



Campus Institutional Review Board
University of Missouri-Columbia


Quality Assessment and Improvement

Policy Number 2876.40

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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) will conduct quality assessments of the internal operations to monitor and measure the effectiveness of its human research protection program and determine if its review processes are performed and recorded in the record in compliance with established standards. The Campus IRB will strive to meet the objective of improving review performance in relation to the established standards of the IRB industry.

2.0 Scope

The Campus IRB shall provide compliance oversight to all human subject research activities under its jurisdiction by methods that strategically improve the quality of the internal operations if its human subjects protection program.

3.0 Purpose

The Campus IRB will conduct continued quality assessments of its internal operations through an auditing process to heighten the awareness of regulatory requirements for the research community, and improve the ethical conduct of human subject research. The Campus IRB recognizes that additional safeguards must be in place to assure the protection of all human subjects involved in research, by providing an audit program consisting of a proactive, nonpunitive, process that educates investigators about their ethical and regulatory responsibilities.

4.0 Standard Operating Procedure

The Campus IRB Quality Assurance Associate is responsible for conducting quality assessments of the internal operations, documentation processes, and record keeping monitoring and measuring the effectiveness of our human subject research protection program. The Quality Assurance processes will assure all activities meeting the institution's definition of human research receive IRB review.

The Quality Assurance Associate is responsible for directing the following assessments:

I. CONDUCTING AUDITS OF THE INVESTIGATOR COMMUNITY

A. Proactive Efforts

The Campus IRB understands that undesirable issues of noncompliance may arise during the auditing process and present challenges the Campus IRB process. In an effort to proactively address this possibility, the Campus IRB will organize a Quality Assurance and Audit Team to appropriately monitor all research activity under its jurisdiction, for compliance with State, Local, Federal and University laws.

B. Composition of Auditors

The Campus IRB audit team will be comprised of individuals that possess the professional credentials and expertise to understand, review and enforce compliance with the regulations that govern the protection of human subjects involved in research. The Team shall receive the full administrative support of the Office of Research, in conducting audit review and quality assurance monitoring of research projects under the jurisdiction of Campus IRB.

Quality Assessment and Improvement
Policy Number 2876.40

C. Approach

The Campus IRB will adapt its auditing processes to meet the specific needs of its research community. The Campus IRB will consider the following procedures when conducting Quality Assessment audits:

1. Establish the criteria for selecting the studies to be audited.
2. The audit staff will conduct a comprehensive review of the IRB file records, in advance, of the selected projects subject to audit review.
3. The audit process can be conducted in by two methods:
 - a. Onsite investigation of all research records and or activities
 - b. Paper Audit: The investigator is requested to submit documentation to meet the audit objective.
4. The Campus IRB should make every effort to give the investigator prior notice in writing, outlining the date, time, place and selected protocols subject to audit. The Campus IRB reserves the right to conduct an unannounced onsite audit in an effort to protect human subject participants.
5. The Campus IRB may also interview or survey research subject participants, observe the actual consent or research process, to provide information to address concerns.
6. The Campus IRB should establish a reasonable time frame for completing the audit and preparing the report.
7. The Campus IRB will coordinate its findings with the Office of Research, who will take the necessary actions to assure any academic concerns are appropriately addressed by institutional officials.
8. The Campus IRB will assure the audit records are maintained for period of 3 years after closure of the project.

D. MECHANICS OF THE CAMPUS IRB AUDIT

The mechanics of the audit processes are critical to a successful Quality Assessment and Improvement objective. The mechanics criteria are based upon the FDA and DHHS regulations that focus the audit on goals of increasing investigator and IRB awareness of regulatory requirements. The mechanics can be divided into the following categories:

1. AUDIT OF IRB RECORDS
2. AUDIT OF INVESTIGATOR RESEARCH STUDY RECORDS
3. OBSERVATION OF THE CONSENT PROCESS
4. INTERVIEWS WITH THE INVESTIGATOR
5. INTERVIEW WITH THE RESEARCH PERSONNEL
6. INTERVIEWS WITH THE RESEARCH SUBJECTS
7. PREPARATION OF THE AUDIT REPORT AND FOLLOW-UP

QUESTIONS THAT MUST BE ANSWERED DURING THE AUDIT PROCESS:

1. AUDIT OF IRB RECORDS

- a. All activities and ACTIONS taken by the convened board must be documented in compliance with the “Minutes” Policy. See Policy.
- b. All IRB review processes must be documented in the record in compliance with the “Record Keeping” Policy. See Policy.
- c. Do the Campus IRB files contain all of the records required by 45 CFR 46 in sufficient detail to demonstrate compliance and performance of a substantive review(s)?
- d. Are the Campus IRB Minutes pertaining to the protocol in question sufficiently detailed with documentation in compliance with the governing regulations?
- e. Is the approved Consent form tailored to the targeted research community in compliance with the regulations?
- f. Did the Campus IRB perform all reviews in a timely and efficient manner?

Quality Assessment and Improvement
Policy Number 2876.40

- g. Was the Continuing Review process substantive and in compliance with the regulations? Was the Continuing Review Interval appropriate for the level of risk proposed?
- h. Were adverse events or other unanticipated problems involving risk to the subject or others promptly reported in accordance with the federal regulations governing human subject research?
- i. Was serious or continuing noncompliance promptly report in accordance with the policies of the Campus IRB?
- j. Were the Campus IRB review activities conducted under exempt or expedited review processes permissible under the regulations?

2. AUDIT OF INVESTIGATOR RESEARCH STUDY RECORDS

Record keeping

- a. Does the investigator possess a comprehensive and secured file?
- b. Does the investigator possess copies of all brochures and documents distributed to the research subject?
- c. Does the investigator possess a current IRB approved copy of the Consent forms, adverse event reports (if applicable), or other relevant safety information?
- d. Does the investigator possess a copy of all Continuing Reviews and correspondence between the investigator and the Campus IRB?

Implementation

- a. Did the investigator implement the current, Campus IRB approved version of the proposed methodology?
- b. Did the investigator implement the most current, Campus IRB approved Consent process properly?
- c. Did the investigator secure a dated signed copy of the most current approved Consent form?
- d. Did the investigator comply with the proposed inclusion and exclusion criteria?
- e. Did the investigator implement the research by the approved timeframe as proposed?
- f. Did the investigator assure that all protocol modifications were prospectively approved and implemented accordingly?
- g. Did the investigator comply with the approved confidentiality, data storage, and publication methods as proposed?
- h. Is the number of evaluable subjects accrued to date, within the Campus IRB approved limit?

3. OBSERVATION OF THE CONSENT PROCESS

- a. Did the investigator conduct the consent process, as approved?
- b. Did the investigator ensure the subject's comprehension?
- c. Did the investigator appropriately document the process?
- d. Was the environment in which the consent process took place conducive to rational and thoughtful decision-making on the part of the subject?
- e. Was the length of time devoted to the consent process sufficient?
- f. Was the subject given adequate opportunity to ask questions?
- g. Was the subject given an adequate explanation of the research using appropriate simplified language?
- h. Did the subject demonstrate an acceptable understanding of the research process before consenting, during the research, and during follow up?

Quality Assessment and Improvement
Policy Number 2876.40

4. INTERVIEWS WITH THE INVESTIGATOR
 - a. Did the investigator provide the requested information? If not, the audit team shall be prudent and take additional measures to confirm compliance. This may include auditing ALL research activities.
 - b. Did the investigator encounter any problems in recruitment, subject retention, or other areas? If so, what was the nature of the problem and how was it addressed?
 - c. Did any subject suffer a serious, unanticipated adverse event? If so, what was the nature of the event and how was it treated? Did the investigator comply with Campus IRB policies in reporting the event?
 - d. Did the research team encounter any problems with the Campus IRB, Campus IRB staff or IRB processes? If so, what was the nature of the problem and proposed solution?
5. INTERVIEW WITH THE RESEARCH PERSONNEL
 - a. Was the research personnel properly trained to conduct the proposed activities?
 - b. Were the personnel managed properly?
 - c. What were the responsibilities delegated to the personnel?
 - d. Were the personnel qualified to perform the delegated duties?
6. INTERVIEWS WITH THE RESEARCH SUBJECTS
 - a. Did the subject comprehend the consent process?
 - b. Did the investigator maintain an “ongoing” consent process?
 - c. Did the investigator address any research concerns of the subject?
 - d. Did the research raise any concerns?
 - e. Did participation have any adverse affects on the subject?

7. PREPARATION OF THE AUDIT REPORT AND FOLLOW-UP

After the audit is complete and all findings are analyzed and determined to be valid, a written report should be developed. It should be structured to be proactive and educational in nature by providing comments concerning the findings, strengths and weaknesses. The Campus IRB will make recommendations on how the investigator can resolve deficiencies, with reference to the relevant citations and Campus IRB policies.

The audit activities should include appropriate follow-up to ensure that deficiencies are corrected in a timely manner. The follow-up may include a Corrective Action Plan to address the deficiencies to appropriately protect the safety and welfare of human subject research participants.

- E. ADDITIONAL ASSURANCES

During the Campus IRB auditing activities, the staff will also:

1. Assure that the investigator(s) possesses the professional qualifications and experiences to adequately meet the degree of proposal complexity and risk to human subjects;
2. Assure that all Campus IRB applications are submitted in accordance with the ethical guidelines set forth in the Belmont Report, University of Missouri-Columbia’s FWA, and Federal regulations, and Campus IRB Standard Operating Policies and Procedures;
3. Assure that all applications are complete and provide supportive documentation;
4. Assure that all investigators complete the educational training that provides the guidance and directions to maintain the integrity of the human subject research activities under the jurisdiction of the Campus IRB;
5. Initiate an investigation into learned, suspected, or questionable commission of a wrongful act(s) within 5 business days of notice of the allegation;

Quality Assessment and Improvement
Policy Number 2876.40

6. Take every precaution necessary to adequately safeguard the protection of human subjects involved in research and to determine whether the issue raises a significant question of data integrity or reliability regarding the research project;
7. Initiate an audit of the research project which may include coordination between the Campus IRB, Campus IRB Authorized Representatives, and the Campus IRB Audit/Quality Assurance Team, to conduct an onsite inspection and any additional measures necessary, within reason, to verify compliance, including the scope and extent, of the suspected noncompliance activities -- and to safeguard the welfare and rights of human subjects involved in research;
8. May request the investigator(s) to provide documentation and appear before the Board to verify or address the noncompliance matter, including the scope and extent of the act(s) or result(s);
9. Assure no application is reviewed and approved until the Campus IRB is satisfied that the issues in question are resolved;
10. Investigate matters of application data reliability, or data integrity, safety, or efficacy concerns, until the Campus IRB satisfied that the issues in question are resolved;
11. Report the results of an investigation or monitoring outcome to the Office of Research; and
12. Retain all research records for a period of at least 3 years after the completion or termination of a project.

II. CONDUCTING AUDITS OF INTERNAL CAMPUS IRB PROCESSES

- A. The Campus IRB and staff shall review it's policies and procedures in an ongoing manner to assure compliance with current laws, regulations, and emerging ethical and scientific issues by developing a method to continually assess the quality of the human research protection program.
- B. The Campus IRB shall conduct an assessment of the internal review activities, documentation processes and record-keeping practices to create an efficient and effective system that promotes a culture of compliance.
- C. The Campus IRB eIRB system is an automated compliance structure that receives, organizes, stores records and monitors data submitted for prospective review and approval.
- D. The Campus IRB and staff shall assure that all review activities, documentation processes, and record-keeping practices are conducted in the absence of undue influence in compliance with the institutional and all Campus IRB policies.
- E. Assure the Campus IRB Membership and Staff periodic evaluations are recorded annually in compliance with the "Board Membership", "Board Chair" and "Administrative Staff" and "Record Keeping" policies.

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