**FSU- HRS Biological Research Application**

**Revision date: 16 May 2017**

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| 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) * Certificates of CITI use training for investigators and all key personnel * 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 Programs  Attn: Dr Carla Raineri Padilla  School of Business and Economics, Room 314  Fayetteville, NC 28301  This 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 Biological samples/organisms or Recombinant DNA in Research and Teaching Application, 2) assurance that proper protocol will be followed to ensure the safe and legal use of the samples or organisms or recombinant DNA 3) the performance of research interventions, and 4) the presentation or publication of the data.] | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **PI campus email:** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **PI Status: (check one)**: FSU Faculty FSUStaff FSUUndergraduate StudentFSU 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:** | | |  | | | | | | | | | | |  | | | | | | | |  | | | | | |
| **Identify the Biologicals) to be used** | | |  | | | | | | | | | | |  | | | | | | | |  | | | | | |
| **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** | | | | | | | | |
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| **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  No  Project 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** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| |  | | --- | | **Principle Investigator Information** | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Experience:  Check all that apply:  Prior hands on experience working with biological samples \_\_\_\_\_  Prior hands on experience working with infections agents \_\_\_\_\_ If applicable, number of years \_\_\_\_\_  Prior hands on experience working with recombinant DNA \_\_\_\_\_ If applicable, number of years \_\_\_\_\_  Prior hands on experience working with human tissues/cells/cultures \_\_\_\_ If applicable, number of years \_\_\_\_\_  Prior hands on experience working with cancer \_\_\_\_ If applicable number of years \_\_\_\_  No prior hands on experience \_\_\_\_ But will receive training from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Principal Investigator’s Signature | | | | | | | | | | | | | | | |  | | | | | Date | | | | | | |
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| 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. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Department Chair’s or Dean’s Signature | | | | | | | | | | | | | | | |  | | | | | Date | | | | | | |
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| 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 | | | | |  | | | | | | | |
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| Has the Thesis/Dissertation Committee approved the proposal? ❑ Yes Date Approved: / /  No | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Name of Thesis/Dissertation Advisor: | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
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| Advisor’s Department: | | | |  | | | | | | | | | | | Advisor’s Phone No.: | | | | | | | |  | | | | |
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| 1. **COMPLETE THIS SECTION IF THE PRINCIPAL INVESTIGATOR IS AN UNDERGRADUATE STUDENT** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Check one: | Class Project/Paper | | | | | Honors Project | | | | | | Independent Study | | | | | | | | | | Other | | |  | | |
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| Name of Research Supervisor/Class Instructor: | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
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| Department: | |  | | | | | | | | | | | | | | | Phone No.: | | | | |  | | | | | |
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| Course Name (if applicable): | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
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| 1. **INVESTIGATOR ASSURANCES AND AFFIRMATION OF COMPLIANCE** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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 biological materials of any form or any problems with the containment of biological materials 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. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Principal Investigator’s Signature | | | | | | | | | |  | Date |  | | | Co-Principal investigator’s Signature | | | | | | | | | | |  | Date |
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| 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 | | | |
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| 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 biological materials (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** |   **1.** Where will the research occur? (Specific Laboratory): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2. Will a Biosafety Cabinet (Tissue Culture Hood) be used? \_\_\_\_\_\_\_ Location of Cabinet: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3. Will and environmental chamber (cold room or hot room ) be used? \_\_\_\_\_ Location of Chamber: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  4. Will the research involve recombinant DNA? YES \_\_\_\_\_ (if yes complete 4a-4f) NO\_\_\_\_\_  a. Describe the DNA to be inserted in the recombinant vector  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  b. Is expression of this gene associated with any human disease? (If so what disease(s)?)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  c. What is the origin of the DNA?  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  d. Where will you obtain the DNA from?  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  e. Is the DNA derived from a potential pathogen and/ or encode a toxin and/or an oncogene? YES \_\_\_\_\_ NO \_\_\_\_\_  f. If the answer to 4e is YES, what risk group does it belong to? Refer to http://www.absa.org/riskgroups/index.html, to make determination. Check the appropriate risk group    \_\_\_\_\_Risk Group 1 (RG1) Agents that are not associated with disease in healthy adult humans. Includes a list of animal viral etiologic agents in common use.  \_\_\_\_\_Risk Group 2 (RG2) Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.  \_\_\_\_\_Risk Group 3 (RG3) Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).  \_\_\_\_\_Risk Group 4 (RG4) Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5. What is/ are the biological agents to be used (i.e. specific name for bacteria, other microscopic organisms, viruses, DNA, RNA, etc.)to be used biohazardous agents (excluding recombinant DNA) list all  b. What is the source of the agent/ where was it acquired? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  c. What is the required biosafety level, refer to NIH guidelines and Refer to http://www.absa.org/riskgroups/index.html to make the determination. Check the appropriate biosafety level.  **\_\_\_\_\_Biosafety Level 1 (BSL 1):** well characterized agents not consistently known to cause disease in healthy adult humans of minimal potential hazard to laboratory personnel and the environment  **\_\_\_\_\_Biosafety Level 2 (BSL 2):** agents of moderate potential hazard to personnel and the environment  **\_\_\_\_\_Biosafety Level 3 (BSL 3):** indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route (applicable to clinical, diagnostic, teaching, research or production facilities)  **\_\_\_\_\_Biosafety Level 4 (BSL 4):** dangerous and exotic agents which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  6. Will radioactive materials be used? YES \_\_\_\_\_ NO\_\_\_\_\_  7. Will human subjects be used in the protocol? YES \_\_\_\_ NO\_\_\_\_\_  8. Will living animals be used in the protocol? YES \_\_\_\_\_ NO\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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.  Adequate safeguards are in place to ensure the containment of all biological materials and to prevent the accidental or purposeful release of biological materials/agents/tissues/organism or etc..  Adequate safeguards have been made for the safety of researchers involved in conducting the research. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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 biological materials associated with this research. 2. I understand the requirements for the safe use of biological materials, government regulations and FSU’s policies governing the use of biological materials 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 Biologicals 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 Biological materials use; 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.** | | | |
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| Signature of Principal Investigator |  | Date |  |
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| Signature of Co-Principal Investigator |  | Date |  |
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| Signature of Co-Principal Investigator |  | Date |  |
|  |  |  |  |
| Signature of Responsible Faculty Advisor (If P.I. is not faculty) |  | Date |  |
|  |  |  |  |
| Signature of Department/Division Chair |  | Date |  |
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