



Campus Institutional Review Board
University of Missouri-Columbia


Application Submission Process

Policy Number 2876.19

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Effective Date: December 12, 2007

Board Review

Signed 
IRB Chair

Date December 12, 2007

Administrative Review

Signed 
Associate Vice-Chancellor for Research

Date December 12, 2007

1.0 Policy

The Campus Institutional Review Board (Campus IRB) review process is conducted through an automated paperless system. All investigators proposing to conduct human subject research under the jurisdiction of the Campus IRB must electronically submit all application proposals and supportive documents through the automated online system for review consideration.

2.0 Scope

This policy applies to all human subject proposals submitted to the Campus IRB for review consideration.

3.0 Purpose

The Campus IRB must maintain a reliable database to effectively monitor human subject research activities. The eIRB electronic review system instantly tracks all activities submitted from the researcher. The eIRB automated system provides the Campus IRB with the most reliable system for monitoring the safety and welfare of human subject research participants.

4.0 Standard Operating Procedures

A. Submission Requirements to Determine “if” and “when” Proposed Activities Meet the Criteria for Human Subject Research

1. How do you know IF proposed activities are human subject research? All research involving human subject participants (human subjects’ research), *regardless of sponsorship*, must be reviewed by the Campus Institutional Review Board. The determination of whether the activities are subject to review **MUST** be made by the Campus IRB, **NOT** the investigator.
2. WHEN do you contact the Campus IRB? An investigator must submit an application to the Campus IRB when they propose to conduct research involving human subject participants. If an investigator has questions about whether proposed activities involving human participants are subject to review, they must contact the Campus IRB at (573) 882-9585. The determination of whether the activities are subject to review **MUST** be made by the Campus IRB, **NOT** the investigator.

B. Submission Requirements for EXEMPT Human Subject Research

Required Information and Documentation: Investigators applying for EXEMPT review status of proposed human subject research activities must comply with the “Campus IRB Review Process” policy and submit the following, if applicable to the proposal:

- Campus IRB Exempt Application
- Documentation of current Human Subjects Training
- Advisor Approval Form
- Description of the Study Population
- Description of the Recruitment Process
- Description of the Risks and Benefits
- Description of the Informed Consent/Parental Consent/ Youth Assent Process
- List of study tools, instruments, activities to collect data
- Disclosure of Conflicts of Interest Disclosure

NOTE: If the application fails to meet the criteria for EXEMPT review, the applicant must complete the application submission requirements for INITIAL REVIEW at the expedited or full board level. All reviews will be conducted in compliance with the “Campus IRB Review Process” policy. See policy.

C. Submission Requirements for INITIAL REVIEW (EXPEDITED OR FULLBOARD)

WHAT needs to be submitted to the Campus IRB? The investigator must submit all relevant information and supportive documents, or any requested supplemental documentation to assist the board's review of the proposed activities.

Required Information and Documentation: Investigators applying for approval of proposed human subject research activities must activities must comply with the "Campus IRB Review Process" policy and submit the following, *if applicable* to the proposal:

- Campus IRB Application
- Documentation of Current Human Subject Research Training Certification
- Advisor Approval Form
- Funding proposal, People Soft Signature Routing Sheet, and Letter of Award
- Office of Registrar's Approval Documentation
- Financial Conflict of Interest Disclosure
- Instruments/Inventories/Research Tools/Sample Interview Questions/Focus Group Protocol
- Description of the Recruitment Process
- Copy of the final recruitment materials and incentive plans
- Accounting Services Approval Documentation for relevant incentive plans
- Proposed and Final website access/information
- Proposed subject instructions
- Letters of Permission
- Certificate of Confidentiality
- Proposed Informed Consent/ Parental Consent/ Youth Assent Methods, Forms and Documentation
- Description of the Risks and Benefits
- Collaborative Institution or Multi-Center Supportive Documentation
- IRB Approval Documentation from Collaborative Institutions
- Data Safety Monitoring Plan (DSMP) or Data and Safety Monitoring Board Plan (DSMB), (If the research involves more than minimal risk, when appropriate, the Campus IRB will require the application (EXCEPT those qualifying as exempt) to include a Data Safety and Monitoring Plan (DSMP) to provide a description of the provisions for monitoring the data to ensure the safety of participants in compliance with the "Assessing the Level of Risk" policy.
- Memorandum(s) of Understanding
- Data Use Agreements
- Proposed Publication Plan
- HIPAA Documentation
- Debriefing Materials
- Any requested supplemental documentation to assist the board's review of the proposed activities.

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.

D. Submission Requirements for Proposed CHANGES to an Approved Project

Investigators must submit an Amendment application to the IRB requesting to implement proposed changes in compliance with the “Amendment Review Process” Policy, and receive *PRIOR* approval of those changes BEFORE initiation. The following information must be submitted, but not necessarily limited to:

- Amendment Application
- Advisor Approval Form
- Documentation of Current Human Subject Training Certification
- Proposed Consent Document(s)
- Proposed REVISED Instruments/Inventories
- Interim Data Results
- Total Subjects Enrolled
- Total Number of Complaints/Nature of Complaints/Action Plan
- Total Number of Subjects who Withdrew from Participation/Reason for Withdrawal /Action Plan
- Summary of Adverse Events or Unanticipated Problems
- Any other relevant documents to support the proposed changes
- Any requested supplemental documentation to assist the board’s review of the proposed activities.

E. Submission Requirements for the CONTINUING REVIEW PROCESS:

The Investigators must submit the Continuing Review Report (CRR) to the Campus IRB *PRIOR* to the expiration date and in compliance with the deadlines and requirements set forth in the Continuing Review Process policy. SEE Policy.

NOTE:

1. All submissions will be reviewed internally, in accordance with the Campus IRB policies to determine if it is complete and adequate.
 - a. If the submission is inadequate, the Compliance Specialist will communicate this via e-mail to the investigators.
2. The Compliance Specialist is responsible for preparing board member review materials and review of initial submissions, amendment submissions, and continuing review submissions.

The Campus IRB automated application submission database (eIRB) is a secure system designed to permit researchers with an opportunity to electronically submit research proposals for review consideration. The system provides the Campus IRB with a more reliable and efficient review and tracking device.

The system has continued support by Information System experts, to assure that data is properly stored in a confidential manner.

F. ACCESSING THE AUTOMATED eIRB APPLICATION

An investigator or key personnel must follow certain procedures to access the secure eIRB system. The procedures are as follows:

INTRODUCTION: WHAT TO DO BEFORE YOU CAN ACCESS THE eIRB SYSTEM.

Internal USERS

Step 1 Go to <http://irb.missouri.edu/eirb>

Step 2 Enter your UM Sign On LOGIN information. The username is the portion of your University email address that is listed immediately prior to the "@" sign. The password is your UM password associated with your username.

External USERS

Step 1 NEW USERS must establish an eIRB account

Step 2 Establish a new account by clicking on "Create a New Account"

Step 3 You may update your eIRB account or change your password at any time by selecting the "Update Personal Information" link from the main menu

NOTE: ALL Key Personnel and Investigators must complete the requisite "Human Subject Training" before the system will allow you to submit an application. The training date is automatically recorded in the database.

1. ACCESSING THE AUTOMATED eIRB SYSTEM

All applicants must create a USER ID to set up an account for access to the eIRB system. The Applicant should:

- a. Login to the Campus eIRB Website at: <http://irb.missouri.edu/eirb/>.
- b. Enter your Username and Password.
- c. From the main menu, choose **IRB Forms**.
- d. Choose the appropriate Campus IRB form (i.e., Main Application, Amendment, Continuing Review Report).
- e. To view the form, select "**Preview**", or select "**Start**" to begin completing the form.
- f. Complete ALL relevant fields (required fields are marked with an asterisk).
- g. To SAVE entries, click **Save & Continue** at the bottom before moving to another section. Use the section headings on the left to navigate through the application.
- h. At the end of the form, a list of omitted sections that must be completed will be provided in red. Return to each omitted section and complete it, remembering to save new entries on each page by clicking **Save and Continue**.
- i. When finished, return to the **Submit/Print** section of the application.
- j. At the **Submit/Print** section of the form, you may:
 - REVIEW your form or print a copy for your records by clicking the **Print** button.
 - ATTACH documents to your form. To attach documents, click the **Document Storage** link. A new browser window will open where documents may be added to the application. Please BRIEFLY describe the document in the NOTES prompt when uploading each document. When all documents have been added, close the browser window and return to the application.

NOTE: To avoid a delay in the processing of your application, you must upload all relevant supportive documentation including, but not limited to, consent forms, grants, and instruments, which pertain to your project.

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2. SUBMITTING THE APPLICATION: When the form is complete and all supportive documentation is “uploaded”, you may SUBMIT the form. Submission is a two-step process:
 1. FIRST, click the **Start Submission Process** button, and review the reminder notices. Please resolve all reminder notices prior to exiting the system. If, your form is incomplete, you may exit eIRB. Your form will be saved and you can return to it for submission at a later date.
 2. SECOND, if your form is complete and you wish to submit the form click the **Submit** button.

NOTE: A message will appear stating **Submission is Complete**.

3. SAVING YOUR IRB APPLICATION
 1. The eIRB system is a secure database that has automated features to protect the information of those accessing the system. One feature is an automated log off that occurs after extended periods of inactivity. Before leaving each page of the application, make sure to click the "**Save and Continue**" button at the bottom of the page. It is important to remember to “save” throughout the application to assure your information is properly stored. CLICK "**Save and Continue**" to save your entries at **least every thirty minutes**. [NOTE: As a security feature, the eIRB system will log you off after periods of extended inactivity and any information entered, but not saved, will be lost.]

NOTE: Only SAVED information is retrievable;

4. RETURNING TO A SAVED IRB APPLICATION
 1. You may continue to work on any saved application that has not been “submitted” to the IRB. If an application has been “submitted”, the applicant will not be able to make revisions. This feature provides the information submitted to the database with the protection necessary to make it vulnerable to unauthorized revisions.
 2. At the main menu choose **Open Saved IRB Project**. A list of all projects you have with the IRB will be displayed.
 3. You may view any project by clicking the **Project Forms** button. All IRB forms associated with the selected project will be viewable here.

5. VIEWING AND EDITING A SAVED APPLICATION
 1. To view a PRINTPREVIEW of a new application, go to the Campus Application box, click the **Print** button.
 2. To edit the application, click the **Open** button. The applicant can only “edit” an application that has not been submitted to the Campus IRB.

Remember: Applications submitted to the eIRB become a permanent record in the Campus IRB database and can’t be edited. You may view the completed application by using the **Print** button, but no changes can be made. If you need to make changes to an application that has already been submitted, please contact the Campus IRB Office (882-9585).

6. UPLOADING A DOCUMENT
 1. Investigators must UPLOAD all responses, revisions, and supportive documents requested by the IRB office during the application review process. That information must be UPLOADED into the Document Storage section of the eIRB system.
 2. When uploading each document, it is important to SELECT the appropriate **Document Type** that corresponds with the document requested by the reviewer.
 3. Once all requested documents are uploaded, the application form can be SUBMITTED to initiate the review process.

G. COMPLETING THE APPLICATION

1. KEY PERSONNEL AND INVESTIGATOR TRAINING

All key personnel involved with human subject research shall receive specialized training that will verse them in the ethical foundations underlying research participant protection. The Training requirement must be renewed every two years. Please contact the Campus IRB Office or go to the website for directives.

2. STUDENT INVESTIGATORS

- a. All student investigators must have an Advisor (who has completed Human Subject Training) assigned to the file before they can submit an application to the Campus IRB.
- b. The Advisor's responsibilities in the submission process:
 1. Review the application prior to submission to the Campus IRB
 2. Complete an "Advisor Approval" Form" certifying that the application has been approved and will be monitored by the Advisor.

3. COMPLETING THE APPLICATION FORM

- a. The applicant shall complete all relevant questions on the Campus IRB online application;
- b. The applicant shall UPLOAD all supportive documents, including but not limited to informed consent documents, and any other research materials required for Campus IRB review. These include, but are not limited to:
 1. Recruitment materials;
 2. Permission letters;
 3. Consent or Assent forms;
 4. Instruments and inventories;
 5. Focus group questions;
 6. Web site materials;
 7. Funding proposals; and/or
 8. Cooperative site materials;
- c. The applicant will receive notification of the date of application receipt and assigned IRB docket number;
- d. Investigators and key personnel are informed to monitor their review status online;
- e. Investigators and key personnel are informed to monitor their e-mail accounts for Campus IRB correspondence to avoid delay in the review process;
- f. Any applicant applying for exemption shall provide an explanation (along with supportive documentation) of why the proposed activities are eligible for review and which exempt criterion the investigator believes the activities meet.

If an application meets the criteria of an Exempt review:

- A Campus IRB authorized individual will review the proposed submissions in concert with the investigator's responses to assure that the file is complete;
- If the application is incomplete, it will be placed on hold pending the response and/or revisions from the investigators;
- If the file is complete, the investigators will receive certification of its approval status within 5-10 business days;

If an application meets the criteria of an Expedited review:

- A Campus IRB authorized individual will review the proposed submissions in concert with the investigator's responses and conduct an initial review to assure that all necessary documents are attached and assign the proposal to an IRB member for a substantive review;
- If the application is incomplete, it will be placed on hold pending the response and/or revisions from the investigators;

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- If the file is complete, the investigators will receive certification of its approval status within 5-10 business days;
- If an application meets the criteria of Full Board review:
- The application will be placed on the next available Campus IRB agenda;
 - The investigator(s) will receive notice from the Campus IRB office, specifying the date, time and location of the IRB meeting and request that the investigator(s) be available to the Board to address any concerns that they may have;
 - A Campus IRB authorized individual will conduct an initial review to assure that all necessary documents are attached and assign the proposal to a primary reviewer;
 - The primary reviewer will conduct a substantive review(s) to assure that the application is complete prior to the board meeting;
 - The member will receive the file and all supportive documents at least 14 days prior to the meeting and have full access to the file via the electronic paperless system. All documents submitted by the investigator are visible in the eIRB database. The member will respond to an investigator's response within 5 business days. Each subsequent response will result in the reviewer having 5 business days to respond.
 - The primary reviewer will conduct a substantive review. The review will be communicated to the investigator(s) by a Campus IRB administrative staff member. The primary reviewer's identity will remain confidential;
 - The investigator(s) shall respond to the review in a timely manner and upload all revisions and responses in enough time to permit the primary reviewer enough time to conduct a substantive review of the proposed activities. It is preferred that the responses are received at least 7 days prior to the board meeting;
- g. If needed, the primary reviewer will conduct an additional review and if there are additional questions or concerns, the investigator(s) will be notified in writing. The investigator(s) shall respond to the additional requests and upload any information or revisions prior to the board meeting in a timely manner.
- i. **FAILURE TO TIMELY RESPOND MAY RESULT IN THE FILE BEING REMOVED FROM THE AGENDA** due the inability of the primary reviewer to conduct a substantive review, or to provide ample time for the board members to properly review the file and deliberate.
 - ii. Once the requested information has been timely received, it will be reviewed at the next available meeting. The convened IRB will review, deliberate, and take action upon the submitted information in accordance with "Campus IRB Authority" and "Campus IRB Review Process" policies.
 - iii. The investigator(s) will receive written notice of the Board's decision on the proposal in a timely manner;
- h. Incomplete applications are placed on hold pending the response of the investigator(s). Incomplete applications do not receive priority review. It is the responsibility of the investigator(s) to make sure all Campus IRB requests are promptly submitted to complete the application process; and
- i. The investigator(s) shall assure that all research records are accessible for inspection and copying by authorized Campus IRB representatives for at least three years after the completion of the project.

H. REVIEW PROCESS

1. Initial Review
 - a. All applications submitted to the Campus IRB will be reviewed in compliance with the “Campus IRB Review Process” policy. See policy for directives.
 - b. When the IRB receives new information, including adverse event reports, publications, complaints, DSMB reports, breaches of confidentiality, or other information, it should decide whether the information represents an unanticipated problem involving risks to participants or others or is determined to be noncompliant in accordance with the “Unanticipated Problems and Adverse Events Involving Risks to Participants and Others” “Complaint” and “Noncompliance with Campus IRB Policies and Procedures.”
2. Incomplete Applications
 - a. Definition: An “Incomplete Application” is an IRB submission that is either insufficient, requires additional information, inadequate responses to the IRB requests for information, or lacks sufficient documentation that will permit the IRB to adequately review the proposal.
 - b. Incomplete applications will not receive priority review. Any investigator submitting an incomplete application may jeopardize the turn-around-time of the application and cause substantial delays with the IRB review/approval process.
 - c. Incomplete applications are ineligible for approval until the CIRB has enough information to assess the proposed research activities. Investigators will be required to submit responses, additional information, or appear before the board to answer questions raised during the IRB review process to effectuate a proper review.
 - d. If the Campus IRB determines that the application or information submitted is incomplete, inadequate, or additional information is required, the proposal will be returned to ON HOLD status, and the proposal “as is” will be ineligible for approval. The investigator must submit the requested information, documentation, or appear before the board for review/approval consideration by the Campus IRB.
 - e. ON HOLD does not receive priority status for review, and will return to the electronic eIRB queue for review in chronological order of date of “receipt” of documentation or completion.
3. Complete Applications
 - a. All COMPLETE applications submitted to the Campus IRB will be reviewed in compliance with the “Campus IRB Review Process” policy, and progress forward for an “Action” determination to be taken by the board.
 - b. The investigator will receive written notification of the “Action” taken by the board, in compliance with the “Campus IRB Review Process” policy.

Revised May 2006
Revised June 2007
Revised November 2007