

D-4. Receipt, Possession, Use and Transfer of Select Agents

I. Introduction

In the performance of scientific research, the NCI-Frederick may have occasion to use Select Agents as defined by 42 CFR §73, or High Consequence Animal or Plant Pathogens and Toxins as defined by 9 CFR §121 and 7 CFR §331. It is the policy of the NCI-Frederick to ensure that receipt, usage, storage, shipping and disposal of this material are performed in compliance with all applicable federal and state regulations and laws.

II. Scope

All on-site and off-site laboratories of NCI-Frederick receiving, using and transferring regulated select agents as defined in 42 CFR §73, 9 CFR §121 or 7 CFR §331 will comply with the requirements set forth in this chapter.

III. Definitions

APHIS – Animal and Plant Health Inspection Service; Agricultural Select Agent Program for the United States Department of Agriculture (USDA)

APHIS/CDC FORM 1 – Application for laboratory registration for possession, use and transfer of select agents and toxins.

APHIS/CDC FORM 2 – Request to transfer select agents and toxins.

APHIS/CDC FORM 3 – Report of theft, loss, or release of select agents and toxins.

APHIS/CDC FORM 4 – Report of the identification of a select agent or toxin.

APHIS/CDC FORM 5 – Request for the exemption of select agents and toxins for public health or agricultural emergency or investigational/experimental product.

APHIS Select Agent– A biological agent, plant pathogen, or toxin listed in 42CFR73, 7 CFR 331.3 or 9 CFR 121.3 that poses a risk to either animals or plants.

Biological Agent – Any microorganism or infectious substance, or any naturally

occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

- Death, disease or other biological malfunction in a human, animal, plant, or another living organism
- Deterioration of food, water, equipment, supplies, or material of any kind
- Deleterious alteration of the environment

Centers for Disease Control and Prevention (CDC) – Division of select agents and toxins for the United States Department of Health and Human Services (DHHS)

CDC Select Agent - a biological agent or toxin included in 42 CFR § 73.4.

Facility - Any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a regulated biological agent subject to 42 CFR §73, 9 CFR §121 or 7 CFR §331. Facility for the purpose of this chapter is the geographical and organizational confines of the NCI-Frederick.

Institutional Biosafety Committee (IBC) – Is a committee established to meet the requirements specified in Section IV-B-2 of the NIH Guidelines. It reviews, approves, and maintains all protocols. Membership of the committee will consist of no fewer than five individuals with experience and expertise in rDNA technology and other biosafety issues. At least two members will not be affiliated with the NCI-Frederick and should represent the surrounding community with respect to public health and protection of the environment. At least one member will have expertise in animal containment principles and one member will be the Biological Safety Officer (BSO). The IBC will be chaired by a senior member of the NCI-Frederick management.

Interfacility Transfer - The conveyance or movement from point of origin to a point of destination either from one state or territory to another entirely within one contiguous state or territory, or from one registered facility to another registered facility.

Intrafacility Transfer - a transfer of a Select Agent within the geographic and organizational confines of NCI-Frederick. Transfers of CDC select agents or USDA high consequence pathogen or toxin to other agencies located at Ft. Detrick (i.e., USAMRIID) are not intrafacility transfers.

Requestor - Any individual who receives or seeks to receive through any means a CDC select agent or USDA high consequence pathogen or toxin from any other person or institution.

Responsible Official (RO) or Alternate Responsible Official (ARO) - An official authorized to transfer and receive regulated select agents covered by 42 CFR 73, 9 CFR 121 and 7 CFR 331, on behalf of the transferor and/or requestors facility. The Biological Safety Officer is listed as the "Responsible Official" on the NCI-Frederick Registration Document that was submitted to the regulatory agencies and has been granted the authority and control to ensure compliance with applicable regulations. The Biological Safety Officer or Alternate Responsible Official is the individual at the NCI-Frederick authorized to approve the transfer and use of regulated biological agents on behalf of NCI-Frederick researchers. In the case that the Biosafety Officer is not readily available due to absence from the facility, at least one other EHS staff member has been registered with the regulatory agency as alternate responsible official (ARO) of record for this facility.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or (2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

Transferor - Any person who transfers or seeks to transfer through any means a Select Agent to any other person.

IV. Procedure

The Environment, Health and Safety Program (EHS) has obtained and maintains the NCI-Frederick Registration granted by the U.S. Department of Agriculture (USDA) and/or the Centers of Disease Control and Prevention (CDC) as applicable. The NCI-Frederick RO and the NCI-Frederick Institutional Biosafety Committee (IBC) must approve the use of regulated select agents before a request for procurement is granted.

A. Procurement of Regulated Select Agents, Plant Pathogens and Toxins

1. The procurement or acquisition of all select agents, plant pathogens, and toxins will be accomplished only with the documented approval of the RO or ARO, and the NCI-Frederick IBC. The list of CDC and APHIS regulated agents is attached to this document in Appendix D-4-A. Refer to the following link for a current select agent list and notification of exclusions: (<http://www.selectagents.gov>)
2. An NCI-Frederick employee who is requesting to obtain a CDC/APHIS select agent or toxin, shall contact the NCI-Frederick Biological Safety Officer. Requirements for receiving regulated biological agents or toxins will be discussed at that time.

Requirements for receiving a CDC/APHIS select agent may include:

- a. Registration of proposed work with the agent with EHS and the NCI-Frederick IBC via the Research Registration Program. Refer to Chapter C-4.
- b. Inspection of laboratory facilities by appropriate regulating authority.
- c. Review of research protocol and SOPs to include receipt, inventory.
- d. EHS review and approval for all procedures including receipt, inventory, storage, and final disposal of materials when the work has been completed.

- e. A list of staff involved with the project will be submitted. These individuals shall comply with the NCI-Frederick biosecurity plan and obtain any and all necessary clearances prior to working with regulated agents. A review of training records of cleared laboratory staff will be conducted to ensure proficiency of individuals working with regulated agents.
- f. The RO and the PI will provide all necessary information to the relevant regulatory agencies to request select agent registration or amend the current registration.

Additional information concerning the procedure for the procurement of regulated biological agents and toxins is available from the Biological Safety Officer.

3. CDC/APHIS select agents, plant pathogens, and toxins arriving at NCI-Frederick shall be delivered to the Biosafety Officer or Alternate Responsible Official at Building 426, Rm. 118. The Biosafety Officer or Alternate Responsible Official shall accomplish final delivery after reviewing the associated documentation and checking the contents. If packages arrive mistakenly at Receiving and Delivery (Bldg. 1050), the biosafety officer shall be notified immediately by the Logistics and Support Manager or designee, and the select agent material will be picked up by the Biosafety Officer or Alternate Responsible Official, who will accomplish final delivery after a check of contents and review of documentation.

B. Regulated Agent Inventory and Shipment

1. The registered principal Investigator shall maintain an inventory of regulated agents in their possession for control purposes. EHS and the RO reserves the right to request periodic reports concerning the use and location of regulated biological agents. Select Agent inventory audits and lab inspections will occur on a monthly basis.
2. Each Principal Investigator shall keep accurate records of receipt, expenditure, and relocation of the regulated agents for which he/she is responsible. Principal Investigator(s)/Area Supervisor(s) will utilize the NIH Select Agent Log (Appendix D-4-B) to maintain inventory records. Intrafacility transfer records shall include the name and location of the recipient, the amount of agent transferred, the date of transfer, the intended use of agent. EHS shall maintain a copy of all transfer documentation.
3. Intrafacility transfer records must be maintained for a period of five years after the date of transfer or for five years after the agents are spent or properly disposed, whichever is longer. Intrafacility transfer of regulated agents requires documented approval by the Biological Safety Officer (Responsible Official) or Alternate RO. All requests for Intra-facility transfer of regulated agents must be documented on the attached request form (Appendix D-4-C) and submitted to

EHS 24-hours prior to the Intra-facility transfer. Transfer of any amount of regulated agents to unauthorized areas or persons is prohibited. EHS reserves the right to perform random and unannounced audits of all inventory, intrafacility transfer records and other related records kept by the P.I./Lab Chief/Lab Manager.

4. Interfacility shipments of regulated agents from NCI-Frederick to other destinations must be cleared in advance through the Biological Safety Officer to assure conformance with CDC/APHIS regulations, DHHS (42 CFR 73), USDA (9 CFR 121 and 7 CFR 331), Department of Transportation (49CFR Part 172), Postal, and other shipping regulations. The CDC/APHIS Form 2 will be completed and submitted to CDC or the USDA as appropriate for approval. Only after the regulatory agency has provided the approval confirmation number will the material be shipped to the requesting facility.
5. When transferring a regulated agent to an outside entity, researchers shall provide a Request for Shipment form to Transportation and EHS 48 hours in advance for all pre-approved shipments of regulated agents.
 - a. A copy of the completed form shall be faxed to CDC/APHIS and NCI-Frederick Biosafety Officer or Designee by the consignee (requesting facility), when the transfer of materials has taken place.

V. Responsibilities

A. Purchasing Department:

1. Ensures that the Biosafety Officer or Alternate Responsible Official has previously approved purchase requests for select agent materials prior to placing an order with a vendor.
2. Instructs the vendor to deliver select agent material to only the Biosafety Officer or designee at Building 426, Rm. 118.

B. Environment, Health and Safety Program:

1. Through its regulatory and auditing role, ensures that the receipt, storage, inventory issue, use, and disposal of regulated select agents at the NCI-Frederick are in compliance with federal and state regulations.
2. Provides assistance to laboratory personnel on inventory control procedures, secure storage, and proper disposal of select agents.
3. Maintains records (all CDC/APHIS Forms) on all select agent transfers of CDC select agents, CDC/APHIS select agents, plant pathogens and toxins at the NCI-Frederick. Records of interfacility transfers are retained for a period of five years after the date of shipment or for five years after the regulated agent(s) are spent or

properly disposed, whichever is longer.

4. Maintains the NCI-Frederick Select Agent Registration issued by CDC/APHIS. EHS will provide CDC/APHIS updated information on any additions, deletions, or changes to the NCI-Frederick Select Agent Registration.
 5. Provides annual biosecurity training, testing, and exercises/drills.
 6. Performs annual program reviews and updates.
- C. NCI-Frederick Investigators (includes government and contractor investigators)
1. Review, confirm, and communicate to staff the requirements for working with regulated select agents in laboratories for which they are responsible.
 2. Control access to laboratories for which they are responsible and restrict access to regulated agents to only those individuals that have obtained the necessary clearance and training to work with research material regulated by 42 CFR 73, 9 CFR 121 and 7 CFR 331.
 3. Maintain accurate records of receipt, usage, inventory, relocation and disposal of regulated select agents for which they are responsible. Receipt, storage, use, and disposal of regulated select agents in compliance with relevant regulations and NCI-Frederick policy.
 4. Forward information regarding method and date of agent disposal to the responsible official (RO). EHS approval must be acquired prior to disposal.

Select Agent and Toxin List

USDA/HHS Overlap Agents and Toxins

- *Bacillus anthracis*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Hendra virus
- Nipah virus
- Rift Valley fever virus
- Venezuelan equine encephalitis virus

USDA Only Agents and Toxins (Plants)

- *Peronosclerospora philippinensis*
- (*Peronosclerospora sacchari*)
- *Phoma glycinicola* (*Pyrenochaeta glycines*)
- *Ralstonia solanacearum*, race 3, biovar 2
- *Rhizoctonia solani*
- *Scirpophthora rayssiae* var. *zeae*
- *Synchytrium endobioticum*
- *Xanthomonas oryzae*
- *Xylella fastidiosa* (citrus variegated chlorosis strain)

USDA Only Agents and Toxins (Livestock)

- African horse sickness virus
- African swine fever virus
- Akabane virus
- Avian influenza virus (Highly pathogenic)
- Bluetongue virus (exotic)
- Bovine spongiform encephalopathy
- Camel pox virus
- Classic swine fever virus
- Foot-and-mouth disease virus
- Goat pox virus
- Japanese encephalitis virus
- Lumpy skin disease virus
- Malignant catarrhal fever virus
- (Alcelpahine herpesvirus type 1)
- Menangle virus
- Mycoides small colony (MmmSC)
- (Contagious bovine pleuropneumonia)
- Peste des petits ruminants virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus (exotic)
- Indiana subtypes VSV-IN2, VSV-IN3
- Virulent Newcastle disease virus

Appendix D-4-B

CDC USDA Select Agent Inventory

Principal Investigator: _____

Select Agent : _____

Storage Lab Building/Room: _____

Date of Receipt	Initials of Receiver		Quantity	Number of Vials /Containers

Date	Initials	Generation/Use/Dispose (indicate appropriate action)	Quantity	Number of Vials
TOTAL				
TOTAL				
TOTAL				
TOTAL				
TOTAL				
TOTAL				

Appendix D-4-C Intra Facility Transfer Request

For the approval of INTRA FACILITY Select Agent Transfers, please forward transfer request with all pertinent information to the Biological Safety Officer, Building 426 Room 118, no less than 24 hours prior to the desired transfer date.

Agent Information

Select Agent Name _____

Of Primary Containers to be transferred _____ Volume Per Container _____

Transferor Information

Date Of Request _____ Date Of Requested Transfer _____

Transferor Name _____ Work Phone _____

Program / Dept. _____

Reason For Transfer Request _____

Transferor Signature _____ Date _____

Recipient Information

(Upon consumption of select agent materials it is the responsibility of the recipient to forward to the Biological Safety Officer information regarding the method and date of select agent disposal)

Recipient Name _____ Work Phone _____

Program / Dept. _____

Location of Select Agent Use and Storage: Building _____ Room _____

BioSafety Level of Receiving Laboratory: BL-2 _____ BL-3 _____ Other _____

Method of Disposal _____ Date of Disposal _____

Transfer Authorization (EHS Use Only)

Approved _____

Not Approved _____

Comments: _____

EHS Authorized Individual

Date _____

Tracking ID _____