D-4. USE AND TRANSFER OF SELECT AGENTS

I. INTRODUCTION

In the performance of scientific research, the NCI-Frederick Cancer Research and Development Center (NCI-Frederick) uses Select Agents as defined by 42 CFR 72.6. It is the policy of the NCI-Frederick to ensure that receiving, usage, shipping and disposal of this material are performed in compliance with all applicable federal and state regulations

II. SCOPE

All laboratories at NCI-Frederick receiving, using and transferring Select Agents as defined in 42 CFR 72.6 will comply with the requirements set forth in this chapter.

III. DEFINITIONS

EA-101 Form - CDC form which documents interfacility transfers of Select Agents listed in Appendix A, 42 CFR 72.6.

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 select agent subject to 42 CFR 72.6. Facility for the purpose of this chapter is the geographical and organizational confines of the NCI-Frederick.

Interfacility Transfer - The conveyance or movement from point of origination 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 Select Agents 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 Select Agent from any other person or institution.

Responsible Facility Official (RFO) - An official authorized to transfer and receive select agents covered by 42 CFR 72.6 on behalf of the transferor and/or requestors facility. The Biological Safety Officer is listed as the “Responsible

Facility Official" on the NCI-Frederick Select Agent Registration that was approved by the Centers for Disease Control and Prevention. **The Biological Safety Officer is the individual at the NCI-Frederick legally authorized to transfer and receive select agents on behalf of NCI-Frederick researchers.** In the case that the Biosafety Officer is not readily available due to absence from the facility, the Manager, EHS and the Manager, OEHB, EHS have been registered with the CDC as alternate responsible facility officials for this facility.

Select Agent - A microorganism (virus, bacterium, fungus, rickettsia) or toxin listed in Appendix A of 42 CFR 72.6. The term also includes:

a. Genetically modified microorganisms or genetic elements from organisms listed on Appendix A of 42 CFR 72.6, shown to produce or encode for a factor associated with a disease, and

b. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on Appendix A of 42 CFR 72.6, or their toxic subunits.

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

IV. PROCEDURE

The Safety and Environmental Protection Program (EHS) through the NCI-appointed Responsible Facility Official (RFO) has obtained and maintains the NCI-Frederick Select Agent Registration granted by the Centers of Disease Control and Prevention (CDC). Select Agent use must be approved by the RFO before a request for procurement approval is made.

A. Procurement Of Select Agents

1. The procurement of all Select Agents will be accomplished only with the prior approval of EHS and the Institutional Biosafety Committee. The list of CDC Select Agents is attached to this document in Appendix D-4-A.

2. An NCI-Frederick employee who is requesting to obtain a "Select Agent" as defined by 42 CFR 72.6, shall contact the NCI-Frederick Biological Safety Officer. Requirements for receiving a Select Agent will be discussed at that time.

Requirements for receiving a Select Agent may include:

a. Registration of proposed work with a Select Agent with EHS and the IBC via the Pathogen Registration and/or rDNA Registration Programs. Refer to Chapters C-3 and C-5.

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.

e. Review of training records of staff who will be involved with the project. This review will ensure proficiency of individuals working with select agents.

Additional information concerning the procedure for the procurement of Select Agents is available from the Biological Safety Officer.

3. The Biosafety Officer or Designee shall be notified immediately when a shipment containing Select Agents arrives at the NCI-Frederick. Small packages that arrive at Receiving and Delivery (Bldg. 1050) will be picked up by Biological Safety, Building 426, who will accomplish final delivery after a check of contents and review of documentation. Notify the Biosafety Officer immediately upon receipt of larger items for clearance prior to delivery. Transfer from USAMRIID may be delivered directly to the registered Principal Investigator's laboratory.

B. Select Agent Inventory and Shipment

1. EHS will request Select Agent inventories be maintained for control purposes and reserves the right to request periodic reports concerning the use and location of Select Agents.

2. Each Principal Investigator/Area Supervisor shall keep accurate records of receipt, expenditure, and relocation of Select Agents for which he is responsible. Principal Investigator(s)/Area Supervisor(s) will utilize the NIH Select Agent Log (Appendix D-4-B) sheet to maintain select agent 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.

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 consumed or properly disposed, whichever is longer. Intrafacility transfer of Select Agents requires prior approval by the Biological Safety Officer. All requests for Intra-facility transfer of materials containing Select 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 Select Agents to unauthorized areas is **prohibited**. EHS reserves the right to periodically audit all inventory, intrafacility transfer records and other Select Agent related records kept by the P.I./Lab Chief/Lab Manager.

4. Interfacility shipments of Select 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 72.6), Department of Transportation, Postal, and other shipping regulations.

5. When transferring a Select Agent, researchers shall provide a Request for Shipment form to Transportation and EHS **48 hours** in advance for all pre-approved shipments of Select Agents. Prior to the transfer of a Select Agent a CDC EA-101 form must be completed. The EA-101 form will be jointly completed by all involved parties. The form must have the following information:

   a. The name of the requestor and requesting facility;
   b. The name of the transferror and transferring facility;
   c. The name of the transferors and requestors responsible facility official;
   d. The requesting and transferring facilities CDC registration #;
   e. The name of the agent being shipped;
   f. The proposed use of the agent; and the quantity (# of containers and amount per container) of the agent being shipped.

   The EA-101 form must be signed by the transferror and requestor, and the responsible facility officials of both facilities.

   A copy of the completed form should be faxed to CDC by the

requestor, after the transfer has taken place.

V. RESPONSIBILITIES

A. Warehouse and Inventory Control Department:

1. Ensures that the receipt, storage, and issue of Select Agents at the NCI-Frederick are in compliance with federal and state regulations.

B. Environment, Health and Safety Program:

1. Provides assistance to laboratory personnel in inventory control procedures, secure storage, and proper disposal of Select Agents.

2. Maintains records (CDC Form EA-101) on all interfacility transfers of Select 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 Select agent(s) are consumed or properly disposed, whichever is longer.

3. Maintains the NCI-Frederick Select Agents Registration issued by CDC. EHS will provide CDC updated information on any additions, deletions, or changes to the NCI-Frederick Registration.

C. NCI-Frederick Investigators

1. Review, confirm, and communicate requirements for working with Select Agents in laboratories for which they are responsible.

2. Maintain accurate records of receipt, expenditure, relocation and disposal of Select Agents for which they are responsible.

3. Forward information regarding method and date of Select Agent disposal to the responsible facility official (RFO).

APPENDIX D-4-A

42 CFR 72.6 SELECT AGENTS

Viruses

1. Crimean-Congo hemorrhagic fever virus
2. Eastern equine encephalitis virus
3. Ebola viruses
4. Equine morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American hemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan equine encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

Bacteria

1. Bacillus anthracis
2. Brucella abortus, B. melitensis, B. suis
3. Burkholderia (Pseudomonas) mallei
4. Burkholderia (Pseudomonas) pseudomallei
5. Clostridium botulinum
6. Francisella tularensis
7. Yersinia pestis

Exemptions: vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

Rickettsiae

1. Coxiella burnetii
2. Rickettsia prowazekii
3. Rickettsia rickettsii

Fungi

1. Coccidioides immitis

Toxins

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. Clostridium perfringens epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD_{50} for vertebrates of more than 100 nanograms per # kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

Recombinant organisms/molecules

1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.

2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed above, or their toxic subunits.

Other restrictions

The deliberate transfer of a drug resistance trait to microorganisms listed in this list that are not known to acquire the trait naturally is prohibited by NIH "Guidelines for Research Involving Recombinant DNA Molecules," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

Additional Exemptions

1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. § 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. § 2601 et seq.) are exempt.

2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted.

APPENDIX D-4-B

Select Agent Logbook

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				
TOTAL				

APPENDIX D-4-C

SELECT AGENT 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.

SELECT 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:

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