

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: 05-31-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	
Approved By: Markey Cancer Center Director/CEO	Signature	Date	
Approved By: Markey Cancer Center Associate Director for Clinical Research	Signature	Date	Revision Date: 12-15-09

OBJECTIVE

To describe the procedures for coordination between the Institutional Review Board (IRB)/Office of Research Integrity (ORI) and the Markey Cancer Center (MCC) on protocols to be conducted at the University of Kentucky (UK) MCC

GENERAL DESCRIPTION

Both the Markey Cancer Center and the IRB are committed to ensuring the protection of human subjects involved in clinical research. They have enacted a number of coordination activities in significant areas including: protocol review; complaints and alleged noncompliance; quality assurance/improvement findings.

RESPONSIBILITY

Execution of SOP: MCC Staff, MCC Director/CEO, MCC Associate Director for Clinical Research or designee, IRB Members, ORI Staff, ORI Quality Improvement Program (QIP)

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Coordinator, ORI Research Compliance Officer (RCO), Principal Investigator (PI)/Study Personnel, Protocol Review Committee (PRC).

DEFINITIONS

National Cancer Institute (NCI) and the Markey Cancer Center define *clinical trial* as a type of research study that tests how well new medical approaches work in people. These studies test new methods of screening prevention, diagnosis, or treatment of a disease. Examples include therapeutic and prevention intervention or non-intervention trials (e.g, patient records, epidemiologic/observation, screening, early detection diagnostic studies).

PROCEDURES

Protocol Review Procedures

1. Investigators submit proposed cancer clinical trials to the IRB in accord with IRB SOP.
2. ORI staff screen IRB applications to determine whether the study involves cancer research and if so, forward a copy of the IRB submission to the PRC.
3. The PRC is responsible for determining whether the study meets NCI definition of a clinical trial and for issuing documentation to the investigator which confirms either that PRC approval has been obtained or that PRC review is not required.
4. ORI staff schedule the IRB application for review and the IRB proceeds with review in accord with IRB SOP independent of the PRC 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 cancer clinical trial to the ORI Research Compliance Officer following IRB standard operating procedures.
2. The ORI RCO handles the complaint, concern, or allegation in accord with standard IRB/ORI operating procedures.
3. At the completion of the IRB review of the complaint, concern, or alleged noncompliance regarding a cancer clinical trial, the ORI RCO provides the Associate Director for Clinical Research with a copy of the final IRB deliberation and any federal reports submitted as a result of the allegation. The MCC Associate Director for Clinical Research disseminates the

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copy of the final deliberation and/or federal report to the Director of the MCC in accord with standard MCC operating procedures.

4. If the MCC 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 of human subjects, involving a cancer clinical trial, the Associate Director for Clinical Research, or designee, informs the ORI RCO immediately (i.e., within 2 days). The MCC may confer with the ORI RCO to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, MCC, or both

Quality Assurance/Improvement Findings

1. If the ORI Quality Improvement Program (QIP) Coordinator conducts a directed or routine Quality Improvement Review of a cancer clinical trial, the QIP Coordinator provides the MCC Associate Director for Clinical Research a copy of the final report. The Associate Director for Clinical Research disseminates a copy to the appropriate personnel in accord with standard MCC operating procedures.
2. If the MCC conducts an audit or inspection of an IRB approved study, the auditor or designee forwards a copy of the final report to the ORI QIP Coordinator. The ORI QIP Coordinator forwards the report to the IRB and/or ORI Director and RCO in accord with standard ORI operating procedures.

REFERENCES

Not applicable