# C-3. PATHOGEN PROGRAM

## I. SCOPE

The NCI-Frederick Pathogen Program is applicable to all laboratories at the NCI-Frederick working with human pathogens, oncogenes, biological toxins, and other materials potentially pathogenic to humans. This includes, but is not limited to, human pathogens, blood, blood components, human cell lines and other potentially infectious material (OPIM).

## II. PURPOSE

The program is designed to protect the health and safety of all employees at the NCI-Frederick, ensure that the facility is in compliance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard, 29 CFR 1910.1030, and ensure that all laboratories are following the appropriate Centers for Disease Control (CDC)/NIH Biosafety Level (BSL) guidelines. The registration process, administered by the Environment, Health and Safety Program (EHS), reviewed by the NCI-Frederick Institutional Biosafety Committee, documents the use of potential human pathogens, oncogenes, and toxins in the laboratories at the NCI-Frederick.

## III. DEFINITIONS

**Additional Initial Training** - Training required for employees working in Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV) laboratories and production facilities without prior experience handling human pathogens, oncogenes, and toxins.

**Biosafety Level (BSL)** - Combination of laboratory practices and techniques, safety equipment, and laboratory facilities.

**Biosafety Level 2* (BSL-2*)** - Laboratory that meets Biosafety Level 2 facility requirements but is operated using BSL-3 practices, procedures, and equipment.

**Blood** - Human blood, human blood components, and products made from human blood.

**Bloodborne Pathogens** - Microorganisms that are present in human blood and can cause disease in humans. These include, but are not limited to, HBV and HIV and HCV.

**Exposure Control Plan** - A site-specific manual required by the OSHA Bloodborne Pathogen Standard (29CFR1910.1030) to describe institutional policies to prevent the transmission of bloodborne pathogens in the work setting.

**Exposure Incident** - A specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

**Occupational Exposure** - Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

**Other Potential Infectious Material (OPIM)** - 1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; 2) Any unfixed human tissue or organ (other than intact skin); and 3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

**Production Facility** - Facility engaged in industrial-scale, large-volume, or high-concentration production of HIV or HBV.

**Research Laboratory** - For the purpose of this chapter, a laboratory producing or using research laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

## IV. RESPONSIBILITIES

A. Principal Investigators (PIs) are responsible for:

1. Ensuring all laboratory employees are adequately trained per requirements of OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030(g)(2)(ix) “Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities”.

2. Registering all materials potentially infectious to humans with the EHS Office and the Institutional Biosafety Committee (IBC).

3. Developing and providing to EHS a standard operating procedure (SOP) for all work conducted at BSL-2, BSL-3, or BSL-2*.

4. Ensuring all employees with occupational exposure to bloodborne pathogens attend annual Bloodborne Pathogen Training offered by EHS.

5. Updating the pathogen registration form when changes occur in protocol, location, and personnel. The PI will submit these changes to EHS for approval.

6. Providing EHS with a copy of a signed BSL-2, BSL-3/BSL-2* SOP and Additional Initial Training Form for each BSL-2, BSL-3/BSL-2* employee prior to the employee's working with BSL-2, BSL-3/BSL-2* material.

7. Following pre-operational laboratory procedures.

8. Contacting Manager, OHS to arrange for any vaccinations or medical surveillance programs.

B. Supervisors are responsible for:

1. Reporting to the PI and EHS all biological spills and potential exposure incidents.

2. Assisting EHS and Occupational Health Services (OHS) in the investigation of potential exposure incidents.

3. Reviewing lab SOPs and registration forms with laboratory employees.

4. Weekly ventilation checks for airflow direction.

5. Ensure all employees with occupational exposure to BBP are enrolled in the BBP program within 10 days of beginning work

C. Employees are responsible for:

1. Following assigned Biosafety Level guidelines.

2. Attending annual Bloodborne Pathogen Training and other safety training programs.

3. Reporting spills involving biological material to the Principal Investigator and EHS.

4. Reporting all potential exposure incidents to OHS and the lab supervisor.

5. Complying with the procedures established in the NCI-Frederick Exposure Control Plan.

D. EHS is responsible for:

1. Maintaining a current registry to include SOPs, inspection reports, and approved pathogen registration forms for work with human pathogens, blood, oncogenes, toxins, and OPIM.

2. Maintaining training records in accordance with the OSHA Bloodborne Pathogen Standard.

3. Assigning a Biosafety Level for all registered laboratories.

4. In conjunction with Occupational Health Services (OHS), identify all personnel on a registered program for enrollment in appropriate medical surveillance program(s).

5. Working with OHS on all accident investigations involving potential biological hazard exposure incidents.

6. Provide initial and annual refresher bloodborne pathogen training.

7. Assisting the PI in developing and then approving lab-specific SOPs.

8. Conduct semi-annual inspections of all areas registered as a BSL-3 or BSL-2* laboratories and generate inspection reports on findings. All other laboratories are inspected on an annual basis.

## V. PROCEDURES

### A. Pathogen Registration

1. PIs shall obtain an NCI-Frederick Pathogen Registration Form and SOP guidelines from EHS and Surveillance Eligibility and Addition to Pathogen Registration Forms from OHS for each employee when work with the following materials is to begin: human pathogens, toxins, blood, and/or OPIM.

2. The PI sends the completed NCI-Frederick Pathogen Registration Form and standard operating procedure to EHS, Bldg. 426, for review. EHS facilitates the review of the registration document by the IBC. EHS will send a memo to the PI acknowledging IBC approval of the documents and the assigned Biosafety Level and Pathogen Registration Number (PATH#).

3. The PI shall review the approved laboratory SOPs with each employee and have them sign a copy to document their understanding of the occupational hazards and BSL-3/BSL-2* procedures. The signed copies are then to be forwarded to EHS, Bldg. 426 for inclusion in the Registration documentation

4. The PI sends the Surveillance Eligibility and Addition to Pathogen Registration Forms to OHS, Bldg. 426.

5. The PI who is responsible for BSL-3/BSL-2* facilities shall:

    a. Provide program-specific additional initial training for each BL-3/BSL-2* employee within 6 months after their start date. OSHA's bloodborne pathogen standard requires that proficiency in handling human pathogens or tissue culture be demonstrated to the employee's supervisor. This is especially critical for individuals that have limited or no experience in handling human pathogens. The Program will document this training. Additional Initial Training forms available from EHS or equivalent departmental forms may be used. The forms should document:

        i. That the PI has given the employee additional instruction regarding standard microbiological practices and handling human pathogens, or

ii. That an exemption is requested because of previous educational and/or on-the-job training.

B. Pre-Operational Laboratory Procedures

1. Warning labels with the biohazard symbol and indicating the biohazard involved must be affixed to containers of special medical waste, freezers, refrigerators, and incubators storing and containing human pathogens, blood, and/or OPIM. Appropriate labels and signs are available from EHS.

2. Door signs depicting the universal biohazard symbol must be affixed to all entrances of the lab. The information on these signs must be current and complete. The signs are available from EHS.

3. Ensure vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent.

4. Access to BSL-2 and BSL-3 areas shall be limited or restricted as appropriate. The laboratory Director/P.I. controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes.

5. Use of glass and sharps in BSL-3/BSL-2* facilities shall be restricted by utilizing plastic alternatives whenever possible.

6. A stock of first aid kits, povidone scrub brushes, and disinfectant solutions shall be maintained for biological spills and potential exposures. Povidone scrub brush kits are available from Biological Safety, EHS.

7. Ventilation in BSL-3/BSL-2* facilities shall be maintained under negative pressure. Guidance can be obtained from EHS.

C. Addition/Deletion of Employees to Medical Surveillance Programs and Registration Programs

1. For each employee with potential occupational exposure to bloodborne pathogens, PIs shall obtain from OHS a Surveillance Eligibility Form and Addition to Pathogen Registration Form. The forms shall be completed and returned to OHS, Bldg. 426. Receipt of these forms adds an employee to the pathogen program

specified on the surveillance eligibility form.

2. PIs shall forward a memo or send an e-mail to EHS when personnel terminate employment or transfer to another program. The memo or e-mail should include date of termination and PATH#.

D. Bloodborne Pathogen Training

1. Initial Bloodborne Pathogen Training is provided by EHS upon the supervisor's request for all new employees covered by the NCI-Frederick Exposure Control Plan. Work with HIV, HBV, OPIM, or BSL-3/BSL-2* agents is prohibited until this training has been completed.

2. Annual Bloodborne Pathogen Training in compliance with federal mandates is scheduled and provided by EHS. Completion of annual refresher training is required by any employee with occupational exposure to bloodborne pathogens or OPIM.

E. Accident Reporting

1. All potential exposure incidents shall be reported to OHS and the employee's supervisor immediately.

2. An Accident Report Form shall be completed and submitted to OHS within 24 hours. (Refer to Sections B-2 Accident Reporting and C-7 Medical Surveillance.)

## VI. **REFERENCES**

29 CFR 1910.1030 - OSHA Bloodborne Pathogen Standard.
Biological Safety in Microbiological and Biomedical Laboratories, current version.
NIH Recombinant DNA guidelines, current version.
NCI-Frederick Bloodborne Pathogen Exposure Control Plan, current version.