POLICIES AND PROCEDURES

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Biological Safety Manual

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1.0 Introduction:

1.1 Scope

This Administrative Policy sets forth the authority, limitations and responsibilities of the University of New Haven's Officers and other administrative personnel with regard to managing the storage, use and disposal of biological materials.

1.2 Policy Statement

This Biosafety Manual is written in conjunction with the University of New Haven's Exposure Control Plan 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.

2.0 Policy Sections:

2.1 Definitions

- a) Class 1 Agents. Agents of no or minimal hazard under ordinary conditions of handling.
- b) <u>Class 2 Agents</u>. Agents of ordinary potential hazard. This class includes agents which may produce disease of varying degrees of severity from accidental inoculation or injection or other means of cutaneous penetration but which are contained by ordinary laboratory techniques.
- c) <u>Class 3 Agents</u>. Agents involving special hazard or agents derived from outside the U.S. which requires federal permit for importation. This class includes pathogens which require special conditions for containment.
- d) <u>Class 4 Agents</u>. Agents that require the most stringent conditions for their containment because they are extremely hazardous to laboratory personnel or may cause serious epidemic disease. This class includes Class 3 agents from outside the U.S. when they are employed in entomological experiments or when other entomological experiments are conducted in the same laboratory area.
- e) <u>Class 5 Agents</u>. Foreign animal pathogens that are excluded from the U.S. by law or whose entry is restricted by the USDA administrative policy.
- f) <u>Unrestricted Assets</u>. Assets with no legal or donor-imposed restrictions regarding how they may be spent.
- g) <u>Biosafety Level 1 (BSL-1)</u>. Biosafety level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, or of minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is neither required nor generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science.

- h) <u>Biosafety Level 2 (BSL-2).</u> Biosafety Level 2 is similar to BSL-1 and is suitable for experiments involving agents of moderate potential hazard to personnel and the environment. It differs in that laboratory personnel have specific training in handling pathogenic agents and is supervised by competent scientists. The lab has limited access when experiments are being conducted, and procedures involving large volumes or high concentrations of agents, or in which aerosols are likely to be created, are conducted in biological safety cabinets or other containment equipment.
- i) Biosafety Level 3 (BSL-3). Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents. All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.
- Biosafety Level 3 (BSL-4). Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and lifethreatening disease. Agents with a close of identical antigenic relationship to Biosafety Level 4 agents are handled at this level until sufficient data are obtained either to confirm continued work at this level, or to work with them at a lower level. Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents and they understand the primary and secondary containment functions of the standard and special practices, the containment equipment, and the laboratory design characteristics. They are supervised by competent scientists who are trained and experienced in working with these agents. Access to the laboratory is strictly controlled by the laboratory director. The facility is either in a separate building or in a controlled area within a building which is completely isolated from all other areas of the building. A specific facility operations manual is prepared or adopted. Within work areas of the facility, all activities are confined to Class III biological safety cabinets, or Class II biological safety cabinets used with one-piece positive pressure personnel suits ventilated by a life support system. The Biosafety Level 4 laboratory has special engineering and design features to prevent microorganisms from being disseminated into the environment.
- k) No Class 1 or 2 agents may be used at the University. Contact the Environmental Health and Safety Department for assistance in determining what Class of organism you have. Please refer to the link provided for a list of organisms in each risk group: Riskgroups | my.ABSA.org For the Biosafety and Biosecurity Professional
- The University has only BSL-1 and BSL-2 laboratories. Please refer to the University of New Haven Hazard Assessment/Job Safety Analysis for questions regarding hazards in the facility and how to minimize these hazards.

2.2 Standard Practices for University BSL-2 Laboratories

During times when work with human blood, body fluids, 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:

- a) They have trained and shown proficiency with the microbiological practices used in the laboratory
- b) They have been trained in the procedures used in the laboratory
- c) They have been advised of the potential hazards
- d) 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.

2.3 Work Practice Controls

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, smoke, apply lip balm or cosmetics, or handle contact lenses. Mouth pipetting is not allowed at any time.

2.4 Containment

All refrigerators, freezers, biological safety cabinets 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 leak-proof 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).

2.5 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 at the University.

2.6 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.

2.7 Needles and 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, bend 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 stored properly for pick-up by the University's contracted licensed hauler of medical waste. In case of a needle stick or other sharps injury, immediately notify your supervisor and seek medical attention.

2.8 Accidents and Spills

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

2.9 Contaminated Waste

All contaminated items must be placed in red or biohazard labeled bags that are contained in leak-proof and labeled receptacles. This material will be stored properly for disposal by the University's contacted licensed hauler of medical waste.

2.10 Centrifuges

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

2.11 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. Disposable gloves and gowns will be disposed through incineration. Contaminated clothing will be kept isolated until the contracting company picks it up for laundering. All linen service contractors handle all laundry with Universal Precautions.

Gloves must be work 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 such as lab coats and/or repellant gowns will be worn whenever potentially infected substances are in use. These must be changed in contaminated and should not be worn outside the laboratory.

Eye protection such as Visorgogs and/or face shields must be worn whenever potentially infected substances are in use.

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

2.12 Training Requirements

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

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