



Campus Institutional Review Board
University of Missouri-Columbia


Complaint Procedures

Policy Number 2876.37

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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) shall provide a mechanism to investigate a complaint made regarding any human subject research activity, investigator, or IRB processes as soon as possible, but no later than 5 business days, in an effort to assure the safety and welfare of research participants.

2.0 Scope

All human subjects deserve respect, beneficence, and justice through practices that assures their safety and welfare during participation in research by implementing a “Complaint Procedure” to encourage communications, concerns or suggestions regarding the Human Research Protection Program and processes. This policy is applicable to all human subject research being conducted under the jurisdiction of the Campus IRB University of Missouri-Columbia.

3.0 Purpose

The Campus IRB is charged with protecting human subject participants by assuring that research activities are conducted in a culture of compliance in accordance with mission of the IRB by providing a mechanism for receiving and addressing complaints, concerns or suggestions.

4.0 Standard Operating Procedure

The Campus IRB will make every effort to maintain a safe, confidential, and reliable channel for current, prospective, or past participants or their designated representatives to discuss issues or obtain information; make recommendations; discuss a confidential matter with an individual who is unaffiliated with a specific research protocol, or if necessary, who is part of the research team.

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

The Campus IRB will review any complaints that threaten the integrity of any of the following:

- a. Federal regulations set forth in 45 CFR 46;
- b. Ethical principles and guidelines included in the Belmont Report;
- c. Federalwide Assurance agreement;
- d. Campus IRB’s Standard Operating Procedures; and/or
- e. Campus IRB’s approval agreement.

All complaints will be reviewed as soon as possible, but no later than 5 business days.

I. CATEGORIES OF COMPLAINTS

A. COMPLAINTS ABOUT THE INVESTIGATOR

The Informed Consent process MUST provide prospective participants with contact information for the Campus IRB, as a person independent of the research team, in the event the research staff can’t be reached; or the participant wishes to speak with someone other than the research team about question/concern/or complaints about the research team.

When the Campus IRB receives a complaint about the investigator, the issue will be triaged internally from the Compliance Specialist, and communicated to the Compliance Officer as soon as possible, but no later than 5 business days.

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1. The Compliance Officer, in cooperation with Campus IRB Chair, will review the complaint and discuss the matter.
2. The Compliance Officer will initiate the investigation process by:
 - a. Requesting information from the complainant
 - b. Maintaining the confidentiality of the complainant, as much as reasonably possible.
 - c. The complainant may “waive” confidentiality at anytime
 - d. Requesting information from the investigator

NOTE: The Investigator should provide a mechanism for the participant to contact them or someone else in the event the investigator is not available. While it may not initially be a complaint, failure to communicate with the researcher may progress to a complaint if not resolved. The IRB encourages the research team to provide a backup contact individual in case the primary investigator is unavailable.

- e. Conducting a file review
- f. Proceeding through the review of the investigative materials to effectuate a determination
 1. If the Campus IRB determines that the Complaint is an unanticipated problem involving risks to participants or others, the Campus IRB shall comply with the “Unanticipated Problems or Adverse Events Review Process” policy.
 2. If the Campus IRB determines that the Complaint is a Compliance Breach, it shall comply with the “Compliance Breach” Policy.
 3. The Campus IRB will comply with the “Review Process” Policy where applicable.
 4. The Campus IRB will comply with the “Reporting Requirements” policy.
- g. Render a decision
- h. Refer the file to a reviewer for determination if necessary
- i. Refer the file to the convened board for determination if necessary.
- j. Document in the file accordingly

B. COMPLAINTS ABOUT RESEARCH TEAM ACTIVITIES OR PROCESS

The Complaint Process and Informed Consent should document procedures implemented to provide the subject with an opportunity to ask questions and voice concerns or complaints to the investigator.

1. The Informed Consent process **MUST** provide prospective participants with contact information for a research team in the event they want to ask questions and voice concerns or complaints to the investigator
2. The Informed Consent process **MUST** provide prospective participants with contact information for the Campus IRB, as a person independent of the research team, in the event the research staff can’t be reached; or the participant wishes to speak with someone other than the research team about question/concern/or complaints about the research team.
3. If the PI hosts a website, it should contain this information also.

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PROCESS FOR REVIEW

1. The Compliance Officer, in cooperation with Campus IRB Chair, will review the complaint and discuss the matter in compliance with the “Review Process Policy.”
2. The complainant (investigator, subject, research team or staff) may contact the Compliance Officer (573-882-9585) OR the Associate Vice-Chancellor of Research (573-882-9500) to discuss report, identify or make suggestions about the human subject research program.
 - a. The complainant must provide information to assist with the assessment
 - b. The complainant may either identify themselves or report the matter anonymously (recognizing that follow-up may be compromised)
3. The Compliance Officer will initiate the investigative review process by:
 - a. Gathering information from the complainant
 - b. Maintaining the confidentiality of the complainant, as much as reasonably possible.
 - c. The complainant may “waive” confidentiality at anytime
 - d. Gathering information from the investigator
 - e. Conducting a file review
 - f. Proceeding through the review of the investigative materials to effectuate a determination
 1. If the Campus IRB determines that the Complaint is an unanticipated problem involving risks to participants or others, the Campus IRB shall comply with the “Unanticipated Problems or Adverse Events Review Process” policy.
 2. The Campus IRB will comply with the “Review Process” Policy where applicable.
 3. The Campus IRB will comply with the “Reporting Requirements” policy.
 - g. Render a decision
 - h. Refer the file to a reviewer if necessary
 - i. Refer the file to the convened board if necessary.
 - j. Refer the file to the Office of Research Associate Vice-Chancellor if necessary
 - k. Document in the file accordingly

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.

NOTE: The Investigator shall provide a mechanism for the participant to contact them or someone else in the event the investigator is not available. While it may not initially be a complaint, failure to communicate with the researcher may progress to a complaint if not resolved. The IRB encourages the research team to provide a backup contact individual in case the primary investigator is unavailable.

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C. COMPLAINTS ABOUT AN IRB MEMBER OR STAFF COMPLAINTS

1. The Compliance Officer, in cooperation with Campus IRB Chair, will review the complaint and discuss the matter.
2. The complainant (investigator, subject, research team or staff) may contact the Compliance Officer (573-882-9585) OR the Associate Vice-Chancellor of Research (573-882-9500) to discuss, report, identify or make suggestions about the human subject research program.
 - a. The complainant must provide information to assist with the assessment
 - b. The complainant may either identify themselves or report the matter anonymously (recognizing that follow-up may be compromised)
3. The Compliance Officer will initiate the review process by:
 - a. Gathering information from the complainant
 - b. Maintaining the confidentiality of the complainant, as much as reasonably possible.
 - c. The complainant may “waive” confidentiality at anytime
 - d. Gathering information from the member or staff
 - e. Conducting an investigation and review
 - f. Proceeding through the review of the materials to effectuate a determination
 1. If the Campus IRB determines that the Complaint is an unanticipated problem involving risks to participants or others, the Campus IRB shall comply with the “Unanticipated Problems or Adverse Events Review Process” policy.
 2. The Campus IRB will comply with the “Review Process” Policy where applicable.
 3. The Campus IRB will comply with the “Reporting Requirements” policy.
 - g. Render a decision
 - h. Refer the incident to the Office of Research if necessary due to:
 - 1) Conflicts of Interest
 - 2) The complaint goes to the essence of Departmental Standards (i.e. Academic in Nature)
 - i. Refer the file to the convened board if necessary.
 - j. Document in the file accordingly

D. COMPLAINTS ABOUT CAMPUS IRB REVIEW PROCESSES

1. The Compliance Officer, in cooperation with Campus IRB Chair, will review the complaint and discuss the matter.
2. The complainant (investigator, subject, research team or staff) may contact the Compliance Officer (573-882-9585) OR the Associate Vice-Chancellor of Research (573-882-9500) to discuss report, identify or make suggestions about the human subject research program.
 - a. The complainant must provide information to assist with the assessment
 - b. The complainant may either identify themselves or report the matter anonymously (recognizing that follow-up may be compromised)
3. The Compliance Officer will initiate the review process by:
 - a. Gathering information from the complainant
 - b. Maintaining the confidentiality of the complainant, as much as reasonably possible.
 - c. The complainant may “waive” confidentiality at anytime
 - d. Gathering information from the member or staff
 - e. Conducting an investigation and review

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- f. Proceeding through the review of the materials to effectuate a determination
 - 1. If the Campus IRB determines that the Complaint is an unanticipated problem involving risks to participants or others, the Campus IRB shall comply with the “Unanticipated Problems or Adverse Events Review Process” policy.
 - 2. The Campus IRB will comply with the “Review Process” Policy where applicable.
 - 3. The Campus IRB will comply with the “Reporting Requirements” policy.
- g. Render a decision
- h. Refer the incident to the Office of Research if necessary due to:
 - 1) Conflicts of Interest
 - 2) The complaint goes to the essence of Departmental Standards (i.e. Academic in Nature)
- i. Refer the file to the convened board if necessary.
- j. Document in the file accordingly

E. UNDUE INTERFERENCE WITH THE IRB REVIEW PROCESSES

- 1. The Compliance Officer, in cooperation with Campus IRB Chair, will review the complaint and discuss the matter.
- 2. The Compliance Officer will initiate the review process by:
 - a. Gathering information from the complainant
 - b. Maintaining the confidentiality of the complainant, as much as reasonably possible.
 - c. The complainant may “waive” confidentiality at anytime
 - d. Gathering information from the member or staff
 - e. Conducting an investigation and review
 - f. Reporting the matter to the Associate Vice Chancellor of Research
 - g. Await a decision
 - h. Document in the file accordingly

F. INVESTIGATOR QUESTIONS, CONCERNS OR SUGGESTIONS

- 1. The Investigator may contact the Campus IRB and discuss any questions, concerns or suggestions that it has regarding the IRB processes.
- 2. If the investigator desires to contact someone outside the Campus IRB, they may contact the Office of Research (OR), Associate Vice Chancellor of Research/Director of Compliance or the Vice Chancellor of Research regarding questions, concerns or suggestions regarding the Campus IRB activities, processes, or staff matters.
- 3. The Office of Research (OR) shall provide the Investigator with a response according to OR policies and procedures.
- 4. The Office of Research and Campus IRB will communicate regularly to discuss IRB processes and may coordinate efforts to address the questions, concerns or suggestions.

II. MAKING A DETERMINATION: IS THE MATTER AN UNANTICIPATED PROBLEM OR ADVERSE EVENTS INVOLVING RISKS TO PARTICIPANTS OR OTHERS?

- A. The Campus IRB “intake” recipient of the information will review the complaint and initiate the process for determining whether it is an unanticipated problem or adverse event involving risks to the participants or others in compliance with the “Unanticipated Problems or Adverse Events” and “CIRB Review Process” policy.

III. ADDITIONAL APPLICABLE POLICIES REQUIRING COMPLIANCE

The investigator shall comply with the additional policies listed below in accordance with the Campus IRB policies and procedures:

- A. Campus IRB "Review Process"
- B. Unanticipated Problems or Adverse Events Review Process
- C. Reporting Requirements

IV. INTERNAL PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

The Campus IRB will review all complaints as soon as possible, but no later than 5 business days and assure that the complainant receives followup communication. The Campus IRB will also comply with the Campus IRB Review Process, Unanticipated Problems or Adverse Events Review Process, and Reporting Requirements policies if applicable. If the complaint creates a conflict of interest or the complainant desires to address the matter "outside" of the Campus IRB, the matter will immediately forwarded to the Office of Research.

Revised December 2006

Revised June 2007

Revised December 2007