University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #10	**TITLE: Deviations and Exceptions - IRB Review of Changes**		**Page 1 of 4**
Approved By: ORI Director	Signature	Date	Date First Effective: 05-15-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 03-15-19

Previously a part of SOP C2.0300 Modification – IRB Review of Changes

OBJECTIVE

To describe the policies and procedures for requesting IRB review of a one-time deviation from the currently approved protocol or one-time exception to the currently approved enrollment criteria prior to implementation.

GENERAL DESCRIPTION

Investigators must obtain prospective IRB approval for deviations from the IRB approved protocol or research procedures, except where necessary to eliminate apparent immediate hazards to the subject. Investigators are responsible for obtaining both IRB approval and if applicable, sponsor approval prior to implementing a deviation/exception. Investigators are responsible for compliance with sponsor or local policies prohibiting protocol exceptions (i.e., National Cancer Institute).

Definitions

Exceptions or *deviations* are one-time changes that impact individual subjects and do not change the overall protocol. Investigators may not implement these changes without prior IRB review and approval except where necessary to eliminate apparent hazards to the subject(s).

The IRB considers the enrollment of a research subject in a protocol who either fails to meet current IRB approved protocol inclusion criteria or who falls under protocol exclusion criteria to be a protocol *exception*.

The IRB considers a departure from the current IRB approved procedures that impact an individual subject to be a protocol *deviation*.

If the investigator makes and implements protocol changes (i.e., exceptions or deviations) without prior IRB approval in order to eliminate apparent hazards to the subject(s), the investigator must immediately report the changes to the IRB. The IRB will review the changes and make a determination as to whether the changes are consistent with the subject's continued welfare (See Protocol Violations SOP).

RESPONSIBILITY

Execution of SOP: Principal Investigators (PI)/Study Personnel (SP), IRB Chair, IRB, Office of Research Integrity (ORI) Staff, ORI Research Privacy Specialist

PROCEDURES

Submission of Deviations and Exceptions

1. The PI is responsible for submitting a deviation/exception request to the study sponsor, as applicable, and the IRB prior to the implementation of any change.

2. The PI answers all questions on the Deviation or Exception Form.

3. The PI includes additional documentation to be considered for approval, when applicable.

Screening of Submissions

1. ORI staff screen the deviation/exception for completeness and accuracy. ORI staff request additional information from the PI as necessary.

2. If UK is the reviewing IRB for a reliance study, ORI staff contact the Reliance Team to determine if the proposed deviation or exception conflicts with the reliance agreement/communication plan and/or local context form.

3. ORI staff ensure relevant materials are available for IRB review as needed if the deviation/exception adds vulnerable populations or requires documentation of specific regulatory findings.

4. ORI staff may also secure additional review (i.e., prisoner representative) depending on the nature of the requested change. The reviewer in such cases is responsible for applying the applicable regulatory requirements or ethical principles.

5. ORI staff select the IRB Chair or other IRB member as the primary reviewer.

6. ORI staff screen for compliance with HIPAA regulatory requirements. ORI staff assign the deviation/exception to the Research Privacy Specialist (RPS) to review the submission in accordance with the HIPAA in Research SOP when applicable.

Expedited Review Procedures

1. The IRB Chair or other IRB member conducts a deviation or exception request review using expedited procedures if the requested changes are minor. A minor change is one which makes no substantial alteration in:
   - The level of risk to subjects;
   - The research design or methodology;
   - The subject population;
   - Qualifications of the research team;
   - The facilities available to support the safe conduct of the research; or
   - Any other factor that would warrant review of the proposed changes by the convened IRB

2. The IRB Chair or designated IRB member reviews the deviation or exception undergoing expedited review using standard expedited review procedures. The expedited reviewer exercises all the authority of the IRB except the reviewer cannot disapprove the research. The listing of the item on an agenda for the convened IRB serves to advise the IRB of the expedited review.

3. The IRB Chair or designated IRB member is responsible for reviewing the proposed deviation or exception request, determining whether the research continues to fulfill the criteria for IRB approval, and documenting his/her determinations on the Protocol Deviation/Exception Signature Page.

Full Review Procedures

1. ORI staff place the deviation or exception request on an agenda for a convened meeting, following procedures outlined in the Initial Full Review SOP when the request involves substantial deviations or exceptions, an IRB Chair or designated IRB member recommends full review, or the sponsor or PI specifically request full review procedures.

2. ORI staff invite the PI to attend the meeting if the IRB requires that he/she attend. The convened IRB reviews the deviation or exception request following procedures outlined in the Initial Full Review SOP and applies the federal criteria for approval as applicable to the request.

3. Approximately 5-10 days prior to the meeting, ORI staff close the agenda. The deviation or exception request becomes available to the full board for review.

4. The IRB Chair or designated IRB member who serves as the primary reviewer reports recommendations to the IRB at the convened meeting. The IRB Chair or designated IRB member makes recommendations on issues he/she determines do not meet the federal criteria for approval, involve controverted issues, or need additional information. If the IRB Chair or designated IRB member is unable to attend the meeting, written comments or recommendations are provided to the IRB at the convened meeting.

5. The convened IRB reviews and votes on the deviation or exception request consistent with procedure outlined in the Initial Full Review SOP. The IRB chair or designated IRB member documents the IRB determination on the Protocol Deviation/Exception Signature Page.

Review Outcome(s)

1. ORI staff notify the PI of the IRB's decision following the procedures in the Initial Full and Initial Expedited Review SOP.

2. The end date of the protocol approval period remains the same as that assigned during initial or continuation review when the IRB approves a deviation or exception request.

3. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit his/her concerns via a written appeal that includes justification for changing the IRB decision. The PI sends the request to the ORI. The expedited reviewer, IRB Chair, or convened IRB review the appeal. The appeal determination is final.

REFERENCES

21 CFR 56.110(b)(2)
45 CFR 46.110(b)(2)
45 CFR 46.111
21 CFR 56.111
21 CFR 312
21 CFR 812