

Upstate Medical University
Institutional Bio-Safety Committee

Policy and Procedures for Research Involving Human Blood,
Fresh Human Tissue, or Body Fluids.

I. Policy

All human blood, fresh tissue, or body fluids must be regarded as possibly infected with blood borne pathogens such as Human Immunodeficiency Virus (HIV) or Hepatitis B Virus (HBV). Therefore, the Upstate IBC will review research protocols which involve the use of human blood, fresh human tissue, or body fluids in a research lab or by Upstate research personnel to ensure maximum safety.

All persons working in laboratories that deal with these substances must be informed of the potential hazard and instructed in the procedures needed to avoid exposure and infection. It is the responsibility of the principal investigator to inform and instruct those persons under his/her supervision.

Specifically excluded from these requirements are hospital and patient-related service activities at University Hospital. These activities are governed separately under guidelines developed by the Department of Environmental Health & Safety and the Hospital Infections Committee.

The IBC is authorized to inspect research facilities, approve research practices and procedures, and to take actions, such as enforcement or cessation of research activities, in the event of an unsafe workplace situation.

II. Definitions

**III. Procedures for Reviewing Research Involving Human Blood,
Fresh Human Tissue, or Body Fluids.**

Review of the project shall include: (i) assessment of the containment levels required; and (ii) assessment of the facilities (a site visit may be required), procedures, practices, and training of personnel involved in the research. Biosafety Level 2 is appropriate when work is done with any human-derived blood, body fluids, tissues, or primary human cell lines where the presence of an infectious agent may be unknown.

- A. Submission of an application and laboratory manual to the IBC is required for all experiments and research studies involving the use of human blood, fresh human tissue, or body fluids in a research lab or by Upstate research personnel.
 - a. The IBC application and a sample laboratory safety manual are available on the IBC website. The sample lab manual can be used as a template and modified as appropriate.

- B. The IBC Chair or his/her designee will review the materials for confirmation of investigator assessment. The investigator will be notified in writing if further information is required, or if the document is acceptable as written. An approval date will be issued, so that tracking for annual renewal can be initiated.

IV. Continuing Review of IBC Approved Projects

Annual Review of all projects which have been reviewed and approved by the IBC is required. A Progress report form should be submitted to the IBC office for review at least one week prior to the project's expiration date. The Committee will re-review all approved research every five years to ensure compliance with the NIH and Institutional Guidelines. Investigators will be asked to submit an updated Application Form, Bio-Safety Manual and Personnel form, for the five year review.

V. Training Requirements

All employees working with potentially infected substances must participate in the basic required training for all employees offered by the Department of Environmental Health & Safety, and extended training offered by their laboratory supervisor

VI. Helpful Links

American Biological Safety Association

<http://www.absa.org/restool.html>

Upstate Environmental Health and Safety

<http://www.upstate.edu/ehs/>

Upstate Environmental Health and Safety Training Programs

http://www.upstate.edu/ehs/ehs_training.shtml

Questions concerning this policy/procedure and/or the IBC approval process may be directed to:

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**SUNY UPSTATE MEDICAL UNIVERSITY
INSTITUTIONAL BIOSAFETY COMMITTEE
BIOSAFETY MANUAL Template**

This Biosafety Manual is written to comply with the requirements of the OSHA Bloodborne Pathogen Standard, 29 CFR 1910.1030. This manual shall be reviewed annually, and updated as necessary.

AREA ACCESS

During times when work with human blood, body fluid, tissue or pathogenic organisms is in progress, each laboratory shall have access restricted to only those individuals who are authorized. Any individual may be “authorized” to enter, if they have met the following criteria:

- they have trained, and shown proficiency with the microbiological practices used in the laboratory
- they have been trained in the procedures used in the laboratory
- they have been advised of the potential hazards

While work with potentially infected substances is in progress, each laboratory must have its doors closed and labeled. The label must be red or orange in color, contain the universal biohazard symbol, a listing of the pathogen being used, and the name and telephone number of the individual in charge of the laboratory.

WORK PRACTICES

All work areas will be properly equipped for hand washing, waste disposal and sharps disposal facilities. While working with potentially infected materials employees will not be allowed to eat, drink, needless to say smoke, apply lip balm or cosmetics or handle contact lenses. Mouth pipetting is not allowed at any time.

CONTAINMENT

All refrigerators, freezers, biological safety cabinets, animal cages or other storage containers that contain potentially infected samples or tissues must be labeled with the biohazard symbol and pathogen. Food may not be stored in these refrigerators or freezers. All potentially infectious specimens will be kept in leakproof containers during transport and storage. For transport between work areas, samples should be in nested, sealed containers (e.g., tubes in a sealed pouch, pouch in a latched cooler.).

BIOLOGICAL SAFETY CABINETS

Class II biological safety cabinets must be used for work with potentially infectious substances that are likely to produce significant aerosols, and for any work with materials known to contain Class II pathogens, as defined in Federal Register 51, #88, pp. 16967-68, 1986. No work with Class III or Class IV pathogens is presently permitted in the SUNY Upstate Medical University.

VACUUM LINES

Vacuum lines used to aspirate potentially infectious fluids shall be protected by a liquid disinfectant trap and a HEPA filter in line between the collection flask and the control valve. These will be checked periodically and replaced when necessary.

NEEDLES & SHARPS

Accidental needle sticks or other sharps injuries are a major health risk for lab personnel who work with body fluids or tissues, and every effort must be made to prevent needless sharps exposures. Proper disposal of syringes requires that the needles are not removed, recapped, bent or sheared, but that the syringe and attached needle is promptly and carefully deposited in a puncture-proof, leak-proof, lockable sharps container which is labeled with the universal biohazard symbol. Over-filled containers are hazardous and cause unnecessary needle sticks. Never force the syringe into the sharps container; replace the container. Full containers should be incinerated. In case of a needle stick or other sharps injury, immediately notify your supervisor and contact the Hospital Infection Control Nurse on call – through the telephone Operator.

ACCIDENTS & SPILLS

Spills or other accidents which result in overt exposure to potentially infectious substances will be reported immediately to the laboratory director who will report to Environmental Health & Safety. Medical evaluation, surveillance and treatment will be provided as appropriate and written records maintained.

CONTAMINATED WASTE

All contaminated items must be placed in red or biohazard labeled bags that are contained in leakproof and labeled receptacles. This material will be autoclaved and/or incinerated for disposal.

CENTRIFUGES

Centrifugation of potentially contaminated samples will be done only in sealed tubes and rotors or with approved biohazard safety cups.

PERSONAL PROTECTIVE EQUIPMENT

Universal Precautions will be employed by all individuals with potential exposure to any human bloodborne pathogen.

All contaminated personal protective equipment must be handled as biohazardous. Disposables (gloves and gowns) will be disposed through incineration. Contaminated clothing will be kept isolated until the contracting company will pick up for laundering. All linen service contractors handle all laundry with Universal Precautions.

Gloves must be worn whenever potentially infected substances are in use.

Gloves will be suitable for the task, changed if torn or contaminated and should not be worn outside the laboratory. Hands will be washed when gloves are removed.

Clothing

Lab coats and/or repellent gowns will be worn whenever potentially infected substances are in use. These must be changed if contaminated and should not be worn outside the laboratory.

Eye Protection

Glasses with side shields, goggles and/or face shields must be worn whenever potentially infected substances are in use.

Masks

Water repellent masks will be worn when there is potential of spray, splash, splatter or the generation of aerosols.

TRAINING REQUIREMENTS

All employees working with potentially infected substances must participate in the basic required training for all employees offered by the Department of Environmental Health & Safety, and extended training offered by their laboratory supervisor.