflicts of Interest policy. See policy.

B. EXPERTISE

The Campus IRB membership will be periodically reviewed with the necessary adjustment of the membership and composition of the IRB to reflect the scientific expertise necessary to review research proposals under the jurisdiction of the Campus IRB. The Compliance Officer/Chair is charged with managing the administrative operations of the Campus IRB and shall assure the evaluations and adjustments are made.

The Campus IRB Chair and Compliance Officer are charged with assuring that one or more individuals are knowledgeable about or experienced in working with participants vulnerable to coercion or undue influence, and that the individual is available at the meeting when the IRB reviewed research that involved such participants. All activities proposing to research participants vulnerable to coercion or undue influence requires an individual knowledgeable about or experienced in working with such participants to be present at the meeting when the

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IRB reviews the research in compliance with the “Administrative Staff Policy,” “Recruitment of Vulnerable Subjects”, “Recruitment Process”, “Recruiting Vulnerable Subject “, “Assessing the Level of Risk”, “Assessment Scientific Merit”, and “Campus IRB Review Process” policies.

The Compliance Specialist assigned to the file will coordinate communications and file management activities to assure it is complete and ready for review at the meeting. The Primary Reviewer shall receive the file 14 days prior to the scheduled meeting unless circumstances arise for the necessity of an emergent review. In such a case, the primary reviewer and members shall receive the information in a timely manner to permit a substantive review of the proposal.

The reviewer is expected to respond and request any additional information as efficiently as possible to facilitate the IRB processes. The investigator is expected to any additional requests from the reviewer as soon as possible to permit the board membership the opportunity to timely review materials and facilitate the IRB processes.

1. All members are provided and expected to review:
 - The Initial IRB Application form
 - The Continuing Review IRB Application form
 - The Amendment Application form
 - The current consent document
 - Any newly proposed consent documents
 - All modified documents

The Primary reviewers are provided and are expected to review in depth:

- The Initial IRB Application form
- The Continuing Review IRB Application form
- The Amendment Application Form
- The current consent document
- Any newly proposed consent documents
- All modified documents
- The complete protocol including any protocol modifications previously approved by the IRB.

II. PREPARING THE AGENDA

All human subject research activities under the jurisdiction of the Campus IRB recommended for full board review must be timely docketed by the deadline (1st day of the month in which the meeting is held) in accordance with the Campus IRB “Meeting Agenda” policy.

Successful submission of a complete research proposal for full board review is dependent upon the investigator satisfying all of the procedural and substantive requirements by the agenda deadline (1st of the month). The purpose of timely submissions is to ensure that a sufficient amount of time is available for members to complete a comprehensive review of all of the relevant materials PRIOR TO the convened meeting. A proposal will be placed on the Agenda in accordance with the docketing deadlines to be considered for review by the Campus IRB. The Campus IRB reserves the right to determine when the docket is full. If an investigator requests a matter be placed on an agenda that is full, the Compliance Officer and Board Chair will coordinate efforts to make a determination of when the matter will be reviewed. Every effort will be made to review the matter at its earliest opportunity. The Campus IRB has the right to decline review of a request on the agenda of a full docket.

The IRB meeting shall be conducted in a productive and efficient manner. It is essential for the Campus IRB to complete a wide range of administrative tasks before the meeting begins

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to facilitate an efficient IRB review process. The Campus IRB Staff will make every effort to distribute the board meeting agenda to all members at least 7 days prior to the board meeting, unless special circumstances arise. In that case, the membership will receive the agenda in a sufficient amount of time to assure all proposals have been reviewed in order for the meeting to be conducted. The Compliance Specialists will authorize file access to all board members not having a Conflict of Interest at least 7 days prior to the board meeting, unless special circumstances arise at which time it will be distributed as soon as possible to permit enough time for review prior to the meeting

A. Preparation of the Campus IRB agenda

The Campus IRB agenda for all convened meetings will be distributed to each board member *prior to the meeting* in compliance with the “Agenda” policy.

The Minutes shall be electronically distributed to all members for review prior to approval in accordance with the “Minutes” policy.

A copy of all approved IRB Minutes are provided to institutional officials in accordance with the “Reporting” policy to meet the requirements for notification to the organization of IRB findings/actions.

The Campus IRB must maintain the Agenda and Meeting records for a period of 3 years in compliance with the “Record Keeping Policy”.

B. Submission Deadlines

The Campus IRB office will accept proposals or issues for full board review at any time. However, a matter must be submitted by the 1st of the month to be reviewed at that month’s meeting. The investigator must meet the following deadline requirements to docket a matter on the Campus IRB agenda docket.

1. Proposed Research Activities

SCHEDULING DEADLINE: The Campus IRB office will docket a “COMPLETE” proposal on the full board agenda if it is received by the FIRST (1st) of the Month of the respective scheduled Board Meeting Date. (Example: February 1st for a February 28th meeting). A complete application/proposal is a submission that has provided all of the requisite information requested by the reviewer or board.

The Campus IRB does not docket incomplete applications/proposals on the meeting agenda. Incomplete applications/proposals do not receive priority review and will be docketed on the agenda once the requisite information has been received and the file is categorized as “complete.” The file must be “complete” by the FIRST of the month of the respective scheduled meeting date.

2. Proposed Research Issues

The Campus IRB office will docket a research issue on the full board agenda if it is:

- a. A “complete” proposal. A complete issue proposed is a matter whereby an issue has been raised and the Campus IRB has had the opportunity to ask questions and receive responses from the individual(s). If a timely response is not received for the Campus IRB’s requests, the matter will not be docketed until it is “complete”.
- b. Received by the FIRST (1st) of the Month of the respective scheduled Board Meeting Date. (Example: February 1st for a February 28th meeting).

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NOTE: A “complete” file is a submission that has provided all of the information previously requested by the Campus IRB.

3. Urgent Campus IRB Meetings

At the discretion of the Compliance Officer in coordination with the Chair, the Campus IRB may schedule meetings to review matters involving urgent circumstances. The membership will receive the agenda and materials to be reviewed in a sufficient enough time to permit review of the file before the meeting.

III. CAMPUS IRB BOARD MEETING PROCEDURES

Campus IRB meetings shall promptly convene at the designated time and adjourn at the completion of all business matters, in the absence of a non-scientific member, or the loss of quorum. All participating voting members will be physically present unless circumstances warrant conducting a board meeting via telephone conference call or using speakerphone.

A “Telephone conference call” permits official Campus IRB business to be conducted and actions taken whereby members participate via telephone when each participating member (i) has received all pertinent material prior to the meeting, and (ii) can actively and equally participate in the discussion of all protocols. All members must be heard clearly, and in the absence of technical interference. Satisfaction of these two conditions in addition to the standard board meeting procedures will be documented accordingly in the minutes in accordance with the “Minutes” policy.

A “Speakerphone” may permit official Campus IRB business to be conducted and actions taken whereby a member is not able to be physically present during a convened meeting but is available by telephone, the meeting may be convened utilizing a speakerphone system. The member who is not physically present will be connected via the speakerphone to the rest of the members who are present at the convened meeting to participate in discussions. All members must be heard clearly, and in the absence of technical interference. Members utilizing the speakerphone may vote provided they have had an opportunity to review all of the materials the other members have reviewed. All actions will be conducted in accordance with the Campus IRB policies and documented accordingly in the minutes in accordance with the “Minutes” policy.

All Campus IRB members’ votes will be deemed equal and no proxy votes will be considered.

A. ASSURANCE OF PROPER QUORUM

The board meetings shall promptly convene at the designated time and adjourn at the completion of all business matters, in the absence of a non-scientific member, or the loss of quorum. Proper quorum is defined 1) when one more than half of the majority of the board is present; and 2) at least one nonscientific member is included in the calculation of quorum.

1. The Campus IRB shall assure “proper quorum” as follows:

45 CFR 46 Section 108(b) “requires attendance by a majority of IRB members and proper quorum to conduct a full-committee (board) meeting. Proper quorum must be established by a majority of members at the meeting in order for research to be approved.” Majority means “one more than half.”

The regulations further require that at least one nonscientific member is represented in the calculation of the majority to assure proper quorum. If the nonscientific

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member is absent, quorum is improper and can't be established. The Campus IRB is prohibited from conducting business in the absence of proper quorum.

- a. The Campus IRB Board Chair and Compliance Officer shall assure a proper quorum is present, which includes at least one nonscientific member :
 - i. Prior to calling the meeting to order;
 - ii. Before any research activities can be reviewed or approved; and
 - iii. Before any actions can be taken or business conducted on behalf of the Board;
2. If quorum fails OR the nonscientific member vacates at anytime during a convened meeting:
 - a. The meeting is terminated and further IRB action or business must cease until proper quorum with the presence of a nonscientific member can be restored;
 - b. Any actions taken in the absence of a proper quorum or at least one nonscientific member is prohibitive and lacks Campus IRB authority to conduct business.

B. CALL TO ORDER

1. The Campus IRB Chair shall:
 - a. "Call the meeting to order" after assuring proper quorum and the presence of a nonscientific member on the record;
 - b. If the meeting is conducted with the use of a member via telephone or speakerphone, the procedures must comply with the aforementioned requirements outline in this policy for such use.
 - c. Make any announcements necessary to preface the meeting;
 - d. Distribution of the Expedited Approvals and Minutes.
 - e. Initiate and proceed with the items of business as documented on the agenda;
 - f. The Campus IRB Chair shall assure:
 - i. The names of every member present are recorded in the Minutes of the convened meeting as evidence of a valid quorum and a nonscientific member; and
 - ii. The Campus IRB Chair shall assure that the minutes record specific findings including information justifying those findings: a) the level of risk; b) approval period; c) which proposals require continuing review more often than annually.

C. REVIEW OF PREVIOUS MEETING MINUTES

1. The Minutes are electronically sent to all members prior to every meeting. All members may access the CIRB database and view all previous Minutes at any time. Upon request, a copy of previous minutes can be distributed.
2. The Board shall review the Minutes from the previous meeting and make a motion to approve, approve with revisions, or disapprove.

D. ORDER OF BUSINESS

1. The Campus IRB Chair will identify whether any member has a conflict of interest with the files or matters docketed on the agenda in compliance with the "Conflict of Interest" policy.
2. The Campus IRB Chair will identify and initiate review procedures for each item on the agenda
3. The Campus IRB Chair will oversee the convened meeting activities;
4. Each agenda item category will be announced. Examples may include, but are not limited to:

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- a. New Application
- b. Continuing Review
- c. Amendment
- d. Serious or Continuing Compliance Breach
- e. Deviation
- f. Serious or Continuing Adverse events
- g. Unanticipated Problems or events that Pose Greater than Minimal Risk to Subjects
- h. Issues that may pose greater than minimal risk to subjects.

NOTE: If a member has a conflict of interest on a proposal being reviewed, they will be excused from the meeting and it will be recorded in the Minutes in compliance with the “Minutes”, “Board Membership” and “Conflicts of Interest” policy.

5. The assigned primary reviewer will deliver an overview of the proposal or matter to the board, including but not limited to, the relevant requirements set forth by 45 CFR 46, the proposed informed consent process, any supplemental materials, recommendations and rationale for proposed actions. The primary reviewer must also determine if the Board has a sufficient amount of information to take action;
6. Invitees: Guests or Consultants (See “Invitees: Guests or Consultants” Policy)
 - a. The Compliance Officer will assure solicitation of the guest or consultant if the board requests to facilitate the review process.
 - b. The Compliance Officer will confirm for the membership that the guest or consultant has no conflicting interest with the matter.
 - c. The Campus IRB Compliance Officer will notify the board if there are any Conflicts of Interest.
 - d. The Campus IRB Chair will announce the guest or consultant has any conflicting interests *prior* to them entering the room or any discussions.
 - e. The Campus IRB Chair will invite the guest or consultant to enter the room to address the board when appropriate.
 - f. The Campus IRB Chair shall request any invited guest or consultants to vacate the room if their purpose for attendance has been achieved; any consultant is *prohibited* from participating in the review of protocols in which they have a conflict of interest, except to provide information request by the IRB.
7. The Campus IRB will review the proposed submissions and investigator responses and may take ACTION in accordance with the CIRB Review Process Policy. SEE POLICY FOR SPECIFIC ACTIONS.
8. The Campus IRB Chair or member shall make a Motion to place the proposed action up for a final vote along with the Continuing Review Interval be placed on the floor by the convened board;
9. A separate member, other than the Primary Mover, must second the motion;
10. The seconded motion shall be subject to an open vote by the Campus IRB members to either:
 - a. Approve
 - b. Abstain
 - c. Deny
11. Proper quorum must be established by a majority of members at the meeting in order for business to be conducted. In order for the research to be approved, it must receive the vote of approval by a majority of members present at the meeting.
12. The Campus IRB Chair shall announce the results of the vote to the Board and include:
 - a. Status of Approval
 - b. Approval Period

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The approval period shall start on the date of the convened meeting at which the IRB approved the protocol or approved the research with modifications.

- c. Level of Risk
- d. Form of Consent
- e. Continuing Review Interval (Must comply with the Policy entitled Continuing Review Process)

E. RECORDING PROCEDURES

The Campus IRB Chair shall assure that the Minutes record the board's activities and specific findings in accordance with the Campus IRB "Minutes Policy".

- 1. The Campus IRB Chair shall assure the board meeting minutes are recorded in a manner that provides information about the actions taken, in accordance with the "Meeting Procedures" Policy, as follows:
 - a. The Campus IRB shall record the names of every member present at each convened meeting in the Minutes as evidence of proper quorum;
 - b. The Campus IRB shall record the name of the non-scientific member present at each convened meeting in the Minutes as evidence of proper quorum;
 - c. The Campus IRB shall record when a member either enters or leaves the convened meeting in the Minutes as evidence of proper quorum; in particular, the Minutes shall reflect when the Non-Scientific Member leaves in that proper quorum will cease to exist. As a result, all business activities shall cease.
 - d. The Campus IRB shall record when the Prisoner Representative enters or leaves the convened meeting;
 - e. The Campus IRB shall record when a Consultant, or Guest either enters or leaves the convened meeting in the Minutes;
 - f. The Campus IRB shall record any presence of a Conflict of Interest
 - g. The Campus IRB shall record the precise time of all Board Meeting Procedures. This record shall include, but is not limited to,
 - h. Assurance of Proper Quorum and the presence of a nonscientific member
 - i. Call to Order
 - j. Announcements
 - k. Review of Previous Meeting Minutes and Expedited Approvals
 - l. Order of business for each proposal; including when the discussion begins and ends

Campus IRB Review:

All members are expected to review all materials and investigator responses in enough depth to be prepared to discuss the proposal and make a meaningful contribution to the convened meeting.

The following information shall be communicated in the reviewer's presentation to the board:

- a. The title of the Proposal, Name of the Investigator, and Department.
- b. The proposal or issue "category" which may include, but is not limited to:
 - 1. New Application
 - 2. Continuing Review
 - 3. Amendment
 - 4. Serious or Continuing Compliance Breach

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5. Deviation
6. Serious or Continuing Adverse events
7. Unanticipated Problems That Pose Greater than Minimal Risk to Subjects
8. Issues that may pose greater than minimal risk to subjects
- c. Description of the Proposal
 1. Purpose
 2. Proposed Methodology
- d. The Level of Risk
 1. Minimal (Explain why it is being reviewed by the convened board)
 2. Moderate
 3. Substantial
- e. Protocol specific justification for:
 1. Research involving pregnant women, human fetuses and neonates
 2. Research involving prisoners
 - a. The presence of the Prisoner Representative at the meeting
 3. Research involving children
- f. Issues and Concerns raised by the board
- g. Risk Benefit Analysis
 1. Scientific Merit
 2. Academic Merit
- h. Informed Consent
 1. Type of Consent Proposed
 2. Proposed Modifications or deletions of DHHS approved sample Informed Consent
 - a. Justification for modification or deletion
 3. Justification for Waiver Proposals, if applicable
- i. The basis for requiring changes in research
- j. The board's requests for additional information
- k. If applicable, the basis for disapproving research
- l. A written summary of the discussion of controverted issues and their resolution
- m. The Approval Period (Initial or Continuing Review)

NOTE: "The approval period for research shall start on the *date of the convened meeting* at which the IRB approved the protocol or approved the research with modifications." The IRB must document if the Approval Interval is shortened and the rationale for the action.
- n. Motions for action
- o. Proper quorum must be established by a majority of members at the meeting in order for business to be conducted. In order for the research to be approved, it must receive the vote of approval by a majority of members present at the meeting.
- p. The Campus IRB shall record in the Minutes the number of votes for all actions in accordance with 45 CFR 46.115(a)(2) specifying:
 - i. The total votes for each action;
 - ii. The total votes against the action; and
 - iii. The total votes abstaining from voting;
- q. The Campus IRB shall retain the Minute records for at least 3 years after closure of the projects reviewed on the respective agenda.
- r. The Campus IRB Board Chair shall complete the "Minutes Procedure" Checklist

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2. At the close of business, the loss of the nonscientific member representative, or loss of quorum, the Campus IRB Chair will ask for a Motion to “Adjourn” the meeting. The MINUTES should reflect the when the following occurs:
 - a. A voting member shall raise a Motion to adjourn the meeting.
 - b. A different member (other than the Primary Movant) shall second the Motion to adjourn.
 - c. The Motion shall be record in the Minutes.
 - d. The Meeting shall close and all business activity shall cease.
3. The Campus IRB shall retain the Minute records for at least 3 years after closure of the projects reviewed on the respective agenda in compliance with the “Record Keeping” Policy.

F. ADJOURN OF BUSINESS

1. At the close of business or the loss of quorum, the Campus IRB Chair will ask for a Motion to “Adjourn” the meeting.
 - a. A voting member shall raise a Motion to adjourn the meeting.
 - b. A different member (other than the Primary Movant) shall second the Motion to adjourn.
 - c. The Motion shall be recorded in the Minutes.
 - d. The Meeting shall close and all business activity shall cease.

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