RESEARCH LABORATORIES
CONDUCTING HIV/HBV RESEARCH
AND PRODUCTION

A. Definition of HIV/HBV Research and Production Laboratories

   Research laboratory means a laboratory which produces or uses research laboratory scale amounts of HIV or HBV. Although research laboratories may not have the volume found in production facilities, they deal with solutions containing higher viral titers than those normally found in patients’ blood. Academic research laboratories are included in this definition. Laboratories that conduct research on blood and other Body fluids unrelated to HIV or HBV, or that use unconcentrated blood or blood components as the source of HIV or HBV, are not considered research laboratories for the purpose of this paragraph, (CPL 2-2.44D, pg 51).

   Production facilities are those engaged in industrial scale, large volume, or high concentration production of HIV or HBV, (CPL 2-2.44D, pg 51).

B. Biosafety Guidelines

   A biosafety guideline must be prepared or adopted and periodically reviewed. It must be reviewed and updated at least annually, or as often as necessary. Personnel shall be advised of potential hazards, required to read instructions on practices and procedures, and required to follow them.

C. General Requirements

   1. Research laboratories dealing with human pathogens must determine the level of risk.

   2. They must meet the requirements of the Biosafety Committee in addition to meeting the following criteria:

      a. Laboratory door must be kept closed when work involving HIV and HBV is in progress.

      b. Contaminated materials that are able to be decontaminated at a site away from the network area must be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

      c. Written policies must be established to ensure access to the work area is limited to authorized persons who:

         (1.) Have been advised of the potential biohazard.

         (2.) Have been trained in necessary procedures.

         (3.) Meet specific entry requirements.

         (4.) Comply with entry and exit procedures.

D. Work Areas

   1. Work areas and animal rooms shall be separated from areas that are open to unrestricted traffic flow within the building and warn of the hazards associated with bloodborne pathogens.

   2. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contagious areas.
3. Separation of the high-containment work area from access corridors to other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

4. Surfaces of doors, walls, floors, and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

5. Access doors to the work area or containment module shall be self-closing.

E. Identifying Biohazardous Agents

1. A universal biohazard symbol must be posted on all access doors when other potentially infectious materials or infected animals are present in the work area or containment module.

2. The biohazard sign shall also include:
   a. Special requirements for entering the area.
   b. The name and telephone number of the laboratory director or other responsible person.

3. The sign shall be fluorescent orange-red or predominantly so, with lettering or symbols in a contrasting color.

F. Ventilation System

A ducted exhaust-air ventilation system shall be provided.

1. This system shall create directional airflow that draws air into the work area through the entry area.

2. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes.

3. The proper direction of the airflow shall be verified (i.e., into the work area).

4. Routine maintenance and/or replacement of all filters and traps shall be included in maintaining the air ventilation system.

G. Biological Safety Cabinets

Work with blood, body fluids, tissues or other potentially infectious material is not permitted on the open bench. Work must be conducted in certified biological safety cabinets or other physical-containment devices within the containment module.

Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

H. Certification of Biological Cabinets

Specific containment equipment is required to minimize or eliminate exposure to the viruses.

1. If the compliance officer determines that biological safety cabinets (BSC) have been chosen as the means of containment, they must be certified (Class I, Class II, or Class III, as appropriate) when installed or moved, and at least annually.
2. The compliance officer should check that a dated tag is affixed to the BSC indicating who performed the certification.
3. Alternatively, a certification report attesting to a minimum inward face velocity of at least 75 linear feet per minute and the integrity of the HEPA filters should be reviewed by the compliance officer.
4. The report must be dated and signed by the trained technician performing the measurements and integrity tests.
5. Alternatively, appropriate combinations of PPE or physical containment devices, (examples listed in the Federal Standard) will be accepted.

I. Appropriate Clothing
   1. Appropriate protective clothing must be worn in the work area and animal rooms.
      a. Protective clothing, including laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be worn in the work area and animal rooms.
      b. This protective clothing must not be worn outside or removed from the work area, unless bagged for decontamination.
      c. Protective clothing must be decontaminated before laundering.
   2. Gloves must be worn when handling infected animals and when making hand contact with other potentially infectious materials. Special care must be taken to avoid skin contact and needle punctures.

J. Sharps
   Use of needles and syringes should be kept to a minimum and handled properly, as required. Puncture-resistant containers that sharps are placed in must be properly autoclaved or decontaminated before being discarded, reused, or incinerated.

K. Autoclave
   An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

L. Waste Disposal
   Before disposal, waste from work areas and animal rooms must be either incinerated or decontaminated by a method such as autoclaving.

M. Vacuum Lines
   1. Vacuum lines must be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters, or filter of equivalent or superior efficiency.
   2. These items must be checked routinely and maintained or replaced as needed.

N. Infectious Spills
   1. Spills must be contained and cleaned up immediately by appropriate professional staff or others properly trained and equipped to work with potentially concentrated forms of infectious materials.
   2. Any employee or student with a potential bloodborne pathogen exposure should contact the OUCH pager at *9-888-6824 (OUCH). Employees with other injuries should report to The Nebraska Medical Center Employee Health during regular business hours. Students with other injuries should report to UNMC Student Health during regular hours. If an injury that is not a bloodborne pathogen exposure should occur over a weekend, holiday, or during off hours, the employee or student should report to University emergency room.
3. Any employee or student that suffers an injury in the lab (e.g., animal bite), or is exposed to a hazardous biological or chemical that results in an exposure incident must be reported immediately to the laboratory director, the Director of Comparative Medicine (559-4034).

4. An UNMC incident report must be completed in accordance with UNMC policies and procedures no. safety 05.

O. Hand and Eyewashing Facilities
   1. Hand and eye washing facilities must be readily available in each laboratory, as well as an autoclave for decontaminating waste.
      a. Each work area shall contain a sink for washing hands that is foot, elbow, or automatically operated and shall be located near the exit door of the work area. The handwashing facility must be supplied with at least tepid water, soap, and hand towels.
      b. Each work area shall have an eyewash facility readily available. The eyewash must supply a sufficient quantity of water to completely flush the eyes. (1.) A fifteen minute supply of continuous, free-flowing water is acceptable.
The hands must be free to hold the eyelids open to aid in the complete flushing of the eyes.

2. Eyewash and exposure showers must meet certain design criteria. Contact the UNMC Safety Office for details.

P. HIV and HBV Requirements for Training

1. Employees must demonstrate proficiency in standard microbial practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

2. Likewise, employers shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

3. The employer shall provide a training program to employees who have no prior experience in handling human pathogens.

4. These employees shall not handle human pathogens as part of their initial work activities.

5. Work activities shall progress as techniques are learned and proficiency is developed. It is the employer’s responsibility to see that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.