Submissions of Human Subjects Protocols
Involving
Radioactive Materials and/or Ionizing Radiation

If any research involves the introduction of radioactive materials or radioactive devices into humans, **prior approval** from the UAB Radiation Safety Program is required. Send all required documentation described below, preferably by e-mail attachment, to: smp@uab.edu. Any information that cannot be e-mailed can be faxed to the UAB Radiation Safety Program office (934-7487). Alternatively, hard copies can be sent by Campus Mail to the following address:

Bradley S. Brinkley, M.S., M.B.A.
Radiation Safety Officer
University of Alabama at Birmingham
445 Community Health Services Building-2041

All information received is date-stamped upon receipt and logged in. It is best to have all of the information together at one time before submission.

The Radiation Safety Officer verifies that all required documentation described below has been submitted, and will request additional documentation if necessary. After verifying that all necessary documentation has been submitted, the Radiation Safety Officer forwards the documentation to either the members of the Subcommittee for Human Use (SCHU), or the members of the Radioactive Drug Research Committee (RDRC), of the Radioisotope and Radiation Safety Committee (RRSC), for consideration. Additional information may be requested by the members of the SCHU or by the members of the RDRC. The Human Subjects Protocol can be approved by the Radiation Safety Officer when a majority of the members of the SCHU, or a majority of the members of the RDRC, vote to approve the study without reservations.

Subcommittee for Human Use (SCHU) Human Subjects Protocol Submittal Instructions

Almost all Human Subjects Protocol studies are forwarded to the members of the SCHU, instead of the RDRC, for consideration. The SCHU evaluates Human Subjects Protocols that have immediate diagnostic or therapeutic intent, including clinical trials done to evaluate diagnostic or therapeutic uses of a radiopharmaceutical.

Radiopharmaceuticals or Radioactive Devices

Human Subjects Protocols that involve the use of radiopharmaceuticals or radioactive devices officially approved by the US Food and Drug Administration (FDA), (i.e. have New Drug Application numbers for radiopharmaceuticals or Pre-Marketing Approval numbers for radioactive devices), and Human Subjects Protocols that involve the use of radiopharmaceuticals or radioactive devices that have been issued an Investigational New Drug (IND) number for radiopharmaceuticals or Investigational Device Exemption (IDE) number by the FDA, are evaluated by the SCHU. When an investigator comes to UAB from another institution where they had approval for research work conducted under an IND, they must also obtain the same SCHU approval to perform the work at UAB. Human Subjects Protocols covered by a Radioactive Drug Research Committee outside of UAB filing both quarterly and annual reports with the FDA are forwarded to the UAB Subcommittee for Human Use for consideration, instead of to the UAB Radioactive Drug Research Committee.

If the Human Subjects Protocol **does not involve** the use of therapeutic amounts of radioactivity, the following information must be submitted for consideration by the members of the SCHU:

- The completed **Human Subjects Protocol** being submitted to the IRB
- A copy of the sponsors protocol describing the study
- The name of an "Authorized Physician User" named on a UAB-issued radioactive materials license authorizing the individual to perform the particular study. The UAB-issued radioactive materials license is reviewed by the Radiation Safety Officer to ensure that the request meets the conditions and approvals granted by the license.
- Patient Consent Form*
- Complete information concerning where (location) the patient would be dosed and studies (i.e., imaging, taking radioactive specimens) conducted**.
- If the patient is requested to return any radioactive specimens to the hospital, this must be clearly stated so that authorization by the Alabama Department of Public Health, Office of Radiation Control, can be properly reviewed for approval.

If the Human Subjects Protocol **involves** the use of therapeutic amounts of radioactivity, additional information is required as follows for consideration by the members of the SCHU:

- Patient Instructions
- Patient Itinerary***
- Nursing Instructions

Ionizing Electromagnetic Radiation

Human Subjects Protocols involving the use of any ionizing electromagnetic radiation (x-rays, computed topography, particle accelerator radiation, etc.) must be reviewed and approved by the SCHU. This is a requirement of the State of Alabama and Jefferson County Health Departments. The Alabama Department of Public Health, Office of Radiation Control, must give final approval before any screening studies are initiated involving the use of x-rays in humans. The additional attachments required for consideration by the members of the SCHU are similar to those listed above:

- The completed **Human Subjects Protocol** being submitted to the IRB
- A copy of the sponsors protocol describing the study
- Radiation dose information similar to that required above for radiopharmaceuticals or radioactive devices
- Patient Consent Form*

Radioactive Drug Research Committee (RDRC) Human Subjects Protocol Submittal Instructions

Human Subjects Protocols that are intended to obtain basic information regarding the **metabolism** (including kinetics, distribution, dosimetry, and localization) of a radioactive drug or regarding **human physiology, pathophysiology, or biochemistry**, **not** intended for immediate therapeutic, diagnostic or similar purposes (e.g. preventive benefit to the study subject from the research), and **not** intended to determine the safety and effectiveness of a radioactive drug in humans, are forwarded to the members of the Radioactive Drug Research Committee (RDRC) for consideration. (Certain basic research studies, e.g., studies to determine whether a drug localizes in a particular organ or fluid space and to describe the kinetics of that localization, may have eventual therapeutic or diagnostic implications, but the initial studies are considered to be basic metabolic research within the meaning of this section.) Basic metabolic studies generally involve the administration of ^{3}H or ^{14}C to human research subjects. **The UAB Radioactive Drug Research Committee is currently inactive, but can be reactivated by applying to the United States Food and Drug Administration (FDA) when needed.**

The following information must be submitted for consideration by the members of the RDRC:

- The completed **APPLICATION FOR RADIOPHARMACEUTICAL RESEARCH IN HUMANS (FORM RDR)**
- The completed **Human Subjects Protocol** being submitted to the IRB
- A copy of the sponsors protocol describing the study
- The name of a "physician user" named on a UAB-issued radioactive materials license authorizing the individual to perform the particular study. The UAB-issued radioactive materials license is reviewed by the Radiation Safety Officer to ensure that the request meets the conditions and approvals granted by the license.
- Patient Consent Form*
- Complete information concerning where (location) the patient would be dosed and studies (i.e., imaging, taking radioactive specimens) conducted**.
- If the patient is requested to return any radioactive specimens to the hospital, this must be clearly stated so that authorization by the Alabama Department of Public Health, Office of Radiation Control, can be properly reviewed for approval.

The **APPLICATION FOR RADIOPHARMACEUTICAL RESEARCH IN HUMANS (FORM RDR)** can be obtained by contacting the Radiation Safety Officer. Investigators considering filing an "Investigational New Drug" or "Notice of Claimed Investigational Exemption for a New Drug" with the FDA for human use research using a radioactive pharmaceutical for studies that would be initially started at UAB, must first gain approval from the UAB RDRC. The same information submitted on the FDA Form 1571 (http://www.fda.gov/cder/forms/1571-1572-help.html) must be submitted to the UAB RDRC for review in addition to the other information required above. If you have any questions, please contact the Radiation Safety Officer for UAB at brin2929@uab.edu or 934-7418.

* The patient consent form must address the risks of radiation in a manner that the common lay person can understand. The RRSC requires that the risks be compared to natural background radiation levels where the annual dose is 3 mSv. Comparing risks to natural background radiation levels is not required for therapeutic doses of radiopharmaceuticals. The consent form should state: "A small risk of cancer, cataracts, and other radiation effects which may not be known at this time may develop from this [radiopharmaceutical, x-rays, computed topography, etc.]" If the human research subject has cancer, it is not required to mention a small risk of developing cancer in the patient consent form. Also, if the radiation dose to the lens of the eye is less than 0.1 Sv, it is not required to mention a small risk of developing cataracts in the patient consent form.

** UAB release criteria of patients or human research subjects administered radioactive materials can be accessed at the following UAB Occupational Health & Safety website:

http://www.healthsafe.uab.edu/pages/radiationsafety/patient_release_criteria.html.

*** From the time the patient receives the radioactive dose at the Medical Center, the locations the patient would be sent including the final location the patient would be surveyed for radiation levels prior to being released.