

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: 01-05-07

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) Coordinator, ORI Research Compliance Officer (RCO), Principal Investigator (PI)/Study Personnel

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PROCEDURES

Protocol Review Procedures

1. Investigators submit their proposed clinical cancer research studies to the MCC prior to submission of the IRB application. MCC staff review projects for both scientific and administrative approval in accord with standard MCC operating procedures.
2. Investigators include the MCC approval letter with their IRB applications.
3. ORI staff screen IRB applications to determine whether the study involves clinical cancer research. If so, ORI staff ensure that the IRB application includes the MCC approval letter.
4. If the clinical cancer research application does not include the MCC approval letter, ORI staff may schedule the IRB application for review; however, the IRB will not issue final approval without final MCC approval. ORI staff screen to ensure that the investigator has submitted this documentation before issuing IRB approval.

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 to the ORI Research Compliance Officer immediately upon receipt of the information.
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, 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 copy of the final deliberation and/or federal report to the Director of the MCC in accord with standard MCC operating procedures.

Quality Assurance/Improvement Findings

1. If the ORI Quality Improvement Program (QIP) Coordinator conducts a directed or routine Quality Improvement Review of an MCC protocol, the QIP Coordinator provides the MCC Assistant Director for Clinical Research a copy of the final report. The Associate Director for Clinical

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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