

Noncompliance with Campus IRB Policies and Procedures  
Policy Number 2876.34



**Campus Institutional Review Board**  
University of Missouri-Columbia


**Noncompliance with Campus IRB Policies and Procedures**

Policy Number 2876.34

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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) shall provide a mechanism to immediately investigate reports of noncompliance to further protect study participants, and shall have the authority to take action to assure research activities are conducted in accordance with the regulations that govern human subject research.

**2.0 Scope**

All human subjects deserve respect, beneficence, and justice to assure the safety and welfare during participation in research. The procedures governing Noncompliance will apply to all human subject research being conducted under the jurisdiction of the University of Missouri-Columbia.

**3.0 Purpose**

The Campus IRB views noncompliance as potentially one of the highest risks exposed to subjects. Reports or notice of noncompliance shall receive priority consideration and review by the Campus IRB with the goal of assuring human subjects are protected.

**4.0 Standard Operating Procedure**

The Campus IRB is charged with adequately safeguarding all human subjects involved in research. All research involving human subjects, which is under the jurisdiction of the University of Missouri-Columbia, must receive prior Campus IRB approval. Noncompliance procedures will apply to any human subject research activity under the jurisdiction of the Campus IRB that does not comply with federal regulations and Campus IRB policies.

The Campus IRB will conduct its processes in accordance with the “Campus IRB Review Processes”, “Assessing the Level of Risk”, and “Privacy and Confidentiality”, “Complaints”, “Deviation”, and “Reporting” policies. The investigator must comply with these policies.

**DETERMINING NON-COMPLIANCE**

I. Definitions of noncompliance:

A. Noncompliance is defined as any failure to comply with any of the following governing human subject research activities:

- Federal, State or Local Law or regulations
- Ethical principles and guidelines provided in the Belmont Report
- Federalwide Assurance agreement
- University of Missouri Institutional policies and procedures
- Campus IRB Policies and Standard Operating Procedures
- Campus IRB guidance, determinations or decisions

B. Categories of Non-compliance may be minor, serious or continuous.

NOTE: The Campus IRB reserves the right to require the investigators to disclose acts of noncompliance to participants, sponsors, organizations, associations or institutions affiliated with the research activities proposed.

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1. Minor noncompliance is noncompliance that is considered diminutive or administrative in nature.

*Examples: Failing to date a consent form; Failure to forward a permission letter to the IRB after receiving it; and release of a URL that was approved by the IRB in hard copy but before the site was released to the IRB for access.*

2. Serious noncompliance is noncompliance that negatively affects a participants' rights and welfare, and/or negatively impacts the anticipated risks or benefits to research participants

*Examples: Conducting human subject research prior to IRB approval; continuing to conduct human subject research after IRB approval has expired; failing to obtain and document Informed Consent prior to conducting human subject research; subjecting research participants to undue influence and coercion practices; failure to maintain complete records in compliance with IRB policies and procedures; and intentional disregard and violation of IRB regulations and policies.*

3. Continuing noncompliance is noncompliance indicating a pattern of disregard, activities or omission of an act that indicates a lack of the ability or willingness to comply with the governing regulations, or that suggests that instances of noncompliance will continue without intervention.

*Examples: Habitual failure to timely submit Continuing Review Reports while continuing to conduct human subject research; patterns of practice whereby the investigator either frequently or routinely fails to follow IRB guidelines, directives or restrictions.*

**THE PROCESS FOR DETERMINING WHETHER THE ACTIVITY  
IS SERIOUS OR CONTINUING NON-COMPLIANCE**

II. How do you know there is an issue of NON-COMPLIANCE?

All human subject research key personnel are required to complete "Human Subject Research Training" before submitting an application to the Campus IRB via the eIRB electronic submission process. The system will not permit an investigator to electronically submit an application until the training certification is complete, and all key personnel listed on the application have also completed training.

How will the researcher learn of suspected, or that they engaged in research activities that are considered serious or continuing non-compliance?

The training modules include a specific session defining non-compliance, distinguishing between serious and continuing, and directing the researcher regarding the "process" to follow when noncompliance occurs. The training modules are also available on the website and readily available for public view to anyone accessing the site. The Campus IRB provides the information publicly to assure that subjects and research team members are aware of the IRB responsibilities associated with human subject research activities.

When can noncompliance occur? The Campus IRB will assess the activities to determine if they meet the definition of "Noncompliance." Noncompliance can occur whenever any IRB governing regulations, guidance, policies and procedures, or decisions have been violated. See DEFINITIONS of Noncompliance listed above. Acts of noncompliance are not limited to the researcher, and may result as a violation committed by a team member or failure to

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comply with administrative processes. If you suspect an act of noncompliance, you should contact the Campus IRB for immediate assistance at (573) 882-9585.

Who will tell me noncompliance occurred? The Campus IRB will make the determination of whether noncompliance has occurred once it has received notification, by 1) initiating an investigation into the allegation; and 2) Making a determination of findings from the investigation; and 3) Notifying the individual responsible and relevant to the breach of compliance. Investigators conducting human subject research must be responsible for the welfare and safety of participants, and be knowledgeable of the applicable rules, regulations, ethical standards and policies governing their research practices. The Campus IRB expects all researchers to be aware of the policies governing sound ethical research practices.

**CAMPUS IRB APPROACH:**

1. **Initiate an inquiry** into learned, suspected, alleged, or questionable commissions of noncompliance activities within 5 business days of receipt of notice to investigate any allegation of noncompliance. An allegation can be defined as any information contributing to an unproven assertion of noncompliance. Allegations of noncompliance may be communicated to the Campus IRB by a variety of sources or methods. An inquiry may consist of, but not limited to, any investigative fact finding methods that probe into the allegation of noncompliance and may aid in the determination of a finding.

NOTE: The Campus IRB Compliance Officer or Board Chair has the authority to initiate an inquiry into the allegation of noncompliance. If a board or staff member learns of an allegation of noncompliance, they should immediately report it to the Campus IRB Compliance Officer or Board Chair.

APPROACH

- a. Step 1: The Campus IRB Compliance Officer or Board Chair shall have the authority to initiate an inquiry into an allegation of noncompliance, and designate the appropriate resources to facilitate gathering the information necessary to support an informed review of the allegation of noncompliance.
- b. Step 2: The Campus IRB Compliance Officer or Board Chair shall have the authority to designate the appropriate resources to conduct an initial review of the allegation to determine if an act of noncompliance has occurred.
- c. Step 3: The Campus IRB shall have the authority to access any information from the research team that facilitates the investigation of noncompliance.

NOTE: Anonymous Callers. The Campus IRB will investigate allegations of noncompliance, even when the caller desires to remain anonymous. If the caller desires to remain anonymous, the Campus IRB recipient of the call should inform the caller that the matter will be investigated to the extent possible under the circumstances, and given the information provided. The recipient of the call should ask the caller for any available evidence that the caller is willing to give that will facilitate an investigation into the matter, but should not encourage the caller to provide a name or contact information if the caller has expressed a desire to remain anonymous. It is permissible to advise the caller to provide the IRB with follow-up details, or additional supportive information at a later date if necessary. The caller is encouraged to contact the IRB if new information becomes available or if the caller remembers details that were not presented originally. Every effort will be made to maintain the confidentiality and identity of the caller, when reasonably possible.

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2. **Make a determination of findings.** The investigation process shall result in a determination of findings of whether the allegation of noncompliance is proven. The Campus IRB Chair or Compliance Officer's "finding" determination must be the result of a fact-finding investigation according to this policy, based upon:
  - a. Step 1: Conducting an initial review of the noncompliance allegation, investigative materials and any supportive information that assists the decision-making process of whether noncompliance has occurred.
  - b. Step 2: If the activity is not deemed noncompliance, the Campus IRB will communicate to the investigator in writing in accordance with its policies and procedures.
  - c. Step 3: The determination of whether the noncompliance allegation is serious or continuing can be made by the Campus IRB Chair, Campus IRB Compliance Officer, or a convened Campus IRB.
  - d. Step 4: If the activity is deemed noncompliance, but not serious or continuing – the Campus IRB will communicate to the investigator in writing in accordance with its policies and procedures. The matter will be subject to the "expedited review" process.
  - e. Step 5: If the activity is deemed serious or continuing noncompliance– the Campus IRB will communicate this information to the investigator in writing in accordance with its policies and procedures. *The matter will be docketed on the next available convened board meeting.* The activities may include, but are not limited to:
    - i. What immediate actions need to be taken to protect the research participants or any individual involved or affected by the research project
    - ii. All noncompliance deemed to be serious or continuing must go before a convened Campus IRB for review and a final determination in accordance with its policies and procedures.

III. What are the research team member's responsibilities in findings of noncompliance?

- A. The research team and any individual under the jurisdiction of the Campus IRB shall comply with all Federal, State or Local Law, Institutional policies and procedures, Ethical principles and guidelines provided in the Belmont Report, Federalwide Assurance agreement, Campus IRB Policies and Standard Operating Procedures, or a Campus IRB approval determination regarding human subject research activities. When a FINDING of noncompliance has been determined, the research team member or individual under the jurisdiction of the Campus IRB shall comply with the following:
  1. Assure that the research project has provisions in place for the adequate protections of the rights and welfare of human subjects, and are in compliance with the Federal regulations, University of Missouri-Columbia's FWA, and Campus IRB Policies;
  2. Contact the Campus IRB immediately (within 5 days) and follow the directives provided by the Campus IRB;
  3. **Complete a Compliance Breach Report** within 5 days of becoming aware of the noncompliant activities. (See Campus IRB online system and complete a "Compliance Breach Report.")
  4. Attach any additional documentation or supportive materials that will assist the Campus IRB in reviewing the noncompliance activities(s);
  5. Provide the Campus IRB with information:
    - a. about the event;
    - b. the level of risk to the subject;
    - c. actions taken regarding how the investigator minimized the risk;
    - d. the impact on the subject(s);
    - e. any reports or documents describing the incident, treatment or observation;
    - f. the Corrective Action Plan;

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- g. any other information that will assist the IRB in making a determination regarding continuation of the research activities.
6. Be subject to an onsite audit evaluation by the Campus IRB to assess the adequacy of the procedures in place for protecting human research subjects; and
7. Provide the Campus IRB with any additional information or documentation necessary to continue to investigate and monitor the research activities to assure the safety and welfare of human subject participants.
8. All research team members and key personnel will be notified in writing of the Campus IRB directives.
9. Must schedule a Campus IRB live training session;
10. **Notification of Relevant Parties, Agencies, institutions, organizations, associations, affiliations of Reports and Findings of Serious or Continuing Noncompliance.**

If the activity involves cooperative institutions, associations, organizations, affiliations, the Campus IRB will notify them if the final determination of “serious or continuing noncompliance.”.

Once the Campus IRB has made a decision regarding the research activities, it may distribute a copy of the report to any federal agency or sponsor requiring separate reporting from that to OHRP within 30 days of the final decision. If the noncompliance is serious or continuing, the IRB shall notify OHRP within 30 days of the final decision.

11. Be subject to a follow-up onsite audit evaluation by the Campus IRB to assess the adequacy of the procedures in place for protecting human research subjects; and
12. Assure that all research records are accessible for inspection and copying by authorized Campus IRB representatives for at least 3 years after the termination or completion of the project.

**IF THE ACTIVITIES ARE DEEMED SERIOUS OR CONTINUING NONCOMPLIANCE**, the investigator must comply with all directives for noncompliance entitled, “What is the research team member’s responsibilities in findings of noncompliance?”, and the following additional requirements:

1. All research team members and key personnel will be notified in writing, that the activity is considered “Serious or Continuing Noncompliance”, and that the matter has been docketed for review by a convened Campus IRB. The research team members shall be available to address any concerns of the convened Campus IRB. The final determination shall be made by the convened Campus IRB.

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NOTE: All human subject research without PRIOR IRB approval has the potential to be considered as serious or continuing noncompliance.

Any investigator involved in human subject research that does not have prior Campus IRB approval, and is under the jurisdiction of the Campus IRB may be participating in research considered to be serious or continuing noncompliance with IRB standards. The investigator and research team must:

- a. Assure that the research project has provisions in place for the adequate protections of the rights and welfare of human subjects, and are in compliance with the Federal regulations, University of Missouri-Columbia's FWA, and Campus IRB Policies;
- b. Notify the Campus IRB as soon as possible within 5 days
- c. Follow the directives provided by the Campus IRB.

IV. Campus IRB Authority, Responsibilities and Actions in Noncompliance Issues

- A. Authority The Campus IRB shall have the authority to provide a mechanism to immediately investigate reports of noncompliance to further protect participants and take any action necessary to assure the research activities are conducted in accordance with the regulations that govern human subject research.
- B. Responsibilities:  
The Campus IRB shall:
  1. Comply with the aforementioned policies governing "Initiate an Inquiry into Noncompliance" AND "Make a Finding Determination" regarding Noncompliance.
  2. Assure that the investigator(s) possess the professional qualifications and experience to adequately meet the degree of proposal complexity and risk to human subjects;
  3. Shall assure the Compliance Breach Report is assigned to the Chair or designated IRB member:

**Research Team Member Attendance at the IRB Meeting:** The investigator may be asked or may choose to attend a meeting of the full IRB. The investigator would be scheduled to appear at the meeting only after the full IRB had the opportunity to discuss the issues and findings.

If the investigator initiates the request to attend the full IRB meeting, the request must be received by the IRB office (2) weeks in advance of the IRB meeting.

If the investigator attends the IRB meeting, the investigator shall have an opportunity to present a response to the IRB immediately following the presentation of the allegation and before the conclusion of the investigation.

*Note: During the investigation, the IRB may impose restrictions to the research study until satisfactory answers are received by the IRB.*

PRIMARY REVIEWER SYSTEM for Serious and Continuing Noncompliance:

The Campus IRB utilizes an electronic paperless system for review of human subject research activities. All IRB members will have access to review the entire file, including the investigation report, correspondence of any communication between the reviewers or research team and investigators, the approved consent, protocol, the last approved IRB application or Continuing Review Report, Amendments, Deviations, Compliance Breach and any other pertinent information.

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All members attending the IRB meeting will review ALL relevant documents and determine if more information is needed, or if enough information is available to make a final decision.

The convened Campus IRB will determine if:

1. If the investigator offers a timely and satisfactory explanation for how the matter occurred, and a plan to eliminate future incidents of such noncompliance.
2. The IRB elects to terminate the noncompliance investigation process and determine that the noncompliance issue was satisfactorily resolved with no further action.
3. The IRB elects to expand the noncompliance investigation process and receive additional information to determine when the noncompliance issue is satisfactorily resolved.
4. If the corrective action plan is acceptable, or if it calls for any changes to the previously approved research.
5. The convened board may determine that the change is only a minor modification that can be reviewed by expedited review.

FULL BOARD (Serious or Continuing)

- a. The administrative staff will DOCKET the Compliance Breach Report on the agenda of the next available Convened Campus IRB meeting and assign a primary reviewer;
- b. The Compliance Specialist assigned to the file will coordinate communications and file management activities between the reviewer and the research team to assure it is prepared for review at the meeting.
- c. The Campus IRB processes are a paperless system, and therefore all submissions are in electronic format. The Agenda will identify the IRB number for each item placed on the agenda. All members of the Campus IRB may access the IRB files that are scheduled for review at the meeting. If a member has a conflict of interest, the electronic system has a process whereby that particular member can be denied access to the file. A note will be placed in the file documenting why a member is denied access. The information is verbally communicated to the board. The information is also documented in the internal Campus IRB Administrative notes.
- d. The Primary Reviewer shall receive the Breach Report as soon as possible and have full access to the file via the electronic paperless system. The convened Campus IRB members may access ALL documents related to a proposal, which have been submitted by the investigator into the eIRB database.
- e. The reviewer is encouraged to respond as soon as possible to allow the investigator a sufficient amount of time to submit the requested information.
- f. The investigator is encouraged to respond to any additional requests from the reviewer as soon as possible, preferably within 3 calendar days, to permit the board membership the opportunity to timely review materials.
- g. Delays in the review process may occur if the primary reviewer doesn't feel there is a sufficient amount of information available to present the file to the board. The file will be categorized as "incomplete." Incomplete files do not receive priority review. The primary reviewer and Campus IRB have the authority to remove incomplete files from the docket, awaiting for the principal investigator's response. The investigator will be notified in writing when the file is incomplete and lacking a sufficient amount of information to be submitted to the convened board for review.
- h. The primary reviewer's identity will remain confidential;
- i. The primary reviewer will present the file history and description of the "Compliance Breach" to the board along with a recommended action, in the form of a motion, at the convened meeting;
- j. **PROCESS FOR SUPPLEMENTING THE PRIMARY REVIEWER'S REVIEW:** Any member present may communicate any concerns or questions noted from the review(s) and indicate the need for discussion of any issues they found during the review of the

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application or proposed consent. The Campus IRB retains “full authority” to request additional information and take any action necessary, secure consultants, guests or advocates to provide details to supplement the review *prior to making a decision*. Once all deliberations have ceased, an action vote in the form of a motion will be placed on the table;

- k. A decision will be rendered;
- l. The investigator(s) will receive written notice of the Board’s decision on the proposal in a timely manner.

If the Campus IRB Chair or Compliance Officer determines that the noncompliance activity can be reviewed at the EXPEDITED level, the Campus IRB office staff shall:

- a. Correspond with the reviewer to determine if additional information is needed to make a decision on the action of the noncompliance activity. If additional information is needed, the Campus IRB office will communicate the requested items to the investigator(s);
- b. Comply with “IRB Review Process” policies and procedures.
- c. Retain all correspondence in the file.

**C. ACTIONS TAKEN DURING OR AFTER THE INVESTIGATION PROCESS:**

The Campus IRB shall take any action necessary to assure the research activities are conducted in accordance with the regulations that govern human subject research. The actions taken upon a Compliance Breach will be in compliance with the “CIRB Review Process” Policy. See Policy for ACTIONS taken.

**ADDITIONAL ACTIONS:**

The Campus IRB may:

- 1. Request that the investigator(s):
  - a) modify the research protocol;
  - b) modify the consent process;
  - c) provide additional information to previous or current participants;
  - d) notify participants of the noncompliance activity when such information may relate to their willingness to continue to take part in the research;
  - e) re-consent the participants; and/or
  - f) provide more information for IRB review.
  - g) Modify the Continuing Review Interval/or Process
- 2. Monitor the research and/or consent process.
- 3. Require a new application to be submitted for IRB review and approval.
- 4. Consult with Legal Counsel.
- 5. Initiate audit of all or some of the investigator’s active human subject research activities.
- 6. Take no action.

**REPORTING REQUIREMENTS:**

The Campus IRB shall report all findings of Serious and Continuing Noncompliance to the Vice-Chancellor for Research, appropriate Federal departments or agencies, and OHRP by the appropriate methods in compliance with the Campus IRB “Reporting” policy.

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