University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #7	**TITLE: Termination or Suspension of Research by the IRB**		**Page 1 of 4**
Approved By: ORI Director	Signature	Date	Date First Effective: 07-08-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 07/08/2011

OBJECTIVE

To describe policies and procedures for suspending or terminating research approved by the Institutional Review Board (IRB)

GENERAL DESCRIPTION

The convened IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB approval, that has been associated with serious or continuing noncompliance, or that has been associated with substantive harm to the rights and welfare of human subjects. Any suspension or termination of approval shall include a statement of the reason for the IRB action.

The IRB Chair or designee has the authority to request that the IRB suspend approval when the continuation of the research may adversely affect the rights and welfare of research subjects or when the IRB needs additional information to ensure that the rights and welfare of subjects are protected and there is insufficient time to have the convened IRB review the situation.

The IRB reports the suspension or termination promptly to the investigator and appropriate institutional official(s). If the research is funded by an extramural agency, federal regulations dictate whether the funding agency must be informed that IRB approval has been suspended or terminated. Principal investigators (PIs) are responsible for informing the funding agency of any suspension or termination of funded research.

Reporting to federal regulatory agencies is not required if the PI voluntarily closes down a study to new subject accrual or temporarily halts the research procedures. The IRB, IRB Chair, Office of Research Integrity (ORI), or administrative officials may recommend voluntary closure to the PI, but the PI makes the decision whether closure is appropriate. However, if the IRB or IRB Chair requires suspension or termination, then the incident is reportable under the Mandated Reporting to External Agencies SOP.

Definitions

A *suspension* of IRB approved research is a temporary interruption in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

A *termination* of IRB approval refers to a permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

RESPONSIBILITY

Execution of SOP: IRB, IRB Chair, Office of Research Integrity Staff, Principal Investigator/Study Personnel

PROCEDURES

Suspension of IRB Approval

1. The convened IRB determines and documents in the minutes the reasons for suspending the research and any information needed from the PI and/or corrective actions or events that need to take place for the IRB to consider a withdrawal of the suspension.

2. If the IRB Chair or designee suspends IRB approval, the IRB Chair documents the reason for suspension and notifies the PI in writing or requests that ORI staff prepare the correspondence. ORI staff inform the IRB, and the IRB discusses the suspension at a convened meeting.

3. If UK is the reviewing IRB for a reliance study, ORI staff informs the Reliance Team who notifies the relying institution according to the reliance agreement, communication plan, or local context form.

4. When a suspension involves the withdrawal of current subjects from a research protocol, the IRB considers alternatives that protect subjects currently enrolled to ensure that harm is not incurred from such withdrawal. Such considerations may include possible transfer of subjects to another investigator, arrangement of clinical care outside the research, continuation of some research activities under the supervision of an independent monitor, permitting follow-up of subjects for safety reasons, or requiring reporting of adverse events or outcomes to the IRB and the sponsor.

5. ORI staff notify the PI in writing of the suspension. The correspondence may include, but is not limited to, the following:

- An explanation of the extent of the suspension in terms of enrollment, recruitment, interventions, interactions, and data analysis;
- The reasons for the suspension, an explanation of the reasons for the decision, and an offer to the investigator to respond to the convened IRB in writing;
- A request for a description of any procedures needed to protect the rights and welfare of current subjects if the suspension involves currently enrolled subjects;
- A description of whether follow-up of subjects for safety reasons is permitted or required.

6. The PI notifies enrolled subjects of any suspended research protocol, and the PI considers the appropriate procedures for withdrawal of enrolled subjects, taking into account their rights and welfare. (See Principal Investigator Responsibilities Guidance Document.)

6. The IRB determines which institutional officials to notify of the suspension and whether to report the suspension to an external agency. (See Mandated IRB Reporting to External Agencies SOP.) Also, ORI staff send copies of suspension correspondence to other UK administrative units in accordance with the coordination SOPs (e.g., Institutional Biosafety Committee, Markey Cancer Center, Radiation Safety Committee, Investigational Drug Service, and the Office of Sponsored Projects Administration).

Termination of IRB Approval

1. The convened IRB determines and documents in the minutes the reasons for terminating the research.

2. When a termination involves the withdrawal of current subjects from a research protocol, the IRB considers alternatives that protect subjects currently enrolled to ensure that harm is not incurred from such withdrawal. Such considerations may include possible transfer of subjects to another investigator, arrangement of clinical care outside the research, continuation of some research activities under the supervision of an independent monitor, permitting follow-up of subjects for safety reasons, or requiring reporting of adverse events or outcomes to the IRB and the sponsor.

3. ORI staff notify the PI of the termination. The notification may include, but is not limited to, the following:
   - An explanation of the extent of the termination in terms of enrollment, recruitment, interventions, interactions, and data analysis;
   - The reasons for the termination, an explanation of the reasons for the decision, and an offer to the investigator to respond to the convened IRB in writing;

- A request for a description of any procedures that need to be followed to protect the rights and welfare of current subjects if the termination involves currently enrolled subjects;
- A description of whether follow-up of subjects for safety reasons is permitted or required;
- An explanation that any request for the IRB to reconsider the termination must be made within 30 days from date of the notification.

4. The PI notifies enrolled subjects of any termination of a research protocol, and the PI considers the appropriate procedures for withdrawal of enrolled subjects, taking into account their rights and welfare. (See Principal Investigator Responsibilities Guidance Document)

5. The IRB determines which institutional official to notify of the termination and whether a report to an external agency is required (See Mandated Reporting to External Agencies SOP). Also, ORI staff send copies of the termination notification to other administrative units in accordance with the coordination SOPs (e.g., Institutional Biosafety Committee, Markey Cancer Center, Radiation Safety Committee, Investigational Drug Service, and the Office of Sponsored Projects Administration).

6. If UK is the reviewing IRB for a reliance study, ORI staff informs the Reliance Team who notifies the relying institution according to the reliance agreement, communication plan, or local context form.

Reporting and Recordkeeping of Suspension or Termination

1. See the Mandated Reporting to External Agencies SOP for a description of policies and procedures regarding reporting and recordkeeping of UK studies.

REFERENCES

21 CFR 56.113
45 CFR 46.113