**FSU- HRS Application**

**USE OF RADIOACTIVE MATERIAS, RADIATION GENERATING MATERIALS,**

**OR DEVICES, OR LASERS IN RESEARCH**

**Revision date: 16 May 2017**

|  |
| --- |
| 1. **Instructions:**  All materials must be typed.
2. A signed original is required. It must have all required signatures
3. Include all requested, applicable documents, see the questions below.
4. Omission of documents will yield an incomplete application and prolong your review process. Responses are rendered within 14 business days to the Principal Investigator**.**
5. This application must be submitted, single sided and not stapled
6. **Questions can be directed to Dr. Carla Raineri Padilla, cpadilla@uncfsu.edu or 910.627.1569**
 |
| **Checklist for application submission:*** HRS Application with applicable signatures (original and one copy)
* Certificates of CITI training for investigators and all key personnel
* Certificates of Safety training for appropriate areas, LASERs, Radiation, Radiation Generating Machines
* Letter(s) of support or agreement (if conducting research at another agency, school, etc)
* When appropriate, include HRS approved protocol from other involved institution or organizations

**Applications should be delivered to:**The Office of Sponsored Research and ProgramsAttn: Dr. Carla Raineri PadillaSchool of Business and Economics, Room 314Fayetteville, NC 28301This study will be reviewed in accordance with federal regulations governing the safe use of biological samples/organisms or Recombinant DNA. |
| **Principal Investigator (PI):** [This individual assumes **overall** responsibility for 1) development and submission of this Hazardous Chemicals or Controlled Substances in Research and Teaching Application, 2) assurance that proper protocol will be followed to ensure the safe and legal use and disposal of all hazardous chemicals and/or controlled substances 3) the performance of research interventions, and 4) the presentation or publication of the data.] |
| **PI FSU email:** |
| **PI Status: (check one)**: [ ] FSU Faculty [ ] FSUStaff [ ] FSUUndergraduate Student[ ] FSU GraduateStudent [ ] Visiting Scholar [ ]  Non FSU Affiliation (Specify Institution): (Complete appropriate section below) |
| **Office Location or Mailing Address:** (This is the address to where all IACUC correspondence will be sent.) |
| **Department:** |  |  |  |
| **Project Title:** |  |  |  |
| **If any biologicals are used please list them in this section. If none- write “None”** |  |  |  |
| [ ]  **New Protocol OR** [ ]  **Replacement for Protocol #:** |
| **Phone Number:**  | **( )**  | **University Email:** |  |
| **Co-Investigator #1:**  |  | **Department:** |  |
| **Co Investigator #2:**  |  | **Department:** |  |
| **Key Study Personnel:** Key personnel are defined as individuals who participate in the design, conduct, or reporting of Hazardous Materials as defined by the HRS. At a minimum, these individuals may be involved in conducting procedures and obtainment of legally effective informed consent/assent. All key personnel must have sufficient knowledge about the protocol to facilitate effective animal use in research and teaching as well as complete the Animal Use in Research and Teaching Training. If personnel have not been identified please list TBD in the Name column. |
| **Names (or TBD\*)** | **Position** | **Department** |
|  |  |  |
|  |  |  |
| **Is internal or external funding being sought for this research?** [ ]  **Yes** [ ]  **No** **Funding Source(s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_If yes, you must (1) submit a complete copy of that proposal as soon as it is available and (2) provide one copy of the funding announcement and all relevant forms, instructions, etc., with your original copy of this application. Does the funding agency require notification of Institutional Review Board approval? [ ]  Yes [ ]  NoProject period dates to \_*This is required information, must be future dates - after you have received final HRS approval to conduct your research.***Other Institutional Review Boards** Does the research involve another institution or site? [ ]  Yes [ ]  No * If yes, please list all institutions and sites: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Has any other IRB approved this project? [ ]  Yes [ ]  No If **Yes**, please provide a copy of the approval letter with this application. If **No**, will any other IRB be asked for approval? [ ]  Yes (please specify which IRB) [ ]  No

[ ]  Departmental Support[ ]  Teaching (if applicable): Course Number(s), Year(s), Semester(s) offered: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Other: Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Certificates of training are required: acceptable certificates are from CITI. All researchers must take Ethics for Researchers, and all other CITI trainings applicable to their research.****For questions on training requirements contact Carla Raineri Padilla** **cpadilla@uncfsu.edu****.****All researchers involved in research involving either radiation generating devices or radioactive materials, must have acceptable training certificates****For questions on acceptable trainings/certificates contact Carla Raineri Padilla cpadilla@uncfsu.edu** |
|  |
|

|  |
| --- |
| **Principle Investigator Information**  |

 |
|  |
| Experience:Check all that apply:Prior hands on experience working with radioactive materials \_\_\_\_\_ If applicable, number of years \_\_\_\_\_Prior hands on experience working with radiation generating materials or devices \_\_\_\_\_ If applicable, number of years \_\_\_\_\_Prior hands on experience working with LASERs \_\_\_\_\_ If applicable, number of years \_\_\_\_\_No prior hands on experience \_\_\_\_ But will receive training from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |
| Principal Investigator’s Signature |  | Date |
|  |
| The activity described herein is in conformity with the standards set by our department and I assure that the Principal Investigator has met all departmental requirements for review and approval of this research.  |
|  |
|  |
| Department Chair’s or Dean’s Signature |  | Date |
|  |
|  |
| 1. **COMPLETE THIS SECTION IF THE PRINCIPAL INVESTIGATOR IS A GRADUATE STUDENT (NOTE: Graduate Faculty Status is required for all Thesis/Dissertation Chair or Advisors.)**
 |
| Check one:  | [ ]  Thesis | [ ]  Dissertation | [ ]  Other  |  |
|  |
| Has the Thesis/Dissertation Committee approved the proposal? ❑ Yes Date Approved: / / [ ]  No |
|  |  |
| Name of Thesis/Dissertation Advisor:  |  |
|  |
| Advisor’s Department: |  | Advisor’s Phone No.:  |  |
|  |
| 1. **COMPLETE THIS SECTION IF THE PRINCIPAL INVESTIGATOR IS AN UNDERGRADUATE STUDENT**
 |
| Check one:  | [ ]  Class Project/Paper | [ ]  Honors Project | [ ]  Independent Study | [ ]  Other |  |
|  |
| Name of Research Supervisor/Class Instructor:  |  |
|  |
| Department:  |  | Phone No.: |  |
|  |
| Course Name (if applicable): |  |
|  |
| 1. **INVESTIGATOR ASSURANCES AND AFFIRMATION OF COMPLIANCE**
 |
|  |
| I agree to follow the procedures outlined in the summary description and any attachments to ensure that my project is properly protected. I understand that the study will not commence until I have received approval of these procedures from the HRS; I have complied with any required modifications in connection with that approval. I understand that additions to or changes in the procedures involving hazardous materials or controlled substances of any form or any problems with the containment of radioactive materials, radiation generating materials or devices, or LASERs must be promptly reported to the HRS. I further understand that if the project continues for more than one year from the approval date, it must be re-submitted as a renewal application. \***NOTE**: You (the investigator/researcher) are required to notify the HRS if any substantive changes are made in your research prospectus/protocol, if any unanticipated adverse events are observed on the subjects during your research, and when your project has ended. **Important:** If your project lasts longer than one year, you (the investigator/researcher) are required to notify the Office of Sponsored Research and Programs in writing of *Notice of Project Ending* or *Request for Continuation* at the end of each year. See the OSRP website for the proper form at <http://uncfsu.edu/research> Failure to notify the HRS of the above may result in disciplinary action under the FSU campus student and faculty misconduct policy. You are required to keep copies of the informed consent forms and data for at least three years.\*(**Required for all Investigators**):I affirm the accuracy of this application, and I accept responsibility for the conduct of this research, the supervision of research conducted on animal subjects, and maintenance of owner’s informed consent documentation as required by the HRS.  |
|  |
| Principal Investigator’s Signature |  | Date |  | Co-Principal investigator’s Signature |  | Date |
|  |
| 1. **APPROVAL OF FACULTY ADVISOR/SPONSOR**
 |
| \*(Required for all faculty advisors) By signing - you as Faculty Advisor affirm the accuracy of your students application and accept responsibility for the conduct of this research, the supervision of the researcher (student) in ethical conduct of research, and maintenance of informed consent documentation as required by the HRS. |
| Supervisor or Committee Chair Signature (for student investigator) |  | Date |
|  |
| 1. **NON-SCIENTIFIC SUMMARY OF THE PROPOSED WORK [Please *REMOVE* the information within the blue brackets and only provide your response in that area]**
 |
| [Provide a BRIEF description of the project, including the purpose and importance of the use of radioactive materials, radiation generating materials or devices or LASERs (any and all) in this activity. Include statements of the purpose, importance of and a description of the procedures to be used including the need for the specific species that will be used. A prepared study proposal (e.g., thesis; course project; independent study) may be attached in lieu of a description. The description must be sufficient to allow the HRS to achieve a clear understanding of the project objectives, methods, and significance.] |

|  |  |
| --- | --- |
|

|  |
| --- |
| **Laboratory and Research Specifications**  |

**RADIOACTIVE MATERIALS:**1. What isotopes and in what quantities will be used?ISOTOPE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Amount: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ISOTOPE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Amount: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ISOTOPE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Amount: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_2. What lab will the research occur in? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_3. Will the isotopes be in any room besides the research lab? YES \_\_\_ NO \_\_\_\_ If YES specify where \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_4. Can non-isotopic materials be substituted for any of the isotopic material? YES \_\_\_\_\_ NO \_\_\_\_ If non-isotopic materials can be substituted for isotopic, why are isotopes being used in the proposed research?5. Why types of protective devices/equipment will be used?6. What types of dosimeters will be used and where will they be worn? How will personal monitoring be done?7. How will contamination surveys be done, where and how often?8. Describe the plan to secure the isotopes and to ensure safe storage, usage and disposal.**RADIATION GENERATING MATERIALS OR DEVICES**7. What radiation generating device will be used? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_8. What type and what amount of radiation will be generated? Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Amount: \_\_\_\_\_\_\_\_9. What is the specific purpose of this device in the proposed research?10. How will the device be secured/ isolated from the general public?11. How will researcher/worker protection be ensured?12. What types of dosimeters will be used and where will they be worn? How will personal monitoring be done?13. How will contamination surveys be done, where and how often? (Be specific)  **LASERS**8. What LASER will be used in the protocol? (Provide a full description)9. What laser classification does the device belong to. See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1040.10 for guidance \_\_\_\_\_CLASS 1 \_\_\_\_\_ CLASS 2 \_\_\_\_\_ CLASS 3 \_\_\_\_\_ CLASS 4 10. Where will the LASER be? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_11. How will the laser generating device be safe-guarded? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_12. What human protections will be in place?13. What is the value of the laser to the proposed research?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**GENERAL QUESTIONS**14. Will radioactive materials be used with either hazardous chemicals or controlled substances? YES \_\_\_\_\_ NO\_\_\_\_\_15. Will human subjects be used? YES \_\_\_\_ NO\_\_\_\_\_16. Will living animals be used? YES \_\_\_\_\_ NO\_\_\_\_\_ |

|  |
| --- |
|  |
| 1. **Project Evaluation by PI**
 |
| For evaluation of your project, indicate that the following conditions have been met:[ ]  The study and its associated facilities meet all appropriate federal, state, and local regulations.[ ]  All radioactive material, radiation generating devices or lasers will be legally obtained, operated in and safely disposed of in accordance with all applicable, federal, state and local regulation.[ ]  All safeguards required for safe usage and handling and human protection will be in place and utilized at all times.[ ]  If specific licensures are required it is the responsibility of the researcher to coordinate with the Fayetteville State University Radiation Safety Board to obtain the necessary licensure, prior to obtaining any licensed materials or equipment or to the commencement of any research.[ ]  Adequate safeguards are in place to ensure the containment of all radioactive or otherwise harmful energy and to prevent the accidental or purposeful release of radioactive or otherwise harmful energy.[ ]  Regular periodic monitoring will be done for contamination of labs, equipment and personnel. |
|  |

|  |
| --- |
| 1. **SIGNATURE SECTION**
 |
| THE PRINCIPAL INVESTIGATOR MUST ASSURE THE HAZARDOUS MATERIALS RESEARCH AND SAFETY COMMITTEE THAT ALL PROCEDURES PERFORMED UNDER THE PROJECT WILL BE CONDUCTED BY INDIVIDUALS LEGALLY AND RESPONSIBLY ENTITLED TO DO SO, AND THAT ANY DEVIATION FROM THE PROJECT (E.G., CHANGE IN PRINCIPAL INVESTIGATORSHIP, RESEARCH METHODOLOGY, SUBJECT RECRUITMENT PROCEDURES, ETC.) WILL BE SUBMITTED TO THE HRS FOR ITS APPROVAL PRIOR TO ITS IMPLEMENTAION.1. I hereby apply for approval for the project described, and assume responsibility for care and use of radioactive materials or radiation generating materials or devices or lasers associated with this research.
2. I understand the requirements for the safe use and disposal of radioactive materials or radiation generating materials or devices or lasers, government regulations and FSU’s policies governing the use of radioactive materials or radiation generating materials or devices or lasers for research, testing, teaching or demonstration purposes. My signature certifies that I will conduct the project in full compliance with the aforementioned requirements.
3. I certify that the activities listed in this protocol do not unnecessarily duplicate previous experiments.
4. I certify that all personnel involved in the use of radioactive materials or radiation generating materials or devices or lasers in all aspects of this protocol are, or will be, adequately trained prior to participation in this study.
5. I certify that I will obtain approval from the HRS before initiating any significant changes to the study. Significant changes include but are not limited to: changes in the objectives of the study; changes in radioactive materials or radiation generating materials or devices or lasers; and changes in personnel involved in laboratory procedure.

**NOTE: Applications and any additional material requested by the HRS will not be processed unless legible, properly prepared, and signed personally by the Principal Investigator, Sponsor (if applicable), and the Principal Investigator’s supervisor or department/division chair.**  |
|  |
| Signature of Principal Investigator |  | Date |  |
|  |  |  |  |
| Signature of Co-Principal Investigator |  | Date |  |
|  |  |  |  |
| Signature of Co-Principal Investigator |  | Date |  |
|  |  |  |  |
| Signature of Responsible Faculty Advisor (If P.I. is not faculty) |  | Date |  |
|  |  |  |  |
| Signature of Department/Division Chair |  | Date |  |
|  |