

# 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 Dose in rad <sup>1</sup>	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.

## 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  $H_T$ , CRSCo has prepared different statements you may want to consider when developing your "Informed Consent Form."

Suggested language for Category I effective dose proposals. You will be exposed to radiation during this research. Your total effective dose will be about X millirems. The risk from this exposure is too small to be measured and is low compared to many other everyday risks. You receive about 300 millirems each year from natural sources. The limit for radiation workers is 5,000 millirems each year.

Suggested language for Category II effective dose proposals. You will be exposed to radiation during this research. Your total effective dose will be about X rems. This dose has an estimated risk of fatal cancer of about X percent (assume  $4E-2/Sv$ ). This is in addition to the natural fatal cancer risk of about 25 percent.

**If individual organ doses are in the Category II levels then a statement regarding the acute risks should be added to the draft language for the effective dose proposals listed above as appropriate.**

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.