

TITLE:**GUIDELINE FOR RADIATION SAFETY COMMITTEE REVIEW OF HUMAN RESEARCH STUDIES**

1.0 Introduction

1.1 Purpose

This guideline is for the preparation, review and approval of human research studies (hereinafter referred to as “studies”) by the Emory University Radiation Safety Committee for Human Use of Radiation. It is provided to assist the Principal Investigator (PI) and research coordinator in preparing studies for review by the Committee as well as what to expect in the process. This is not a procedure, as the process is subject to change depending on circumstances.

1.2 Scope

The Committee serves as an oversight committee for the Emory IRB for any study using radiation or radioactive materials, either diagnostic or therapeutic. It also reviews any study that will be performed at Emory, whether or not the study uses Emory IRB as the primary IRB. If the Emory IRB is not the primary IRB and the study will not be performed at Emory, then the study may not need to be reviewed by the Committee. Please ask the EHSO Radiation Safety representative if you have any questions about a particular study.

The Committee reviews applications and amendments for the human research use of radioactive materials and machine-produced radiation with respect to procedures, exposure to the subject, and risk information provided to the subject.

Studies involving radiopharmaceuticals that are not FDA-approved or being studied under an IND will be submitted to the RDRC for approval. The EHSO Radiation Safety representative will let you know if RDRC approval is necessary and will forward additional forms.

1.3 Definitions

eIRB. Online database for the Emory IRB

HSA. Human Studies Application/Amendment for Radionuclide Use

ICF. Informed Consent Form, also referred to as the consent

IND. Investigational New Drug

IRB. Institutional Research Board, a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans

RDRC. Radioactive Drug Research Committee, a committee chartered by the US Food and Drug Administration for radioactive drug research

RSC1. Radiation Safety Committee for Human Use of Radiation, also referred to as the Committee

RSF. Radiation Summary Form, an Excel spreadsheet for generating radiation risk language based on the number and type of radiological procedures performed in the study

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RSO. Radiation Safety Officer

WIRB. Western IRB, a company that performs IRB services for Emory University for nationwide studies.

2.0 Initial Protocol Review

- A study may be submitted to EHSO prior to submission to Emory IRB, but it is preferred that it at least have an eIRB number for tracking.
- Review the study protocol for the radiological procedures. Determine whether the procedures are research driven or SOC. Some procedures are performed only due to the patient being enrolled in the study; these procedures are research driven. In most cases, imaging procedures are performed as SOC, but a study may call for more frequent imaging than SOC would normally dictate. Therefore, some studies would be research driven.
- The procedures listed in the protocol should be listed in the consent as well, including the timing and frequency of each. Descriptions of the procedures should also be included.

3.0 Radiation Risk Language

- [Download the RSF from the EHSO website](#) and save a copy with the study number added to the filename. Add the title, eIRB number, and contact information to the top of the form.
- Add the number of each procedure to the RSF, as either SOC or research driven. Include all procedures for the anticipated length of the study. In certain cases, researchers may consider adjusting the number of procedures based on expected clinical outcomes, but the Committee may ask for a justification.
- For x-ray or CT procedures that are not otherwise listed, please add the name(s) of the procedure(s) under “X-Ray: Other” or “CT: Other” and include the expected total effective dose in millisieverts (mSv) from these procedures. For help in determining this, please consult with the PI, Radiation Safety, or use the American Society of Radiologic Technologists’ [X-Ray Risk Calculator](#).
- For nuclear medicine procedures that are not otherwise listed, please add the name(s) of the procedure(s) under “Nuclear Medicine: Other” and include the expected total effective dose in millisieverts (mSv) from these procedures. For help in determining this, please consult with the PI, Radiation Safety, or use the Society of Nuclear Medicine and Molecular Imaging’s [Nuclear Medicine Radiation Dose Tool](#).
- Check the appropriate boxes at the bottom of the procedures section if the study involves pediatric subjects or radiation therapy.
- The RSF generates appropriate radiation risk language at the bottom of the form. This language should be added to the risk language section of the ICF. Superfluous radiation risk language should be removed, as it may contradict the Committee’s recommended language.
- If the study will be processed through WIRB, please add the radiation risk language under the “Radiation Language” section of the Emory Checklist and indicate what radiation risk language, if any, should be removed.
- Please note that the RSF generates the language assuming that all studies will be performed; i.e., it does not distinguish whether certain studies, like PET/CT vs

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diagnostic CT, can be substituted for each other. Please consult with Radiation Safety if this presents a problem.

- Please also note that studies involving research driven nuclear medicine procedures must be added to an Authorized User's (AU) radioactive materials authorization for human research. The AU must complete and sign the HSA for these studies. Please consult with Radiation Safety if you have questions about appropriate Authorized Users for a given study.

4.0 Non-radiological Risk Language

The Committee has also suggested risk language for non-radiological risks of certain radiological procedures, including contrast injections and allergic reactions, MRI scans, injections of radioactive materials, and procedures associated with CT angiographies. Please see Appendix A for the latest recommended language and include in the consent as appropriate. If existing language for the non-radiological risks is present, the committee may consider keeping it, but that is not guaranteed. Superfluous risk language for these procedures should be removed, as it may contradict the Committee's recommended language. If the study will be processed through WIRB, please add the appropriate risk language under the "Radiation Language" section of the Emory Checklist and indicate what risk language, if any, should be replaced.

5.0 Submission of Study to Radiation Safety

Submit the protocol, the consent, the RSF, the Emory Checklist (for studies being submitted through WIRB), and the signed HSA (if applicable), **by email** to the EHSO Radiation Safety representative. Please include the Emory IRB study number in the subject line of the email. Call EHSO Radiation Safety at 404-727-5922 if you need a contact name.

6.0 Committee Review and Approval

- Radiation Safety first reviews the consent and RSF for accuracy and completeness in preparation for Committee review. Questions regarding the initial review will be sent to the study team member from whom the application was received. Once all questions are resolved, Radiation Safety then highlights passages for committee review and posts the study schedule from the protocol, the RSF, the HSA (as appropriate), and the ICF for Committee review.
- Two Committee members will be assigned as primary reviewers. The study will be available for comment for ten (10) business days, unless the investigator provides justification for a shorter review time in writing. Radiation Safety will forward questions to the research coordinator and will post answers and updated documents to the reviewers. When both primary reviewers have recommended the study, and there are no outstanding questions, the study will be approved and the approval ballot signed by the Committee Chair and the RSO. Outstanding questions must be resolved prior to approval.
- Radiation Safety will forward approval ballots for approved studies. If the study was approved conditionally, Radiation Safety will forward the conditions for approval and will forward the approval letter after all conditions have been met.
- Approval letters will be posted to the eIRB database as well, but since the studies are not always listed on eIRB at the time the studies are approved, please contact Radiation Safety if there is a study that has been approved and requires oversight committee approval on eIRB.

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Appendix A: Standard IRB Consent Language for Non-radiological Risks of Radiologic Procedures

From Radiation Safety Committee for Machine-Produced Radiation and Department of Radiology, May 2016; Nuc Med/Pet edited by RSC1 November 2016

MRI

MRI exams use powerful magnets to create images of the body. In addition to the possible reactions to contrast materials, you may feel claustrophobic while in the magnet, and will hear loud beeping or hammering noises. If you have tattoos or any metal items in your body such as implants, pacemakers, clips or shrapnel, we will do special screening to make sure your MRI scan is done safely.

Contrast Agents

Your [x-ray, CT or MRI] procedure may require the use of a contrast agent, which is a substance that helps the radiologist interpret the images. The contrast agent will be injected by either a hand-held needle or a machine that does the injection. Most contrast agents stay in your body for only a few minutes, but some of them can remain for a few hours or days without any harm to you or anyone near you. Contrast agents are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The contrast agent could affect kidney function or cause an allergic reaction, though these outcomes are rare. The contrast agent could also leak from your veins a little, causing swelling and discomfort, which is typically treated with ice packs.

Nuc Med/PET

For your [Nuclear Medicine or PET] scan, a small amount of radioactive material will be injected by either a hand-held needle or a machine. Such injections are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The radioactive material could also leak from your veins a little, causing swelling and discomfort. After injection and a waiting period for the drug to circulate within your body, you will be asked to lie very still for several minutes while the scan takes place.