University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
SOP #6-9 Revision #2	**TITLE: Radioactive Drug Research Committee/IRB/ORI Coordination**		**Page 1 of 4**
Approved By: ORI Director	Signature	Date	Date First Effective: 08-15-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	
Approved By: RDRC Chair	Signature	Date	Revision Date: 07-24-06

OBJECTIVE

To describe the procedures for the coordination between the Institutional Review Board (IRB)/Office of Research Integrity (ORI) and the University of Kentucky (UK) Radioactive Drug Research Committee (RDRC) on protocols involving the use of radioactive drugs for research projects designed to obtain basic information regarding metabolism (e.g., kinetics, distribution, and localization) or human physiology, pathophysiology, or biochemistry

GENERAL DESCRIPTION

Both the Radioactive Drug Research Committee and the IRB are committed to ensuring the protection of human subjects involved in research. They have enacted a number of coordination activities in significant areas including: joint committee membership; protocol review; complaints and alleged noncompliance; quality assurance/improvement findings; and joint policy/procedures. Coordination is also facilitated through ORI, administrator of both the RDRC and IRB.

UK's RDRC is responsible for reviewing and approving all radioactive drug research projects that fall under the purview of the Food and Drug Administration (FDA) regulations as specified in 21 CFR 361. Investigators must submit research projects which meet the criteria for review as outlined in the regulations to the RDRC for approval prior to initiation of the study. IRB approval is also required before initiation of the study.

RDRC review is not required if the use of radioactive drugs is for immediate, diagnostic, or similar purposes, or use of safety and effectiveness of drugs in humans (i.e., to carry out a clinical trial).

Review by the RDRC occurs prior to review by the Medical IRB so that the IRB may rely upon the expertise of the RDRC in reviewing protocols that involve radioactive drugs for research purposes.

RESPONSIBILITY

Execution of SOP: Radioactive Drug Research Committee (RDRC), IRB Members, ORI Staff, ORI Quality Improvement Program (QIP) Coordinator, ORI Research Compliance Officer (RCO), Principal Investigator (PI)/Study Personnel

PROCEDURES

Protocol Review Procedures

1. When a PI proposes research which falls under the purview of the RDRC, the PI must submit his/her protocol to the RDRC via the ORI. The IRB application forms also serve as the RDRC application. The PI may submit copies of the RDRC and IRB applications simultaneously. However, the RDRC review must occur prior to IRB review.

2. If ORI staff receive a proposal that may require RDRC review in addition to IRB review, ORI staff contact the RDRC Chair for assistance in determining whether RDRC review is required. If the proposal does fall under the purview of the RDRC, the RDRC schedules a meeting and places the protocol on the agenda for RDRC review. IRB review takes place after RDRC review. ORI staff inform the PI of both RDRC and IRB review dates.

3. Upon receipt of an appropriately completed protocol submission that falls under purview of the RDRC, ORI staff assign an IRB number to the IRB protocol and an RDRC number to the RDRC protocol. ORI staff maintain two separate files.

4. ORI staff are responsible for providing the RDRC initial review letter to IRB members with IRB protocol review packets, following standard ORI operating procedures for disseminating information prior to the IRB meeting.

5. The RDRC provides the IRB with data safety expertise, especially with respect to risk assessment through the initial review letter sent to the PI. The RDRC sends a copy to the IRB at initial review. ORI staff maintain a copy in the RDRC file in the ORI.

6. The RDRC membership includes someone who is also a member (voting or ex officio) of the IRB. That member serves as a liaison between the two committees, answering questions as

needed, especially if IRB members have questions regarding revisions requested by the RDRC as conveyed in the initial review letter to the PI.

7. ORI staff assigned to the RDRC also manage an IRB and serve as a liaison between both the RDRC and IRB.

Complaints and Alleged Noncompliance

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

2. If the RCO receives a complaint or alleged noncompliance involving an RDRC protocol, he/she immediately (i.e., within 2 days) notifies the RDRC. The ORI RCO may confer with the RDRC Chair to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, RDRC, or both committees.

3. If the complaint/alleged noncompliance falls under IRB or RDRC purview, the ORI initiates an inquiry following standard ORI/IRB operating procedures. The IRB is also responsible for determining whether the incident meets requirements for reporting to the federal regulatory agencies. In making the determination, standard operating procedures for reporting are followed. The RDRC is responsible for adhering to Food and Drug Administration requirements. (See the Mandated Reporting to External Agencies SOP.)

4. After review of the complaint/alleged noncompliance is complete, the ORI RCO is responsible for providing the RDRC with a copy of the final deliberations. If the IRB determines that the incident is reportable to a federal regulatory agency, the RCO is responsible for sending a copy of the federal report to the RDRC.

Quality Assurance/Improvement Findings

1. If the ORI Quality Improvement Program Coordinator conducts a directed or routine Quality Improvement Review of an RDRC protocol, the QIP Coordinator is responsible for providing the RDRC with a copy of the findings.

2. If the RDRC audits or inspects a protocol, the RDRC is responsible for providing the ORI QIP Coordinator with a copy of the report. The ORI QIP Coordinator is responsible for sending the report to the IRB to determine whether additional IRB action is necessary.

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Joint Policy/Procedures

1. The ORI Director, when appropriate, is responsible for initiating efforts to establish joint IRB/RDRC policy, procedures, and submission forms.

2. RDRC staff, ORI staff, the IRB, or UK researchers or administrators may submit suggestions or recommendations for the joint policy/procedure/form initiatives to the ORI Director.

REFERENCES

21 CFR 361