



## HUMAN STUDIES APPLICATION/AMENDMENT FOR RADIONUCLIDE USE (Committee I)

**Instructions:** This form is for non-RDRC studies. If RDRC approval is required, contact Ike Hall ([mjhall@emory.edu](mailto:mjhall@emory.edu)) for an RDRC application.)

- Complete this form electronically, using the tab key or mouse to maneuver between fields
- Print, sign, and submit by fax (404-727-5904) or scanned email to **Ike Hall** ([mjhall@emory.edu](mailto:mjhall@emory.edu))

|                                                         |                                       |                                        |                 |
|---------------------------------------------------------|---------------------------------------|----------------------------------------|-----------------|
| <b>SECTION I-A: APPLICATION INFORMATION</b>             |                                       | <input type="checkbox"/> INITIAL       | <b>RH#:</b>     |
|                                                         |                                       | <input type="checkbox"/> AMENDMENT     | <b>PETHR #:</b> |
| Study Title:                                            |                                       |                                        |                 |
| Authorized User Name ( <i>serves as Radiation PI</i> ): |                                       |                                        |                 |
| Campus Address:                                         |                                       | Dept:                                  |                 |
| Phone No ( <i>10 digits</i> ):                          |                                       | E-mail address:                        |                 |
| Study PI ( <i>if different than Authorized User</i> ):  |                                       |                                        |                 |
| Campus Address:                                         |                                       | Dept:                                  |                 |
| Phone No ( <i>10 digits</i> ):                          |                                       | E-mail address:                        |                 |
| Research Coordinator:                                   |                                       |                                        |                 |
| Campus Address:                                         |                                       | Dept:                                  |                 |
| Phone No ( <i>10 digits</i> ):                          |                                       | E-mail address:                        |                 |
| <b>PHYSICAL LOCATION OF USE – attach map</b>            |                                       |                                        |                 |
| Facility Name:                                          |                                       |                                        |                 |
| Building:                                               |                                       | Room No.:                              |                 |
| IRB Approval status                                     | <input type="checkbox"/> Pending / #: | <input type="checkbox"/> Approved / #: |                 |
| Number of Subjects:                                     |                                       | Number of Controls:                    |                 |
| Purpose of Study:                                       |                                       |                                        |                 |

| SECTION II: DOSIMETRY INFORMATION                       |  |                         |                                 |                   |  |
|---------------------------------------------------------|--|-------------------------|---------------------------------|-------------------|--|
| <i>NOTE: "session" below refers to a 24 hour period</i> |  |                         |                                 |                   |  |
| Isotope A:                                              |  |                         | Chemical Form:                  |                   |  |
| Administration Method:                                  |  |                         |                                 |                   |  |
| Radiopharmaceutical FDA Status:                         |  |                         |                                 |                   |  |
| Number of Subjects:                                     |  |                         | Number of Sessions per subject: |                   |  |
| Total activity administered per session:                |  |                         | MBq (1mCi = 37 MBq)             |                   |  |
| Critical Organ:                                         |  | Dose per session (mGy): |                                 | Total Dose (mGy): |  |
| Whole Body Dose per session (mSv):                      |  |                         |                                 | Total Dose (mSv): |  |
| Reference(s) Used (attach copy):                        |  |                         |                                 |                   |  |
| Isotope B:                                              |  |                         | Chemical Form:                  |                   |  |
| Administration Method:                                  |  |                         |                                 |                   |  |
| Radiopharmaceutical FDA Status:                         |  |                         |                                 |                   |  |
| Number of Subjects:                                     |  |                         | Number of Sessions per subject: |                   |  |
| Total activity administered per session:                |  |                         | MBq (1mCi = 37 MBq)             |                   |  |
| Critical Organ:                                         |  | Dose per session (mGy): |                                 | Total Dose (mGy): |  |
| Whole Body Dose per session (mSv):                      |  |                         |                                 | Total Dose (mSv): |  |
| Reference(s) Used (attach copy):                        |  |                         |                                 |                   |  |
| Isotope C:                                              |  |                         | Chemical Form:                  |                   |  |
| Administration Method:                                  |  |                         |                                 |                   |  |
| Radiopharmaceutical FDA Status:                         |  |                         |                                 |                   |  |
| Number of Subjects:                                     |  |                         | Number of Sessions per subject: |                   |  |
| Total activity administered per session:                |  |                         | MBq (1mCi = 37 MBq)             |                   |  |
| Critical Organ:                                         |  | Dose per session (mGy): |                                 | Total Dose (mGy): |  |
| Whole Body Dose per session (mSv):                      |  |                         |                                 | Total Dose (mSv): |  |
| Reference(s) Used (attach copy):                        |  |                         |                                 |                   |  |

| <b>SECTION III: PERSONNEL</b>                                                              |                                                                                                                                                  |
|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Select Applicable Category</b> ( <i>See Radiation Safety Manual, Sec. 41.2</i> ):       | <input type="checkbox"/> Radiopharmaceutical(s) are approved by the FDA for routine use (skip to FDA-approved radiopharmaceutical section below) |
|                                                                                            | <input type="checkbox"/> FDA approval under IND or eIND (add additional Authorized Users below, if any, and attach IND letter from FDA)          |
| <b>Additional Authorized Users with Written Directive authority for this study:</b>        | 1.                                                                                                                                               |
|                                                                                            | 2.                                                                                                                                               |
|                                                                                            | 3.                                                                                                                                               |
| <b>For FDA-approved radiopharmaceuticals, choose AUs with Written Directive authority:</b> | <input type="checkbox"/> Authorized Users listed on Nuclear Medicine authorization                                                               |
|                                                                                            | <input type="checkbox"/> Authorized Users for brachytherapy listed on Radiation Oncology authorization                                           |
| <b>Other investigators/workers involved or working around radioactive material</b>         | 1.                                                                                                                                               |
|                                                                                            | 2.                                                                                                                                               |
|                                                                                            | 3.                                                                                                                                               |

**SECTION IV: CERTIFICATE – ALARA COMMITMENT**

- I will evaluate all approved procedures before using radioactive materials to ensure that exposures be kept as low as reasonably achievable or ALARA.
- I will maintain exposures ALARA to all laboratory personnel - both users of radioactive material and those who do not use radioactive materials - in their laboratory protocols.
- I will ensure that persons working under my supervision are trained and educated in good radiation safety practices which contribute to maintaining exposures ALARA for all laboratory personnel.

***I certify that I have become familiar with the Emory University Radiation Safety Policy Manual and will implement requirements contained therein in the pursuit of this work.***

**SIGNATURE SECTION:**

The applicant and any official executing the certificate on behalf of the applicant named in Section I, certify that this application is prepared in conformity with Emory University Radiation Safety Procedures and with Georgia Department of Natural Resources Rules and Regulations, designated Chapter 391-3-17 and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge.

\_\_\_\_\_  
*Title*

\_\_\_\_\_  
*Department*

\_\_\_\_\_  
*Printed Name*

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Date*

*By signing this form, I acknowledge that all statements are true and accurate.*

➡ Save the form as <CommI-PI name>, e.g., CommI-JDoe

➡ Submit electronically to [mjhall@emory.edu](mailto:mjhall@emory.edu)

➡ Check all attachments that have been included:

- ☐ Section I, Building / Room Map ☐ on file
- ☐ Section I, Personnel History Form(s)
- ☐ Section II, References for Dosimetry - Isotope A
- ☐ Section II, References for Dosimetry - Isotope B
- ☐ Section II, References for Dosimetry - Isotope C
- ☐ Section II, References for Dosimetry - CT Scan
- ☐ Section II, References for Dosimetry - Transmission Scan
- ☐ Other:

**↑ You Are Done! ↑**

**ⓘ FOR RSO USE ONLY ⓘ**

RH # assigned: \_\_\_\_\_

Other Tracking: \_\_\_\_\_