

Radiation Safety Committee

Application for Research Protocols Involving the Administration of Radiation to Human Subjects

Section 1 - Basic Information

HIC No :

Title of Study :

Principal Investigator Information :

Name :

Title / Department :

Email :

Phone :

The PI assures that the information provided in this submission is complete and accurate. The PI assures that modifications to the originally approved project will not occur without prior review and approval by the Institutional Review Board, and that all activities will be performed in accordance with state and federal regulations as well as Yale New Haven Hospital Policies and Procedures.

Application Submitted By :

Name :

Title / Department :

Email :

Phone :

Authorized User (AU) for radioactive materials (if applicable):

Name :

Title / Department :

Email :

Phone :

General Notes: Approval of a protocol can only be obtained if i) the AU is approved by YNHHC RSC, and ii) the use of the radioactive materials is permitted by the YNHHC NRC license.

Section 2(a) -Submission Type

Type of Submission :

Initial (New) Submission

Amendment*

**For an amendment, describe the protocol changes relevant to radiation exposure. Add the amended information with the date of the amendment request*

Change in the number of radiation exams (increase / decrease; R vs SOC modifications)

Change in the number of subjects in current study cohort(s)

Addition of a new aim with a new study cohort

Other (explain below) :

Amendment Comments (if applicable):

Section 2(b) - Radiation Use & Committee Oversight

The following questions pertain to research radiation procedures ONLY; Consult PI to clarify R vs SOC

The research radiation use in this study is for :

Does the research radiation use involve radioactive materials? No Yes*

**If you answered YES, an NRC Authorized User must be identified on Page 1 of the application.*

Radiopharmaceuticals / radioactive materials are approved by the FDA for routine use

Radiopharmaceuticals / radioactive materials are approved under IND or eIND

Will all research radiation use be conducted at Yale New Haven Hospital? Yes No (explain)*

Section 3(a) - Study Methodology Design

Plan of Investigation :

State the scientific aim(s) of the study, specifically involving radiation exposure. Cross-reference IRB protocol, if appropriate. If there are additional treatment arms to the protocol with different radiation exposures (e.g., one arm with 2 radiation exams and one arm with 3 radiation exams), please identify these parts individually.

Subjects diagnosis and prognosis :

Subjects method of selection :

Section 3(b) - Human Subjects

Subjects Gender

Male Female

Subjects Population

Adults Pediatric (minors)

Will healthy control subjects be subjected to research radiation exams?

No Yes

Subjects :

Age :

min

max

Research Subjects?

Subjects :

Age :

min

max

Pregnancy (if applicable):

Are women of child-bearing potential included in this study? Yes No

If YES, will pregnancy testing be performed? Yes No

Describe Pregnancy Testing Protocol:

Adverse Event Reporting:

Please, review Adverse Event Reporting Requirements in 940 GD.1 Guidance on Committee Reviews Required for Human Subjects Research Protocols Using Radiation, section 7, and confirm the following:

Acknowledge that adverse reactions will be reported to the YNHH RSC immediately. Yes No

Section 4 - Radiation Procedures & Administrations

Summarize the total effective dose from ionizing radiation research procedures that the subject will receive during the course of this study. Do NOT submit standard of care exams; Consult PI to clarify R vs SOC.

Upload a completed spreadsheet with dosimetry calculations as Attachment 1 to this application. YNHH RSC has provided a tool to assist PIs with generating effective dose summaries. It can be found in the IRES IRB Library under the Other Forms tab. If an ionizing radiation procedure / radiopharmaceutical is NOT listed in the YNHH RSC tool, then the PI must provide a dosimetry model or contact the appropriate clinical service for assistance generating a custom dosimetry entry in Section 3.

Section 4 - Radiation Procedures & Administrations (continued)

Total Effective Dose (mSv) :

sum of all procedures listed below

Procedure 1 :

Number of Exams / Administrations :

Total Effective Dose (mSv) :

Rationale for the use of ionizing radiation :

YNHH RSC reviewers must assess the cumulative radiation risk to subjects. Please provide a detailed explanation for the use of ionizing radiation. If subjects will undergo multiple exams describe the timing and frequency of the exams. Provide specifics such as weeks 1, 2, & 3 or C1D20 and define cycle duration.

Procedure 2 :

Number of Exams / Administrations :

Total Effective Dose (mSv) :

Rationale for the use of ionizing radiation :

YNHH RSC reviewers must assess the cumulative radiation risk to subjects. Please provide a detailed explanation for the use of ionizing radiation. If subjects will undergo multiple exams describe the timing and frequency of the exams. Provide specifics such as weeks 1, 2, & 3 or C1D20 and define cycle duration.

Procedure 3 :

Number of Exams / Administrations :

Total Effective Dose (mSv) :

Rationale for the use of ionizing radiation :

YNHH RSC reviewers must assess the cumulative radiation risk to subjects. Please provide a detailed explanation for the use of ionizing radiation. If subjects will undergo multiple exams describe the timing and frequency of the exams. Provide specifics such as weeks 1, 2, & 3 or C1D20 and define cycle duration.

Section 4 - Radiation Procedures & Administrations (continued)

Procedure 4 :

Number of Exams / Administrations : Total Effective Dose (mSv) :

Rationale for the use of ionizing radiation :

YNHH RSC reviewers must assess the cumulative radiation risk to subjects. Please provide a detailed explanation for the use of ionizing radiation. If subjects will undergo multiple exams describe the timing and frequency of the exams. Provide specifics such as weeks 1, 2, & 3 or C1D20 and define cycle duration.

Procedure 5 :

Number of Exams / Administrations : Total Effective Dose (mSv) :

Rationale for the use of ionizing radiation :

YNHH RSC reviewers must assess the cumulative radiation risk to subjects. Please provide a detailed explanation for the use of ionizing radiation. If subjects will undergo multiple exams describe the timing and frequency of the exams. Provide specifics such as weeks 1, 2, & 3 or C1D20 and define cycle duration.

Procedure 6 :

Number of Exams / Administrations : Total Effective Dose (mSv) :

Rationale for the use of ionizing radiation :

YNHH RSC reviewers must assess the cumulative radiation risk to subjects. Please provide a detailed explanation for the use of ionizing radiation. If subjects will undergo multiple exams describe the timing and frequency of the exams. Provide specifics such as weeks 1, 2, & 3 or C1D20 and define cycle duration.

Attachment 1

Yale New Haven Hospital
Radiation Safety Committee
Effective Dose Summary (Dosimetry Calculations)