Subject: Procedure for Radioactive Drug Research Committee (RDRC) Review

Procedure:
The purpose of this procedure is to provide guidance for the submission, review, and approval for the use of a radioactive drug in human subjects research.

I. Investigator Responsibilities.
A. The request for “Radioactive Drug Research Application” will be completed in its entirety and submitted to the IRB/RDRC for both initial applications and amendments to currently approved studies. The application and instructions for the application are located on the IRB Website at http://www.mc.vanderbilt.edu/irb/.
B. Assistance with radiation dose calculations for radioactive drugs may be obtained by contacting the IRB.
C. Requirements for IRB submission. The IRB application is to be completed and submitted at the same time as the RDRC application.
D. All documents are to be electronically submitted to the IRB as indicated in the application instructions. This will allow the IRB to facilitate the review process and decrease turn around time.
E. The Investigator will reply to all requests for revision(s) and/or clarifications by the pre-reviewers or Committee reviewers, when advised.
F. Appropriate pregnancy testing is to be used to exclude pregnant women from participation in research involving radiation exposure, due to the serious risks to the fetus.
G. Any proposed changes, adverse events and/or unanticipated problems to participants or others are to be reported immediately to the RDRC/IRB in accordance with HRPP policies and procedures (See HRPP Procedure XII.D.2).
H. The Investigator will provide quarterly updates in a timely manner on all active research studies involving radioactive drugs for review by the RDRC. The RDRC is required by the FDA to review this information quarterly and report it to the FDA annually.
I. The Investigator will provide annual radioactive drug use information following the fourth Quarterly Report, and before January 15th of each year by completing the FDA 2915 form and submitting the completed and signed form to the IRB for final submission to the FDA.

II. RDRC Responsibilities/Full RDRC Review.
A. A quorum consisting of more than 50% of the membership and the required specialist representation of the RDRC must be present to review and make a determination on the use of radiological procedures involving radioactive drugs in human subjects research.
B. The assigned reviewers will review a copy of the research application prior to the scheduled meeting to allow adequate time for review and the requesting of additional information, as needed.
C. Each study will be assigned a primary and secondary reviewer.
1. 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 Eskin Biomedical Library.

2. The Secondary reviewer will be prepared to provide additional information not presented by the Primary Reviewer, and request modifications, if applicable.

3. In addition to the primary and secondary reviewers, all RDRC submissions will be evaluated by the Radiation Safety Officer to ensure appropriate qualifications have been obtained to administer radionuclides.

4. The dosimetrist will verify all calculations for the proposed use of radiation involving radioactive drugs to be used in the proposed research.

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

6. 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 determining the RDRC Committee’s decision.

III. Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA will conduct a pre-review for the study for dose calculations, appropriate pregnancy testing and consent language for radiation exposure involving radioactive drugs. The RCA will request any additional documents needed for the review, as well as any pre-review changes.

B. The RCA will forward the study to the dosimetrist for verification of calculations and assistance with appropriate consent form language.

C. Once the pre-review revisions are received from the Investigator, the RCA will upload all appropriate documents to the review history and assign a Primary and Secondary Reviewer.

D. Approximately one week prior to the RDRC meeting, all Committee members will receive a copy of the agenda electronically. The review histories should include:
   1. A copy of the RDRC Application;
   2. A copy of the informed consent document;
   3. A copy of the IRB Application; and
   4. A copy of the research study protocol.

E. After the committee makes a determination, the RCA will draft a letter requesting revisions from the reviewers or a final RDRC approval letter using the appropriate template. The letter will be forwarded to the Chairperson or his/her designee for signature and sent to the Investigator.

F. The RCA will complete the appropriate database entries.

G. Adverse events are to be processed in accordance with HRPP polices and procedures for the IRB/RDRC review (See HRPP Procedure XII.D.2).