SOP#: RPS-8	**Submissions to the Radiation Safety Committee**
Version #: 2.0	**Next Review Date: 02/2023**
Approved Date: 02/2021	**Review Interval Period: Biennial**
NCI Clinical Director Signature:	William L. Dahut -S Digitally signed by William L. Dahut -S Date: 2021.02.24 17:21:19 -05'00'

POLICY

Approval by the Radiation Safety Committee (RSC) is required before the initiation of clinical research studies involving the use of the following:

- Radioactive research drug(s) regulated under the FDA requirements for review by the Radioactive Drug Research Committee (RDRC)
- The use of any radiation in pediatric participants (<18 years old) with an annual effective dose > 0.5 rem or healthy pediatric volunteers (any dose level)
- Any radiation in healthy adult volunteers, excluding DEXA and chest X-ray
- Therapeutic administration of radioactive materials, novel uses of radiation, including any radioactive Investigational New Drugs (IND) and radiation-producing investigational device
- The radiation itself is the research agent being studied

PURPOSE

To identify the process for submitting protocols to the Radiation Safety Committee (RSC) for those studies that contain research-indicated imaging or therapy.

RESOURCES

- NIH Radiation Safety Committee website
- Radiation Dose Library for Common Procedures website

PROCEDURES

STEP 1: If a Protocol Meets the Criteria for submitting to the RSC:

- Create “Radiation Safety Committee (RSC)” folder in the relevant protocol folder on the CCR PSO Shared Drive.
- Save the following documents:
  - For initial protocol: Clean version of the protocol and consent(s) and assent(s), if applicable
  - For amendment: Tracked version of the protocol and consent(s) and assent(s), if applicable
  - Dosimetry Table(s)
  - Radiation Exposure Worksheet (as applicable)
  - Any correspondence relevant to the submission

STEP 2: Submit a Protocol to the RSC for Initial Review or Amendment in iRIS

Refer to the "iRIS Helpful Document" as a resource to help complete the NIH Radiation Safety Form, as needed.

- Create a new "NIH Radiation Safety Form" in iRIS and fill in any details that correspond with the submission.
- Upload the following documents in iRIS:
  - Protocol
  - Consent(s) and Assent(s), if applicable
  - Dosimetry Table(s)
- Assign the NIH Radiation Safety Form for signatures as indicated in iRIS

Notes regarding protocol amendments:

- An amendment needs to be submitted to RSC when the radiation risk to the research population increases. This includes an increase in overall radiation exposure, addition of a scan or procedure using radiation, inclusion of minors on the protocol, and a 10% or greater increase of the participant population.
- Any change that results in a decrease in radiation risk can be updated at the time of the protocol's triennial review.

STEP 3: Respond to Stipulations (if applicable)

- Create a "Response to RSC Stips" subfolder in the relevant protocol RSC folder on the CCR PSO Shared Drive
- Save the RSC Stipulation outcome letter in the folder for reference
- Draft the response on the protocol and consent documents:
  - When responding to RSC stipulations use the clean version of the documents and track the changes
  - Assign a new Version Date for all response documents
  - Contact PI to discuss any items that require their input and/or their final approval
    - Save relevant correspondence with PI regarding the submission review/response input in the "Correspondence" RSC sub-folder
- Enter the explanation of the changes for each stipulation in the Review Response Submission Form in iRIS. Indicate section numbers where changes to the protocol or consent/assent were made in the response text box as applicable.

Note**:** Response to stipulations must be submitted by the Due Date on the RSC Outcome Letter. Extensions may be requested in extenuating circumstances by emailing the Radiation Safety Committee: RSCExecSec@nih.gov.

- Review the changes against the stipulations itemized in iRIS to ensure that all changes are documented, and the NIH Radiation Safety Form have been updated as necessary.
- Create final versions of the protocol and consent(s)/assent(s) (**tracked)**, making sure to update Table of Contents (TOC) and pagination as needed.

- Upload all response documents in iRIS by creating a revision of each relevant submission document using the 'create a revision' function, as applicable. (Make sure to enter the document's new Version Date within the document attachment window.)
  - **Tracked** Protocol (as necessary)
  - **Tracked** Consent(s) and Assent(s) (as necessary)
  - **Revised** Dosimetry Table(s) (as necessary)
- Assign for signature as indicated in iRIS.

STEP 4: RSC Approval

- The PI and Study Contacts will be notified of approval through iRIS Notification.
- Within the RSC folder, create a subfolder in the protocol file labeled "Approved Documents" and save the following documents from iRIS:
  - RSC outcome letter
  - Approved Consent(s) and Assent(s) as downloaded from iRIS
  - Final, clean version of the protocol
- Save the approved documents in the regulatory file.
- Save the RSC outcome letter in the appropriate submission folder (Initial Review or Amendment) for submission to the IRB.

STEP 5: Triennial Review

Submit relevant documents to the RSC every three years.

- The PI and Study Contacts will receive notification from RSC about 60 days before the expiration date.
- Create a new "NIH Radiation Safety Form" in iRIS and fill in any details that correspond with the submission:
  - Select Triennial Review
- Upload the following documents in iRIS:
  - current version of the protocol
  - current version of the consent(s) and assent(s)
  - dosimetry table(s), if this is the first submission in iRIS or the dose has decreased since last review
- Assign for signature as indicated in iRIS.

STEP 6: Deactivation

When a protocol no longer requires RSC review (No Longer Recruiting, Data/Specimen Analysis, No Longer Using Radiation) the Study Team should notify the RSC in one of the following ways:

- For protocols that have been reviewed in iRIS previously:
  - Create a new "NIH Radiation Safety Form" in iRIS, choose Amendment as the action type and then choose Inactive for the Study Status
  - Assign the NIH Radiation Safety Form for signatures as indicated in iRIS

- For protocols that have never been reviewed in iRIS send an email notification to the Radiation Safety Committee RSCExecSec@nih.gov

STEP 7: Deviations and Adverse Events

- Complete the Radiation Safety Committee Incident Report found here. If the form cannot be downloaded contact Radiation Safety Committee: RSCExecSec@nih.gov
- Email the completed form to: Radiation Safety Committee: RSCExecSec@nih.gov

Notes regarding deviations and adverse events:

- Any deviation from the protocol or an adverse event that involves radiation that could threaten patient safety or compromise data integrity or information in the protocol should be reported to the RSC.
- Notifications should be sent within 2 workdays to the Clinical Protocol Administrator / Executive Secretary, the Radiation Safety Officer, and the RSC Chair.
- A full report is due to the Clinical Protocol Administrator / Executive Secretary no more than 14 days (or 10 business days).
- If you have questions if a report is necessary, please email the Clinical Protocol Administrator / Executive Secretary or call 301-496-2253.