Biosafety Requirements

The following information describes the requirements for NYU researchers as defined by EHS. It is the responsibility of each PI to ensure the laboratory is in compliance.

Biological Laboratory Survey

Institutions with research and teaching activities are obligated by federal and/or state regulations to know which biological agents are used or stored in their buildings. The identification of the biohazard materials present in an institution is a crucial step in the development of an effective biological safety program.

The Principal Investigators (PI) are required to complete a biological laboratory survey. It is used to identify laboratories and personnel who are handling biological materials. The information provided will be reviewed by the Senior Biosafety Specialist. The Biosafety review will:

- Determine appropriate risk groups and biological safety containment levels (BSL),
- Identify recombinant or synthetic nucleic acid molecule activities,
- Determine the adequacy of the laboratory for the research activities,
- Determine and establish appropriate biosecurity measures,
- Determine bloodborne pathogens exposure risk,
- Determine and develop necessary and appropriate training/training tools,
- Determine medical surveillance needs,
- Comply with all applicable regulations,
- Determine appropriate shipping and transport procedures,
- Identify related environmental issues (waste handling, facility ventilation), and
- Assist emergency response planning.

The Survey must be updated for the following reasons:

- New agents and materials are brought in the laboratory
- Location of laboratory changes
- Removal or addition of personnel

Registration of Recombinant and Synthetic Nucleic Acid Molecule (r-sNA) Experiments

PIs are required to register all r-sNA activities with NYU Medical Center’s Institutional Biosafety Committee. Committee approval is required prior to the initiation of all r-sNA activities. The r-sNA registration form is available on NYU School of Medicine’s IBC webpage through the Kerberos Research Portal System.

Human Blood, Body Fluids, Tissues and Other Potentially Infectious Materials

The Occupational Safety and Health Administration (OSHA) created the Occupational Exposure to Bloodborne Pathogens Standard, 29 CFR Part 1910.1030 (the Standard) to minimize or eliminate exposure to infectious agents that may be present in human blood, tissues or certain body fluids (bloodborne pathogens.) The Standard applies to all employers having employees that may be “occupationally exposed” to human blood or other potentially infectious materials.

An employee is considered occupationally exposed if there is “reasonably anticipated skin, eye, mucous membrane, or parenteral contact with human blood or other potentially infectious materials (OPIM) in the performance of an employee’s duties.” Other potentially infectious materials include:
- Human cell/tissue cultures, including embryonic stem cells,
- Organ cultures,
- Any unfixed tissue or organ, other than intact skin, from a human being (living or dead),
- HIV- or HBV-containing culture media or other solutions,
- Human body fluids, except urine, feces, saliva or tears unless visibly contaminated with blood,
- Blood, organs or other tissues from experimental animals infected with HIV or HBV or other bloodborne pathogens,

An individual is also considered occupationally exposed if they do not have direct contact with blood or other potentially infectious material, but operate equipment that is used to process or store blood or OPIMs.

The BMBL recommends that human and non-human primate (NHP) cells, tissues, and bodily fluids be handled using Biosafety Level 2 (BSL-2) practices and containment. Human and NHP materials, even in the absence of overt contamination, may contain adventitious viruses and/or other opportunistic pathogens or zoonotic agents. Since it is extremely difficult to screen for every pathogen, all human and NHP materials must be handled with standard precautions (e.g. treated as though they are contaminated with infectious agents) and utilize BSL-2 practices.

Moreover, all cell lines and tissue cultures of human and NHP origin, including established cell lines and bodily fluids will be handled in accordance with the OSHA Bloodborne Pathogens Standard and under Biosafety Level 2 (BSL-2) containment. Other mammalian cell lines used to propagate viruses will also require BSL-2 practices. Laboratory personnel working with these cultures must maintain a written record of their annual training as required by OSHA Bloodborne Pathogens Standard. Contact EHS at 212-998-1450 for a training schedule. NYU’s Exposure Control Program is located at the following website policy #110, Bloodborne Pathogens Exposure Control Program.

Animal Use
All research involving animals must be conducted in accordance with an approved University Animal Welfare Committee (UAWC) protocol. Additionally, animal research that contains biohazards must receive approval from the IBC prior to the conduct of research. Contact the UAWC for additional information. The UAWC is charged with responsibility for reviewing New York University’s program for the humane care and use of animals in research and teaching labs. The Biosafety Officer works with the UAWC when protocols involve the use of biohazard materials and the IBC when materials are of an r-sNA nature. Contact Biosafety if there are any questions or concerns regarding biohazards and animal use.

Biological Safety Cabinets (BSC), Laminar Flow Benches (LFB) and Chemical Fume Hoods
Clean air devices are equipment that use one or more HEPA filters to deliver clean, nearly particulate free, air to a work surface. BSC are designed to protect the user and the environment from contamination, most protect the product as well. Laminar flow benches (LFB) only protect the product from contamination. The efficacy of BSCs and LFBs depends upon the behavior of the operator, the unit’s orientation in the facility, and the movement of personnel in the laboratory.

Chemical fume hoods and other capture devices must be used for operations that might result in the release of toxic chemical vapors, fumes, or dusts. Benchtop use of chemicals that present an inhalation hazard is not permitted. Fume hoods must be used when conducting new experiments with unknown consequences from reactions or when the potential for a fire exists.
EHS has implemented and Inspection Program, designated to ensure the health and safety of NYU’s laboratory personnel and prevent environmental release of infectious materials or the inhalation of chemical vapors, fumes, or dust. This is done through annual certification of all BSCs, LFBs and fume hoods to ensure the unit’s ability to perform the intended function.

All clean air devices and fume hoods must be placed on the NYU service contract and be certified at least annually. Biosafety coordinates the certification with a contracted vendor. Units that are not certified annually will be rendered non-functional until such time as a certification is performed. The Office of Environmental Health and Safety will contact you to schedule the required annual certification.

Notify Biosafety in advance when you plan to have BSCs or LFBs moved, placed in storage, transferred to a new owner, discarded, removed from NYU or obtained from another institution or manufacturer. Contact Biosafety if service or repairs (e.g., replacing fluorescent lamps) are needed for your unit. BSCs must be professionally decontaminated with formaldehyde, by a certified technician, before a unit is relocated, stored, serviced (interior) or discarded.

**Training**

Successful completion of certain EHS training may be required **prior to the conduct of research or work assignment**. The training program was developed and is offered by EHS via classroom and online (NYU Classes). A schedule of trainings is provided to the NYU community at the start of each semester. If a specific training is required for work in the laboratory, health center or clinic, please contact Environmental Health and Safety at x81450 or ehs@nyu.edu to schedule a training time.

EHS maintains a list of individuals who have completed various training modules. Please contact EHS if you require proof of training. Principal investigators are responsible for providing laboratory personnel with information regarding specific hazards or situations not covered in EHS trainings. This may include information about health hazards, location and use of PPE, spill clean-up materials, and the presence of any particularly hazardous materials in the laboratory. Additional training, provided by the principal investigator, should be specific to the activities conducted in the laboratory. It should include:

- Health risks (biological, chemical and physical) posed by the experimental procedures conducted in their lab,
- Regulated Medical Waste (RMW) training and proper disposal methods for biological, chemical and hazardous materials,
- The existence and location of all designated areas in the laboratory,
- The selection and use of personal protective equipment appropriate for laboratory tasks.

PI’s can work with EHS to schedule laboratory or department specific trainings. For more information on training requirements visit the **Training webpage**.
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Table 1: EHS Laboratory Science Trainings

**Standard Operating Procedures**

Standard operating procedures (SOPs) are intended to provide individuals with general guidance on how to safely work with a specific class of biological agent or hazard. While SOPs provide only general guidance, observance of all the safety practices listed in them is mandatory. If compliance with all the requirements of a specific standard operating procedure is not possible, the principal investigator must develop a written procedure that will be used in its place. This alternate procedure must provide the same level of protection as the SOP it replaces. Biosafety is available to provide guidance during the development of alternate procedures.

SOPs, at minimum, should include step-by-step instructions of the tasks emphasizing safety controls, (i.e. Personal Protective equipment, use of fume hoods). They should also state the type of personnel authorized to perform the task.

In order to provide flexibility, standard operating procedures are generic in nature. They address the use and handling of substances by hazard class only. In some instances, multiple SOPs may be applicable for a specific biological agent. All SOPs should be incorporated into a Laboratory Specific Biosafety Manual and be accessible to all laboratory personnel. If you have questions concerning the applicability of any item listed in an SOP, contact the Principal Investigator of your laboratory or Biosafety at 212-998-1440.