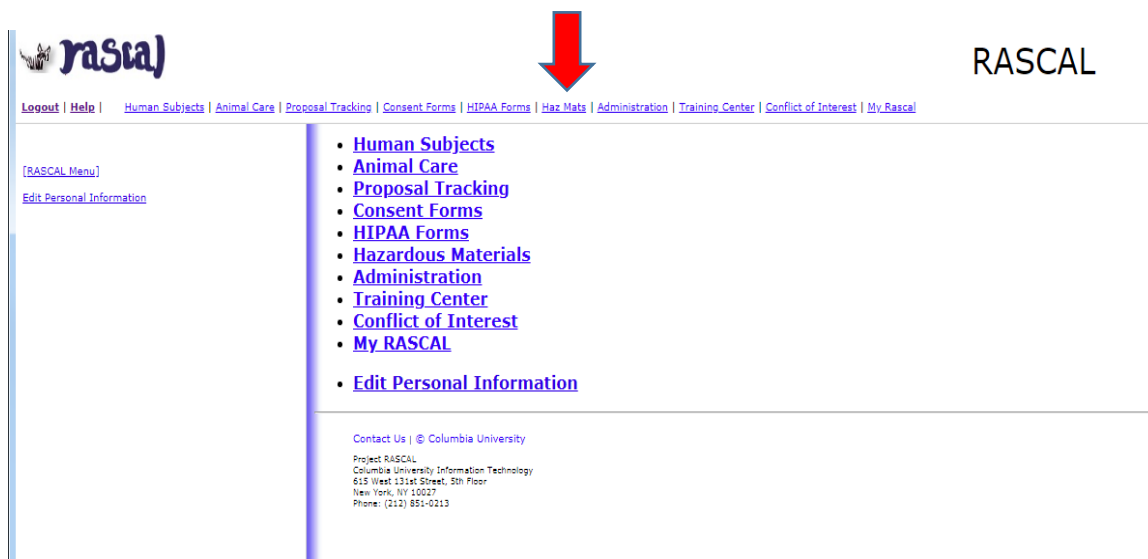


## How to Create an Appendix H and Attach to an IRB Protocol

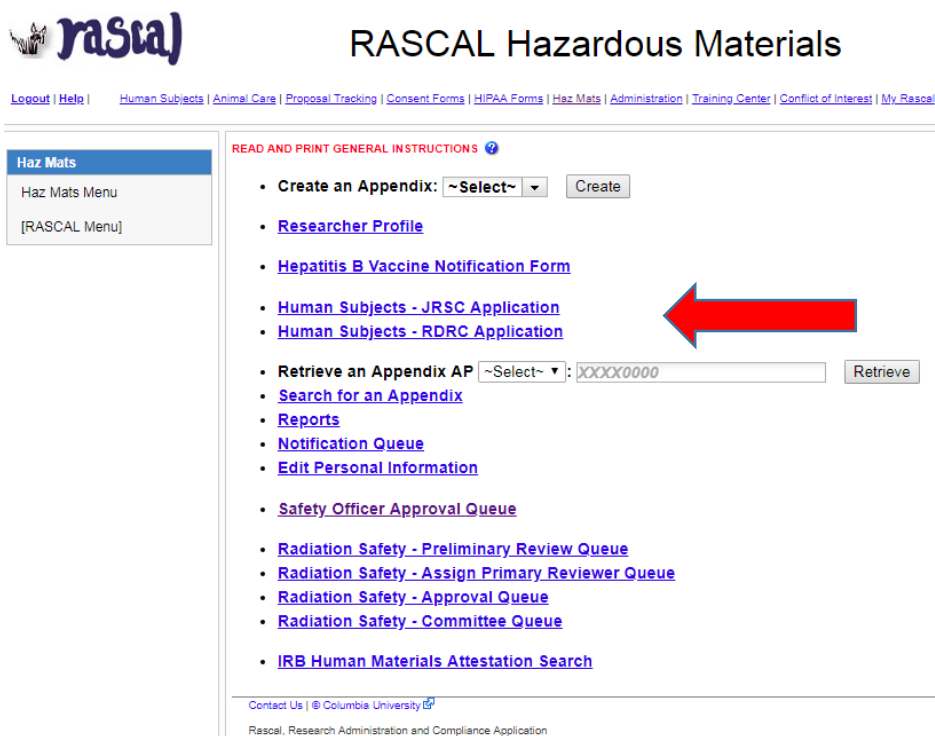
This guide outlines the steps to create an Appendix H for studies involving the research use of radiation that must be submitted to the Joint Radiation Safety Committee (JRSC) for approval. The "[Guidelines for the Use of Radiation in Research Studies Involving Human Subjects](#)" is an important companion to this guide. Go to: (<https://research.columbia.edu/system/files/EHS/Policies/JRSCGuidelines.pdf>).

This guide does not address studies that must be submitted to the Radioactive Drug Research Committee (RDRC). For guidance on those studies, please see the "[Guidelines for Conducting Research Studies under the Auspices of The Columbia University Radioactive Drug Research Committee](#)." Go to: (<https://research.columbia.edu/system/files/EHS/Policies/RDRCGuidelines.pdf>).

1. Go to RASCAL ([www.rascal.columbia.edu](http://www.rascal.columbia.edu)) and login with your UNI and password.
2. Select HazMats from the top menu bar.



3. To start a new Appendix H, click on "Human Subjects - JRSC Application"



**Tips:** There are multiple sections to this Appendix. Fill out in order and always save when section is completed. Each page must be filled in its entirety to save. If cannot fill out Appendix H in one session, fill out remaining section you are working on, and return back to the Appendix later to complete the remaining sections.

4. Fill out the “Study Information” (Section I):

- Add IRB Protocol number before the study title
- If updating a previously approved Appendix, be sure to check the box and include the reference to the previous Appendix
- The following changes require a modification submission:
  - Change in number of subjects
  - Change in study population
  - Change in type, number and/or frequency of radiographic or nuclear medicine studies
  - Change in Principal Investigator
  - Change in Clinical Authorized User (if applicable)
  - Change in Physician Liaison (if applicable)

**Tips:** To submit a modification go to the previously approved Appendix, click on “Copy Appendix”. A new Appendix H with a new number will be created with all the information prepopulated from the previously approved one.

- Complete the information in each section
- Click Save
- Criteria for Administrative Review go to:  
(<https://research.columbia.edu/sites/default/files/content/EHS/Rad%20Safety/CriteriaForAdministrativeReview.pdf>)

5. Fill out “Personnel” (Section II).

- Principal Investigator: required for all studies
- Clinical Authorized User: required if radiopharmaceuticals are included in the study
- Physician Liaison: required if the Principal Investigator is not a Physician
- Click Save

6. Complete the remaining sections (Section III through IX), as described below:

## Columbia Dose Calculator

Whenever possible, it is recommended to use the Columbia Dose Calculator <http://radio-sea.cpmc.columbia.edu:5025/#/> to provide the dosimetry information for the Appendix. The Calculator will output a PDF with all of the information needed for the entries listed below, which can then be attached to the Appendix. (At present, the Calculator can only be accessed while on campus or via VPN connection).

## Dose calculations

If assistance is needed to fill out the dosimetry tables, forward a request via email to [jrsc@columbia.edu](mailto:jrsc@columbia.edu) for submission of a JRSC Application (Appendix H) or [rdrc@columbia.edu](mailto:rdrc@columbia.edu) for submission of a RDRC Application (Appendix H) along with a copy of the Sponsors Protocol and a brief explanation of what the study involves.

**radiation safety**

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### I. Study Information

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Created On	11/12/2019 15:48:23
Created By	Yvette Acevedo (yc21)
You are	Yvette Acevedo (yc21)

General Instructions

For assistance in filling out this Application, please see Guidelines for the Use of Radiation in Research Studies Involving Human Subjects (the "JRSC Guidelines") and Guidelines for Conducting Research Studies Under the Auspices of the Columbia University Radioactive Drug Research Committee (the "RDRC Guidelines"). Both Guidelines can be found at <http://www.ehs.columbia.edu/RadiationFormsLIC.html>.

If the Protocol relating to this study will be reviewed by the Columbia University IRB, this Application should be submitted as an attachment to the Protocol. If the Protocol will be reviewed by the New York State Psychiatric Institute ("NYSPI") IRB, it should be attached to this Application under Attachments below.

Is this application a modification of an existing application?

Study Title  
SAMPLE

Brief Description of Intent of Study [?](#)  
SAMPLE

Description of Proposed Use of Ionizing Radiation and Justification for Such Use [?](#)  
SAMPLE

Save

## III. Radiopharmaceutical Information:

Complete this section only if your study uses radiopharmaceuticals for research. Do not include procedures ordered as routine standard of care. However, standard of care procedures that would not have been ordered except as a requirement of the research protocol should be included.

In the table, you should identify for each radiopharmaceutical used in the study, the name of the pharmaceutical, the radionuclide (e.g., F-18, Tc-99m, etc.) and the activity to be administered *per procedure* to the subject.

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### III. Radiopharmaceutical Information

Appendix	APH-AABG9451
Created On	12/10/2019 20:18:10
Created By	Yvette Acevedo (yc21)
You are	Yvette Acevedo (yc21)

Add Radiopharmaceutical

Radiopharmaceutical	Radionuclide	Activity to be administered (mCi)	Modify	Delete

## IV. Diagnostic/Interventional Imaging Procedures:

Complete this section for each procedure to be used, if your study uses radiation producing equipment for diagnostic or interventional imaging or image-guided biopsy procedures in research (i.e., radiography, fluoroscopy, CT, Bone Densitometry (DXA), CT Biopsy, etc.). You should include only uses that go beyond that established for the applicable standard of care.

For each procedure, enter the Effective Dose per Administration (from the Dose Calculator or other reference), the total number of administrations of that type in the study, and include the reference for the dose information (if the Columbia Dose Calculator is used, you may simply list "Columbia Dose Calculator")

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### IV. Diagnostic/Interventional Imaging Procedures

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You are	Yvette Acevedo (yc21)

Studies Using Radiation Producing Equipment for Diagnostic or Interventional Imaging or Image-Guided Biopsy Procedures in Research

Add Procedure

Procedure Type	Location	Effective Dose per Administration (mSv)	Total No. of Administrations per Study/Protocol	Total (Whole Body) Effective Dose per Study/Protocol (mSv)	Reference Dose provided	Modify	Delete

## V. Therapeutic Radiation Procedures:

Complete this section for each procedure to be used, if your study uses radiation producing equipment for therapeutic procedures in research (i.e., EBRT, HDRR brachytherapy, proton beam therapy, etc.). You should include only uses that go beyond that established for the applicable standard of care.



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## V. Therapeutic Radiation Procedures

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You are	Yvette Acevedo (yc21)

Studies Using Radiation Producing Equipment For Therapeutic Procedures In Research  
Add Procedure 

### Procedures

Type	Name	Modify	Delete
------	------	--------	--------

## VI. Dosimetry:

This section records the organ doses and the effective dose for radiopharmaceuticals and/or therapeutic radiation (for diagnostic and interventional imaging, the necessary dose is recorded in Section IV).



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## VI. Dosimetry

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You are	Yvette Acevedo (yc21)

Please describe at least one radiopharmaceutical or therapeutic procedure to update the dosimetry data for this study.

[Contact Us](#) | [@ Columbia University](#)

Rascal, Research Administration and Compliance Application  
Columbia University Information Technology  
615 West 131st Street, 5th Floor  
New York, NY 10027  
Phone: (212) 851-0213

For each radiopharmaceutical, the organ dose table must be completed. At a minimum, the dose to Active Blood-forming Organs (red marrow), the Gonads, and the Critical Organ (organ or tissue receiving the highest dose) must be included (additional organ doses can be optionally recorded). The Whole Body (effective) dose must also be entered.

For therapeutic radiation procedures, the appropriate organ doses should be added to the dose table.

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## VI. Dosimetry

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▼ Dosimetry Summary

[dfd \(Radiopharmaceutical\)](#)

▼ **dfd (Radiopharmaceutical)**

Add Organ/Dose Information   

Show Dose References

Organ/Tissue	Critical Organ?	Absorbed Dose per Administration (mGy)	Total No. of Administrations per Study/Protocol	Total Absorbed Dose for Study/Protocol (mGy)	Total Effective Dose Per Study/Protocol (mSv)	Dose Ref Provided	Modify	Delete
Active Blood-forming Organs (red marrow) *								N/A
Gonads *								N/A
Whole Body *								N/A

\* - Invalid dose information for this organ type.

[Back to summary](#)

## VII. Dosimetry Summaries:

This section will provide the summation of the doses recorded in the previous sections. Confirm that dose totals are correct.

You should add a description of any possible injury to the subject from the sum of the doses from the study procedures and the doses from any clinical standard of care used in conjunction with such procedures.



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### VII. Dosimetry Summaries

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You are	Yvette Acevedo (yc21)

### Study Summary

Organ/Tissue  Total Dose for Study/Protocol (mGy) (if not applicable, enter N/A)  Total Effective Dose for Study/Protocol (mSv)

Describe the possible injury to the subject from the sum of the doses from the research study procedures and the doses from any clinical standard of care used in conjunction with such procedures:

### Twelve Month Summary

If, within 12 months of the subject's participation in your study, any subject has received or will receive radiation doses from additional research studies that you have conducted or intend to conduct or of which you have knowledge, complete the table for each study or procedure with respect to all radiation doses within such 12-month period, assuming that each dose will be received by a representative subject in your study.

To the best of my knowledge, no subject in my study has participated and/or will participate in additional research studies involving ionizing radiation during the 12-month period.

Finally, either confirm that, to the best of your knowledge, no subject in the study has participated and/or will participate in additional research studies involving ionizing radiation during the 12-month period, or add the information for any study in which subjects may be co-enrolled:

### Study Name or Procedure:

### IRB Protocol Number (if available):

### Total Effective Dose from Prior or Future Research Studies within 12 Months (mSv):

## VIII. Human Subjects:

Provide the demographics of the study subjects and target enrollment for the study.

1. **Minor Subjects:** Subjects should be at least 18 years of age and legally competent unless there is sufficient justification for the use of minors in the study. All protocols that involve Minors go to a Full Committee Meeting whether a New Submission or a Modification.
2. **Non-pregnant status methodology:** The absence of pregnancy should be confirmed by a urine or other pregnancy test prior to any use of radiation or radioactive materials.



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**VIII. Human Subjects**

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	Adult Subjects	Minor Subjects ?
Male	<input type="text"/>	<input type="text"/>
Female	<input type="text"/>	<input type="text"/>
Total	0	0
Minimum Age	18	0
Maximum Age	<input type="text"/>	17

Non-pregnant status methodology ?

Save



**IX. Documents:** You should attach the following documents to this Application:

- All reference documents listed in the tables and/or the output from the *Columbia Dose Calculator*
- Sponsor protocol and informed consent form (if applicable)
- Email correspondence (if any) between the Principal Investigator, Study Coordinator and JRSC/RDRC reviewer
- Written confirmation by the Principal Investigator if procedure is Standard of Care (if applicable)
- Principal Investigator's CV
- Clinical Authorized User's CV (if applicable)





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Add Attachment ?

### Attached Files

View Document	File Name	Attachment Type	Content Type	Date Attached	Attached By	Modify	Delete

[Contact Us](#) | [@ Columbia University](#)

**X. Protocol:** Click Notify Approver. Click "Submit". Navigate to your IRB Protocol to attach the Appendix H. (In order for the JRSC review process to begin submit the IRB Protocol)



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## X. Protocol

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This Appendix is not attached to any protocols or proposals.