

Part A

REGISTRATION OF RESEARCH WITH MICROORGANISMS, ONCOGENES, AND TOXINS

REGISTRATION #: _____ **APPROVAL DATE:** _____

DO NOT WRITE IN ABOVE SPACE

The NC State University Biosafety Office is required to maintain a registry of all laboratories and personnel working with all hazardous and potentially hazardous biological agents or materials. For purposes of this registration, a biological agent is defined as any organism or toxin regardless of biosafety level. All Biosafety level agents must be registered.

The Principal Investigator (PI) is responsible for completing a Biosafety registration form. This is needed to maintain registries of persons at risk for exposure to biological agents. The registration document and internal safety Standard Operating Procedures (SOP) are to be forwarded to the EHS, BOX 8007 prior to the initiation of work. Submit a separate Part B for EACH BIOLOGICAL AGENT. Each person listed shall initial the document to indicate they have been informed of: the potential hazards associated with this work, the appropriate safety practices to be used, and the availability of occupational medical programs and applicable educational opportunities. The PI is also responsible for notifying the Biosafety Office when work with the organism is terminated or when other significant changes occur which would require modification of Parts A-C of the registration document. Any additions to the list of personnel is done by completing a "HBV and HIV Surveillance Eligibility and Addition to Pathogen Registration Form" and sending it to EHS. Review and update of registration forms and SOPs are required annually. An identification number (BIOS REG#) will be assigned to each protocol. When referring to your registration document, please include your BIOS Registration #.

EHS conducts annual audits of each registered laboratory to review compliance with NIH/CDC guidelines for practices and procedures appropriate to this work. The audit is not intended to take the place of the responsibilities of the PI in supervising daily work with pathogens. Contact the Biological Safety Officer (x6858) if you have any questions regarding this program.

PART A (PLEASE TYPE OR PRINT)

1. Principal Investigator: _____ Telephone: _____
 Supervisor of Project: _____ Telephone: _____
 Bldg/Rm: _____ / _____ Dept. _____ Safety Plan Number: _____
 Project Title: _____
 Type of Registration: New 3 Year Renewal (Current Reg # _____)

2. List all personnel involved with this project who may be at risk of potential exposure. Include lab technicians, animal care-takers, etc. Please print.

| Employee Name/Employee # ¹ | Job Title | Initials ² |
|---------------------------------------|-----------|-----------------------|
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1. Have each employee initial the document to indicate the employee has been informed of potential hazards, safe work practices, availability medical surveillance and training opportunities (additional sheet if needed).
2. Please attach a brief overview of the proposed research containing sufficient information to ensure adequate review of the protocol to determine compliance with local, state, and federal regulation.

PART B To be completed by laboratories handling biological agents or toxins (Provide complete information for each microorganism in use in your laboratory).

1. Biological Agent or Toxin: _____
Specific Strains, Genotype, or CAS #: _____
2. Is agent or material a potential human or animal pathogen or toxin? Human Animal
3. Is agent listed on the CDC List of Select Agents (42 CFR 72.6, Appendix A)? Yes No
4. Is antibiotic resistance expressed? No Yes other markers? _____
5. Location of laboratory(ies): Bldg(s)/Room(s)_____
6. Is a toxin produced? No Yes Work with toxin? No Yes
If yes, does toxin have an LD₅₀ more than 100 nanograms per kilogram body weight? Yes No
7. Largest volume used is: _____ liters. Usual volume used is _____ liters.
8. Is organism inactivated prior to disposal? No Yes
 - a. Specify methods: Heat Chemical Radiation Other
 - b. How do you verify inactivation _____
9. Do you culture the organism? No Yes Specify amount _____
10. Do you concentrate the organism? No Yes
 - a. Specify methods: Centrifugation Precipitation Filtration Other
11. Containment equipment available: Biological Safety Cabinet ,
Containment Centrifuge Other
12. Do you radioactively label the organism? No Yes Isotope _____
 - a. Where is the labeling done? _____
13. Work with the following tissues:_____ cell lines:(indicate whether human or animal source) If human cells are used, complete Part C _____
14. If working with animals, is The "Animal Handling Medical Surveillance" in place? Yes No

I accept the responsibility for the safe conduct of work with this organism at the Biological Safety Level practices and procedures assigned in Part D. I will inform all personnel, who may be at risk of potential exposure to the organism, of the conditions of this work.

Principal Investigator (signature) _____ Date _____

PART C To be completed by laboratories handling human blood, blood components.

1. Location of laboratory(ies): Bldg(s)/Rm(s) _____ / _____, _____, _____
2. Identify human samples to be manipulated:
 Whole blood/serum: _____ Established cell lines: _____
 Blood component: _____ Unfixed tissues: _____
 Cell "strains": _____ Primary explants: _____
 Tissue from animals infected with HIV or HBV: _____
 Cell lines or repository cells infected with HIV/HBV: _____
3. Is material freshly harvested? (less than 24 hrs old) No Yes
4. From where are cell lines obtained? _____
5. Has material been prescreened for pathogens? No Yes
 a. If yes, identify any positive tests: _____
 b. Are cell lines, strains, or explants characterized to be free of bloodborne pathogens? No Yes
 If yes, attach documentation.
6. Has material been infected with any pathogens? No Yes
 a. Will the material be infected with any pathogens as a part of this protocol? No Yes
 Material: _____
7. Frequency of manipulations: Daily Weekly Other
8. Types of manipulations:
 Centrifugation _____ Sonification _____ Dissection _____
 Blending/Mixing _____ Pipetting _____ Other _____
- 9.. Containment equipment available: Biological Safety Cabinet _____ Chemical Fume Hood _____
 Containment Centrifuge _____ Other _____

I accept the responsibility for the safe conduct of work with the above mentioned human blood, body fluids and/or tissues using the Biological Safety Level practices and procedures assigned in Part D. I will inform all personnel, who may be at risk of exposure to these materials of the appropriate procedures for this work.

Principal Investigator (signature) _____ Date _____

PART D To be completed by the NC State University Biosafety Committee, Biological Safety Officer.

Reviewer's comments _____

Parts A - D of this registration document were reviewed by _____ on _____,
and work can proceed in a BL _____ facility using BL _____ practices and procedures. PATH#: _____

Name, Title Date

Biological Safety Officer, Date

Biosafety Chairperson Date

To be completed by the Biosafety Office upon notification that this work has terminated.

Date Registration Document Inactivated: _____ Biosafety Office: _____