Purpose

The Radioactive Drug Research Committee (RDRC) has been established to ensure necessary radiological and pharmacological safety for subjects who participate in certain research protocols using radioactive substances.

Policy

The use in human subjects of any radioactive substance administered at sub-pharmacological dosage for purposes of research on the absorption, uptake, distribution, metabolism, excretion, elimination, or other physiological or biochemical parameter of the substance must be reviewed and approved by the RDRC. Specifically excluded from this policy are studies that are conducted at dosages that have a physiological effect, such as those designed to test the efficacy or safety of a substance for therapeutic or diagnostic purposes. Also excluded are substances that are being studied under designation by the Food and Drug Administration (FDA) as investigational new drugs (IND). All studies reviewed by the RDRC must also be reviewed by the Committee on Human Research (CHR); the approval granted by one is contingent upon approval by the other.

Responsibilities

A. Executive Vice Chancellor

The Executive Vice Chancellor:

1. Appoints the RDRC in compliance with FDA requirements for membership;
2. Has delegated the daily operations regarding radioactive drug research to the Associate Vice Chancellor for Research.

B. Radioactive Drug Research Committee

It is the responsibility of the RDRC to:

1. Review technical and safety-related aspects of the use of radioactive substances that do not have an IND number and that are administered to human subjects for non-therapeutic or non-diagnostic purposes;
2. Ensure that proposed studies entail minimal exposure of subjects to radiation;

3. Advise the Chancellor on matters related to the safe use of radioactively-labeled substances in human subjects, and recommend such policies and procedures as it may deem appropriate to protect their safety;

4. Provide consultation, in collaboration with the Radiation Safety Committee, to faculty for purposes of estimating whole body and specific organ exposures to radiation in proposed protocols;

5. Limit or revoke, by authority of the Chancellor, an investigator's approval to conduct studies under the jurisdiction of the RDRC if conditions are found to pose a hazard to individuals or violate health and safety codes.

C. Radiation Safety Officer: The radiation safety officer provides laboratory inspection and approval, consultation, and education.

D. Principal Investigator

It is the responsibility of the principal investigator to:

1. Provide accurate and detailed calculations of anticipated radiation exposures that will be received by subjects;

2. Comply fully with all aspects of the FDA regulations and any conditions that may be required by the RDRC;

3. Report immediately to the RDRC, the CHR, and the radiation safety officer any injury to, or adverse reaction of, participating subjects.

Related Policies

- 100-16 - Research Involving Human Subjects [3]
- 100-23 - Radiation Safety [4]
- 550-16 - Communication with Environmental Health and Safety Regulatory Agencies (retired) [5]

References

- UCSF Campus Code of Conduct [6]
- Code of Federal Regulations: Food and Drugs (21 CFR 361)
- UCSF Committee on Human Research Website [7]
- UCSF Environmental Health and Safety Website [8]
- UCSF Radiation Safety Manual
- UCSF Radiation Safety Training Manual [9]