RSC Approval of CHR Studies Involving Radiation Exposure to Human Subjects

NOTE: Any questions may be directed to the Technical Committees Coordinator or EH&S Radiation Safety at chr.rsc.coordinator@ucsf.edu ***or 476-2198.***

Background

Radiation sources are useful tools in clinical applications and biomedical investigations. On a health sciences campus, such as the University of California, San Francisco (UCSF), important research often depends upon the use of radiation sources or radioactive materials. These extremely useful tools need to be incorporated into campus activities in such a manner that maximum benefit is achieved while potential risks are reduced to minimum achievable levels.

The UCSF Type A Broad Scope Radioactive Materials License

The University bears responsibility for the use of radiation sources or radioactive materials, and the effects of this radiation on staff, patients, research subjects and members of the public. The requirements and regulations governing this responsibility are detailed in a Type A Broad Scope Radioactive Materials License issued by the California Department of Public Health, Radiologic Health Branch. This license is contingent upon the existence of a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

The UCSF Radiation Safety Committee (RSC)

The UCSF RSC is the holder and administrator of the UCSF Radioactive Materials License and is appointed by the Associate Vice Chancellor, Research. All uses of radiation at UCSF must be approved by the RSC. The RSC and RSO are authorized by the Chancellor to limit or revoke an individual's authority to use radiation if such use presents a hazard to individuals or violates health and safety codes. The RSC supports the UCSF research community by ensuring that proposed uses of radiation on human subjects comply with all state and federal regulations, and that benefits outweigh risks for subjects, investigators and the university as a whole.

Use of Radiation in Research on Human Subjects & RSC Approval

Research subjects are specially protected, and their radiation exposures are given more scrutiny than routine clinical patients. Since the effects of radiation are cumulative, it is important for the RSC to evaluate the radiation exposures to human subjects from both their routine clinical procedures as well as radiation exposures added solely for research purposes. However, the Informed Consent would only include additional radiation risks due to research participation. RSC approval may come by full committee review or by RSC-designated review to EH&S Radiation Safety.

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The Committee for Human Research (CHR) Study Application

When a Principal Investigator (PI) submits an application to the CHR, there is a question within the ***Other Approvals and Registrations*** tab which asks "*The UCSF Radiation Safety Committee requires review of your protocol if it includes administration of radiation as part of standard of care OR research exposures. Does your protocol involve any radiation exposure to patients/subjects*". The PI should mark *Yes* to this question if there is any use of radiation in the study, whether the procedure is part of the subject's routine clinical care or additional for research purposes. For all studies marking *Yes* to this question, the RSC requires a completed one page form in order to perform its review.

NOTE: Do not delay submission to the CHR, since the RSC and CHR review studies in parallel.

Radiation Exposure to Subjects form

For studies which mark *Yes* to use of radiation, this form is required for **New** CHR study applications, for **Continuation** applications if a form has not yet been completed, and for major **Modification** applications where there are changes to radiation use. The Radiation Exposure to Subjects form can be found on the EH&S website on the following page: http://www.ehs.ucsf.edu/radiation-forms

Completing the Radiation Exposure to Subjects form

Any questions regarding completion of this form may be directed to the Technical Committees Coordinator and EH&S Radiation Safety at chr.rsc.coordinator@ucsf.edu or 476-2198. A sample completed form is attached at the end of this document.

Date of RSC submission:

This is date when the form was sent to chr.rsc.coordinator@ucsf.edu. Remember, do not delay your CHR submission, as the RSC and CHR review studies in parallel.

PI/Assistant names and phone:

The PI name should match the name on the CHR study application. Communication regarding RSC review of the study will primarily be through the PI assistant, unless otherwise requested.

CHR study name, iRIS number and CHR Submission Type:

These should match the CHR submission.

IRB of record, if UCSF relying:

Indicate here if another institution is the primary IRB, and the UCSF CHR will be relying on their review. Note that for these reliance studies, including those in the MOU with other UC IRBs, the RSC at each institution is still required to review and approve. If the RSC does not agree with the consent used by the relying institution then an institution-specific consent form is required.

Number of subjects that will be enrolled at UCSF:

This is the number of subjects enrolled at UCSF only, not the total at all institutions.

Are any subjects minors?

If any subject could be under 18 years of age, please mark *Yes.*

Are any subjects healthy volunteers?

Healthy volunteers do not have the condition/disease addressed by the study.

Are subjects under UCSF care for the condition addressed by the study?

Is the subject also a patient at UCSF for their condition/disease.

Will all procedures involving radiation be performed at UCSF?

This includes all UCSF hospital, clinic and research facilities.

Does this study meet the following criteria: 1) metastatic or stage IV cancer subjects, 2) median survival ≤ 24 months, 3) diagnostic radiation only, and 4) not first-line treatment?

If a study meets all four criteria, then this study may qualify for RSC-designated review to EH&S radiation safety. This is an expedited review process which facilitates approval between the monthly RSC meetings.

List all expected procedures involving radiation and answer the questions for each:

List each procedure type separately.

Name of procedure involving radiation

Some examples of diagnostic procedures are CT, X-ray, DXA, FDG PET, MUGA or bone scan. Some examples of therapeutic procedures are IMRT, HDR brachytherapy, Y-90 microspheres or I-131 MIBG.

X-ray region of interest or radiopharmaceutical mCi amount:

For x-ray studies, this could be anatomic region, such as head, chest, abdomen, pelvis or extremity, or could be dynamic region, such as tumor distribution, metabolic uptake, etc. For nuclear medicine studies, this would be the radiopharmaceutical and mCi amount. Examples of the latter would be 20 mCi Tc-99m MDP (for a bone scan), 20-25 mCi Tc-99m RBC (for a MUGA) or 12-15 mCi F-18 FDG (for an FDG PET scan). If details are not known, enter what you can and EH&S Radiation Safety will assist.

Non-radiation alternative

Some studies allow alternatives, such as MRI instead of CT, or ECHO instead of MUGA.

Maximum # of procedures per subject *in any 1 year*

Total the maximum number of times the procedure could be performed in any 12 month period (usually the first year). Distinguish how many of these are for routine clinical and how many are for research based upon the definition below.

Each time a procedure is performed, it is either routine clinical care or research, but not both. The RSC defines a procedure to be 'research' if any of the following are true:

a) The procedure is not typical for clinical care of the subject's condition, or
b) The procedure is scheduled more frequently than is necessary for routine clinical care, or
c) The procedure requires non-standard parameters.

Total # of procedures per subject *for entire study*

Total number of times the procedure will be performed throughout the study. If the study is of indefinite duration or the subject participation may be extended based upon response, enter the frequency in this column instead of the total (ie. every 8 weeks). Distinguish how many of these are for routine clinical and how many are for research based upon the definition above.

Submitting the Radiation Exposure to Subjects form

Email the completed form as a pdf document to chr.rsc.coordinator@ucsf.edu. If additional clarification is required, you will be contacted by EH&S Radiation Safety. When following up on RSC review, please copy a member of EH&S Radiation Safety to ensure timely response. Some studies may require a specific Radiation Use Authorization (RUA). If an RUA is required, you will then be contacted by EH&S Radiation Safety regarding the online RUA application process.

Expedited review options

Normally studies which require RSC full-committee review must wait until the monthly RSC meeting on the 4th Wednesday of each month. If a study is very urgent and requires full RSC review, the RSC will review and approve outside of these meetings on rare occasions. Another option for approval between RSC meetings are studies which qualify for RSC-designated review to EH&S Radiation Safety. These designated review studies fall into four categories:

- Studies involving minors where there is no addition radiation exposure for research purposes.
- Studies involving healthy volunteers where there is <3 mSv additional radiation exposure for research purposes.
- Studies not involving minors or healthy volunteers where there is <30 mSv additional radiation exposure for research purposes.
- Studies not involving minors or healthy volunteers which meet the following criteria: 1) metastatic or stage IV cancer subjects, 2) median survival ≤ 24 months, 3) diagnostic radiation only, and 4) not first-line treatment.

Radiation risk wording in the Informed Consent

All studies which involve radiation exposure added for research purposes will need specific wording in the Informed Consent. For these studies, the RSC will require a pdf copy of the Informed Consent with the RSC-recommended wording. The RSC-recommended wording depends upon the radiation effective dose (ED) added due to study participation. This ED is calculated by EH&S Radiation Safety based upon the information provided on the Radiation Exposure to Subjects form. Protocols in which subjects will receive different total effective doses for each study arm should either use the maximum possible dose that a patient could receive or use multiple consent forms. **IN NO INSTANCE SHOULD A PATIENT RECEIVE MORE RADIATION THAN THE MAXIMUM STATED ON THE CONSENT FORM.** The categories and radiation risk wording are given below.

Effective Dose of <3 mSv

"This research study involves exposure to radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be less than the yearly natural background radiation in the US, which is 3 mSv (a mSv, or milliSievert, is a measurement of radiation). This amount of radiation involves minimal risk. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study."

Effective Dose of 3 – 50 mSv

"This research study involves exposure to radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be a maximum of approximately _____ mSv, which is equivalent to ____ the yearly natural background of radiation in the US, which is 3 mSv (a mSv, or milliSievert, is a measurement of radiation). This amount of radiation may involve a low risk of cancer. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study."

Effective Dose of >50 mSv

"This research study involves exposure to a significant amount of radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be a maximum of approximately _____ mSv, which is equivalent to _____ the yearly natural background of radiation in the US, which is 3 mSv (a mSv, or milliSievert, is a measurement of radiation). This amount of radiation involves a low risk of cancer. However, the UCSF Radiation Safety Committee has reviewed the use of radiation in this research study and has designated this use as acceptable to obtain the benefits provided by the results of the study. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study."

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Cancer studies meeting criteria for designated review where median survival is <24 months

This research study involves exposure to radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. This amount of radiation may involve a low risk of cancer. However, we believe that this risk, given your overall medical condition is not clinically relevant. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

Radiation Therapy studies

For situations involving radiation therapy added for research purposes, special risk language should be developed on a case-specific basis. Doses to individual organs should always be discussed, but the use of Effective Dose and comparison to background exposures is not appropriate.