University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
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Approved By: ORI Director	Signature	Date	Date First Effective: 04-08-13
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	
Approved By: Center for Clinical and Translational Science Director	Signature	Date	Revision Date

OBJECTIVE

To describe the procedures for coordination of human subject protection activity between the Institutional Review Board (IRB)/Office of Research Integrity (ORI) and the Center for Clinical and Translational Science (CCTS) on research studies and their protocols to be conducted at the University of Kentucky (UK) CCTS.

GENERAL DESCRIPTION

Both the CCTS and the IRB are committed to ensuring the protection of human subjects involved in clinical research. This SOP describes the coordination activities that have been enacted between the CCTS and IRB to ensure effective communication of issues during the course of a clinical research trial and include: protocol review; data safety monitoring, quality assurance/improvement findings.

RESPONSIBILITY

Execution of SOP: CCTS staff, CCTS Director Regulatory Support and Research Ethics, IRB Members, ORI Staff, ORI Quality Improvement Program (QIP) Coordinator, ORI Research Compliance Officer (RCO), Principal Investigator (PI)/Study Personnel, Clinical Services Core Review Committee (CSCRC), Data and Safety Monitoring Board (DSMB).

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PROCEDURES

Protocol Review Procedures

1. Investigators submit proposed protocol to the IRB in accordance with IRB SOP for initial review. Investigators are responsible for indicating in the IRB application that the study is supported by CCTS.

2. ORI staff schedule the IRB application for review and the IRB proceeds with review in accordance with IRB SOP for initial review.

Complaints and Alleged Noncompliance

1. Research subjects, family members, or others may report any serious complaint concerning subject rights and welfare or make allegations of investigator noncompliance in a CCTS trial to the ORI Research Compliance Officer as outlined in IRB standard operating procedures.

2. If the CCTS receives a complaint, concern or allegation from a subject, subject family member, staff, or researcher concerning alleged noncompliance or issues with subject rights and welfare, involving a CCTS trial, the CCTS Director, Regulatory Support and Research Ethics or designee, informs the ORI RCO immediately (i.e., within 2 days). The CCTS Director, Regulatory Support and Research Ethics may confer with the ORI RCO to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, CCTS, or both.

3. The ORI RCO handles the complaint, concern, or allegation in accord with standard IRB/ORI operating procedures.

4. At the completion of the IRB review of the complaint, concern, or alleged noncompliance regarding a CCTS trial, the ORI RCO provides the CCTS Director Regulatory Support and Research Ethics with a copy of the final IRB deliberation and any federal reports submitted as a result of the allegation. The CCTS Director, Regulatory Support and Research Ethics disseminates the copy of the final deliberation and/or federal report to the Director of the CCTS.

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Quality Assurance/Improvement Findings

1. If the ORI Quality Improvement Program (QIP) Coordinator conducts a directed or routine Quality Improvement Review of a CCTS trial, the QIP Coordinator provides the CCTS Director, Regulatory Support and Research Ethics a copy of the final report within 15 working days of final review. The CCTS Director, Regulatory Support and Research Ethics disseminates a copy to the CCTS and appropriate personnel in accord with standard CCTS operating procedures.

2. If the CCTS QA auditor, during a routine or "for cause" audit, identifies: 1) evidence that research subjects have been placed at significant risk of harm or the welfare of subjects have been jeopardized, and 2) that the finding has not previously been reported to the RCO/IRB, the CCTS Director, Regulatory Support and Research Ethics notifies the RCO within 24 hours of identification of the issue.

3. If the CCTS DSMB suspends or terminates a study, the Chair of the CCTS DSMB notifies the RCO within 2 working days of suspension or termination of a study.

4. The CCTS Director, Regulatory Support and Research Ethics (or designee) forwards an electronic copy of the routine or "for cause" audit report to the RCO within 15 working days of final review by the DSMB. The CCTS DSMB Chair (or designee) forwards an electronic copy of the suspension or termination report to the RCO within 15 working days of final review by the CCTS DSMB. The RCO forwards the report to the IRB and/or the ORI Director in accord with standard ORI operating procedures.

REFERENCES

Unanticipated Problem/Adverse Event SOP
Termination and Suspension of Research by the IRB SOP
Mandated Reporting to External Agencies SOP