

REGISTRATION OF RESEARCH WITH PATHOGENS, ONCOGENES, AND TOXINS

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

DO NOT WRITE IN ABOVE SPACE

The NCI-FREDERICK 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 known to cause or suspected of causing disease in humans and requiring Biosafety Level 2, 3 or 4 containment practices, equipment and facilities.

The Principal Investigator (PI) is responsible for completing a NCI-FREDERICK 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 NCI-FREDERICK Environment, Health, and Safety Program (EHS), Biological Safety Office, Bldg. 426 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-D 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" (attached) and forwarding it to Occupational Health Services (OHS), Building 426. Review and update of registration forms and SOPs are required annually. An identification number (EHS REG#) will be assigned to each protocol. When referring to your registration document, please include your EHS 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 (x1451) if you have any questions regarding this program.

PART A (PLEASE TYPE OR PRINT)

1. Principal Investigator: _____ Telephone: _____
 Supervisor of Project: _____ Telephone: _____
 Bldg/Rm: _____ Organization: _____ Program: _____
 Project Title: _____
 Type of Registration: New 3 Year Renewal (Current EHS 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

¹ Provide last 4 digits of SSN for government employees.
² Have each employee initial the document to indicate the employee has been informed of potential hazards, safe work practices, availability of medical surveillance and training opportunities (attach additional sheet as needed).
³ **Please attach a copy of your written procedures or requirements for the conduct of safe work practices in the lab.** These must be reviewed and updated on an annual basis. Also 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 as a regulated biological agent (42 CFR 73, 9 CFR 121 or 7 CFR 331)? 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
 - a. If yes, specify the toxin LD₅₀ in dose per kilogram body weight? _____
 - b. amount of toxin in your possession? _____mg
7. Largest volume used is: _____ liters. Usual volume used is _____ liters.
8. Is organism inactivated prior to other manipulations? 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 , Chemical Fume Hood , 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

I accept the responsibility for the safe conduct of work with this organism at the Biological Safety Level practices and procedures assigned in Part E. 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 and/or OPIM.

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 E. 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 **Animal Facility Manager** (as applicable). Please attach the safety SOP for the animal facility.

- 1. Animal Study Proposal #: _____ Bldg(s)/Rm(s) _____
- 2. Specify animals: mice rats rabbits non-human primates other
- 3. Do you expose animals to the live organism? No Yes
Administration routes: SC IM IP IV IC Other
- 4. List animal care personnel associated with this protocol:

Employee Name	Job Title

5. Duration of study _____

I accept the responsibility for the safe conduct of work with the above mentioned animals or animal materials using the Biological Safety Level practices and procedures assigned in Part E. I will inform all personnel, who may be at risk of exposure to these materials of the associated risks and the appropriate procedures for conducting this work.

Animal Facility Manager (signature) _____

Date _____

Principal Investigator (signature) _____

Date _____

Return Completed Form To: Biological Safety Office, EHS, Bldg. 426

PART E To be completed by the NCI-FREDERICK Institutional Biosafety Committee, Biological Safety Officer and/or EHS.

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#: _____

Lab was certified on _____ by _____

Name, Title _____ Date _____

Medical Surveillance Program indicated: Yes No Program(s): _____

OHS Manager _____ Date _____

Approval:
Biological Safety Officer, EHS _____ Date _____

IBC Chairperson _____ Date _____

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

Date Registration Document Inactivated: _____ Biosafety Office: _____