
UCLA Policy 994: Radiation Safety

Issuing Officer: Vice Chancellor for Research

Responsible Dept: Office of the Radiation Safety Committees

Effective Date: June 17, 2013

Supersedes: New

I. PURPOSE
II. STATEMENT
III. RESPONSIBILITIES
IV. REFERENCES

I. PURPOSE

UCLA consists of diverse campus units that utilize radioactive material in clinical, research and academic settings. All radioactive material and radiation-producing machine use at UCLA is strictly controlled, in accordance with federal and state regulations, radiation usage guidelines, and campus policies and procedures.

The purpose of this Policy is to:

1. Define the roles and the responsibilities of UCLA administrators, faculty and staff responsible for all materials and equipment capable of producing ionizing radiation; and
2. Outline the oversight procedures that ensure the safety of patients, subjects, staff, faculty and the public when radiation is used in clinical, research and academic settings.

II. STATEMENT

The University must comply with all applicable federal regulations, state laws and UC policies governing the use of radiation, including the provisions of UCLA's Type A Broad Scope License for Radioactive Materials (License # 1335-19) issued by the California Department of Public Health (see Section IV., Reference 1).

The UCLA Radiation Safety Committee (RSC) is commissioned to oversee the use of materials and machines producing ionizing radiation in order to evaluate and maintain compliance with federal and state regulations and statutes (see Section IV., Reference 1). The RSC has sole authority, granted by the Chancellor, to review and approve all activities involving the use of ionizing radiation.

III. RESPONSIBILITIES

The safe use of radiation is a shared responsibility at UCLA. The following responsibilities are assigned to specific campus officials and committees in order to ensure compliance with all applicable laws and regulations overseeing the safe use of radiation.

Campus Officials / Committees	Roles and Responsibilities
Chancellor	<ul style="list-style-type: none">• Responsible for all aspects of radiation safety.• Delegates the establishment and implementation of the Radiation Safety Program (RSP) to the Vice Chancellors for Research and Administration (VCR and VCA).
Vice Chancellor for Research (VCR)	<ul style="list-style-type: none">• Responsible for the RSP.• Appoints the Radiation Safety Committee Chair and members, after consultation with appropriate constituencies.• Responsible for enforcement and policy implementation.

Campus Officials / Committees	Roles and Responsibilities
Vice Chancellor for Administration (VCA)	<ul style="list-style-type: none"> Establishes the Radiation Safety Office and appoints the Radiation Safety Officer (RSO). Delegates the oversight responsibility of the RSO to the Assistant Vice Chancellor, Office of Environment, Health and Safety.
Chair, Radiation Safety Committee	<ul style="list-style-type: none"> Advises the VCR. Reports to the VCR on the status of the RSP and immediately reports critical safety and regulatory issues to the VCR.
Radiation Safety Officer (RSO)	<ul style="list-style-type: none"> Authorized by the Chancellor and required by the UCLA Type A Broad Scope Radioactive Materials License. Advises the VCR and provides technical advice to the RSC. Reports to the VCR on the status of the RSP and immediately reports critical safety and regulatory issues to the VCR and RSC. Responsible for the following: <ul style="list-style-type: none"> Inspection and monitoring of all campus sites using radiation; Radiation safety consultation and education; Issuance of Radioisotope Use Authorizations (RUAs) once approved by the committee; and Overseeing transport of all radioactive materials.
Department Chairs	<ul style="list-style-type: none"> Evaluates the activities within their department to ensure proper reviews and approvals have been obtained and appropriate resources are available to safely conduct research involving radiation.
Principal Investigators, Faculty and Physicians	<ul style="list-style-type: none"> Adheres to all local and state laws, federal regulations, and campus policies governing the use of radiation in clinical and academic settings. Retains primary responsibility for the safe use of radiation under their oversight, this includes ensuring that all staff has received required lab specific safety training prior to use of radiation (see Section IV., Reference 11). Maintains all required licensing and certifications for the scope of radiation use.
Office of the Radiation Safety Committees (ORSC)	<ul style="list-style-type: none"> Division of the Office of Human Research Protection Program (OHRPP) with administrative oversight by the Office of Research Administration (ORA). Oversees the daily operations of the RSC and sub-committees.
Radiation Safety Committee (RSC)	<ul style="list-style-type: none"> Authorized by the Chancellor and required by the UCLA Type A Broad Scope Radioactive Materials License. Oversees the use of materials and machines producing ionizing radiation. Authorizes all uses of radiation at UCLA. Consists of 4 sub-committees that are responsible for specific aspects of radiation usage (See Radiation Safety Sub-Committees below).

Radiation Safety Sub-Committees

The UCLA RSC is structured into four sub-committees that are responsible for developing and implementing the policies and procedures pertaining to the use of radiation.

Academic Radiation Safety Committee (ARSC)

The ARSC ensures the safe conduct of radiological procedures for non-human indications, including the review and approval of Radioactive Materials Use Permit (RMP) and Radiation-Producing Machine Permit (RPMP).

Clinical Operations Radiation Safety Committee (CORSC)

The CORSC ensures the safe conduct of radiological procedures in clinical care, including policy oversight and usage of all radiation-producing machines and materials at UCLA and UCLA satellite clinics.

Medical Radiation Safety Committee (MRSC)

The MRSC reviews and authorizes UCLA human-use research protocols that involve standard of care and/or beyond standard of care radiological procedures. The MRSC ensures that UCLA is in compliance with the policies and procedures outlined in the California Code of Regulations, Title

17, requirements of the FDA that pertain to ionizing radiation and conditions of UCLA's Broad Scope Radioactive Materials License relating to the clinical research use of ionizing radiation. The UCLA MRSC also ensures that radiation exposure absorbed dose is within acceptable limits for human-use research procedures. The MRSC works in collaboration with the UCLA Institutional Review Board (IRB) to ensure the protection of human subjects in studies that involve radiation.

Radioactive Drug Research Committee (RDRC)

The RDRC operates under the provisions of 21 CFR 361.1 and reviews and authorizes all UCLA research studies that involve the use of radioactive drugs in humans without an Investigational New Drug (IND), when the drug is administered under the following conditions:

- The research is considered basic science research and is done for the purposes of advancing scientific knowledge under §361.1 (a), this type of research is:
 - intended to obtain basic information regarding the metabolism (including kinetics, distribution, dosimetry, and localization) of a radioactive drug or regarding human physiology, pathophysiology, or biochemistry;
 - not intended for immediate therapeutic, diagnostic or similar purposes (e.g. preventive benefit to the study subject from the research); and
 - not intended to determine the safety and effectiveness of a radioactive drug in humans.

The UCLA RDRC also ensures that approved studies are within radiation exposure limits defined in 21 CFR 361.1. The RDRC works in collaboration with the UCLA IRB to ensure the protection of human subjects in studies where radiation is used.

IV. REFERENCES

1. California Code of Regulations, Title 17, Chapter 5, Subchapter 4;
2. Code of Federal Regulations 21 CFR 361.1;
3. Food and Drug Administration (FDA) RDRC Program;
4. U.S. Nuclear Regulatory Commission Regulation 10 CFR 19.12;
5. UCLA Policy 811, Environment, Health and Safety;
6. UCOP Research Policy 3-500 Radiation;
7. California State Department of Public Health, Radiologic Health Branch;
8. Office of Radiation Safety Committees (ORSC) Website;
9. UCLA Radiation Safety Website;
10. UCLA Radiation Safety Manual;
11. UCLA Policy 905, Research Laboratory Personal Safety and Protective Equipment.

/s/

**James Economou
Vice Chancellor for Research**