

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
	Identification	Page 1 of 2
Title: Review and monitoring of research projects	Date Effective 5/21/04	Supercedes P&P dated

Ionizing Radiation

Background

Human exposure to ionizing radiation, either from external x-ray beams or from internally administered radionuclides, conveys potential risk. Regulations and guidelines of the US Nuclear Regulatory Commission are based on the conservative assumption that any amount of ionizing radiation, no matter how small, can have a harmful effect on an adult, child, or unborn infant. These guidelines describe consent requirements, researcher qualifications and review procedures for studies in which research subjects will be exposed to ionizing radiation.

JHSPH POLICY AND PROCEDURES

Requirement for Informed Consent

Human subjects who will be exposed to ionizing radiation *solely for research purposes* must provide prior informed consent for the radiation exposure.

If research subjects will receive radiation exposure *as part of the subjects' routine clinical care*, clinical informed consent is usually obtained. This is not the responsibility of the researcher. If, however, the results of a radiation-based diagnostic or therapeutic procedure will be used in the research project, informed *consent to use the results* of the procedure is required.

Required Training of Researchers

The FDA and Nuclear Regulatory Commission require that personnel using radioactive materials or radiation in human subjects research satisfy the same training and experience requirements as for medical uses of ionizing radiation. Either the Principal Investigator or an identified co-investigator must meet this requirement.

Review of Applications to Use Ionizing Radiation

All JHSPH human subjects research that involves the use of ionizing radiation must be approved by a specific radiation committee in addition to CHR. There are two radiation committees at the University, one associated with the Joint Committee on Clinical Investigation (JCCI) in the School of Medicine (SOM) and the other with CHR. Both

committees use the same forms to report radiation doses from external irradiation and internally administered radionuclides. In addition, both committees also require the same radiation risk language in the consent document(s).

If human research that involves ionizing radiation will use University or Hospital facilities, or a Johns Hopkins radiation source, State of Maryland regulations require that it must be approved by the *SOM Radiation Committee*. On the other hand, if JHSPH research involves ionizing radiation and the exposure occurs away from University facilities, it must be approved by the *JHSPH Radiation Committee*.

JHSPH investigators should submit research protocols that involve ionizing radiation to the CHR. If the JHSPH Radiation Committee decides that the SOM Radiation Committee must review the protocol, it will be forwarded to the SOM Radiation Committee for review. Otherwise, it will be reviewed by the CHR Radiation Committee. Following approval by the appropriate radiation committee all JHSPH protocols must be reviewed and approved by CHR.

Applying to Use Ionizing Radiation

When a research project involves the use of ionizing radiation, complete and attach [CHR Form J](#), "Request for Radiation in Human Research" and the appropriate accompanying form(s) ([CHR Form K](#) and/or [CHR Form L](#)) with the CHR application AND Include a disclosure statement of the exposure in the consent document.* The following is a suggested statement of comparative risk:

"The radiation exposure you will receive from participating in this study is equivalent to a dose of _____ rems to your whole body. Naturally occurring radiation (cosmic, radiation, radon, etc.) produces whole body radiation doses of about 0.3 rem per year. Occupationally exposed individuals are permitted to receive whole body doses of 5 rems per year."

If women of child bearing age will be included in the study, they must be informed that they can participate only if they are certain they are not pregnant.** The following is a suggested statement to be included in the consent form:

"If you are female, you may participate in this study only if you are certain you are not pregnant. A pregnancy test will be performed to confirm you are not pregnant. If you become pregnant (or suspect pregnancy) before this study is completed, you must immediately inform the investigators."

* Effective dose values should be summed for all procedures involving radiation exposure. Be certain that values are expressed in appropriate units (use rem, 1 rem = 1000mrem) in the consent statement.

** Pregnant subjects are typically excluded from studies that use ionizing radiation. In the rare instances in which pregnant subjects (patients or volunteers) will be recruited for a study that includes ionizing radiation, their involvement will be considered by CHR on a case by case basis.