

Potentially Hazardous Biological Materials Management Plan - Phase I

Clean sweep of all NIH laboratories, clinical spaces, offices associated with laboratories – To Be Completed by September 30, 2014.

This clean sweep applies to all NIH owned or leased or contractor-operated laboratory spaces or facilities (e.g. off-site “freezer farms” and animal facilities) including RML, NIEHS, Frederick, Poolesville, etc.

Phase I. Workplan

Step 1. No later than July 11, the DDIR will inform the SDs of the need to execute a comprehensive search of all NIH laboratory spaces including all refrigerators, freezers (all types), cold rooms, cabinets, shelves, drawers, and storage rooms for potentially hazardous biological materials. There should be special emphasis on regulated materials such as Select Agents and Toxins, but other potentially hazardous biological materials such as infectious agents, non-regulated toxins, poisons, venoms, explosive materials, etc. should also be included.

Step 2. SDs will inform all PIs and other personnel in their ICs of the need to immediately commence a comprehensive search of laboratory and associated spaces including cabinets, drawers, shelves and all refrigerators, freezers (all types), cold rooms and storage rooms. SDs will instruct personnel to label materials properly that are maintained and appropriately discard all materials that are no longer needed, including unneeded materials left by former trainees and investigators. For identifiable clinical samples collected under IRB-approved protocols, special rules apply. Unidentified materials (unlabeled with uncertain contents) should be autoclaved twice. After double autoclaving, Medical Pathological Waste should be placed in a Medical Waste (MWP) (“Burn Box”) and dropped off at designated pickup locations. Any materials discharged to the drain must comply with NIH environmental standards for waste water discharge (see attached Waste Disposal Guide). No materials that are the subject of ongoing investigations or concerns should be destroyed. For materials thought possibly to include select agents, please contact the Division of Occupational Health and Safety (DOHS) in the Office of Research Services (ORS).

Step 3. SDs will assign responsible individual(s) to search common areas (such as cold rooms, instrument rooms, and freezers) and ensure that these areas are surveyed completely.

Step 4. Good laboratory practice indicates that a central list should be maintained by each PI of the nature of materials in each box, rack, or similar container in all storage areas in or around the laboratory or laboratory offices. This will require that the entire contents of each storage container be visually surveyed. All human pathogenic organisms that require BL2 level

containment and above, and biological toxins, venoms, or poisons (please see attached list of such compounds) must be recorded and inventoried as to location and reported to DOHS via an electronic registration system.

Step 5. PIs will be responsible for all spaces assigned to them and must survey all material and discard materials no longer needed.. Regulated but unregistered materials that may be found, such as Select Agents, must be turned over to Division of Occupational Health and Safety (DOHS) and All human pathogenic organisms that require BL2 level containment and above, and biological toxins, venoms, and poisons (please see attachment) must be recorded and inventoried as to location and reported to DOHS via an electronic registration system.

Step 6. PIs will sign an attestation that all potentially hazardous biological materials are properly labeled, stored, inventoried and any unlabeled materials were destroyed or turned over to DOHS. The attestations shall be collected and verified by the Scientific Director to make sure no areas were missed. (Attestation form is attached)

At this time, PIs should also ensure that all hazardous chemicals are properly labeled and stored or use this opportunity to contact the ORF Division of Environmental Protection for the proper disposal of unneeded or expired chemicals and chemical waste. This Division has been alerted to the need for possible expansion of service during this period and will assist promptly.

Step 7. PIs will sign, date and affix stickers to rooms and equipment indicating that under counter and upright freezers and refrigerators, cold rooms, laboratory doors and other closed spaces have been surveyed. **This includes freezers located in freezer farms (including those containing historical collections) or other leased or contracted space on and off campus.** (Stickers will be provided by DOHS)

Step 8. SDs will ensure and attest to OIR that all PIs in their IC have completed this clean sweep by **September 30, 2014.** (Attestation forms are attached).

Step 9. DOHS will perform systematic compliance checks of all the laboratory spaces, all freezers and refrigerators, cold rooms, dry storage areas, etc. including review of the inventories for potentially hazardous biological materials.

Step 10. For registered areas, DOHS will provide follow-up compliance checks of storage areas during annual surveys of registered laboratories (those conducting infectious disease and recombinant nucleic acid research). Safety specialists will document compliance checks in PI Dashboard.

Reminder

As a reminder, failure to comply with the requirements for select agents and toxins can lead to disciplinary actions including removal for an initial offense.

Select Agents and Toxins¹: biological agents and toxins that could pose a severe threat to public health and safety, to animal health, or to animal products. See list attached. This plan is not limited to these Select Agents, but also includes all hazardous biological materials as defined above.

Select Agents and Toxins List

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. The list of excluded agents and toxins can be found at: <http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html>.

HHS AND USDA SELECT AGENTS AND TOXINS 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS AND TOXINS

Abrin
Botulinum neurotoxins*
strain
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins
containing the following amino acid
sequence X₁CCX₂PACGX₃X₄X₅X₆CX₇)¹
Coxiella burnetii

Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus³

OVERLAP SELECT AGENTS

Bacillus anthracis *
Bacillus anthracis Pasteur

Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
Burkholderia pseudomallei

*

Hendra virus
Nipah virus
Rift Valley fever virus

Ebola virus*
encephalitis virus³
*Francisella tularensis**
Lassa fever virus
Lujo virus

AND TOXINS

Marburg virus*
virus
Monkeypox virus³
Reconstructed replication competent forms of the 1918
pandemic influenza virus containing any portion of the
coding regions of all eight gene segments (Reconstructed
virus*

1918 Influenza virus)

Ricin

Rickettsia prowazekii

SARS-associated coronavirus (SARS-CoV)

Saxitoxin

South American Haemorrhagic Fever viruses:
virus

Chapare

Guanarito

Junin

virus

Machupo

Sabia

Staphylococcal enterotoxins A,B,C,D,E subtypes

AND QUARANTINE (PPQ)

T-2 toxin

TOXINS

Tetrodotoxin

pinensis (*Peronosclerospora*

Tick-borne encephalitis complex (flavi) viruses:

Far Eastern

subtype

a glycines)

Siberian subtype

Kyasanur Forest disease virus

Omsk hemorrhagic fever virus

Variola major virus (Smallpox virus)*

Variola minor virus (Alastrim)*

*Yersinia pestis**

Venezuelan equine

USDA SELECT AGENTS

African horse sickness

African swine fever virus

Avian influenza virus³

Classical swine fever virus

Foot-and-mouth disease

Goat pox virus

Lumpy skin disease virus

*Mycoplasma capricolum*³

*Mycoplasma mycoides*³

Newcastle disease virus^{2,3}

Peste des petits ruminants

Rinderpest virus*

Sheep pox virus

Swine vesicular disease

USDA PLANT PROTECTION

SELECT AGENTS AND

Peronosclerospora philip

sacchari)

Phoma glycinicola (formerly *Pyrenochaeta*

Ralstonia solanacearum

Rathayibacter toxicus

Sclerophthora rayssiae

Synchytrium endobioticum

Xanthomonas oryzae

*Denotes Tier 1 Agent

1 C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α -MI and α -GI (shown above) as well as α -GIA, Ac1.1a, α -CnIA, α -CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

2 A virulent Newcastle disease virus (avian paramyxovirus serotype 2) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

3 Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies *Mycoplasma capricolum* except subspecies *capripneumoniae* (contagious caprine pleuropneumonia), all subspecies *Mycoplasma mycoides* except subspecies *mycoides* small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category. 9/10/13