

## Guidance for Preparing Research Proposals Involving Diagnostic Use of Ionizing Radiation in Human Use Research

### Introduction

This guidance has been prepared by the Clinical Radiation Safety Committee (CRSCo) to help ensure a careful, complete, and timely review of research projects that include human use of ionizing radiation. CRSCo serves under California Department of Health Services regulations and Nuclear Regulatory Commission regulations as the Radiation Safety Committee for Stanford and Veterans Affairs Palo Alto Health Care System, and is also chartered by the Food and Drug Administration as a Radioactive Drug Research Committee. It meets quarterly.

### Review and Approval

Health Physics reviews the application for completeness and accuracy.

If the effective dose is less than or equal to 5000 millirem and the organ equivalent dose is less than or equal to the value derived by dividing 5 rad by the associated weighting factor (see table below), Health Physics can approve the application.

If the effective dose is greater than 5000 millirem or the organ equivalent dose is greater than the value derived by dividing 5 rad by the associated weighting factor (see table below), it may be approved before the next CRSCo meeting by the Chairman or his designee, the Radiation Safety Officer (RSO) or his designee, and one physician faculty member, or be approved at the next CRSCo meeting.

The approval levels listed are for adults. For minors, approval levels are 10% of those listed above and in the table.

All of these approvals are reported to CRSCo at its next meeting; it can re-open and revise the approvals. If the proposal requires the approval of the Radioactive Drug Research Committee, CRSCo must review and approve the application at the next meeting. There are also organ dose limits associated with each category.

Category	Effective Dose in millirem	Organ Equivalent <sup>1</sup> Dose in rad	Approval Authority <sup>2</sup>
I	$H \leq 5000$ and	$H_T \leq 5/W_T$ $H_{Skin} \leq 500$	RSO or designee
II	$H > 5000$ or	$H_T > 5/W_T$ $H_{Skin} > 500$	RSO, + Chairman + one physician faculty or CRSCo

<sup>1</sup>  $W_T$  values are from ICRP Report 60, Table 2: gonads 0.20; red bone marrow 0.12; colon 0.12; lung 0.12; stomach 0.12; bladder 0.05; breast 0.05; liver 0.05; esophagus 0.05; thyroid 0.05; skin 0.01, bone surface 0.01; remainder 0.05.

<sup>2</sup> Radioactive Drug Research Committee proposals require full CRSCo approval. Dose limits: whole body, active blood-forming organs, lens and gonads 3 rem per study and 5 rem total; other organs 5 rem per study and 15 rem total. See 29 CFR 361.1.  
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### Draft "Informed Consent Form" Language

To estimate risk associated with a specific procedure, CRSCo uses the dose calculation methodology established by the International Commission on Radiological Protection in Report

60, "1990 Recommendations of the International Commission on Radiological Protection." Based on the whole body effective dose H and organ equivalent dose H<sub>T</sub>, CRSCo has prepared different statements you may want to consider when developing your "Informed Consent Form."

**Suggested language for < 300 mrem:**

This research study involves exposure to radiation from \_\_\_\_ . This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation is approximately equal to \_\_\_\_ days of radiation exposure from natural sources like the sun, ground and water. This amount of radiation involves minimal risk and is necessary to obtain the research information desired.

**Suggested language for >300 mrem and <5 rem:**

This research study involves exposure to radiation from \_\_\_\_ . This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation exposure is about \_\_\_\_ mrem, which is approximately equal to \_\_\_\_% of the limit that radiation workers are allowed to receive in one year. This amount of radiation involves minimal risk and is necessary to obtain the research information desired.

**Suggested language for > 5 rem:**

You will be exposed to radiation during this research. Your radiation exposure will be about \_\_\_\_ rem. This amount of radiation has an estimated risk of fatal cancer of about \_\_\_\_ percent<sup>1</sup>. If randomly selected members of the general population were exposed to the radiation exposure from this research, the extra lifetime risk of dying from fatal cancer may be about \_\_ in 1,000. Statistics represent averages and do not predict what is going to happen to you. They do not take into consideration individual risk factors including lifestyle (smoking, diet, exercise, etc), family history (genetics) or radiation exposure. The majority of cancers occur later in life and the average lifetime risk of dying from cancer is 25% (1 in 4).

1- ICRP, 1991:7 0.05 fatal cancers per person-sievert for the entire population

**Suggested language for Category II organ equivalent dose proposals.** You will be exposed to radiation during this research. The dose to your skin will be about X rads. This dose may result in temporary or permanent hair loss and possible skin changes or damage.

For more information

If you would like a copy of the documents that form the foundation for this guidance, or if you have questions specific to your project, please contact Lance Phillips at 725-1412, Dawn Banghart at 725-1407 or Health Physics at 723-3201.

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