PROPOSED USE OF RADIONUCLIDES IN HUMANS
NON-STANDARDIZED DIAGNOSTIC AND THERAPEUTIC PROCEDURES

INSTRUCTIONS: Original and 15 copies should be completed and submitted to the Radiation Safety Office. Answer all questions to the best of your knowledge. Be prepared to make a report of the study to the Radiation Safety Office. Personal Data Form must accompany this application.

NAME___________________________________ DATE____________________________

1. Radionuclides___________________________ Chemical Form_____________________

2. Maximum possession limit____________________________________________________

3. Location of storage_______________________ Location of use_____________________

4. Amount per administration____________________________________________________

5. Number of administrations___________________________________________________

6. Primary critical organ_______________________________________________________

7. Secondary critical organ______________________________________________________

8. Dose to primary critical organ per administration ________ REM

9. Dose to primary critical organ per study ________ REM

10. Dose to secondary critical organ per administration ________ REM

11. Dose to secondary critical organ per study ________ REM

12. Dose to whole body per study ________ REM

13. Show calculations of items #8, #9, #10, #11, and #12 on separate sheets of paper. State any assumptions and reference all constants.

14. Expected fate of radiopharmaceutical administered. ______________________________

15. Describe the instrument used in measuring the radiation. If possible, give the sensitivity.

16. What radioactive waste is expected?
17. How will radioactive waste be disposed?

18. What is the purpose of this study?

19. Describe on a separate sheet of paper the plan of investigation. Include the following:

   a. Complementary drugs to be used and reason for use.
   b. Number of controls, age range, and sex.
   c. Number of research subjects, age range, and sex.
   d. Will pregnant women be tested? If so, why? How will you prevent pregnant women from being tested?
   e. Duration of study.
   f. Describe the samples to be measured for radioactivity.
   g. Describe any unusual hazards in handling and what precautions will be taken.
   h. Animal data to establish assimilation, distribution, and excretion of the material.
   i. Reference to similar studies.

20. Will the material be obtained in a pharmaceutical form for human use?
    Yes _____ No _____. If no, describe the procedure used to make the material suitable for human use. State who certifies the pharmaceutical quality of the material. Use a separate sheet of paper if necessary.

21. Volunteers should know the intent of the study and the effect of radiation. Will volunteers be given this information? Yes _____ No _____. If no, state reason.