Drexel University College of Medicine

(FWA# 00005917 and FWA# 00001852)
INSTITUTIONAL REVIEW BOARDS (IRB)

GUIDELINES FOR HUMAN RESEARCH INVOLVING RADIATION EXPOSURE

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Certification

GENERAL INFORMATION

Human subjects on occasion are exposed to radiation as part of research investigation. Such exposure may be classified a follows:

- Standard clinical procedures either diagnostic or therapeutic and either via administering a radioactive material or by exposure to an external diagnostic or therapeutic x-ray beam.
- New or non-standard administration of radioactive material or exposure to external source of radiation

The Institutional Review Board (IRB) protects human research subjects and must review such proposed procedures with the following considerations:

- Radiation dose to the subject must be quantitated and made available to the IRB consideration. Of particular concern are pregnant individuals and minors. In general, such individuals do not participate in research protocols.
- Informed consent which accurately outlines procedure and possible risks must be obtained from the research subject or the legally authorized.

PRECONDITIONS FOR REVIEW

Protocols involving radiation exposure to human subjects to be considered for review must demonstrate that:

1. The radiation exposure is justified by the quality of the study being undertaken and
2. The research protocol is configured such that subject receives the smallest radiation dose with which it is practical to perform the study without jeopardizing the benefits to be obtained from the study.

PRCEDURES FOR REVIEW

1. All proposed investigational application of radiation sources on humans must be reviewed as per Item # 3 below. Applications must contain the following information:
   - Number of individuals in the study including ages, sex and pregnancy status
   - Description of scientific aim of the study
   - A protocol outlining procedures requiring radiation exposure, and the justification for such exposures
   - Statement of the radiation dose to the human subject (Contact Radiation Safety Office to obtain assistance in preparing this statement)
   - Proposed informed consent document for research subject outlining research radiation exposure
2. Research proposals are categorized into three classes as follows:

   Class 1: Radiation Exposure or application of radioactive material as related to a standard clinical procedure that the individual as a patient would have received anyway.

   Class 2: Radiation exposure or application or a radioactive material due to a standard clinical procedure that the human subject would not have normally received but which is part of proposed research protocol.

   Class 3: Radiation exposure due to a non-standard procedure

3. Procedure for approval is dependent on particular class under which the proposed protocol involving human use falls:

Class 1: No Radiation Safety Committee or Radiation Safety Office (RSC) review necessary.

Class 2: Application and associated consent form will receive a summary review jointly by the IRB and the Chair of the RSC. The Radiation Safety Office shall assure that the radiation doses are appropriately documented. Full review by the RSC will be necessary, but the action taken will be reported, for the record, at the next Radiation Safety Committee.

Class 3: The full IRB and the RSC must review Application and associated consent forms.(AT Drexel University College of Medicine, there are separate RSC for each of the Tenet Hospitals and those committees will review, approve or disapprove our research protocols)

4. Inter-relationship between the IRB and the RSC.

- Protocols failing under class 2 and 3 categories will be referred to the RSO as they are received.
- The RSO will determine radiation doses to be received by the subject and will send out the application to the RSC for full review.
- RSO will review informed consent as to the accuracy of radiation doses specified to be used and any simplifying comparisons made.
- Recommendations of the RSC to the IRB will be via the established transmittal form.
- Final decisions regarding approval of the research protocol shall reside with the IRB

5. Copies of applications involving nationally joining nationally-reviewed protocols will be forwarded to the RSO for review, including review of consent form. A copy will remain at the Radiation Safety Office.

6. Federal Guidelines (21 CFR 361.1) governing maximum radiation doses to human research subjects are as follows:

· Single dose, whole body	3 Rems
· Annual dose, whole body	5 Rems
· Single dose, other organs	5 Rems
· Annual, other organs	15 Rems
· Subjects under 18 years of age	10% of each of the categories above

Whole body means: Whole body or blood forming organs, lens of eye and gonads

The above limits are specified for administration of radioactive materials and do not necessarily apply to external beam exposures. For instance, a standard CT scan examination may well give e Rems to a single organ and to a major portion of the torso. The above dose listings may however, still serve as guidelines at the discretion of the IRB and RSC.

7. For reference, comparison of the following approximate typical doses is listed below.

A. From Natural Background Radiation:

·Coast to coast round trip	2 mr/roundtrip
·New York to Europe air flight	3 mr/roundtrip
·Living in a wood house	4 mr/year
·Living in a brick house	10 mr/year
·Living at sea level (Total from all sources excluding radon)	80 - 100 mr/year
·Living in Denver, Colorado	200 mr/year

B. From Typical Medical Radiographic/fluoroscopic Procedure (to skin)

·PA chest view	25 mr/film
·Lat. Chest view	175 mr/film
·Abdominal AP view	500 mr/film
·CT scan of body	2000 - 4000 mr/exam
·CT scan of head	4000 - 6000 mr/exam
·Fluoroscopy rate (GI study of 3 -5 minutes of fluoroscopy time)	1000 - 3000 mr/minute

C. From Typical Nuclear Medicine Procedures

·Thyroid I-123 scan (25% uptake)

o Total body	25 mr
o Gonads	10 mr
o Thyroid	30 mr

··Thallium 201 heart stress scan

o Total body	735 mr
o Kidney	4200 mr
o Gonads	1750 mr

· Bond Tc9m. MDP scan

o Total body	130 mr
o Ovaries 4.8 hr. void	340 mr
o Testes, 4.8 hr. void	220 mr
o Bladder wall, 4.8 hr void	6200 mr

· Lung Tc99 , MAA scan

o Total body	16 mr
o Ovaries 4.8 hr. void	35mr
o Testes, 4.8 hr. void	25mr
o Lungs	880 mr