

DEPARTMENT: Yale University Human Investigation Committee
POLICY NUMBER: XX.BB
SECTION: Radiation Safety Committee Review of Uses of Radiation
Connected with Research Protocols
REVIEW RESPONSIBILITY: HIC Policy and RSC
ORIGINAL CREATION DATE: February 10, 2006

Yale University School of Medicine HIC Policy Regarding: Radiation Safety Committee Review of Uses of Radiation Connected with Research Protocols

I. Purpose: To identify HIC protocols that require review by the Radiation Safety Committee prior to performing research related procedures involving radiation.

II. 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. ^{131}I or $^{99\text{m}}\text{Tc}$), or PET studies (e.g. ^{18}F).

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.

III. Policy:

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 its subcommittee, the Radioactive Drug Research Committee (RDRC), before implementation. The RDRC is specifically responsible for the FDA-required review of protocols using radioactivity and radioactive drugs.

The broad classes of research which must be reviewed by the RSC include:

- a) Studies that use 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.

Procedure:

A. Investigators may submit the proposed research protocol to the RSC or RDRC for its review and approval prior to submitting the protocol to the HIC. Investigators should include a copy of the RSC or RDRC approval with the new protocol package submission to the HIC.

B. Alternatively, the HIC may approve the protocol with the stipulation that RSC or RDRC review and approval is obtained and submitted to the HIC prior to the initiation of any research related procedures involving radiation.

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

Guidance:

A. Examples of studies that require review and approval by the Radiation Safety Committee or the Radioactive Drug Research Committee include:

1. Any research protocols involving the use of investigational (non FDA-approved) radiopharmaceuticals. [A radiopharmaceutical is defined for this purpose as any radioactive isotope or any drug, antibody, metabolic tracer, or other material carrying 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 in 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 in during routine care.
5. Any protocol using an FDA-approved radiopharmaceutical or FDA-approved radiation-producing equipment or device for off-label applications.