
Yale Radioactive Investigational Drug Committee

CHARTER & PROCEDURES

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1. Charter

The Yale Radioactive Investigational Drug Committee (RIDC) is a standing committee established by the Provost to ensure the appropriate use of the following: All human subject research protocols conducted at Yale PET Center or other Yale University facility authorized by the Yale University NRC medical use license for human subjects research involving the use of investigational radioactive drugs with an IND, amended IND, or an FDA allowed IND exemption (as well as the use of FDA-approved radiopharmaceuticals).

Subject to the Yale University's Institutional Review Board's final approval, the RIDC has the authority to approve, disapprove or require modifications to the protocol, consent form, and other study related documents related to the use of radiopharmaceuticals in human subjects for research.

The RIDC will provide oversight to protocols conducted at Yale New Haven Hospital under review by the YNHH Radiation Safety Committee (RSC) when requested by the YNHH RSC.

2. Responsibilities

The RIDC is responsible for ensuring that that the radioactive materials administered are appropriate. In the committee's review of protocols the YU RIDC:

- i. Ensures the underlying science and research protocol are of sound design;
- ii. Reviews and approves the consent form language related to radiation ;
- iii. Evaluates radiation dosimetry (i.e., dosimetry is valid, at or below radiation dose limits, meets exposure justification criteria, acceptable rationale for amount of activity to be administered, etc.);
- iv. Confirms consistency between the FDA application and Yale University study-related documents.
- v. Ensures that the PI and research personnel are trained in relation to use of radioactive pharmaceuticals and procedures; and

The RIDC also is responsible for the review of adverse events reported to the committee when required.

3. Membership

The RIDC shall be composed of: (i) a physician recognized as a specialist in nuclear medicine; (ii) a person qualified by training and experience to formulate radioactive drugs; (iii) a person with special competence in radiation safety and radiation dosimetry; and (iv) other members qualified in various disciplines pertinent to the field of nuclear medicine (e.g., radiology, internal medicine, clinical pathology, hematology, endocrinology, radiation therapy, radiation physics, radiation biophysics, health physics and radiopharmacy).

Consultants in other pertinent medical disciplines may be included, as necessary, for review of specific studies.

The RIDC shall have a designated chairperson ("Chair"). A Chair shall be appointed by the Provost. The Chair or designee will sign all minutes, committee action letters, and reports of the RIDC to the extent required. The Provost may also appoint a designated vice-chairperson ("Vice-Chair") to assist the Chair or designee with these duties.

4. Procedures

4.1. Meetings

In order to facilitate the timely review of protocols and amendments, the RIDC will meet at least monthly (when there is business to transact). At the request of the Chair or Vice-Chair, ad hoc meetings may be convened to review time-sensitive applications, amendments, or other issues. The materials for review will be sent to the members a week in advance via email.

4.2. Quorum

A quorum of the RIDC voting membership at a convened meeting is required for the RIDC to take action on a study. A quorum is constituted when a majority of the voting members of the Committee are present. Members may participate in RIDC meetings in person, or by other means such as telephone or videoconference that permit real-time communication with other committee members and be counted as “present” for the purpose of establishing a quorum. Quorum may not be established through means that do not allow real-time communication with other committee members such as email and absentee ballots.

4.3. Minutes

Minutes of the meetings of the committee will be prepared and signed by the Chair or Vice-Chair or designee. The minutes will include the results of votes on new research protocols and protocol amendments involving the use of human subjects. No member of the Committee may vote on a protocol for which he or she participates as an investigator/collaborator, and any such abstentions will be recorded in the minutes. Minutes will be reviewed and approved by the committee members.

4.4. Committee Actions

Protocols reviewed by the YU-RIDC may be approved, disapproved, or found to be approvable pending IRB approval and pending resolution of other contingencies, if applicable. Investigator responses to substantive contingencies will be reviewed at a subsequently convened Committee meeting or the Chair/Chair’s designee.

5. Review Procedures

5.1. New Applications

As all new applications will undergo full-committee review by the YU-RIDC, a detailed form, “Application to Involve Human Subjects in Biomedical Research with Ionizing Radiation” must be submitted for review.

All investigators who submit research applications to the YU-RIDC must be qualified by training and experience to conduct the proposed research. In addition, the responsible investigator shall be authorized under Yale University’s U.S. Nuclear Regulatory Commission license to possess and use the specific radioactive drugs proposed in the research. At Yale University, this is accomplished via application to the Yale University Radiation Safety Committee.

All applications submitted to the committee should contain complete answers to all of the questions in the application. All applications must also be accompanied by a completed application to the IRB. The

IRB will not release approved consent forms for a study involving the use of radioactive drugs until the YU-RIDC has provided approval of the application.

All new submissions are initially screened by the YU-RIDC administrator to determine whether all required documents have been submitted.

Protocols subject to the requirements of 21 CFR 361.1 that involve administration of radioactive drugs to research subjects under 18 years of age are also reviewed by Pediatric Protocol Review Committee. The approval letter will be made available to the RIDC.

5.2. Amendments to Approved Protocols

Any significant alteration of the original proposed research plan requires submission of a request for an amendment to the Committee, the form, “Application to Involve Human Subjects in Biomedical Research with Ionizing Radiation” must be used. An amendment is required for any changes in the IRB protocol that has an impact on radiotracer administration.

6. Reporting Procedures

The PI and the PET Center must report all adverse events experienced by the subject that are potentially associated with the use of the radioactive drug in the research study. This includes ANY adverse event whether or not it is considered to be serious. Examples of adverse events include headache, dizziness and sore throat.

The initial report of the incident must be sent to RIDC@yale.edu immediately, but no later than 24 hours. Unless submitted at the time of the initial report, the PET Center will submit a follow-up report within 3 calendar days (but no later than 7 days) using internal ‘Adverse Event Report’.

All potential adverse reactions associated with use of a radioactive drug will be reviewed by the committee at the next available meeting.

7. YU-RIDC Record Retention

YU-RIDC records will be retained for three (3) years after closure of a protocol. After protocol closure, records may be retained either as original paper documents or as scanned electronic documents (pdf files).

Related Documents

Guidance: [940 GD.1 Guidance on Committee Reviews Required for Human Subjects Research Protocols Using Radiation](#)

Submission Form: Application to Involve Human Subjects in Biomedical Research with Ionizing Radiation, [uploaded in IRES IRB](#)

Work Instructions: 940.1 Review of Research Protocols Involving Use of Ionizing Radiation at Yale PET Center

Revision History

Date	Description of the revision
12/02/2019	Initial effective date
03/25/2022	Clarify the locations of research under RIDC oversight