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 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 as 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 Exemptions

Research studies from the following IRBs are exempt from review by the Radiation Safety Committee:

- NCI CIRB
- NCI NCTN
- NCI ETCTN

1.4 Definitions

AU. Authorized User, a physician specifically authorized to prescribe radioactive materials or radiation from radioactive materials to a patient or research subject

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

NCI CIRB. National Cancer Institute Central Institutional Review Board

NCI ETCTN. National Cancer Institute Experimental Therapeutics Clinical Trials Network

NCI NCTN. National Cancer Institute National Clinical Trials Network

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

RSO. Radiation Safety Officer

SOC. Standard of Care

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 within the first 12 months of the study. 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 (SOC imaging is usually not more frequent than q8w). 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 first 12 months 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 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 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 diagnostic CT, can be substituted for each other. Please consult with Radiation Safety if this overestimates the radiation dose or otherwise presents a problem.
Please also note that studies involving research driven nuclear medicine procedures must be added to an AU's 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 AUs 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 ICF 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 language, if any, should be replaced.

5.0 Submission of Study to Radiation Safety

Submit the protocol, the ICF, 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 protocol, ICF 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 forwards the protocol, the ICF, the RSF, and the HSA (as appropriate) for Committee review.

- Studies that only involve SOC procedures that are not more frequent than Emory standards or involve less than 15 minutes of fluoroscopy as SOC may be approved administratively if the existing risk language is appropriate.
- For all other studies, 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. Outstanding questions must be resolved prior to approval. 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.
- Radiation Safety will forward letters of approval for approved studies. If the study was approved conditionally, Radiation Safety will advise the research team of 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.

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 performed safely. If it cannot be performed safely, you will not receive an MRI.

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.