

Deviation Review Process
Policy Number 2876.31



Campus Institutional Review Board
University of Missouri-Columbia


Deviation Review Process

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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

1.0 Policy

The Campus Institutional Review Board (Campus IRB) appreciates that unforeseen circumstances may arise that require a researcher to deviate from the IRB approved methodology, in the best interest of the safety of a human subject research participant. It is paramount that the researcher grants top priority to assuring the subject's safety and welfare, followed by immediate contact to the Campus IRB. It is the policy of the Campus IRB that the researcher must report all deviations from the IRB approved research proposal and await a determination in accordance with this policy.

2.0 Scope

The deviation review process applies to all human subject research being conducted under the jurisdiction of the University of Missouri-Columbia that requires review and approval of the Campus IRB.

3.0 Purpose

The Campus IRB must prospectively review all research proposals, revisions, continuing reviews, and activities. When an unforeseen circumstances warrants the need for a researcher to deviate beyond the scope of the IRB approved research, the Campus IRB must be notified immediately to assess the situation for further directives to further protect human subject research.

4.0 Standard Operating Procedure

Investigators must complete the Deviation Report when extenuating circumstances has resulted in a deviation from the IRB approved methodology. The investigator(s) must comply with the Campus IRB Deviation Process policy and immediately report any new developments or changes related to the research to the Compliance Campus IRB.

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.

A. UPON NOTIFICATION, the Campus IRB is required to take immediate action by addressing the following:

1. Assure that the investigator(s) possess the professional qualifications and experience to adequately meet the degree of proposal complexity and risk to human subjects;
2. Inquire into the nature of the deviation; and
3. Request that the Deviation Report be submitted within 5 days.

The Campus IRB DEVIATION REVIEW PROCESS is as follows:

The Campus IRB must comply with the "Campus IRB Review Process" policy when reviewing Deviation Reports.

The Campus IRB must:

1. Review the Deviation Report to assess the level of risk to the subjects;
2. Review the Deviation Report and assess to determine if the problem was an unanticipated problem involving risks to participants or others in compliance with the "Unanticipated Problems or Adverse Events Review Process" policy.
3. The Campus IRB will comply with the "Reporting Requirements" policy, if applicable.

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4. Determine if the status of the project should remain active or be suspended or terminated to further protect human subjects;
5. Require the Campus IRB to review the status of the project, depending on the seriousness of the deviation, if necessary;
6. Conduct an audit evaluation of the research project, if necessary;
7. Decrease the approval period interval, if necessary; and
8. Require monitoring and reporting intervals from the investigator(s), if necessary.
9. SEE "Campus IRB Review Process" policy for ACTIONS taken by the Campus IRB.

B. ADDITIONAL APPLICABLE POLICIES REQUIRING COMPLIANCE

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

1. 2876.20 Campus IRB "Review Process"
2. 2876.32 Unanticipated Problems or Adverse Events Review Process
3. 2876.36 Reporting Requirements

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