University of Colorado
Denver | Anschutz Medical Campus

Responsibilities of the Principal Investigator using Radioactive Drugs Under the Purview of the RDRC

The purpose of this policy is to outline the responsibilities of the principal investigator using radioactive drugs under the purview of the RDRC.

The investigator intending to use a radioactive drug on human subjects must provide the RDRC with the required documents (completed RDRC application, research protocol, consent form, labels and batch records as required) for review. In addition the investigator must furnish the RDRC with the following information, in writing:

Radiation Dose to Subjects

To assure that the radiation dose to research subjects is as low as achievable to perform the study and meet the criteria of applicable regulations, the RDRC shall require that:

i. The investigator provide absorbed dose calculations based on biologic distribution data available from published literature or from other valid studies

ii. The investigator provide for an acceptable method of radio-assay of the radioactive drug prior to its use to assure that the dose calculations actually reflect the administered dose

iii. The radioactive drug chosen for the study has a combination of half-life, types of radiations, radiation energy, metabolism, chemical properties, etc., which results in the lowest dose to the whole body or specific organs with which it is possible to obtain the necessary information

iv. The investigator utilizes adequate and appropriate instrumentation for the detection and measurement of the specific radionuclide

Pharmacological Dose Limits

To determine that the amount of active ingredients to be administered or combination of active ingredients shall be known not to cause any clinically detectable pharmacological effect in human beings. A drug is considered to have a clinically detectable pharmacologic effect if any of the following occur:

• After the drug is administered, research subjects report symptoms in response to questions about how they are feeling

• An adverse event occurs

• A change outside the range of normal variation from baseline vital signs is observed (e.g., change in baseline systolic blood pressure, diastolic blood pressure, heart rate, temperature, mental status, or respiratory rate)

•Targeted monitoring based on the drug's pharmacology, such as blood testing, urine analysis, papillary reactions, or an EKG reveals a pharmacologic effect

Qualifications of Investigators

The investigator must provide documentation demonstrating that he or she is qualified by training and experience to conduct the proposed research studies.

Human Research Subjects

The investigator must provide documentation demonstrating that the study will include appropriate human subjects and shall obtain the consent of such human beings or their representatives in accordance with FDA regulations. The research subjects shall be at least 18 years of age and legally competent. Exceptions are permitted only in those special situations when it can be demonstrated to the Committee that the study presents a unique opportunity to gain information not presently available and requires the use of research subjects less than 18 years of age and is without significant risk to the subject. Studies involving minors shall be supported with review by qualified pediatric consultants to the RDRC.

Pregnancy Testing

Each female research subject of child bearing potential shall state in writing that she is not pregnant, or, on the basis of a pregnancy test, be confirmed as not pregnant before she may participate in any study (see policy on Pregnancy Testing).

Quality of Radioactive Drug

Documentation must be provided demonstrating that the radioactive drug used in the research study shall meet appropriate chemical, pharmaceutical, radiochemical, and radionuclide standards of identity, strength, quality, and purity as needed for safety and be of such uniform and reproducible quality as to give significance to the research study conducted. If the drug used is commercially available then a copy of the package insert shall be submitted to the RDRC. If the drug is being produced by the UCD cyclotron, the PI shall submit test batch records to the RDRC as well as the label for review. The PI shall maintain the batch records for each drug produced (originals will be kept at the cyclotron facility) and administered for the study with the subject records.

Research Protocol

No matter how small the amount of radioactivity, no study involving administration of a radioactive drug, as defined by FDA, to research subjects, shall be permitted unless the Radioactive Drug Research Committee concludes, in its judgment, that scientific knowledge and benefit is likely to result from that study. Therefore, the protocol shall be based upon a sound rationale derived from appropriate animal studies or published literature and shall be of sound design such that information of scientific value may result. The radiation dose shall be both sufficient and no greater than necessary to obtain valid measurement. The projected number of subjects shall be sufficient but no greater than necessary for the purpose of the study. The number of subjects shall also reflect the fact that the study is intended to obtain basic research information and not intended for immediate therapeutic, diagnostic or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial).

Amendments

Any amendment to an RDRC approved protocol shall be initially reviewed by the RDRC Chair and the RSO. If the amendment impacts elements outlined in the amendment SOP, it must be reviewed by the full RDRC.

Adverse Reactions

The investigator shall immediately, but no later than 7 calendar days, report to the RDRC all adverse effects associated with the use of the radioactive drug in the research study using the RDRC AE form. This process is separate from any reporting requirements that the investigator has to the IRB.

Reports

The PI is responsible to complete the annual report to the FDA, form 2915.

Participate in Reviews by the Quality Assurance Review Team

The investigator and authorized user must participate in a study initiation visit by the QA team prior to enrolling any subjects in the RDRC approved study. Additionally, and at least annually, the investigator must participate in monitoring visits to assure compliance with all RDRC requirements, relevant regulations and reporting requirements. The investigator must provide information to the RDRC on a quarterly basis regarding numbers of subjects enrolled.

History of SOP	Date
Initial approval	12/16/15
Review by the RDRC	
Re-review:	