



Campus Institutional Review Board
University of Missouri-Columbia


Record Keeping Process

Policy Number 2876.13

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

Approval Authority:

Signed 
IRB Chair

Date December 12, 2007

Institutional Approval:

Signed 
Associate Vice-Chancellor for Research

Date December 12, 2007

1.0 Policy

The Campus Institutional Review Board (Campus IRB) utilizes an automated electronic database system (eIRB) for the purpose of “Record Keeping” to efficiently track all human subject research proposals by 1) storing all data entries submitted by researchers; 2) storing all data entered by the Campus IRB during the review process; and 3) developing reports specific to the Campus IRB needs. The paperless system provides a more reliable and efficient medium for ensuring data integrity and performing continuing quality improvement activities. All Campus IRB processes will be managed through the automated electronic database and maintained in accordance with all Campus IRB policies and procedures.

2.0 Scope

The eIRB record keeping system tracks all human subject research activities conducted under the jurisdiction of the Campus IRB.

3.0 Purpose

The Campus IRB oversees a large volume of human subject research annually. A high quality electronic record keeping system provides the research community with a system that is efficient, more comprehensive, and specifically tailored to the campus academic research environment. The electronic system permits the Campus IRB to conduct reviews, archive large volumes of records, and monitor compliance activities through a more reliable process.

4.0 Standard Operating Procedure

The Campus IRB must maintain a community of compliance by accurately maintaining records of the IRB review processes. The success of its operation depends substantially on the ability to manage information flow. Properly trained staff with detail-oriented case management skills must be accompanied by the ability to efficiently navigate through a network tracking system.

A. The eIRB system has the following capabilities:

1) Data Entry 2) Tracking 3) Reporting 4) Search Options 5) Historical Activity Chronology 6) Training Records 7) Record Documentation 8) Investigator Profiles 9) Document Review and Storage 10) Review and Approval periods 11) Regulatory Designation 12) Date stamping for restricted activities 13) Quality Management Capabilities.

The Campus IRB database is an automated system that must provide tracking information with precision to preserve data integrity. Key features that improve the productivity of the review process are as follows:

1. DATA ENTRY

FRONT END (End-User): Investigators may submit proposals directly into the Campus IRB database by entering information on the application, which corresponds to specific fields. The entered data can be immediately assigned an IRB number and can be tracked in direct relation to the fields populated in the eIRB database. The number is unique to that application, and can not be reused or modified by the end user. The application fields include requests for specific information about the investigator, key personnel, and the research proposal. Once the end user “saves” the application, it is stored on the “back-end” of the system and unavailable for modifications by the applicant. If the applicant desires to edit or modify information, they must follow directions specifically designed for revision activities. This action prevents the Campus IRB of performing duplicative efforts and reduces the risk of

the internal records being modified by external users. A system for editing involves interactions with a Compliance Specialist, in an effort to maintain the integrity of the review process.

BACK END (IRB Members/Staff): IRB Members/Staff may access files unless there is a conflict of interest. The system provides several levels of access permission, depending upon the role of the back-end user. All proposals and information submitted by the researcher through eIRB is directly written into the Campus IRB database and can be immediately viewed by the IRB on the “desktop” application which provides a “user view” or a “back-end field view.” The eIRB system is paperless, and provides a mechanism for electronic signatures on behalf of the IRB. The investigator receives all notices, correspondence, approvals and directives from the IRB in written form which is immediately recorded in the eIRB system. This action prevents the Campus IRB of performing duplicative efforts and reduces the risk of the human error. A system for updates involves interactions with a Compliance Specialist, in an effort to maintain the integrity of the review process.

2. TRACKING

All applications submitted to the Campus IRB are conducted in compliance with Campus IRB policies and assigned an identifying number. The application is then stored in the file “Staging” area, which categorizes the file type. The “Staging” area identifies where each proposal is in the review cycle. The review process is initiated in accordance with the “CIRB Review Process Policy” as follows:

Stage I Pre-Screening

All eIRB file submissions enter the database in Stage I. This stage places the file in “*pending*” status and indicates the applicant has submitted the document to the Campus IRB for review. The applications are reviewed to determine if they meet the criteria for “human subject research” subject to IRB review, are in the proper forum, are FDA or VA regulated. If the human research activities are FDA or VA regulated, they will be transferred to the Health Sciences IRB. All activities under the Campus IRB jurisdiction will receive a preliminary screening by CIRB staff, to assure the key personnel have completed the training requirements. If the applicants and key personnel have not completed training, the file is not moved to Stage II for review. The file is considered “incomplete.” If a file is incomplete and missing relevant documents, it is not moved forward to Stage II for review.

The Level of Review determination is made in Stage 1, in accordance with the “Campus IRB Review” and “Level of Risk” policies. If the application meets the criteria for exemption, the review process is conducted via the “Do The Research Qualify for Exempt Review?” checklist. If the activity meets the exempt criteria, the activity will move to Stage IV for approval.

If the review determination is expedited, it is confirmed via the “Do The Research Qualify for Expedited Review?” checklist. If the activities meet the criteria for full board review, they are confirmed via the “Do The Research Qualify for Full Board Review?” checklist. The expedited or full board activities will move to Stage II.

The applicants receive notification that training certification is required for review of the activities. Stage I initiates an automated “Letter of Receipt” and assignment of the IRB file number. The applicant is informed of the IRB process and notified that the file is in the system. Requests for training will be made. Incomplete files do not receive priority review consideration, over complete application submissions.

Stage II Compliance Specialist

The screened file moves to Stage II for review by the Compliance Specialist. The file is prepared for review by a board member. This stage places the file “under review” status which signifies that the file has moved forward to the Compliance Specialist for a cursory

Record Keeping Process
Policy Number 2876.13

review. The application is screened in preparation to be forward to a reviewer for expedited or full board review. Stage II files must be complete before they can move to Stage III (Board Member Review). If the file is incomplete, it is ineligible to move to Stage III. Stage III reviews require the file to be complete, to be eligible to move to Stage IV (Approval Stage). Incomplete applications are *returned* to “Pending Status”, which may result in a delay in the review process. Incomplete applications are ineligible for approval and will not receive priority review status. The Compliance Specialist will communicate directly with the key personnel in an effort to prepare the file for completion to move to Stage III. The Compliance Specialist will make every effort to assure the integrity of the review process, but it will be dependent upon the prompt reply from the investigator to effectuate moving to Stage III. Once the file is complete, the file is reviewed by the specialist and forwarded to a reviewer.

Stage III Board Member Review

The substantive file review will be conducted by a voting member. The review process, recommendations and actions are documented in the eIRB record in the “internal” COMMENT field. These records are confidential. Documentation will include the regulatory requirements for the review determination, along with any other comments regarding the review process and recommendations. The member will document any actions, specific findings mandated under the regulations, determinations required by the regulations and protocol-specific findings supporting those determinations, specific determination when one of multiple mutually exclusive determinations was required.

The member reserves the right to ask additional questions, which results in the file being moved back to Stage II for resolution of the issue. When the file is eligible for approval, it is moved to Stage IV. If approval is denied, it must be docketed on the full board agenda.

Once the review has been conducted, the reviewer will electronically send notice to the Compliance Specialist, documenting that all regulatory and internal requirements have been met for approval.

Stage IV Approval Stage

The approval process, recommendation, and/or action are certified in the record by electronic signature in this stage. The Compliance Specialist will work with the member and CIRB staff designee to assure that all approval documentation is complete in compliance with Campus IRB policies. Once all relevant Approval Documents are completed, the file moves to the Stage V “Reservoir” for “active” file storage.

Stage V CRR/Reservoir

This is the storage vault for “active” files that have approval or has been closed. Stage V is the file cabinet for the eIRB system. All records are stored here for 3 years after closure of the project. At that time, they may be destroyed. Active files are stored and calendar marked for the Continuing Review Interval. All approved proposals are filed in the electronic reservoir with a scheduled date for CRR review. If the file was not approved and withdrawn, expired or closed, it will remain in the “reservoir” for 3 years, at which time it is no longer required to be stored in accordance with the regulations.

All Active Stage V files are marked with alert warnings which can be defined at any interval prior to expiration. This expiration date corresponds to the date communicated to the principal investigator in the “Initial Approval Letter”, “Continuing Review Report”, and “Amendment” approval letters. The Campus IRB sends the investigator a courtesy reminder notice at least 45 days prior to the expiration of the Continuing Review Interval requesting the report 45 days prior to the expiration date, in an effort to avoid interruptions with IRB approval. If the Investigator fails to timely respond before the requested date, there is no guarantee that the application can be timely reviewed before expiration of IRB approval. If the investigator’s IRB expires, and they wish to continue research activities, a new application must be submitted. No research activities may be conducted until IRB approval has been

granted in writing.

ARCHIVAL VAULT: The eIRB system has an “Archive” Storage feature that permits the Campus IRB to store closed, terminated, withdrawn or expired files. The system permits storage by assigning the file to a “box” which is automatically populated with data entry by the administrative staff, and is stored and categorized according to “date” of entry. As a safety feature, the system doesn’t automatically destroy the records. The Campus IRB schedules monthly purging activities whereby communications are sent to the investigator regarding intentions of research activities, or destroyed because the file has been closed and 3 years have passed. The Campus IRB policy for destruction of records complies with the University of Missouri-Columbia’s Records Management Department’s policies, in consultation with the General Counsel’s office.

3. REPORTING

The eIRB system is an efficient automated data reporting system called ePRAIS. This system has the capability of preparing specified “search” reports based on name of Investigator, Department, Key Search terms, Dates, Consent, Level of Review or Approval, Reviewer, and sponsor. The system is also capable of preparing “audit” reports. The Campus IRB intends to enhance this system to provide more sophisticated Auditing Tools and Continuing Quality Improvement activities.

4. SEARCH OPTIONS

This feature permits the Campus IRB to search the database utilizing Key search terms. The ePRAIS reporting feature interfaces with the eIRB system to run the search based on data input requests. The reports serve as an integral part of the internal compliance monitoring system.

5. HISTORICAL ACTIVITY CHRONOLOGY

This feature permits the Campus IRB to run a dated chronology of all activities regarding a specific proposal, investigator, or reviewer.

6. TRAINING

The system is designed to prevent access to the eIRB online system until the requisite Human Subject Research training has been completed. This feature automatically enters the date of successful completion of the online training, and requires the Campus IRB office to manually enter any live trainings or Continuing Education sessions attended. The system will automatically create the expiration date three years from the date of training. If the applicant attempts to access the system after training has expired, they are prohibited from viewing any of their information until the training issue has been resolved.

7. RECORD DOCUMENTATION

The system provides a permanent record of all data submitted to the IRB for review, all internal review activities, and all historical information related to the files. The record must provide access to copies of the protocols reviewed, scientific evaluations, DHHS approved sample consent documents, progress reports submitted by investigators, reports of injuries to participants, records of continuing review activities, all correspondence between the IRB and investigator, statements of significant findings provided to participants.

Record Keeping Process
Policy Number 2876.13

a. Internal Documentation

The eIRB records reflect documentation of the IRB review process in compliance with all CIRB policies and Procedures, but specifically the “CIRB Review Process”; “Amendment Review Process”; “Continuing Review Process”; “Board Meeting Procedures”; “Recruitment”; “Informed Consent”; “Minutes” and any other policy regarding the CIRB review processes.

The record should document the following, but is not limited to:

- i. All review level determinations must document the specific regulatory category of review. If the review is by the convened board, the IRB must record the justification for a full board review level
- ii. Descriptions of actions taken by the reviewer;
- iii. Specific findings mandated under the regulations.
- iv. Determinations required by the regulations and protocol-specific findings supporting those determinations.
- v. Specific determination when one of multiple mutually exclusive determinations was required.
- vi. Initial and continuing review to note the frequency for the next continuing review.
- vii. In practice, the QA Associate is responsible for monitoring the Campus IRB processes for effectiveness, which involves daily review of record documentation.
- viii. All activities and ACTIONS taken by the convened board must be documented in compliance with the “Minutes” Policy. See Policy.
- ix. All IRB review processes must be documented in the record in compliance with the “Quality Assessment and Improvement” Policy. See Policy.

b. Quality Assessment and Improvement

- i. Stage I: Pre-Screening Stage
The eIRB file record is updated on an ongoing basis by the internal staff
- ii. Stage II: Compliance Specialist
The file is reviewed by the specialist and forwarded to a reviewer. If the review has been conducted, the reviewers will electronic send notice to the Compliance Specialist when all regulatory and internal requirements have been met for approval.
- iii. Stage III Board Member Review
The file is reviewed and the process is documented in the eIRB record. Documentation will include regulatory requirements as specified above in “Internal Documentation”, along with any other comments regarding the review process and recommendations. The member will document any actions taken or recommended for the applicable review being conducted.
- iv. Stage IV Approval Stage
The approval process, recommendation, and/or action is certified in the record by electronic signature.
- v. Stage V CRR/Reservoir
The approved proposal is filed in the electronic reservoir with a scheduled date for CRR review. If the file was not approved and withdrawn, expired or closed, it will remain in the reservoir until which time it is no longer required to be stored in accordance with the regulations.

8. INVESTIGATOR PROFILES

The Person Edit compartment comprises the field that possesses the profile of the investigator and key personnel. It provides all contact information, area of expertise, Human Subject training record, internal notes “specific” to the investigator or interactions with the Campus IRB that are not related to a specific proposal. It gives the Campus IRB a field to review interactions that may be important to prospective review processes.

9. DOCUMENT REVIEW AND STORAGE

The system provides an “UPLOAD” feature that permits the investigator to electronically submit documents for review and the IRB to access all submissions relevant to the review process. The documents can be labeled by the investigator in accord with a list provided for convenience, or edited by Campus IRB staff to assure appropriate categorizing of file information. The document is stored with the specific application it is associated with. The investigator and Campus IRB is able to access and view “all” documents submitted for a particular proposal.

10. APPROVAL PERIODS AND CONTINUING REVIEW INTERVALS

The Campus IRB must document all review actions, including but not limited to the initial and continuing review, including the approval and expiration date. The record shall also note the frequency for the next continuing review interval and the due date. All review and approval periods are automatically date stamped after data is entered into the eIRB system by the Campus IRB. The continuing review interval may be shortened if the Campus IRB deems necessary. All Approval and Expiration dates, and Continuing Review intervals require documentation in the record. Intervals shorter than a one-year (12 month) period require specific documentation in the record.

11. REGULATORY DESIGNATION

Each proposal shall have a LEVEL OF REVIEW recorded. Each file shall also have the LEVEL OF RISK recorded. All files must have a “regulation” assigned that confirms the approval determination. Exempt files shall have record of the specific category of exemption for approval. Each proposal must receive a regulatory designation that identifies what regulation serves as the basis for approval. Each applicable proposal must have a record to document the protocol-specific finding and corresponding regulation applicable to grant approval.

12. DATE STAMPING FOR RESTRICTED ACTIVITIES

The system permits the Campus IRB to restrict activities and assign a deadline date. The date will prompt notice that action is necessary. The file “alert” must be manually removed within the given stage and comments documenting the action or process.

13. QUALITY ASSESSMENT AND IMPROVEMENT

The Campus IRB processes are internally monitored for effectiveness and improvement by the QA Associate under the direction of the Compliance Officer. All quality assurance and improvement activities are conducted in accordance with the “Quality Assurance and Improvement” policy. See policy.

The eIRB system provides the Campus IRB with the basic reporting capabilities necessary to provide information about the review activities.

The system also provides basic auditing features which the Campus IRB utilizes to confirm all proposals submitted comply with the regulations governing human subject research. The reporting feature serves as the fundamental framework for the auditing of human subject

research activities. It permits the Campus IRB to run a report of all activities listed in the database, which serves as the basis for the IRB to request the Department verify that the list accurately represents the human research activities being conducted in their unit. If a researcher is conducting research that is not on the list, the individual must contact the Campus IRB immediately to address the matter.

B. ADDITIONAL FEATURES OF THE eIRB SYSTEM

The system also provides these additional features:

1. HELP text for applicants making submissions
2. Form development capabilities
3. Automated Letters of Approval
4. Automated Reminder Letters
5. File Storage Features
6. File Archive Features
7. "External" User view ability feature
8. Campus IRB "internal" desktop feature
9. Specific processes for Initial reviews, continuing reviews, amendment reviews, adverse event reviews, unanticipated problems, compliance breach reviews, deviation reviews, quality assurance and auditing activities;
10. Campus IRB meeting Minutes;
11. Identification of the Campus IRB member(s) providing review
12. Online File Review Screening Tool

C. RECORD RETENTION

Campus IRB records pertaining to research must be retained for 3 years after completion of the research. If a protocol is cancelled prior to participant enrollment, they will be retained for a period of 3 years after cancellation.

All Campus IRB records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research, at reasonable times and in a reasonable manner.

All investigators are informed that their research records must be retained for 3 years after closure or completion and accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research, at reasonable times and in a reasonable manner.

Revised December 2006

Revised June 2007

Revised December 2007