Subject: Procedure for Human Subjects Radiation Review

Definitions:
Minimal Risk: For the purposes of this procedure, minimal risk includes radiological research procedures involving 100 mrem or less in adult subjects.

Procedure:
This procedure provides guidance for the submission, review, and approval for the use of radiation in human subjects research.

I. Investigator Responsibilities.
   A. The request for research using radiation will be completed in its entirety and submitted to the IRB for both initial applications and amendments to currently approved studies. The application and instructions for completion are located on the HRPP Website at http://www.mc.vanderbilt.edu/irb/.
   B. Radiation dose calculations may be determined with the use of the dose calculator and should be entered into the appropriate portions of the application. Copies of the dosimetry calculations are to be submitted with the IRB application. Assistance with dose calculations may be obtained by contacting the IRB.
   C. The Investigator will reply to all requests for revision(s) and/or clarifications by the pre-reviewers or Committee reviewers, when advised.
   D. Any proposed changes, unanticipated problems involving risk to participants or others are to be reported to the IRB in accordance with HRPP policies and procedures (See HRPP Policy III.L).

II. IRB Committee Responsibilities.
   A. IRB Full Committee Review.
      1. The assigned reviewers will review a copy of the research application prior to the scheduled meeting to allow adequate time for review and will request additional information, as needed.
      2. Each study will be assigned a Primary and Secondary Reviewer.
         a. The Primary Reviewer is to present the study in summary form to the Committee with required modifications, if applicable. If clarification is needed, the Primary or Secondary Reviewer will contact the Investigator to obtain any additional information needed for the Committee to make a determination. The RCA can assist in obtaining the information, as needed. A literature search may be requested by any of the reviewers to be conducted by the clinical librarian at the Eskind Biomedical Library.
         b. The Secondary Reviewer will be prepared to provide additional information not presented by the Primary Reviewer, and request modifications, if applicable.
         c. The RCA will verify all calculations for the proposed use of ionizing radiation for FDA approved radioactive drugs or radioactive drugs which have an IND to be used in the proposed research. If needed,
an external Consultant may be utilized with expertise in dosimetry and/or radiological procedures.

d. All Committee members will be given the opportunity to review, ask questions of the reviewers, and request modifications in the application.

e. It is typically, although not required, the Primary reviewer who makes the motion regarding the status of the study. An additional member of the Committee may make the secondary motion and a vote will be taken documenting the Committee's decision.

B. IRB Expedited Review.
1. The designated Committee Member will document the justification for the determination that the research meets minimal risk criteria utilizing the reviewer comment form.
2. At any time, the designated Committee Member may make the determination that the research does not meet the definition of minimal risk and refer the study to Full Committee.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will use the web-based dose calculator to verify the effective dose equivalent calculations.
B. If needed, an expert Consultant in radiation dosimetry will be available to assist the Regulatory Compliance Analyst (RCA) in determining appropriate dose calculations.
C. IRB Committee review.
D. The RCA will conduct a pre-review of the study for dose calculations and consent language for radiation exposure.
E. The RCA will request any additional documents needed for the review, as well as any pre-review changes.
F. The RCA will forward the study to an external Consultant with expertise in dosimetry or radiological procedures for verification of calculations and assistance with appropriate consent form language, if needed.
G. Procedures meeting the definition of minimal risk:
1. When the RCA makes the determination that the research involves no more than minimal risk, he/she may:
   a. Request minor revisions to the submitted documents, prior to granting final approval; or
   b. Agree with the submitted documents, and forward to a designated Committee Member for review.
2. The RCA will create a letter requesting revisions from the Investigators or a final IRB approval letter using the appropriate template.

H. Full IRB Committee review.
1. The RCA will forward all documents to a Primary and Secondary Reviewer.
2. Approximately one week prior to the IRB meeting, all Committee members will receive a copy of the agenda and all required documents. These will include:
   a. A copy of the IRB Application;
   b. A copy of the informed consent document;
   c. A copy of all relevant materials as outlined in HRPP Policy III.E and Procedure III.E.1; and
   d. A copy of the research study protocol.
3. After the committee makes a determination, the RCA will draft a letter requesting revisions from the reviewers or a final IRB approval letter using the appropriate template.
4. The letter will be forwarded to the Chairperson or his/her designee for signature and sent to the Investigator.

I. Unanticipated problems involving risk to participant or others are to be processed in accordance with HRPP policies and procedures for the IRB review (See HRPP
Policy III.L).

**References:**
Dose Reference Card, RadiologyInfo.org