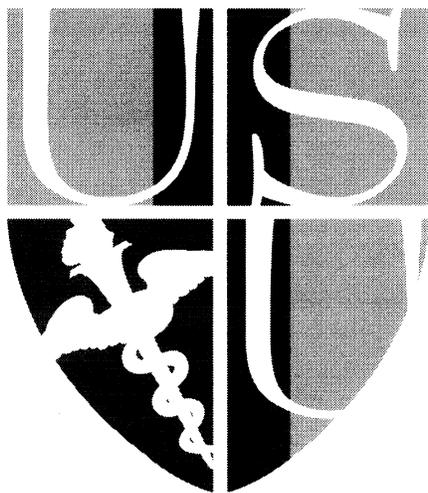


**USUHS
INSTRUCTION
6408**





UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES



SUBJECT: Centers for Disease Control Select Biological Agents Management

Instruction 6408

(EHS)

ABSTRACT

SEP 10 2004

This Instruction prescribes the safety practices, security procedures, and facility requirements for conducting research with Centers for Disease Control (CDC) Select Agents at the Uniformed Services University of the Health Sciences (USUHS). Select biological agents are used in both the Biosafety Level-3 (BSL-3) and BSL-2 laboratory environment.

A. Purpose. This Instruction establishes guidelines for the access, use, storage, security, and transfer (i.e., shipping, receiving, etc.) of CDC Select Agents and Toxins for research purposes at the USUHS.

B. References. See *Enclosure 1*.

C. Applicability. The provisions of this Instruction apply to all personnel involved in accessing, receiving, storing, transferring, shipping, receiving and conducting work with CDC select biological agents in the USUHS BSL-3 suite and BSL-2 laboratory facilities, to include military personnel, government personnel, and contracting personnel (hereinafter referred to as employees).

D. Responsibilities.

1. The President, USUHS is responsible for:

- a. Appointing a CDC Select Agent Responsible Official in accordance with 42 CFR, Part 73.
- b. Ensuring safe procedures with Select Agents; appropriate security for select

agents; quality control; and, that surveillance and accountability mechanisms relating to the use of CDC Select Agents in the BSL-3 suite and BSL-2 USUHS laboratory facilities are in place.

2. The EHS Department shall:
 - a. Provide a “**Responsible Official**” (**RO**) and an alternate RO to manage the CDC Select Agent registration.
 - b. Appoint a Biological Safety Officer to provide medical advice.
 - c. Ensure that during transfer, shipping, and receipt of CDC Select Agents, appropriate documentation (i.e., CDC Form EA-101) is completed.
 - d. Verify that the University holds a valid current registration number for the specific Select Agents and for the specific investigators using the Select Agents, as required by Title 42, CRF Part 73.
 - e. Verify that all requestors of CDC Select Agents are USUHS employees, and that the proposed use of the agent by the requestor is correctly indicated on the CDC Form EA-101.

f. Acknowledge receipt of Select Agents telephonically or electronically within 36 hours of receipt and provide a paper copy to the transferor within two business days of receipt of the agent.

g. Periodically inspect the BSL-3 suite and BSL-2 laboratories at USUHS that use Select Agents and ensure that safe work practices are maintained.

h. Make recommendations to Principal Investigators and the Department of Microbiology concerning maintenance, or replacement of needed safety equipment.

i. Ensure the posting and maintenance of emergency numbers and appropriate Biohazard Warning signs as required by 42 CFR, Part 73.

j. Maintain a record of all authorized uses of CDC Select Agents including identification of authorized users (their home addresses; their supervisors; the types of CDC Select Agents they work with; their laboratories, buildings, and room numbers); identification of Select Agents and toxins; and approved storage/refrigerator/freezer locations. This information will be provided to the Security Department. However, the Security Department does not maintain inventory amounts of CDC Select Agents.

k. Acquire, develop, and update training programs (including self-paced training programs) to meet the general safety and informational requirements of personnel working with Select Agents.

l. Investigate the cause of every facility accident involving Select Agents.

m. Maintain training, transfer, and inspection records.

n. Manage the immunization program for researchers, as needed, based on the Select Agent in use.

3. The -“Responsible Official” (RO) is designated to maintain a current valid institutional CDC registration, which demonstrates that USUHS is a facility equipped and capable of safely handling

Select Agents. The RO is responsible for program oversight and ensuring compliance with 42 CFR Part 73. Specifically, the RO is responsible for:

a. Developing and implementing safety, security, and emergency response plans.

b. Ensuring that only approved individuals have access to Select Agents or toxins.

c. Ensuring that appropriate training for safety, security, and emergency response is conducted.

d. Certifying that only a Principal Investigator, who is officially affiliated with the University and listed on the USUHS CDC registration, conducts transfers of Select Agents or toxins.

e. Confirming receipt of CDC Select Agents material, and ensuring that the laboratory meets established guidelines for working with the requested agent.

f. Providing the CDC with timely notice of any theft, loss, or release of Select Agents or toxins.

g. Maintaining documentation of the program.

h. Maintaining a centralized inventory of all CDC Select Agents and toxins at the University. (*See Enclosure 2 for a list of CDC Select Agents and Toxins.*)

i. Providing ancillary approval in the College and University Financial System (CUFS) for the purchase of all Select Agents.

j. Notifying the Resource Management Information (RMI) and Logistics (LOG) of any request for new Select Agents not currently identified in the CUFS Commodity Table.

4. The Biological Safety Officer (BSO) is designated to provide medical advice and assistance regarding the use of biological agents and in the implementation of the CDC standards.

5. The USUHS Pharmacy is responsible for placing all CDC Select Agent Orders and for contacting Receiving, the PI, and RO once the order has been placed.

6. The University Safety Committee is responsible for accepting or modifying recommendations from the BSL-3 Oversight Committee.

7. The BSL-3 Oversight Committee is responsible for:

a. Ensuring PIs have satisfactory knowledge, training, and experience with the proposed Select Agent, and can assume full responsibility for the training of researchers working under their protocol, and are aware of the additional health and safety needs of concurrent users.

b. Reviewing requests to use the BSL-3 suite for research involving select biological agents.

c. Recommending approval or disapproval of such requests to the Safety Committee.

d. Establishing special training requirements for Principal Investigators and the staff who use Select Agents.

e. Developing uniform guidelines for safe work practices within the BSL-3 suite.

f. Periodically reviewing and providing update comments for the BSL-3 Instruction 6403, "Biohazard Suite Management," and this Instruction.

8. The Chair, Department of Microbiology is responsible for the physical integrity and maintenance of the BSL-3 suite. The Chair maintains electronic card access systems and issues cards based on requests approved by EHS. The Chair also ensures that safety guidelines are adhered to, and responds to requests and concerns raised by Principal Investigators (PIs) and others regarding the work environment or work practices.

9. Supervisors of workers not specifically approved for CDC Select Agent Registration, (Facilities, Logistics, Housekeeping, Technical Support Branch, University Information Systems, contractors, etc.) shall ensure that all personnel wear appropriate personal protective equipment (PPE), are escorted, and are continually monitored by an approved CDC Select Agent worker (someone listed on the USUHS CDC Select Agent registration list, who has a current Department of Justice security clearance) whenever they enter and perform required maintenance in the BSL-3 suite.

10. The Security Division (SEC) shall:

a. Immediately notify EHS of any security incident or adverse condition that involves research with CDC Select Agents.

b. Accept responsibility for the physical security of laboratories containing CDC Select Agents. (*See Enclosure 3 for the detailed CDC Select Agent Security Plan.*)

c. Provide initial training and annual refresher training on the physical security of Select Agents, including all elements of the Security Plan to all authorized users of CDC Select Agents or toxins. SEC does not provide training to auxiliary workers who are signed in for short-term access. SEC maintains a roster of training attendees.

d. Conduct annual security audits (including access procedures and logbooks), ensuring keys or pass cards have been disbursed only to authorized users in laboratories with key locks or electronic access devices.

e. Maintain electronic access systems and issue cards based on requests through Microbiology & Immunology approved by EHS.

f. Collect fingerprints from all USUHS staff approved to work unescorted in laboratories using CDC Select Agents. The fingerprint cards will be submitted (upon initial entry into the program before access is granted to the laboratories) with the FD-961

form, “Federal Bureau of Investigation, Bioterrorism Preparedness Act: Entity/Individual Information” to:

FBI, CJIS, Bioterrorism
IOAU E-3, 1000 Custer Hollow Road
Clarksburg, WV 26306-0147.

g. Update Enclosure 3, “Security Plan,” which provides security measures and access restrictions for Select Agents.

11. The Logistics Division is responsible for:

a. Reviewing procedures for ordering, receiving, shipping, and delivery of Select Agents within the University (Enclosure 4), and providing updates to those procedures to the RO, when necessary.

b. Providing appropriate notification so that the chain-of-custody can be maintained during receipt and delivery of Select Agents to the Principal Investigator or RO.

c. Ensuring the security of Select Agents until delivered to an authorized user/requestor or the RO.

d. Following shipping and receiving procedures as identified in Enclosure 4.

e. Providing information to RMI for updating the CUFS Select Agent commodity table when requested to do so by the RO.

12. The Principal Investigator (PI) is responsible for:

a. Implementing safe work practices for researchers working with Select Agents maximizing the microbiological safety of personnel.

b. Ensuring CDC Select Agents are secured at all times. Security will be provided by storing Select Agents in locked freezers when not in use and ensuring the laboratories are locked at all times when not occupied by an approved CDC Select Agent worker.

c. Assuring safety training and promoting continuing education for experienced and inexperienced personnel.

d. Complying with appropriate security measures (Enclosure 3), and shipping/receiving procedures (Enclosure 4) related to the use of Select Agents.

e. Cooperating with Environmental Health/Occupational Safety (EHS) and Security during safety and security inspections, and implementing their recommendations.

f. Ensuring that each accident involving Select Agents is reported to the RO and Occupational Health Division of EHS, as appropriate.

g. Ensuring that Select Agents shipped from USUHS are correctly packaged and processed per Federal regulations and in accordance with Enclosure 4 procedures.

h. Ensuring Select Agents are ordered or transferred in accordance with approved procedures, which includes the following:

1) Entering an RXD into CUFS for the CDC Select Agent in accordance with the procedures listed in Enclosure 4.

2) Using only the CUFS financial system (no HMJ or Departmental Government Purchase Card) to purchase CDC Select Agents or toxins. HMJ Funds may be transferred to the University in order to make use of the CUFS system for CDC Select Agent purchases.

i. Ensuring all individuals entering or working with Select Agents receive the required vaccination or wear the appropriate personal protective equipment.

j. Notifying the Director of LAM when animals are housed in the BSL-3 suite, and when they are no longer used.

13. Supervisors of approved CDC Select Agent workers shall:

a. Provide direct supervision when the Principal Investigator is not physically present in the facility. When a Select Agent is being used in the facility, a designated

“supervisor” or “lead” among the trained staff shall be present if the PI is not present in the facility.

b. Ensure that appropriate safety orientation and training is conducted and documented for each new employee whose duties require work with a Select Agent. At a minimum, this should include:

(1) Review and comprehension of this Instruction, including Enclosures 3 and 4 which detail the Security Plan and Logistics procedures.

(2) Attend the General Lab Safety and Hazardous Communication (HAZCOM) training provided by EHS.

(3) Provide CDC Select Agent specific training to researchers including a detailed explanation of the Standard Operating Procedures unique to the research protocol.

(4) Affirming that researchers have completed the CDC Select Agent self-paced training, including successfully passing the post test.

(5) Assuring that researchers have completed the security training provided by the Security Division. (6) Affirming that researchers are familiar with the emergency procedures related to working with the CDC Select Agents.

c. Maintaining documentation (sign-in sheets) for each employee’s training. The documentation should be available for audit by EHS or extra-mural inspection teams. EHS will be notified whenever training is completed in order to maintain the electronic training database (EHS Assistant).

F. Effective Date. This Instruction is effective immediately.



Larry W. Laughlin, M.D., Ph.D.
Interim President

Enclosures:

1. References
2. CDC Select Agent List
3. Security Plan
Appendix A: Checklist for BSL-3 Suite Access
4. Ordering, Receiving, and Shipping CDC Select Agents

Enclosure 1

REFERENCES

- (a) Title 42, CFR Part 73, "Possession, Use, and Transfer of Select Agents and Toxins: Interim Final Rule," December 13, 2002
- (b) Title 42, CFR Part 1003, "Civil Money Penalties, Assessments and Exclusions," October 1, 2002.
- (c) Title 29, CFR Part 1910.1200, "Hazard Communication," July 1, 2003
- (d) Title 29, CFR Part 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories," July 1, 2003
- (e) "Select Agent Rule - A Satellite Broadcast," June 22, 2000
- (f) 4th Edition, "Bio-safety in Microbiological and Biomedical Laboratories," CDC, US Department of Health and Human Services, May 1999
- (g) Instruction 6403, "Biohazard Suite Management," June 15, 2004

CDC Select Agent List

(USUHS current CDC Registration authorizes the University to possess only those items marked.)

HHS NON- OVERLAP SELECT AGENTS AND TOXINS

- Crimean-Congo haemorrhagic fever virus
- Coccidioides posadasii*
- Ebola viruses
- Cercopithecine herpes virus 1 (Herpes B virus)
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- Rickettsia prowazekii*
- Rickettsia rickettsii*
 - South American haemorrhagic fever viruses
 - Junin
 - Machupo
 - Sabia
 - Guanarito
 - Tick-borne encephalitis complex (flavi) viruses
 - Central European tick-borne encephalitis
 - Far Eastern tick-borne encephalitis
 - Russian spring and summer encephalitis
 - Kyasanur forest disease
 - Omsk hemorrhagic fever
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- Yersinia pestis*
- Abrin
- Conotoxins
- Diacetoxyscirpenol
- Ricin
- Saxitoxin
- Shiga-like ribosome inactivating proteins
- Tetrodotoxin

HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS/ SELECT AGENTS (OVERLAP AGENTS)

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

USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS (NON-OVERLAP AGENTS AND TOXINS)

- Akabane virus
- African swine fever virus
- African horse sickness virus
- Avian influenza virus (highly pathogenic)
- Blue tongue virus (Exotic)
- Bovine spongiform encephalopathy agent
- Camel pox virus
- Classical swine fever virus
- Cowdria ruminantium*
- Flexal (Heartwater)
- Foot and mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- Japanese encephalitis virus
- Malignant Catarrhal fever virus (Exotic)
- Menangle virus
- Mycoplasma capricolum* / M.F38/M. *mycoides capri*
- Mycoplasma mycoides mycoides*
- Newcastle disease virus (VVND)
- Peste Des Petits Ruminants virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus (Exotic)

LISTED PLANT PATHOGENS

- Liberobacter africanus*
- Liberobacter asiaticus*
- Peronosclerospora philippinensis*
- Phakopsora pachyrhizi*
- Plum Pox Potyvirus
- Ralstonia solanacearum* race 3, biovar 2
- Schlerophthora rayssiae* var *zeae*
- Synchytrium endobioticum*
- Xanthomonas oryzae*
- Xylella fastidiosa* (citrus variegated chlorosis strain)

*Toxins (in purified form or in combinations of pure and impure forms) are exempt from CDC Select Agent consideration if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 100 mg of Conotoxins; 100 mg of Tetrodotoxin; 0.5 mg of Botulinum neurotoxin.

Some USUHS researchers have limited amounts of the toxins listed above but below the amount required to be considered a CDC Select Agent. The term "Sub-CDC Select Agents" is used in this Instruction to identify these toxins.

SECURITY PLAN

1. Responsibility

A. The Security Division (SEC) has overall responsibility for security at USUHS to include all areas where CDC Select Agents are used. The SEC is responsible for maintaining this security plan and providing training to users of CDC Select Agents. The SEC will issue access cards to individuals identified by the Chair of Microbiology as having a legitimate need to access the laboratory/BSL-3 suite after they have been processed through EHS. The SEC is responsible for maintaining the electronic access system to include the software that logs the individual accesses.

B. The Microbiology Department (MIC) has internal responsibility for security of Select Agents, identifying users of Select Agents, controlling access of ancillary personnel (housekeeping, maintenance and repair personnel, etc.), and ensuring control is maintained over keys, combination locks, and electronic pass cards. If CDC Select Agents or toxins are used in a BSL-2 laboratory outside of the MIC, that BSL-2 lab's Department Chair will assume these responsibilities.

C. The Environmental Health and Occupational Safety Department (EHS) has responsibility for reviewing this plan annually and after any incident, processing personnel who require an electronic pass card, and conducting inspections of the laboratories.

2. Personal Security

A. Researchers requiring access to the BSL-3 suite, or any other suite utilizing CDC Select Agents, that are controlled with an electronic card reader will initiate the attached form, "CHECKLIST FOR BSL-3 SUITE ACCESS." MIC will verify that the need is legitimate and direct the individual to EHS where any physical check-up will be conducted; the individual will be fit-tested for a respirator, if necessary. The individual will take the completed checklist to SEC for the issuance of an electronic pass card.

B. Researchers requiring access to CDC Select Agent labs that are controlled by key locks will request a "do not duplicate" key from Dr. Alison O'Brien (MIC), the key custodian. If the Chair and RO authorize access, the key custodian will complete a USUHS Form 5211, which lists the key number, room number, date of issue, and signature of the person assigned a key.

C. The SEC will be notified of all staff changes as soon as possible, so that key cards can be deactivated, or locks changed.

D. All researchers requiring access to CDC Select Agent labs will be required to have an FBI security risk assessment completed. Two documents are required for submission to initiate the risk assessment. The FD-961 (2-24-03), "Bioterrorism Preparedness Act:

Entity/Individual Information Form for the Federal Bureau of Investigation” and two legible fingerprint cards. The Responsible Official, EHS, will maintain copies of the FD-961 form and will assure the form is completed correctly. The SEC will obtain the fingerprint card stock and will manage the fingerprinting process. SEC will forward the completed FD-961 forms and fingerprint cards to the FBI at:

FBI, CJIS, Bioterrorism
IOAU E-3, 1000 Custer Hollow Road
Clarksburg, WV 26306-0147.

E. Only personnel who have been approved in the method described above will be allowed unescorted access to CDC Select Agent laboratories and only when performing a specifically authorized function during hours required to perform the defined job (including delivery to an outside shipping agent for transportation in commerce).

3. Ancillary Personnel

Personnel who perform routine cleaning, maintenance, and repairs are considered ancillary personnel, and will be escorted and continually monitored while working in USUHS laboratories. Logistics (LOG) personnel are not required to be vaccinated, but must wear protective gear when working in the BSL-3 suite. They do not need to suit up going into the labs that have CDC agents. Only researchers who have been properly approved and listed on the CDC registration may provide this monitoring.

4. Unusual Occurrences

A. Unauthorized or suspicious personnel will be queried by the research staff and immediately reported to SEC. The SEC will remove any unauthorized persons from the area, or evaluate the situation and provide a report of the action to the Responsible Official (RO), EHS.

B. Any loss or compromise of keys, passwords, combinations, access cards, etc., will be reported to SEC.

C. Any loss, theft, or accidental release of Select Agents or toxins will be immediately reported to the RO, EHS. The RO will immediately notify the HHS Secretary, State and local law enforcement. Local law enforcement includes both SEC (301) 295-3033 and the NNMC Public Safety Department (301) 295-1246. The notification must be reported to the HHS Secretary either by telephone **(404) 498-2276**, facsimile **(404) 498-2265**, or e-mail **LRSAT@cdc.gov**.

(1) Thefts or losses must be reported whether the Select Agent or toxin is subsequently recovered or the responsible parties are identified.

(2) When reporting a theft or loss, the following information must be provided:

(a) The name of the Select Agent or toxin, and any identifying information (e.g., strain or other characterization information).

- (b) An estimate of the quantity lost, stolen or released.
 - (c) An estimate of the time during which the theft or loss occurred.
 - (d) The location (building, room) from which the theft or loss occurred or from which the release occurred.
 - (e) The environment into which the release occurred (e.g., in building or outside of building, waste system).
 - (f) The number of individuals potentially exposed.
 - (g) Actions taken to respond to the release.
 - (h) Hazards posed by the release.
- (3) Within seven calendar days of theft, loss, or release, the RO must submit a follow-up report in writing to the HHS Secretary on CDC Form 0.1316. That form can be downloaded from the internet at the following CDC approved website address: <http://www.cdc.gov/od/sap/addforms.htm>.

D. Any sign that inventory and use records of Select Agents or toxins have been altered or otherwise compromised must be reported to SEC and the RO.

5. Select Agent Security

A. Select Agents and toxins may be stored and used only in approved laboratories, which are listed on the USUHS registration with the CDC.

B. Select Agents and toxins will always either be under the direct control of an approved individual or secured in a locked container (refrigerator, freezer, etc.). The laboratories containing Select Agents or toxins will remain locked at all times.

C. All adjustments in inventory will be submitted to the RO, who will maintain a USUHS-wide inventory.

D. All packages will be inspected upon entry to and exit from the laboratory.

6. Termination of the Use of a Select Agent or Toxin

A. The Responsible Official will be notified of plans to terminate the use of a Select Agent or toxin.

- B. The Select Agent or toxin may be:
- (1) Securely stored in accordance with the requirements of this section.
 - (2) Transferred to another registered facility.
 - (3) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.

7. Security Training

A. The SEC will provide training to personnel on security procedures and this Instruction.

B. The training will be provided annually in either a self-paced presentation with a written test, or an instructor-provided presentation.

CHECKLIST FOR BSL-3 SUITE ACCESS

In order to obtain access to the BioSafety Level-3 suite, please complete this form and return it to the Security Office, Room UP001.

Key number: _____

Employee Name: _____

Department: _____ Work Phone Number: _____

1. Authorization by Dr. Alison O'Brien: _____

Room B4154
295-3419

Dr. Alison O'Brien

Date

2. EHS Authorization: _____

Room A2020
295-3390

Signature, CDC Select Agent Responsible Officer

Date

3. Security Division Authorization: _____

Room UP001
295-3654

Signature, Security Division

Date

ORDERING, RECEIVING, AND SHIPPING CDC SELECT AGENTS

1. Ordering Select Agents

A. The Responsible Official (RO) will be notified by the Principal Investigator (or his representative) of all requests for purchase of CDC Select Agents or toxins that could be considered Select Agents (Sub-CDC Select Agents) before any other action is taken.

B. All requests for CDC Select Agents or toxins that could be considered Select Agents (Sub-CDC Select Agents) must be entered into the CUFS financial system as an RXD. Purchasing CDC Select Agents or Sub-Select Agents with a department's government credit card or HMJF (People Soft) financial system is **PROHIBITED**.

1. The CUFS transaction (RXD) will list the Principal Investigator (and phone number) as the requestor (not the person entering the order in CUFS).

2. When entering the RXD into CUFS for Select Agents, the Commodity Code "**CDC Biological**" must be used. The Description will include the type of virus or toxin.

3. The CUFS RXD transaction will require EHS approval as part of the Commodity Approval System. The EHS person entering the approval will delete the transaction and make the following coordination:

(a) Prior to Pharmacy placing the order, the RO will complete a CDC Form EA-101 and submit it to the HHS Secretary IAW 73.21 (Fax: 404 498-22265) and the State of Maryland Department of Health and Mental Hygiene (DHMH) (Fax: 410-333-5403). (**Neither actions are required for sub-CDC Select Agents.**)

(b) The RO will obtain authorization from the CDC prior to approving the purchase (**not required for sub-CDC Select Agents**).

4. Once authorization has been received, the EHS Approver will notify the Pharmacy of the CDC Select Agent requisition number (i.e., RXD MIC3R071). The Pharmacy will place the order using the Pharmacy Government Purchase Card or by obtaining a Visa check through Contracting.

C. The Pharmacy will provide the estimated date of delivery, name of the delivery service, the purchase order number, and the tracking number to the following:

Director, Logistics

Deputy Director Logistics

Logistics Administrative Officer

Receiving, Distribution, and Records Branch Chief

Materials Handler Leader (Receiving)

Any other receiving personnel listed on the CDC registration and approved to accept agents

CDC Select Agent Responsible Official

Alternate CDC Select Agent Responsible Official

The requesting Principal Investigator

2. Receiving Select Agents

A. CDC Select Agents will **ONLY** be accepted and processed by Logistics Receiving Section personnel who have been appropriately trained and listed on the USUHS CDC Select Agent registration. Prior to any CDC Select Agent shipment being sent to USUHS a mandatory telephonic notification between the shipper and the USUHS Principal Investigator (PI) will be initiated in order to ensure immediate acceptance of the package by the PI upon it's scheduled arrival date and time.

B. Authorized Logistics' personnel will immediately process and deliver CDC Select Agents to the authorized Principal Investigator. In the event a Select Agent cannot be immediately delivered, the RO (or alternate RO) will be contacted to arrange for appropriate storage until the Select Agent can be delivered. The RO can be contacted by calling the Environmental Health and Occupational Safety Office. Select Agents will be locked in the Receiving Section refrigerator at all times until the agent is either delivered to the authorized PI or turned over to the RO (or alternate RO).

C. Logistics Receiving, Distribution, and Records Section will notify the RO by e-mail once the Select Agent has been delivered to the Principal Investigator/requestor.

D. The RO will provide a paper or facsimile copy of the completed CDC form EA-101 to the HHS Secretary to the State of Maryland DHMH within 2 business days of receipt of the Select Agent or toxin. **(This is not required for sub-CDC Select Agents.)**

E. The RO will immediately report to the HHS Secretary if the Select Agent or toxin has not been received within 48 hours of the expected delivery time, or if the package is leaking or damaged.

3. Shipping Select Agents

A. The RO will be notified by the Principal Investigator (or his representative) of all requests for shipping of CDC Select Agents or toxins that could be considered Select Agents (Sub-CDC Select Agents) before any other action is taken.

B. The RO will contact the recipient and verify that he/she has a certificate of registration that includes the particular Select Agent or toxin to be transferred. **(This is not required for sub-CDC Select Agents.)**

C. The RO will complete a CDC Form EA-101 and submit it to the HHS Secretary IAW 73.21 (Fax 404 498-2265) and to the State of Maryland Department of Health and Mental Hygiene (DHMH) (Fax 410-333-5403) for authorization to make the shipment. **(This is not required for sub-CDC Select Agents.)**

D. The RO will e-mail the Receiving Section with authorization for any Select Agent being shipped out of the University. The e-mail will include the authorized

user/requestor and the destination.

E. Packages of Select Agents, to be shipped, will be packaged IAW all applicable laws concerning packaging and shipping, and brought to the Receiving office before 11:00 a.m. on the day of the shipment. CDC Select Agents will **ONLY** be accepted and processed by Logistics Receiving Section personnel who have been appropriately trained and listed for the USUHS CDC Select registration.

F. If the package cannot be shipped on the same day, the authorized PI will be contacted and required to pick up the package from a Federal Express office for overnight storage. LOG does not store "CDC Select Agent" shipments overnight.

G. All CDC Select Agents being shipped out of the University will be locked in the Receiving Area refrigerator until they are turned over to the commercial carrier.

H. Once the CDC Select Agent is shipped, LOG Receiving must notify the RO in person, by phone, or by e-mail and inform him/her that the Select Agent has left the University.