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, Protocol Review and Monitoring Committee (PRMC), Data and Safety Monitoring Committee (DSMC).
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, or 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, forward a copy of the IRB submission to the PRMC.

3. The PRMC 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 PRMC approval has been obtained or that PRMC review is not required.

4. ORI staff schedule the IRB application for review and the IRB proceeds with review in accord with IRB Initial Full Review SOP 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 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 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 (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 within 15 working days of final review. The Associate Director for Clinical Research disseminates a copy to the MCC DSMC and appropriate personnel in accord with standard MCC operating procedures.

2. If the MCC Audit Committee, 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 that the finding has not previously been reported to the RCO/IRB; or 2) there is evidence of an unacceptable audit finding, the MCC Audit Committee Chair notifies the MCC ADCT and the 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 RCO within 2 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 RCO within 15 working days of final review by the MCC-DSMC Committee. The MCC DSMC Chair forwards an electronic copy of the suspension or termination report to the RCO within 15 working days of final review by the MCC DSMC. 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
NCI Guidelines for Auditing Clinical Trials