

## **Section 11 Security**

Each Principal Investigator must develop and implement a laboratory security plan for ensuring the security of areas containing select agents and toxins under their control. Each security plan must contain written procedures to ensure compliance with the institutional policies set out under this section.

Security plans must be based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks associated with those vulnerabilities are mitigated with a security systems approach. Each plan must describe:

- inventory control procedures,
- physical security, and
- cyber security.

The plans must be consistent with the following UK policies:

### **I. Inventory Control Procedures**

1. Each Principal Investigator must keep an up to date inventory of all select agents and toxins under their control. Detailed records must be kept whenever the stocks of select agents and toxins are accessed. (see Section 17, Records)
2. Each Principal Investigator must develop procedures for controlling access to containers where select agents and toxins are stored. Freezers, refrigerators, cabinets, and other containers where stocks of select agents and toxins are stored must be locked when they are not in the direct view of staff approved under §73.7. Principal Investigators must develop internal procedures for controlling the keys for accessing these containers. Keys must not be used by anyone without permission of the Principal Investigator, and anyone permitted to use a key must not loan that key to any other person.

### **II. Physical Security**

1. Areas containing a select agent or toxin must be locked at all times. Entry will be provided by card access.
2. Principal Investigators requiring access cards for select agent areas for their use or for new employees must submit a written request, using FBI form FD-961 to the Responsible Official prior to accessing any select agents. Upon receipt of approval from the DHHS the Responsible Official will notify the Principal Investigator and schedule a time to meet with the card issuing agent. The Responsible Official must accompany the individual and verify their eligibility to the card issuing agent.
3. Access logs (electronic and handwritten) will be reviewed regularly by designated authorized persons to ensure there are no discrepancies or unauthorized entries.
4. Access cards must not be shared. Anyone sharing an access card or assisting another person to gain entry to an area containing a select agent or toxin without the use of a card (such as opening a door) must be reported to the Responsible Official.
5. Each Principal Investigator must develop procedures for controlling access to areas where select agents and toxins are stored. Principal Investigators shall allow unescorted access only to individuals who have been approved under §73.10 and who are performing a specifically authorized function during hours required to perform the defined job.

6. Personnel not approved under §73.10 who need to enter an area containing a select agent or toxin to perform routine cleaning, maintenance, repairs or other tasks must be escorted and continually monitored at all times by a person approved under §73.10. Personnel not approved under §73.10 must sign the entry log, and the escort must sign also. Any containers, bags, etc., must be inspected by a person approved under §73.10 before being brought into or out of the area.
7. Principal Investigators must ensure that all individuals, including ancillary workers and visitors, given access to select agents and toxins under their control understand the security requirements and are trained and equipped to follow established procedures. All personnel who enter an area containing a select agent or toxin must be given appropriate training regarding security procedures. Training must be documented by signing the Visitor/Training Log .
8. If any access card is lost or stolen, it must be reported immediately to the Principal Investigator and the Responsible Official, giving a brief description of what has occurred and the name of the individual involved. The Responsible Official must notify the card issuing agent of the compromise and request an immediate cancellation of that person's access to the select agent area. The Responsible Official must notify UKPD if the access card was stolen. The Principal Investigator must conduct an inventory to determine whether any storage vials, plates or incubating cultures are missing. If any thing is missing, UK procedures for Notification of Theft, Loss or Release must be followed. If cultures and storage vials are all accounted for, the Responsible Official must be informed that nothing is missing. An incident report must be filed with the Responsible Official and a copy kept with the Principal Investigator's select agent records.

Principal Investigators requiring a change in access codes must apply in writing to the Responsible Official with an explanation of why a change is needed. Upon approval of the request, the Responsible Official will notify the card issuing agent in writing that the access codes may be changed.

No temporary cards or access equipment will be issued. If access is left at home, that individual must notify their supervisor at once and will not be given access to the select agent area. How to handle this situation will be left to the discretion of the Principal Investigator. However, the access card or equipment must be retrieved as soon as possible.

9. Any suspicious persons or activities must be reported immediately to the Principal Investigator, Responsible Official and UKPD.
10. Any known theft or release of listed agents or toxins must be reported immediately to the Principal Investigator, Responsible Official and UKPD. The suspected loss of a select agent or toxin shall be reported immediately to the Responsible Official, who will notify UKPD if appropriate.

In the event of a release, the Environmental Management team or other appropriate units designated in the emergency plan shall be notified. The RO will be notified.

11. Alteration or suspected alteration of any inventory record is a criminal matter and must be reported immediately to the Principal Investigator, Responsible Official and UKPD.
12. Any unauthorized persons in a select agent area must be reported immediately to the Principal Investigator, Responsible Official and UKPD. The police shall respond and block any exit from the area and shall call the Responsible Official for assistance if entry into a high level of contamination area is necessary.

Any subjects found trespassing in a high security laboratory shall be subject to arrest for Criminal Trespass. All subjects will be identified and fingerprinted and photographed. The information shall be forwarded to the FBI immediately, no matter whether an arrest is made or not. If an arrest is not warranted, the subject shall be identified and all information reported to the FBI immediately. If the subject is an employee of the University, his/her supervisor shall be immediately notified of the subject's actions and the Responsible

Official shall see that appropriate action is taken by the University. **Police will treat these incidents as a Homeland Security Issue and will not take any incidents lightly.**

13. All packages must be inspected before entry into and exit from the area. The Principal Investigator must develop written procedures for the inspection of all packages before entry to or exit from the area. Packages include any articles received in shipment from outside the University or prepared in the laboratory for shipment outside of the University. (see also, Section 14, Transfers) Packages also include any articles to be brought into the area by individuals not approved under §73.10, such as maintenance workers, inspectors, etc.
14. Transfers of select agents or toxins within UK, including movement from one laboratory to another laboratory or from a laboratory to a shipping place, must comply with all procedures of Section 14, Transfers.
15. Areas approved for select agent or toxin storage and use must be physically separated from the public areas of the buildings. This must include, at a minimum, keeping select agent and toxin areas locked at all times.

### **Termination of Work with Select Agents**

At least one week prior to finishing work with select agent or terminating employment, authorized personnel must notify the PI in writing of the final date that they will be entering the BSL3 facility in relation to their authorized work.

The PI will notify the RO in writing.

The RO will arrange with Medical Center Security to deactivate permission for BSL3 entry on the next day after the chosen date of final entry.

In the case of an emergency termination or lost access card, the RO will be notified immediately (cell phone 859-619-1553) and the RO will notify Medical Center Security (859-323-6156) to deactivate the card. Backup Security personnel are designated so that this procedure can occur 24 hours a day, 7 days a week.

### **Cyber Security**

1. Individuals not approved under §73.10 must be prevented from accessing sensitive electronic information concerning select agents and toxins.
2. Each Principal Investigator must develop written procedures for securing sensitive electronic information concerning select agents and toxins under their control. Each Principal Investigator must make a determination regarding what information needs to be protected that must, at a minimum, include inventory data, locations, and codes used to identify strains and toxins. Procedures must cover the protection of passwords, desktop drives, servers and removable storage media, as appropriate. Procedures must be consistent with the IT Security policies established by Fiscal Affairs and Information Technology (see <http://www.uky.edu/IT/Security/>).
3. Individuals given electronic access to sensitive data are prohibited from sharing their password with anyone else.
4. Each Principal Investigator will ensure that reference to any select agent on his/her website shall not disclose any physical laboratory location, containment facility information, or other sensitive information that could not be published in a scholarly journal.

### **Other Policies**

1. Principal Investigators must have appropriate qualifications in order to be permitted by the University of Kentucky to obtain, possess, use, ship or receive any select agent or toxin. The Responsible Official must review the education and experience of each Principal Investigator prior to submitting the individual for approval under §73.10 in order to ensure they are qualified to work with select agents.
2. The Principal Investigator must determine minimal education and experience criteria for those individuals under their supervision with access to select agents or toxins.
3. The Responsible Official must review this security plan at least annually and after any incident.
4. Individuals approved under §73.10 must report any of the following immediately to the Responsible Official:
  - Any loss or compromise of their keys, passwords, combinations, etc.;
  - Any suspicious persons or activities;
  - Any loss or theft of select agents or toxins;
  - Any release of select agents or toxins; and
  - Any sign that inventory and use records of select agents or toxins have been altered or otherwise compromised.
5. When a select agent or toxin is no longer needed, the Principal Investigator must notify the Responsible Official of the intention to terminate use. Upon approval by the Responsible Official, the select agent or toxin must be:
  - Securely stored in accordance with the requirements of this section;
  - Transferred to another registered facility in accordance with Section 14; or
  - Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.