D-4. RECEIPT, POSSESSION, USE AND TRANSFER OF REGULATED BIOLOGICAL 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 biological 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

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

EA-101 Form - CDC form which documents interfacility transfers of Select Agents or CDC/USDA overlap agents.

USDA Form 2041 – USDA form that documents the interfacility transfer of USDA High Consequence Plant & Animal Pathogens and toxins. May also be used to document the interfacility transfer of CDC/USDA overlap agents.

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.

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

HHS/USDA Overlap Agent - Any microorganism or toxin that poses a risk to both humans and animal health and that is listed in 42 CFR §73.5 or 9 CFR §121.3(b).

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 biological 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 designee 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.

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

USDA High Consequence Pathogen or Toxin – A microorganism or toxin listed in 7 CFR 331.3 or 9 CFR 121.3 that poses a risk to either animals or plants.

IV. PROCEDURE

The Environment, Heath and Safety Program (EHS) has obtained and maintains the NCI-Frederick Registration granted by the U.S. Department of Agriculture (U.S.D.A.) 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 biological agents before a request for procurement is granted.

A. Procurement Of Regulated Biological Agents

1. The procurement of all regulated biological agents will be accomplished only with the documented approval of the RO or alternate, and the NCI-Frederick Institutional Biosafety Committee. The list of CDC and USDA 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.cdc.gov/od/sap/).

2. An NCI-Frederick employee who is requesting to obtain a CDC select agent, overlap agent or USDA High Consequence agent, 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/USDA regulated 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.

   c. Review of research protocol and SOPs.

   d. Method of storage and disposal of material when the work has been completed

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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 select agents, CDC/USDA overlap agents and USDA high consequence pathogens and toxins arriving at NCI-Frederick shall be delivered to the Biosafety Officer or Designee at Building 426, Rm. 118. The Biosafety Officer or Designee 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 designee, who will accomplish final delivery after a check of contents and review of documentation. Transfers from USAMRIID may be delivered directly to the registered Principal Investigator's laboratory with the documented approval of the Biosafety Officer or the alternate Responsible Official.

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.

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) sheet 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 is **prohibited**. EHS reserves the right to periodically audit 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 Health & Human Services (42 CFR 73), USDA (9 CFR 121 and 7 CFR 331), Department of Transportation, Postal, and other shipping regulations. The CDC EA101 or USDA Form 2041 will be completed and submitted to CDC or the USDA as appropriate for approval. Only after regulatory agency has provided the approval confirmation number will the material be shipped to the requesting facility.

5. When transferring a regulated agent, 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 and NCI-Frederick Biosafety Officer or designee by the 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. 136

B. Environment, Health and Safety Program:

1. Through its regulatory and auditing role, ensures that the receipt, storage, and issue and use 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 (CDC Form EA-101/USDA Form 2041) on all interfacility transfers of CDC select agents, CDC/USDA overlap agents and USDA high consequence animal & plant agents 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 USDA and/or CDC. EHS will provide CDC/USDA updated information on any additions, deletions, or changes to the NCI-Frederick Select Agent Registration.

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, expenditure, relocation and disposal of regulated select agents for which they are responsible.

4. Forward information regarding method and date of agent disposal to the responsible official (RO).

5. Receipt, storage, use, and disposal of regulated select agents in compliance with relevant regulations and NCI-Frederick policy.

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
Cercopithecine herpesvirus 1 (Herpes B virus)
Coccidioides posadasii
Conotoxins
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Ebola virus
Lassa fever virus
Marburg virus
Monkeypox virus
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
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
South American Haemorrhagic Fever viruses
Flexal
Guanarito
Junin
Machupo
Sabia
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses
Central European Tick-borne encephalitis
Far Eastern Tick-borne encephalitis
Kyasanur Forest disease
Omsk Hemorrhagic Fever
Russian Spring and Summer encephalitis
Variola major virus (Smallpox virus) and
Variola minor virus (Alastrim)
Yersinia pestis

OVERLAP SELECT AGENTS AND TOXINS

Bacillus anthracis
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly *Pseudomonas mallei*)
Burkholderia pseudomallei (formerly *Pseudomonas pseudomallei*)
Clostridium perfringens epsilon toxin
Coccidioides immitis
Coxiella burnetii
Eastern Equine Encephalitis virus
Francisella tularensis
Hendra virus
Nipah virus
Rift Valley fever virus
Shigatoxin
Staphylococcal enterotoxins
T-2 toxin
Venezuelan Equine Encephalitis virus

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (Exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Cowdria ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus
(Alcelaphine herpesvirus type 1)
Menangle virus
Mycoplasma capricolum/ M.F38/*M. mycoides Capri*
(contagious caprine pleuropneumonia)
Mycoplasma mycoides mycoides
(contagious bovine pleuropneumonia)
Newcastle disease virus (velogenic)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (Exotic)

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

Candidatus Liberobacter africanus
Candidatus Liberobacter asiaticus
Peronosclerospora philippinensis
Ralstonia solanacearum race 3, biovar 2
Schlerophthora rayssiae var *zeae*
Synchytrium endobioticum
Xanthomonas oryzae pv. *oryzicola*
Xylella fastidiosa (citrus variegated chlorosis strain)

APPENDIX D-4-B

CDC Select/USDA High Consequence Agent Logbook

Principal Investigator: _____

Biological 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				
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 / Safety Environmental Protection Program, building 426 room 118, no less than 24 hours prior to the desired transfer date.

AGENT INFORMATION

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:

_____ Date _____ **Tracking ID** _____
EHS Authorized Individual