University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #3	**TITLE: Radiation Safety Officer/IRB/ORI Coordination**		**Page 1 of 3**
Approved By: ORI Director	Signature	Date	Date First Effective: 03-01-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	
Approved By: Radiation Safety Officer	Signature	Date	Revision Date: 05-09-19

OBJECTIVE

To describe the procedures for coordination between the Institutional Review Board (IRB)/ Office of Research Integrity (ORI) and the Radiation Safety Officer (RSO) on full review protocols to be conducted involving the administration of radiation

GENERAL DESCRIPTION

Both the RSO and the IRB are committed to ensuring the protection of human subjects involved in research. A number of coordination activities in significant areas have been enacted, including joint committee membership, protocol review complaints and alleged noncompliance, quality assurance/improvement findings, and joint policy/procedures.

RESPONSIBILITY

Execution of SOP: RSO or designee, IRB, ORI Staff, ORI Quality Improvement Program (QIP) Coordinator, ORI Research Compliance Officer (RCO); Principal Investigator (PI)/Study Personnel

PROCEDURES

Joint Committee Membership

1. The RSO serves as an *ex-officio* non-voting member of the Medical IRB.

2. The ORI Director is an *ex-officio* member of the Committee on Safety and Environmental Health, of which Radiation Safety is a subcommittee. The ORI Director serves as the primary liaison in the development of joint RSO-IRB policies and procedures.

Protocol Review Procedures

1. When a PI proposes research that falls under the purview of the RSO, the PI contacts the RSO to request review of the laboratory prior to submitting the protocol to the IRB. The PI submits the protocol to the ORI/IRB and indicates the date of RSO review. This RSO laboratory infrastructure approval is not protocol specific but authorizes the laboratory to conduct research involving radiation. If the PI is unsure whether the research falls under RSO purview, he/she contacts the RSO for clarification.

2. Upon receipt of a complete initial submission that falls under the RSO's purview, ORI staff schedule the protocol for review at a convened Medical IRB meeting. ORI staff forward all full review medical protocols that include research procedures involving radiation to the RSO for review. The IRB reviews new protocols that include research procedures involving radiation but withholds final approval until the RSO has reviewed the protocol.

3. ORI staff provide the RSO and IRB members with agenda notices following ORI standard operating procedures for disseminating information prior to the IRB meeting.

4. ORI staff forward any modification requests that add research procedures involving radiation to the RSO for review and comments before IRB review and approval.

5. The RSO or his/her designee provides the IRB with radiation safety expertise, assesses the adequacy of the information in the informed consent form pertaining to radiation risks, and advises the IRB regarding whether radiation safety review is needed. The RSO may attend the IRB meeting or provide comments prior to the meeting.

Complaints and Alleged Noncompliance

1. If the RSO receives a complaint from a subject, subject family member, staff, or researcher concerning alleged noncompliance or subject rights and welfare, the RSO immediately (i.e., within 2 days) notifies the ORI RCO. The RSO confers with the ORI RCO to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, Radiation Safety, or both.

2. If the ORI RCO receives a complaint or alleged noncompliance involving issues pertinent to radiation safety, he/she immediately (within 2 days) notifies the RSO. The ORI RCO confers

with the RSO to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, Radiation Safety, or both.

3. If the complaint/alleged noncompliance falls under IRB purview, the ORI initiates an inquiry following ORI/IRB standard operating procedures. The IRB also determines whether the incident meets requirements for reporting to federal regulatory agencies. In making the determination, the IRB follows the ORI/IRB standard operating procedures for reporting.

4. If the complaint/alleged noncompliance involves issues pertinent to radiation safety, the ORI RCO provides the RSO with a copy of the final IRB determination. If the IRB determines that the incident is reportable to a federal regulatory agency, the ORI RCO sends a copy of the federal report to the RSO.

5. If the complaint/alleged noncompliance falls under RSO purview, the RSO initiates an inquiry. After the RSO completes the review of the complaint/alleged noncompliance, the RSO provides the ORI with a copy of the final determination. If the RSO determines that the incident is reportable to a federal regulatory agency, the RSO sends a copy of the federal report to the ORI.

Quality Assurance/Improvement Findings

1. If the ORI QIP Coordinator conducts a directed or routine Quality Improvement Review of an IRB protocol and finds issues pertinent to radiation safety, the ORI QIP Coordinator provides the RSO with a copy of the QIP review findings.

2. If the RSO audits or inspects a radiation safety protocol/investigator and finds issues pertinent to the IRB process, the RSO provides the ORI QIP Coordinator with a copy of the report. The ORI QIP Coordinator sends the report to the IRB. The IRB determines whether IRB action is necessary.

Joint Policy/Procedures

1. The ORI Director, when appropriate, initiates efforts to establish joint IRB/RSO policies, procedures, and submission forms. The RSO, ORI staff, the IRB, or University researchers or administrators may submit suggestions or recommendations for joint policies/procedures/forms initiatives to the ORI Director.

REFERENCES

Not Applicable