University of Idaho

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MEMORANDUM

TO: All Research Faculty

FROM: John K. McIver, Vice President for Research and Economic Development

DATE: April 23, 2014

SUBJECT: Working with Select Agents and Toxins

Providing researchers the opportunity to conduct research with select agents and toxins is an integral part of the University of Idaho's commitment to supporting knowledge discovery and excellence in teaching and service. To that end, the University maintains a registration with the Centers for Disease Control and Prevention (CDC) in order to allow researchers to possess, use, and transfer biological select agents and toxins (BSAT). Working with BSAT is a privilege that comes with significant responsibility. This memorandum is intended to assist principal investigators (PIs) in fulfilling that responsibility by providing a summary of the Federal Select Agent Program's (FSAP) and University's requirements for working with BSAT.

The U.S. Department of Health and Human Services and U.S. Department of Agriculture (collectively, FSAP) provide regulatory oversight for the possession, use, and transfer of BSAT. The FSAP develops, implements, and enforces the select agent regulations and maintains a list of BSAT, which is attached to this memorandum and is located on the FSAP's website: www.selectagents.gov. Specifically, BSAT are biological agents and toxins that could pose a severe threat to public health, plant health, or to animal or plant products. In addition to the agents and toxins designated on the list, BSAT also include:

1. Nucleic acids that can produce infectious forms of any BSAT on the list;
2. Recombinant or synthetic nucleic acids that encode for the functional form(s) of any of the toxins on the list, if the nucleic acids:
    a. Can be expressed *in vivo* or *in vitro*, or
    b. Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*
3. BSAT on the list that have been genetically modified.

Institutionally, the University provides a Select Agents and Toxins Policy (APM 45.20) to assist the University and PIs in meeting the requirements of the federal select agent regulations. APM 45.20(C) requires that,

> "[a]ll laboratories and other facilities at UI possessing, using, and transferring select agents and toxins must be registered with the [CDC] or the Animal and

> Plant Health Inspection Service (APHIS) and shall comply with the requirements set forth in this policy. Registration at UI will be managed through the Office of Research and Economic Development (ORED)."

Not only must the laboratory or facility be registered with the FSAP, but any individual desiring to possess, use, or transfer a BSAT must undergo a security risk assessment by the Federal Bureau of Investigation (FBI) and be added as personnel on the University's CDC registration. See APM 45.20(E)(1)-(2). That requirement applies to PIs, students, laboratory staff, and any other individual who possesses or has the ability to possess BSAT. All approved laboratories or facilities must have biosafety, security, and incident response plans, and all personnel must be trained on the policies and procedures of each plan. See APM 45.20(E)(4)-(7). Further, as with all research involving potentially hazardous biological materials and recombinant DNA, the University's Institutional Biosafety Committee (IBC) must review and approve all BSAT research. See APM 35.11(C), APM 45.20(E)(12), and FSH 1640.14(A).

All University PIs and any other employees or students working with biological materials should familiarize themselves with the list of BSAT and inform ORED as soon as possible if they intend to work with any agent or toxin on the list. The Responsible Official (RO), John K. McIver, and Alternate Responsible Officials (ARO), Terra A. DuBois and Polly J. Knutson, will assist PIs in registering a laboratory for BSAT use, completing the FBI's security risk assessment, and being added as an approved PI on the University's CDC registration. The RO and AROs, in coordination with the Biosafety Officer, also will help the PI prepare biosafety, security, and incident response plans; train laboratory staff; and meet all other requirements of the select agent regulations.

If you have any questions about the University's select agent program, please contact the RO at 208-885-4989 or the AROs at 208-885-6162.

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

Abrin
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[1]
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus[3]
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus[3]
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses:
- Chapare
- Guanarito
- Junin
- Machupo
- Sabia

Staphylococcal enterotoxins A,B,C,D,E subtypes
T-2 toxin

OVERLAP SELECT AGENTS AND TOXINS

*Bacillus anthracis**
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus[3]

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Avian influenza virus[3]
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum[3]
Mycoplasma mycoides[3]
Newcastle disease virus[2,3]
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses:
Far Eastern subtype
Siberian subtype
Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

Peronosclerospora philippinensis (Peronosclerospora sacchari)
Phoma glycinicola (formerly Pyrenochaeta glycines)
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

Select Agents and Toxins List

**Website is being revamped based on Revised Select Agent regulations.*

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
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Riverdale, MD 20737
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Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096
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