
Yale University Human Research Protection Program

Yale University HRPP Policy 940

Radiation Safety Committee Reviews Required of Research Protocols Using Radiation

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| Responsible Office | Office of Research Administration | Effective Date: May 31, 2007 |
| Responsible Official | Human Research Protection Administrator | Last Revision: June 11, 2009, August 27, 2009 |

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| Policy | 1 |
| 940.1 Protocol Approval by YNHH Radiation Safety Committee and Radioactive Drug Research Committee. | 2 |
| 940.2 Protocol Approval by Yale University Radiation Safety Committee..... | 3 |

Scope

This policy identifies the human research protocols that require review by the Yale New Haven Hospital Radiation Safety Committee (RSC) and/or the Yale University Radiation Safety Committee (YURSC). Review and approval by the appropriate committee(s) must be obtained prior to any research related procedures involving radiation being performed on research participants.

Policy Statement

Any protocol involving the use for research in humans of ionizing radiation that is not the standard of care must be reviewed and approved by the Yale New Haven Hospital Radiation Safety Committee (RSC) or the Radioactive Drug Research Committee (RDRC), before scheduling research participants for procedures. Human research protocols involving ionizing radiation that is not the standard of care must also be approved by the Yale University Radiation Safety Committee (YURSC) when they are conducted at Yale University facilities.

A protocol must be re-reviewed by the RSC, and when appropriate the YURSC, when a currently approved protocol is amended by the principal investigator to include an additional research procedure that is subject to this policy, e.g., a protocol approved by the RSC is amended to include an additional PET scan or a change in a research procedure, e.g. to make a change in the isotope or carrier molecule used in a PET scan.

Definitions

Ionizing Radiation

Radiations having sufficient energy that they dislodge electrons from atoms as they are absorbed by tissues. Ionizing radiations include high energy electromagnetic radiations (e.g. x-rays and gamma rays) and rapidly moving particles (e.g. alpha particles, cosmic rays, and high-energy protons, electrons, and neutrons). Ionizing radiations can be produced by machines that accelerate particles to high energies to produce radiation for use in therapeutic or diagnostic procedures (e.g. linear accelerators, x-ray machines, CT scanners). They can also be produced through the decay of radioactive isotopes such as those used in nuclear medicine procedures (e.g. ¹³¹I or ^{99m}Tc), or PET studies (e.g. ¹⁸F).

Magnetic Resonance Imaging (MRI)

Protocols that involve magnetic resonance imaging (MRI), microwaves, ultrasound, visible light, ultraviolet light, and lasers do not involve ionizing radiations and do not require review by the RSC. Protocols using lasers in research on humans must be reviewed by the Clinical Laser Safety Committee.

Non Ionizing Radiation

Microwaves, ultrasound, visible light, ultraviolet light, and lasers do not involve radiations with sufficient energy to dislodge electrons from atoms. Protocols involving non ionizing radiation do not require review

by the RSC or YURSC. Protocols involving the human use of lasers must be reviewed by the Clinical Laser Safety Committee.

Nuclear Medicine

Protocols involving the injection of radiopharmaceuticals, such as those used in nuclear medicine procedures or PET scans, are subject to oversight by the RSC and YURSC.

Yale New Haven Hospital Radiation Safety Committee (RSC and RDRC)

Responsible for monitoring the radiation exposure to and safety of individuals participating in human research studies conducted at Yale New Haven Hospital and at Yale University. The RDRC is specifically responsible for the FDA – required review of protocols using radioactivity and radioactive drugs that meet the criteria for RDRC review as outlined in the Code of Federal Regulations. 21 CFR 361.1, Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded. The RDRC does not review radioactive drugs that are covered by an IND. For such drugs, research studies must be conducted under 21 CFR part 312, Investigational New Drug Application (IND) and the protocols should be reviewed by the RSC.

The broad classes of research which must be reviewed by this committee include:

- a) Studies using experimental drugs, diagnostics, or devices that emit ionizing radiation and
- b) Protocols which propose any additional exposures to ionizing radiation that would not normally be a part of the subject's medical treatment.

Yale University Radiation Safety Committee (YURSC)

Responsible for monitoring the radiation exposure to and safety of university staff members, trainees, investigators and the public at Yale University facilities where research involving radiation is being performed.

Policy Sections

940.1 Protocol Submission and Approval by the Yale New Haven Hospital Radiation Safety Committee (RSC/RDRC)

All protocols involving the use for research in humans of ionizing radiation that is not the standard of care must be reviewed and approved by the RSC. In addition, a very limited number of protocols using radioactive drugs without an IND can be used for research in a very limited number of human subjects pursuant to federal RDRC regulations (21 CFR 361.1). Under § 361.1, human research using a radioactive drug or biological product may be conducted under an RDRC only (e.g., without an IND) when that research is basic science research, and not research that is intended for immediate therapeutic, diagnostic, or similar purposes, or to determine the safety and effectiveness of the radioactive drug or biological product for such purposes (i.e., the research cannot constitute a clinical trial for the product). For drugs under RDRC protocols, it must also be known that these drugs do not cause any clinically detectable pharmacological effect in humans. The total amount of radiation to be administered as part of the study must be the smallest radiation dose practical to perform the study without jeopardizing the benefits of the study, and must be within specified limits. Protocols involving the use for research in humans of ionizing radiation that is not the standard of care must be reviewed and approved by the RSC/RDRC pursuant to federal RDRC regulations (21 CFR 361.1).

Investigators must submit to the RSC/RDRC an abbreviated version of the research protocol focusing on the radiation aspects of the study. However, the abbreviated version should be in complete agreement with the version that will be reviewed by the Yale IRB.

The RSC/RDRC has the authority to approve, disapprove or require modifications to the protocol.

Investigators must retain within their protocol records a copy of the RSC/RDRC approval. A copy of the RSC/RDRC approval must be provided to the Yale IRB for its records. When the RDRC performs a review in lieu of the Federal Drug Administration (FDA), the Yale IRB will hold up its approval of the research protocol until such time that the investigator demonstrates to the IRB that the RDRC has approved the use of ionizing radiation in the specific research project.

Instructions for submitting protocols to the RSC/ RDRC can be found at <http://rsc.med.yale.edu>

Examples of studies that require review and approval by the RSC/RDRC include:

1. Any research protocols involving the use of investigational (non FDA-approved) radiopharmaceuticals. [A radiopharmaceutical is defined for this purpose as any drug, antibody, metabolic tracer, or other material labeled with a radioactive isotope.]
2. Protocols using investigational (non-FDA approved) equipment or devices that produce ionizing radiations for either diagnostic or therapeutic purposes. [These would include x-ray generating equipment as well as radiation-emitting devices such as radioactive stents.]
3. Studies with FDA-approved radiopharmaceuticals that are needed for research purposes but would not normally be a part of the subjects' care and would therefore expose the subjects to a higher radiation dose than they would receive during routine care. Examples include extra ¹³¹I studies for thyroid function or extra ^{99m}Tc studies such as MUGA scans for heart function.
4. Extra diagnostic imaging studies (for example, x-rays, CT scans, PET studies, SPECT studies, DEXA studies) using x-rays or radioactive isotopes that are needed for research purposes but would not normally be a part of the subjects' care and would therefore expose the subjects to a higher radiation dose than they would receive during routine care.
5. Any protocol using an FDA-approved radiopharmaceutical or FDA-approved radiation-producing equipment or device for an off-label application.

940.2 Protocol Submission and Approval by the Yale University Radiation Safety Committee (YURSC)

Protocols involving the use for research in humans of ionizing radiation that is not the standard of care must also be reviewed by the YURSC when the research will be conducted in or using facilities at Yale University.

Investigators must submit to the YURSC the same version of the research protocol that will be reviewed by the Yale IRB. The review by the YURSC and the RSC/RDRC can be done concurrently.

The YURSC has the authority to approve, disapprove or require modifications to the protocol.

Investigators must retain within their protocol records a copy of the YURSC approval and submit a copy of the approval to the Yale IRB for its records.

Protocols to be reviewed by the YURSC should be sent to the University's Radiation Safety Officer.

Special Situations/Exceptions

In special cases, exceptions to the protocols may be granted in individual cases because of various contingencies that result in higher than approved radiation dose. However, these exceptions should be limited to the specific case and for a specified duration of time and a pre-approval for the exception should be received, if possible. In any case, all exceptions to the protocol should be reported to the RSC/RDRC in writing.

Related Information

Food and Drug Administration: (21 CFR 361.1)

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm085838.pdf>

Contacts

Provide a list of contacts in the table format below.

| Subject | Contact | Phone |
|-----------|--|--------------|
| YNHH RSC | ravinder.nath@yale.edu | 203-785-2971 |
| YNHH RDRC | ravinder.nath@yale.edu | 203-785-2971 |
| YURSC | Radiation Safety Officer, Environmental Health & Safety | 203-737-2140 |

Roles and Responsibilities

Yale New Haven Hospital Radiation Safety Committee (RSC and RDRC)

Responsible for monitoring the radiation exposure to and safety of individuals participating in human research studies conducted at Yale New Haven Hospital and at Yale University. The RDRC is specifically responsible for the FDA -required review of protocols using radioactivity and radioactive drugs that meet the criteria for RDRC review as outlined in the Code of Federal Regulations. The RDRC does not review radioactive drugs that are covered by an IND.

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Revision History

May 31, 2007, June 11, 2009, September 9, 2009, October 7, 2009