

Administrative Staff Responsibilities
Policy Number 2876.7



Campus Institutional Review Board
University of Missouri-Columbia

Administrative Staff Responsibilities

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Reviewed by: Michele Reznicek, Campus IRB Compliance Officer
Reviewed by: Janelle Greening, Quality Assurance Associate
Reviewed by: Campus IRB Membership

Effective Date: December 12, 2007

Board Review

A handwritten signature in black ink, appearing to read 'ChMBLi', written over a horizontal line.

Signed
IRB Chair

Date December 12, 2007

Administrative Review

A handwritten signature in black ink, appearing to read 'R. J. Hall', written over a horizontal line.

Signed
Associate Vice-Chancellor for Research

Date December 12, 2007

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1.0 Policy

The University of Missouri-Columbia endorses a community of respect for the IRB processes and commits to devoting the necessary resources to employ a sufficient number of qualified staff to support the Campus Institutional Review Board operations.

2.0 Scope

The Administrative Staff will provide support to the Campus IRB infrastructure and all human subject research activities under its jurisdiction.

3.0 Purpose

Adequate staffing is crucial to the efficient and effective operations of the Campus IRB. The Office of Research respects the fact that the Campus IRB membership is voluntary, and due to departmental obligations a member's time to devote to the review processes are limited. In an effort to minimize the limitations, the University of Missouri recognizes that the Administrative Staff is valuable to the mission and success of the Campus IRB. The Administrative Staff will assist with the workload by managing the day-to-day operations and tasks required to help meet the objective to protect human subject research participants.

4.0 Standard Operating Procedure

The Campus IRB Administrative Staff may perform a variety of functions. The Office of Research, through the University of Missouri-Columbia, assures that the administrative infrastructure of the Campus IRB shall operate with an adequate amount of personnel, along with sufficient accommodations to adequately carry out the intentions of the Campus IRB.

The administrative staff will be comprised of individuals who possess the professional integrity and qualifications to comply with the policies and procedures of the Campus IRB. The administrative staff will make every effort to ensure the prompt and thorough review of all submissions by coordinating activities to assure the safety and welfare of human subject research participants.

The Campus IRB office is under the direction of the Campus IRB Compliance Officer, who shall serve as the Administrative Director managing the IRB processes. The Campus IRB infrastructure may be supported by, but not limited to, the following positions:

1. Compliance Officer/IRB Administrator/IRB Administrative Director
2. Quality Assurance Associate
3. Senior Compliance Specialist(s)
4. Compliance Specialist(s)
5. Compliance Assistant(s)
6. Administrative Assistant(s)
7. Office Support Staff
8. Student Assistant(s)

NOTE: The Campus IRB reserves the right to add administrative staff to the office as it deems necessary to adequately safeguard the protection of human subjects involved in research.

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A. GENERAL PURPOSE OF THE CAMPUS IRB COMPLIANCE OFFICER

The Campus IRB Compliance Officer is expected to function as an experienced professional with the comprehensive compliance expertise to direct all aspects of the IRB process. The Officer shall be a knowledgeable partner in the leadership of the University of Missouri-Columbia's system for overseeing human subject research activities. The Officer shall strive to:

- Promote an atmosphere that fosters honesty and respect for the IRB process.
- Promote an environment where the IRB is viewed as a collaborator in the research community.
- Promote an environment that fosters research creativity by appreciating the need to apply compliance standards on a case-by-case basis
- Promote an "informed" research community by keeping investigators informed of the changes in the compliance interpretative guidelines and IRB policies
- Promote a receptive "open-door" environment that encourages investigators to communicate and engage in discussions with the IRB
- Promote departmental and unit interactions by engaging in educational offerings and discussion tailored to their needs
- Promote a networking process whereby measures are taken to interact with institutional units that may interface with human subject research activities
- Promote a networking process within the IRB industry to stay abreast of the dynamic changes occurring in the compliance arena

1. Specific Responsibilities of the Campus IRB Compliance Officer:

- a. The Compliance Officer is a voting member of the Campus IRB.
- b. The Office of Research is directly responsible for assuring that the Campus IRB Compliance Officer possesses the professional qualifications, education, and experience to serve as the administrator responsible for monitoring human subject research activities;
- c. Serve as a central contact person for regulatory agencies;
- d. Serve as the Campus IRB liaison in respective IRB representative capacities;
- e. Serve as the resource for media relations regarding matters under the jurisdiction of the Campus IRB;
- f. Coordinate with the Campus IRB in assessing the "Level of Risk" for the purpose of triaging proposals to determine the "Level of Review" by the following:
 1. Determine when a project should be classified as "human subjects research"
 2. Determine when a project should be "exempt" from further IRB review
 3. Determine when a project should be reviewed at the "expedited" Level of Review
 4. Determine when a project should be reviewed by the full convened Campus IRB
 5. Determine when supportive materials or expertise is necessary to review a proposal.
- g. Approve human subjects research with Exempt Review Status in accordance with the checklist.
- h. Approve human subjects research with Expedited Review Status in accordance with the check list.
- i. Serve as a VOTING member of the Campus IRB;
- j. Oversee Campus IRB and Research Education Programs;
- k. Make a reasonable effort to devote a considerable amount of time to Continuing Education opportunities:
 1. Attend seminars specifically aimed at ensuring the protection of the rights and welfare of human subjects involved in research; or
 2. Maintain membership in an organization specifically focused on the operational aspects of the IRB processes; or
 3. A subscription to a journal specifically aimed at compliance with the IRB processes; or
 4. Subscription to Internet Services offering a venue for professional IRB discussions.

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- l. Assure compliance with the Federal regulations protecting the rights and welfare of human subjects involved in research;
- m. Ensure an efficient and comprehensive IRB review process in accordance with Campus IRB policies;
- n. Serve as an expert in regulatory compliance to the Campus IRB human subject research community;
- o. Direct the ongoing development of policies governing the Campus IRB;
- p. Serve as the Administrative Director over the office staff, general office duties, and the processing of Campus IRB proposals;
- q. Make recommendations regarding Board appointments to the Vice Chancellor for Research in cooperation with the Campus IRB Chair;
- r. Educate faculty, staff and students regarding compliance with the IRB processes;
- s. Keep the Office of Research informed of any needs or interventions that are necessary to protect human subject research participants.
- t. Recommend or make a reasonable effort to secure an appropriate consultant on an issue(s) when deemed necessary.
- u. The Compliance Officer is a voting member of the Campus IRB.
- v. When the board does not have at least one person on the IRB with the appropriate scientific and scholarly expertise to conduct an in-depth review of the protocol, or the knowledge to review research *with participants vulnerable to coercion or undue influence*, the Compliance Officer is charged with the responsibility to assure an evaluation of each protocol has been conducted to determine whether there was at least one person on the IRB with the necessary expertise, and if not, invite individuals with competence in that area to assist in the review process.

Process

- i. The Compliance Officer will assure an evaluation of the proposal has been conducted by at least one person on the IRB with the necessary expertise, and if not, invite individuals with competence in that area to assist in the review process in accordance with the Invitees Policy. See policy for guidance.
- w. The Compliance Officer is responsible for the selection and appointment, hiring, training, management and evaluation of all IRB staff and board members.

Conduct Annual Performance Evaluations for the following:

- i. Campus IRB Members (In cooperation with the Office of Research).
- ii. Campus IRB Chair (In cooperation with the Office of Research).
- iii. Campus IRB Staff (Independently)

PROCESS FOR SELECTING AND EVALUATION

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.

1. MEMBERS: All members must meet the regulatory and institutional guidelines representing the requisite expertise necessary to contribute to the review of proposed human subject research activities. All members will be assigned initial, continuing, and amendment review authority by the CIRB Chair in compliance with the “Board Membership” and “Board Chair Responsibilities” policies. Every effort is made to preserve a diverse membership that is representative of the University of Missouri Campus IRB research community. The policies were revised to assure the periodic review and 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. Each year, current members are evaluated to assess their service provided to the board. A determination is made as to whether the member will be

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invited to return to the board. If the member doesn't return, proper actions are taken to secure a membership representing the research community of the Campus IRB. Resigning members reach term on July 30 of each year, with new members invited to begin August 1 (or the new academic year start date for faculty). All new members receive training and are assigned to the roster beginning August 1. Members may be added mid year if the need arises. The Campus IRB Compliance Officer shall complete a Board Membership Screening Form to assure the member meets the expertise for which they were invited to serve. The Compliance Officer will assure that the service purpose appropriate reflects the designation for which the member is to serve. The form will be distributed to member candidates prior to their appointment and require self-identification of potential conflicting interests. All members must comply with the "Conflict of Interest" policy.

2. STAFF

Campus IRB staff are hired based on their experience and expertise in accordance with the Office of Research Policies and MU Human Resources practices.

All members of the IRB staff are evaluated annually to assure they possess the requisite expertise and experience to facilitate the IRB review process functions efficiently and properly.

B. GENERAL PURPOSE OF THE QUALITY ASSURANCE ASSOCIATE

The Campus IRB Quality Assurance Associate is expected to function as an experienced professional with the comprehensive compliance and quality assurance expertise to direct all aspects of the IRB process. The Quality Assurance Associate shall strive to:

- Improve the quality of our human subject research protection program
- Offer educational opportunities to participants, prospective participants, and the community to enhance their understanding of research involving human participants
- Establish a safe, confidential, and reliable channel for research participants that permits them to discuss problems, concerns, or questions
- Promote an environment of compliance with IRB regulations and policies
- Promote an atmosphere that fosters honesty and respect for the IRB process.
- Promote an environment where the IRB is viewed as a collaborator in the research community.
- Promote an environment that fosters research creativity by appreciating the need to apply compliance standards
- Promote a receptive "open-door" environment that encourages investigators to communicate and engage in discussions with the IRB
- Promote departmental and unit interactions by engaging in educational offerings and discussion tailored to their needs
- Promote a networking process whereby measures are taken to interact with institutional units that may interface with human subject research activities
- Promote a networking process within the IRB industry to stay abreast of the dynamic changes occurring in the compliance arena

1. SPECIFIC RESPONSIBILITIES OF THE QUALITY ASSURANCE ASSOCIATE

- a. Perform all administrator duties in the absence of the Compliance Officer
- b. The Compliance Officer is directly responsible for assuring that the Campus IRB Quality Assurance Associate possesses the professional qualifications, education, and experience
- c. Accept all delegations from the Compliance Officer
- d. Determine when a project should be classified as "human subjects research"
- e. Determine when a project should be "Exempt" from further IRB review
- f. Determine when a project should be reviewed at the "Expedited" Level of Review
- g. Determine when a project should be reviewed by the Convened Campus IRB
- h. Oversee Campus IRB and Research Education Programs
- i. Perform on-site audits, as necessary

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- j. Investigate Non-Compliance matters
- k. Perform internal administrative audits in an effort to improve the quality of the review process
- l. Manage the annual departmental audits ensure compliance
- m. Run reports to determine areas that are in need of improvement
- n. Attend seminars specifically aimed at ensuring the protection of the rights and welfare of human subjects involved in research
- o. Attend seminars specifically related to quality assurance and improvement
- p. Maintain membership in an organization specifically focused on the operational aspects of the IRB processes
- q. Assure compliance with the Federal regulations protecting the rights and welfare of human subjects involved in research
- r. Ensure an efficient and comprehensive IRB review process in accordance with Campus IRB policies
- s. Serve as an expert in regulatory compliance to the Campus IRB human subject research community
- t. Assist the Compliance Officer with the ongoing development of policies governing the Campus IRB
- u. Inform the Compliance Officer of any needs or interventions that are necessary to protect human subject research participants.
- v. Conduct Performance Evaluations for the following:
 - i. Campus IRB Members (In cooperation with the Compliance Officer)
 - ii. Campus IRB Chair (In cooperation with the Compliance Officer)
 - iii. Campus IRB Staff (In cooperation with the Compliance Officer)

C. GENERAL RESPONSIBILITIES OF THE ADMINISTRATIVE STAFF

An appropriately qualified and trained Administrative Staff can minimize the burden of review operations for both researchers and the IRB Chair and members. A well qualified high-functioning staff is valuable in permitting the entire Campus IRB to function as a team, while assuring its members can appropriately focus their attention on the business of protecting human subject research participants.

1. The Campus IRB Administrative Staff shall meet all of the following expectations below:

- a. Possess the professional qualifications, education, and experience to process IRB applications
- b. Satisfactorily meet the objectives outlined in the “Performance Evaluation” of their respective Job Description
- c. Prior to processing IRB applications, the administrative staff shall successfully complete both of the requisite Human Subjects Research Education and Training items below:
 - i. Campus IRB online training; or
 - ii. Campus IRB live training;
- d. After the first year of employment, the staff shall annually complete or attend a Human Subjects Research Continuing Education and Training approved by the Campus IRB Compliance Officer.
- e. Remain current and knowledgeable about the IRB Compliance requirements set forth by the governing bodies over human subject research.
- f. Facilitate the internal processing procedures to ensure a prompt and comprehensive review of submitted proposals in accordance with Campus IRB policies by:
- g. Communicating directly with the primary reviewer to determine if the proposed assignment can be reviewed in a timely manner and if additional information is necessary to conduct a comprehensive review.
- h. Provide the primary reviewer with a timeframe whereby their response is due.
- i. Communicate the primary reviewer’s concerns or comments directly with the principal investigator.
- j. When a proposal has been previously approved by an IRB, the staff should obtain copies of the relevant IRB materials necessary for the CIRB to review.

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- k. When the board does not have at least one person on the IRB with the appropriate scientific and scholarly expertise to conduct an in-depth review of the protocol, the staff should contact the Compliance Officer, who will identify a consultant for the Campus IRB.
- l. Proficiently manage assigned files and proposals in accordance with Campus IRB policies;
- m. Communicate and correspond with key research personnel regarding the status of their proposal;
- n. Coordinate the efficient and accurate distribution of IRB reviews, communications, and correspondence with Campus IRB administrative staff and relevant key personnel. (i.e. application received, purge, expiration, completion, withdrawn, and approval letters);
- o. Timely distribute reminder notices to key personnel for continuing review renewal, education & training renewal, contingencies, and any deadlines that may jeopardize the status of a research proposal;
- p. Maintain the confidentiality of the reviewer's identity when communicating with research team members, or when recording the Minutes;
- q. Meet with key personnel to facilitate an understanding of the IRB processes, or to answer questions regarding their specific research proposal;
- r. Maintain the confidentiality of all submitted proposals, internal processes, discussions or communications regarding IRB business.
- s. Facilitate communications between key personnel and board members;
- t. Provide assistance to key personnel regarding IRB procedures and the eIRB submission processes;
- u. Provide assistance to board members to facilitate the IRB review processes;
- v. Assist with the preparation of Campus IRB meeting agenda items;
- w. Prepare and timely distribute the Meeting Agenda;
- x. Order catering;
- y. Attend board meetings;
- z. Record, timely prepare and distribute the Campus IRB meeting Minutes;
- aa. Perform internal and external audits, including departmental audits;
- bb. Maintain accurate records;
- cc. Manage and facilitate the maintenance of the Campus IRB electronic database; and
- dd. Assist with the maintenance of the Campus IRB website;
- ee. Accept any other assignments as necessary to carry out the functions of the Campus IRB.

Revised May 2006
Revised June 2007
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