Rascal Radiation Safety Module – Human Use Submissions
(Live since April 22, 2013)
Human Research

Any research study involving human subjects that will use ionizing radiation must be approved by the Joint Radiation Safety Committee (JRSC) prior to enrolling subjects if the use of radiation goes beyond that established for the applicable standard of care. Studies using radiation can fall into three general categories:

• Studies using radionuclides
• Studies using radiographic or therapeutic radiation such as x-rays (including mammograms, DEXA scans and dental scans), CT scans, radiotherapy (including brachytherapy) and fluoroscopy (including cardiac catheterization)
• Studies using radiopharmaceuticals

A study may use more than one form of radiation in different procedures under that study.

There are a limited number of basic research studies using radiopharmaceuticals that may be conducted under the auspices of the Columbia University Radioactive Drug Research Committee (RDRC).
Log on to Rascal with your CU uni

Note:
- Do not open more than one RASCAL browser window at the same time.
- Please disable any pop-up blockers and enable JavaScript & Cookies.
- This system will log you out after approximately one hour of inactivity. Please save your work often.
Click on "Hazardous Materials" to create an Appendix H (APH)

Click on the Application that applies to the submission:
- Human Subjects - JRSC Application
- Human Subjects - RDRC Application
# Study Information of the Appendix H (APH)

## Radiation Safety

### Study Information

<table>
<thead>
<tr>
<th>Appendix</th>
<th>APH: AAAH100</th>
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<tbody>
<tr>
<td>Created On</td>
<td>04/09/2014 14:45:46</td>
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<tr>
<td>Created By</td>
<td>Yvette Acevedo (yc24)</td>
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<td>You are</td>
<td>Yvette Acevedo (yc24)</td>
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### General Instructions

For assistance in filling out this Application, please see Guidelines for the Use of Radiation in Research Studies involving Human Subjects (the "URSC Guidelines") and Guidelines for Conducting Research Studies Under the Auspices of the Columbia University Radiological Research Committee (the "RDRC Guidelines"). Both Guidelines can be found at [http://www.ehs.columbia.edu/RadiationForm103.html](http://www.ehs.columbia.edu/RadiationForm103.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 study a modification? ☐

### Study Title:

### Brief Description of Intent of Study ☐

### Justification of the Use of Radiation and Description of Proposed Use ☐
Submission of Modifications

All modifications are submitted through the Rascal process. To create a new Appendix H go to the initially approved Appendix H and click on “Copy Appendix”.

Answer the following questions:

• “Is this study a modification?” - Click the box (“true”).
• Was the previous submission submitted to the JRSC in paper? If you click the box, no appendix number is needed.
• If you do not click the box to question mentioned above, answer the question “What appendix number?” - Indicate the previous appendix number.
• “Explain the reason for the modification:” - In the correspondence text box indicate in the reason for the modification.
• Make your changes to the appendix.
• When complete, submit the appendix and go to the protocol and click “Detach” to remove the initially approved appendix from the protocol and attach the Appendix H (modification). All the previous approvals will remain in the “History” section.
Prior to submitting the Appendix H, attach **ALL** corresponding documents in the “Attachments” section and in the “Protocol” section.

- CV for Principal Investigator, (Clinical Authorized User & Physician Liaison, if applicable) and **ALL** the Co-Investigators, on the study.
- Dosimetry reference, if any.
- Protocol
- Consent Form(s)
- If your submission is a Sponsor protocol or a NYPSI IRB protocol, attach a copy of the protocol and a copy of the Consent Form.

**Note:** An incomplete appendix will be returned.
Personnel

- Add the Principal Investigator.
- Add **ALL** the Co-Investigators on the study.
- If your study involves the administration of radioactive materials to humans and you are not a Clinical Authorized User, you must select a Clinical Authorized User.
- If your study involves the use of radiographic procedures only and you are not a licensed physician, you must select a physician (a **Physician Liaison**) to order such radiographic procedures.
- Initiator add your uni and select your role as “Research Staff Member” (this allows you to view the Appendix H).
Radiopharmaceutical Information

- If your study involves the use of radiopharmaceuticals for research, add the radiopharmaceutical(s) in this section.
Radiopharmaceutical Dosimetry

- In this section, click on “Add Organ/Dose Information” to add the dosimetry calculations.
Radiographic Procedures

- If the study involves radiographic procedure, add the procedure(s) name in this section.
Radiographic Dosimetry

- In this section, click on “Add Organ/Dose Information” to add the dosimetry calculations.

**Note:** For assistance in filling out the dosimetry calculations, the Principal Investigator or the Research Staff Member may contact the Radiation Safety Committee Coordinator at 305-4095 or send an email request at jrsc@columbia.edu.
Dosimetry Summaries

- Summary Dosimetry Tables – Provide the total radiation dose for the study (i.e., the sum of doses from all procedures listed in sections Radiopharmaceuticals Information and Radiographic Procedures.

<table>
<thead>
<tr>
<th>Organ/Organ System</th>
<th>Total Dose for Study (mSv)</th>
<th>Total Effective Dose for Study (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Blood-forming Organs (red marrow)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brain</td>
<td>26.0</td>
<td></td>
</tr>
<tr>
<td>Lungs of the Eye</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td>0.0</td>
<td></td>
</tr>
</tbody>
</table>

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

Twelve Month Summary

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

- Indicate the number of subjects (male/female) and indicate if adults or minors, or both.
- Answer the non-pregnant status methodology question.
- When complete, click “Save”.
Submit the Appendix

• **Only** the Principal Investigator can submit the Appendix.
• Go to the protocol and go to the Attach Hazmats section.
• Attach the Appendix H there.
• At that point the protocol number will appear on the Appendix under the “Protocol” section.

**Note:** This is very similar to the Release and Attach methodology that all of the other Appendices use.
Notes:

• Submit the Appendix H by the 1st Friday of the month.

• The Human Use Sub-Committee (JRSC/HUS) meets every 3rd Wednesday of the month.

• If the protocol is in “Creating” status, the JRSC reviewers are not able to view the protocol until it is released.

• To view the status of the Appendix H go to the protocol and view the “Hazardous Materials History” section.

• **Only** the Principal Investigator receives email notifications from Rascal when the appendix is returned. It is recommended that the Principal Investigator or the Research Staff Member checks periodically for correspondence from the Reviewer, if any.

• All the appendices reviewed for the month will be presented at the meeting provided that all issues found during the review process, if any, are addressed by the Principal Investigator prior to the meeting.

• When an Appendix H is approved, the approval status is indicated in the “Hazardous Materials History” section of the “Protocol History” section.

• The review process is entirely electronic and **ALL** communications, including the approval, are sent via email notifications from Rascal to the Principal Investigator **ONLY**.

• Contact Rascal at rascal@columbia.edu or (212) 851-0213 with regard to glitches in the submission of an Appendix H.
Helpful links at the Environmental Health & Safety Homepage:

http://www.ehs.columbia.edu/RadiationCommittees.html

Committees Contact:

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