

RADIATION EXPOSURE TO SUBJECTS (RES) IN CHR STUDIES AT UCSF

Please complete and email form to chr.rsc.coordinator@ucsf.edu. Please allow as much time as possible for review.
Contact the Safety Committees Coordinator by email above or at 476-2198 with any questions.

Date of RSC submission: _____

PI name: _____

PI phone: _____

PI assistant (if preferred contact): _____

Assistant phone: _____

CHR study name: _____

iRIS number: _____ CHR Submission Type: New Continuation Modification

IRB of record, if UCSF is relying: _____ Number of subjects that will be enrolled at UCSF: _____

Are any subjects minors? Yes No Are any subjects healthy volunteers? Yes No

Are subjects under UCSF care for the condition/disease addressed by the study? Yes No

Will all procedures involving radiation be performed at UCSF? Yes No

Does this study meet the following criteria: 1) metastatic or stage IV cancer subjects, 2) median survival \leq 24 months, 3) diagnostic radiation only, and 4) not first-line treatment? Yes No If yes, median survival is _____ months.

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

Name of procedure involving radiation	x-ray region of interest or radiopharm mCi amount	Non-radiation alternative	*Maximum # of procedures per subject <i>in any 1 year</i>		*Total # of procedures per subject <i>for entire study</i>		RSC USE ONLY
			# for routine clinical care	# for research	# for routine clinical care	# for research	Max 1 year research ED

***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.**

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EH&S Designated Review?	Yes	No	Review Date:	Approval Date:			