Yale University
High Risk Biomaterial Management Policy

Approved by Yale University Biosafety Committee on July 16, 2015

PURPOSE

Yale University is committed to providing a safe and healthy place of employment, education and research. We do this in part by ensuring the biosafety and biosecurity of high risk biomaterials (HRBs), such as Select Agents and toxins, stored and handled at Yale. As one of the leading research and teaching institutions, Yale is home to a large number of biomedical laboratories and clinics. A variety of biological agents are stored and used at Yale, and some of them are pathogens and toxins, thus can pose serious health risks to human, animals, or plants. In response to the NIH Directive to all research universities on August 28, 2014[1], a University-wide policy governing the awareness and proper management of all HRBs is needed to reinforce the obligation of Yale researchers to be good stewards of HRBs, to minimize the potential risk of HRB to all Yale personnel, and to ensure the health and wellbeing of the public.

The purpose of this Policy is to set forth requirements for the safe storage, inventory, and handling of HRBs at Yale, consistent with federal and state regulations and Yale policies. In addition to the requirements of this Policy, Yale University also have Biological Safety policies, procedures and programs (see Supplementary Guidance and References toward the end).

APPLICABILITY

This Policy applies to all faculty, staff, and students who possess, or have access to HRB stored in laboratories and clinics at Yale, or are in a position to handle, transfer, or store HRB. This Policy does not preclude the addition of more stringent storage or handling requirements for a specific HRB.

DEFINITIONS AND SCOPE

HRBs include:

- Select Agents and Toxin List: The Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have identified bacteria, viruses, toxins, rickettsia, and fungi that have the potential to pose a severe threat to public health or welfare. These organisms and substances are considered Select Agents and High Consequence Livestock Pathogens and Toxins, which can be found on this website: http://www.selectagents.gov/SelectAgentsandToxinsList.html.
- Other Risk Group 2, 3, and 4 human pathogens, as defined by National Institute of Health (NIH) guidelines[2] and Center for Disease Control and Prevention (CDC) Risk Assessment[3].
- Prions, as defined NIH guidelines and in Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition, section VIII-H.
- Specimens from humans, animals, plants or soil that are known to harbor a pathogen or restricted substance. Restricted substances are materials that require an import, export or possession permit from the Centers for Disease Control and Prevention, the United States

[1] http://www.nih.gov/science/biosafety-memo.pdf.
[2] http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html
[3] http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_sect_II.pdf

Department of Commerce, the United States Department of Agriculture Veterinary Services, Animal Plant Health Inspection Service, Plant Protection and Quarantine, the United States Fish and Wildlife Service, the Convention on International Trade in Endangered Species, or other regulatory agency.

- Unscreened specimens from humans, animals, plants and soil that have an appreciable risk of harboring a pathogen or restricted substance (i.e., samples for locations or populations with a high probability of harboring a human, animal or plant pathogen).
- High risk recombinant and synthetic nucleic acid molecules (non-exempt, including all pathogen vectors) as stipulated by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.
- Biological toxins with an LD50 of < 100 ug/kg body weight, such as venoms and other toxic substances produced by microorganisms, animals or plants. These include poisonous or venomous animals such as snakes, spiders and cone shells.

Note: HRBs don't include: (1) general human, animal, plant, or soil specimens or collections not likely to harbor pathogens or restricted substances; (2) transformed human cell lines that no longer shed any viruses.

Cold Storage Units: freezers, refrigerators, cold rooms, liquid nitrogen storage devices, dry ice storage units, and any other device for storage of hazardous biological materials.

Containers: vials, tubes, boxes of tubes or vials, slants or other vessels harboring HRBs.

Containers With Unidentified Contents: Any container that has unknown biological agents to the owner, including containers in orphaned or abandoned cold storage units, and those inherited from researchers already left Yale University.

ROLES AND RESPONSIBILITIES

Office of Environmental Health and Safety (EHS) Responsibilities

- Develop and update HRB policies, procedures and guidance.
- Manage Yale's information on HRBs and their locations.
- Assist Principle Investigators (PIs) in periodic reviews of their storage locations and inventories.
- Assist PIs in identify containers with unidentified contents.
- Determine the disposition (i.e., storage, use, or disposal) of HRBs of uncertain value by working with the Yale's Biological Safety Committee and department chair/school dean.
- Endeavor to find a proper depository for HRBs that may have value.
- Periodically survey labs and clinics for HRBs, cold storage units, and related information.
- EHS has the authority to require labs and clinics to review the contents of their cold storage units to ensure an accurate inventory of HRBs.

Principal Investigator (PI), Manager, Supervisor and Instructor Responsibilities

PIs, managers, supervisors and instructors are primarily responsible for the safety of the faculty, staff, students, affiliates and visitors who perform activities in their labs or under their direction. These responsibilities include:

- Identify all HRBs present in your lab or clinic according to the scope of this policy. The PI should have a system so that the contents of every container present in the lab can be identified, by labeling containers, by documenting container identity with location, or by other suitable

alternative systems.

- Inventory the quantity and location of all HRBs. Create a record of HRBs to include the following: (1) identification (name and species of HRB), (2) quantity (mg for toxins, or approx. vials for each HRB), (3) location (building, room and cold storage unit ID), (4) name of person familiar with that HRB, (5) date entry created, and (6) other related information, such as source, and variant/strain.
- Review all cold storage units annually to ensure: (1) HRB records are accurate, and (2) any containers with unidentified contents are promptly evaluated, and their disposition is decided.
- Report: (1) notify EHS of any cold storage unit or container for which the owner is not known, (2) notify EHS upon acquiring a new HRB, (3) report HRBs to EHS accurately on annual Form-01 update, (4) make HRB record available to EHS upon inspection, and (5) report any inventory discrepancies, such as theft, loss or alterations in records to Yale EHS for assistance with the investigation.
- Secure HRBs at an appropriate level of security commensurate with the risk. At a minimum, HRBs should be in locked or occupied laboratories or in locked cold storage devices.
- Conduct an exit interview with personnel who are leaving the laboratory: (1) determine if any new HRBs have been generated or acquired, (2) determine which samples to retain and which to discard, (3) ensure that all samples generated by the departing researcher are appropriately labeled, whether an HRB or not, and (4) make sure the lab HRB inventory is updated.
- Train research staff on the appropriate storage, handling and inventory of HRBs.
- Use of shared spaces and cold storage units: PIs and research groups who share space or cold storage units should have a system that identifies every container and associates each container with a PI and a researcher. This can be accomplished by creating a map/table detailing the ownership of the samples of that space (shelves, racks or boxes). All containers inside that shared space should correlate with the assignments on that map/table. Containers with unidentified contents should be promptly identified and their final disposition determined in the PI's annual review of HRBs.

Research Staff Responsibilities

- Participate in and assist PI with the identification, inventory, review, reporting, and documentation of HRBs as stated in the PI responsibilities section.
- Participate in periodic audits of lab HRBs by EHS.
- Maintain an accurate and current inventory of HRBs. Amend and update the inventory as applicable when using or storing HRBs in the laboratory, and document all transactions in the inventory when receiving or shipping out HRBs,
- Notify the PI and if applicable also the Lab Manager whenever a discrepancy is identified in the inventory.
- Ensure that all samples created are appropriately labeled prior to placement in cold storage.
- Participate in exit interview with the PI when leaving the laboratory.
- Dispose of or destroy unwanted HRBs through autoclaving, chemical denaturation, or other approved methods. Disposal and destruction of HRBs should be documented according to EHS procedures.
- If in doubt, cooperate with EHS to determine: (1) if a particular HRB should be kept, (2) if it has been decided to dispose of or transfer, work with EHS in doing so.

Yale University Biological Safety Committee

- The Biological Safety Committee reviews Yale's inventory of HRBs and determines the appropriate location and use of a specific HRB. It will consider NIH and CDC requirements and policies regarding HRBs.
- The Biological Safety Committee has the authority to remove, relocate, or destroy HRBs at Yale.

COMPLIANCE

EHS has the authority to take necessary actions to enforce compliance with this Policy and to address unsafe conditions, including stopping an activity or shutting down a laboratory or other facility if necessary. Issues related to the implementation of this policy will be forwarded to the Biological Safety Committee for their review and advice.

Policy Approval: This Yale Policy was approved by the Yale Biosafety Committee on July 16, 2015

SUPPLEMENTARY GUIDANCE AND REFERENCES

1. For information on Select Agents:
   http://www.selectagents.gov/regulations.html
2. For Risk Group classification and NIH Guidelines:
   http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_APPENDIX_B._CLASSIFICATION
   http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines
3. For OSHA General Industry Standards including Bloodborne Pathogens:
   https://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910
4. For Biosafety in Microbiological and Biomedical Laboratories manual by Center for Disease Control:
   http://www.cdc.gov/biosafety/publications/bmbl5/
5. For American Society of Microbiology policy on freezer storage:
   http://www.asm.org/index.php/public-policy/99-policy/policy/93059-freezer-8-14
6. For Yale Biosafety Manual:
   http://ehs.yale.edu/sites/default/files/BiosafetyManual.pdf
7. For HRB Laboratory Inventory template, Exit Interview template, Shared freezer inventory template, and Storage Box inventory template:
   http://ehs.yale.edu/biological-tools-resources