

University of California, San Diego  
Human Research Protections Program  
Institutional Review Board  
Standard Operating Policies and Procedures

Section 3.15  
Radiation Exposure and Radioisotopes

***Policy***

All projects, including their amendments, involving radiation exposure at UCSD or VASHDS facilities will be referred for review by the radiation safety committees of UCSD and VASHDS, as appropriate to the site where the research will be conducted.

If radioisotopes are involved in the proposed project, additional approval for their use in humans is required. If research is to be conducted at the UCSD Medical Center, the Radiation Safety Officer must be contacted by the investigator for instructions (858-534-1069). If the research is to be conducted at the VA Medical Center, the Radiation Safety Office, VA 552-8585 extension 3911, must be contacted.

The UCSD Human Exposure Review Committee (HERC) approval may be obtained before, during, or after application to the IRB. The IRB has final approval of wording regarding human subject radiation exposure in the consent/assent document.

Investigators will note on the IRB application Facesheets the types of radiation sources proposed for use in the study, and provide in the risk/benefit item of the Research Plan an assessment of the risks of radiation exposure. The Research Plan will be reviewed by both the HERC and IRB. The HERC and IRB will make independent assessments of the risks and benefits of the procedures involving radiation. The review documentation provided by the HERC to the IRB will be incorporated into the archival project file and may at the discretion of the IRB be provided to the PI in association with the IRB's comments and requests.

Interactions between the HERC and the IRB are facilitated by a radiation review status field and a radiation review notes field maintained in the IRB project tracking system. These data can be updated online via a web interface provided to the HERC. The online interface also provides to the HERC copies of all correspondence issued by the IRB relevant to a research project.

***Procedures***

1. HRPP staff will determine the existence of radiation use in protocol submissions, route proposals to the appropriate radiation safety committee so that findings and feedback may be provided to investigators.

***Applicable Regulations***

[21 CFR 56.108\(A\)\(1-2\)](#)

[45 CFR 46.109](#)

[21 CFR 812.2\(b\)\(1\)\(ii\)](#)

[45 CFR 46.111](#)

[21 CFR 812.66](#)