

Stony Brook University

RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC)

Policy and Standard Operating Procedures

Policy

Research protocols conducted under the auspices of Stony Brook University that assess the metabolism of radioactive drugs in human subjects must be reviewed by the RDRC, in accordance with Food and Drug Administration (FDA) regulations at 21 CFR 361.1.

Scope of Authority of the RDRC

The RDRC must review human research protocols involving radioactive drugs that are without a New Drug Application (NDA) filed with the FDA, or an approved Investigational New Drug (IND) application (an IND Exemption may be subject to review by the RDRC in compliance with 21 CFR 361.1.)

To be eligible for review by the RDRC under 21 CFR 361.1, a protocol must:

- Involve certain radioactive compounds generally recognized as safe and effective
- Be designed to use radioactive compounds to obtain basic information regarding either:
 - the metabolism of the compound including kinetics, distribution, dosimetry, and localization or
 - human physiology, pathophysiology, or biochemistry of the compound
- Not be intended for immediate therapeutic, diagnostic, or preventive benefit to the human subject involved
- Not be intended to determine the safety and effectiveness of a drug in human subjects (i.e., the research cannot constitute a clinical trial for the product)
- Not be designed as part of the routine clinical medical management of patients
- Not allow a pharmacological dose to cause a clinically detectable effect
- Be limited with respect to the annual and total radiation dose commitment to the numerical limits specified in 21 CFR 361.1

Responsibilities of the RDRC

- Review, approve, request modification or clarification, or defer approval of human research protocols involving the research-related administration of radioactive material to subjects
- For every study approved by the RDRC, the committee must conclude that scientific knowledge and benefit is likely to result from the study

- Ensure that radioactive drugs are only administered to human research subjects by or under the direct supervision of physicians meeting the specific training and experience requirements specified in the NRC medical regulations (10 CFR 35)
- Document meeting minutes including voting results
- Communicate comments and expectations to the Principal Investigator
- Submit to FDA a special summary report for any study approved by the RDRC which involves exposure either or more than 30 research subjects, or of any research subject under 18 years old
- Submit an annual report by January 31st to the FDA as required by 21 CFR 361.1. The annual report must include a summary of each RDRC-approved study and a list of the current SBU RDRC membership
- Maintain approval by the FDA and ensure compliance with 21 CFR 361.1. The FDA monitors the activities of each institution's RDRC through on-site inspections, notification of deficiencies, and withdrawal of RDRC approvals.

RDRC Meetings

RDRC meetings are held at least quarterly for review of new RDRC applications. A quorum to conduct business is defined as a majority (more than 50%) of the membership, with appropriate representation of the required fields of specialization. The RDRC members vote on each protocol reviewed at the meeting. Any member having involvement in a protocol or some other conflict of interest must abstain from voting on it.

For each protocol, members may vote to do the following:

- Approval
- Modifications required (with response reviewed by the RDRC chair)
- Deferral, requiring substantial or major changes or more information which will be reviewed at a subsequent convened committee meeting
- Disapproval

Committee meeting minutes will be drafted by ORC Staff and signed by the RDRC Chair. The minutes will include a listing of the members who were present for the meeting, voting results and outcome of review.

Permissible Study Populations

Research subjects in studies under RDRC oversight must be at least 18 years of age and legally competent. Exceptions are permitted only in those special situations when it can be demonstrated to the committee that the study:

- presents a unique opportunity to gain information not currently available,
- requires the use of research subjects less than 18 years of age, and

- is without significant risk to the subject.

Studies involving minors will require review by qualified pediatric consultants to the RDRC.

Female research subjects of childbearing potential must state in writing that they are not pregnant, or, on the basis of a pregnancy test be confirmed as not pregnant, before they may participate in any study.

Mandated Reporting Responsibilities of the Principal Investigator

The principal investigator of an RDRC-approved study must report to the RDRC:

- Within 5 working days, all adverse effects associated with the use of the radioactive drug in the research study. All adverse reactions probably attributable to the use of the radioactive drug in the research study will, in turn be immediately reported by the RDRC to the FDA.
- Within 10 working days of administering a radioactive drug into a human subject, a completed FDA Form 2915 (i.e., for each subject).

Mandatory IRB Approval

Once a protocol is approved by the RDRC, it must then be reviewed and approved by the Institutional Review Board (IRB; 'CORIHS'), in compliance with 45 CFR 46 (OHRP) and 21 CFR 50 and 56 (FDA). Any revisions or modifications required by the IRB must be sent to RDRC for review and approval of the modified protocol.

Administrative Support for the RDRC

The committee is administered by the Office of Research Compliance (ORC), which also monitors compliance and promulgates policies and procedures and ensures that the RDRC membership is duly constituted in accordance with 21 CFR 361.1. ORC will ensure that the RDRC chair will sign all applications, minutes, and reports of the committee.