

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>			
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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	Revision Date 03/11/21

## **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 and the UK MCC at Lexington Clinic (MCCLC).

## **GENERAL DESCRIPTION**

The MCC, MCCLC, 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, Protocol Review and Monitoring Committee (PRMC), Data and Safety Monitoring Committee (DSMC), Lexington Clinic Director/CEO.

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### *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).

An *unacceptable audit finding* as defined by the NCI Guidelines for Auditing Clinical Trials includes multiple major deficiencies, a single major flagrant deficiency, or an excessive number of lesser deficiencies.

## **PROCEDURES**

### *Protocol Review Procedures*

1. Investigators submit proposed cancer clinical trials to the IRB in accord with IRB policies and procedures.
2. ORI staff screen IRB applications to determine whether the study involves cancer research and, if so, the PRMC is notified.
3. The PRMC is responsible for determining whether a study meets the NCI definition of a clinical trial and for issuing documentation to the investigator which either confirms that PRMC approval has been obtained or that PRMC review is not required.
4. ORI staff process the IRB application for review and the IRB proceeds with review in accord with ORI/IRB Initial Review SOPs, independent of the PRMC 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 (ORI RCO) following IRB standard operating procedures.
2. The ORI RCO handles the complaint, concern, or allegation in accord with standard ORI/IRB operating procedures.

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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 MCC 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 and MCC DSMC 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 MCC Associate Director for Clinical Research or designee informs the ORI RCO immediately (within two 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 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 within 15 working days of final review. The MCC Associate Director for Clinical Research disseminates a copy to the MCC DSMC and appropriate personnel in accord with standard MCC operating procedures.
2. If during a routine or “for cause” audit the MCC Audit Committee identifies either: 1) evidence that research subjects have been placed at significant risk of harm or the welfare of subjects has been jeopardized and that the finding has not previously been reported to the ORI RCO/IRB; or 2) there is evidence of an unacceptable audit finding, the MCC Audit Committee Chair notifies the MCC Associate Director for Clinical Research and the ORI RCO within 24 hours of identification of the issue. If the MCC DSMC suspends or terminates a study, the Chair of the MCC DSMC notifies the ORI RCO within two working days of suspension or termination of a study.
3. The MCC DSMC Chair forwards an electronic copy of all “for cause” audit reports and any routine audit reports found unacceptable by the DSMC (including the corrective action plan for the findings) to the ORI RCO within 15 working days of final review by the MCC DSMC. The MCC DSMC Chair forwards an electronic copy of the suspension or termination report to the ORI RCO within 15 working days of final review by the MCC DSMC. The ORI RCO forwards the report to the IRB and/or the ORI Director in accord with ORI standard operating procedures.

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*Procedures for MCCLC Research*

1. Investigators submit proposed cancer clinical trial to the IRB in accord with IRB policies and procedures. Investigators indicate within the IRB applications that the proposed research will take place at MCC at Lexington Clinic.
2. ORI reliance staff are assigned as consultants for further determinations regarding offsite/reliance requirements per the IRB Reliance SOP and/or Offsite Research Guidance.
3. ORI staff process the IRB application for review and the IRB proceeds with review in accord with ORI/IRB Initial Review SOPs, independent of the PRMC review.

**REFERENCES**

Unanticipated Problem/Adverse Event SOP  
Termination and Suspension of Research by the IRB SOP  
Mandated Reporting to External Agencies SOP  
NCI Guidelines for Auditing Clinical Trials  
IRB Reliance SOP  
Offsite Research Guidance