

Section 11 Security “UK Security Plan”

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:

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 15 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 §73.8. Keys for accessing these containers must be under the control of the Principal Investigator. 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.

Physical Security

1. Areas containing a select agent or toxin must be locked at all times. Entry will be provided by card access.
2. Upon request by Principal Investigators and approval under §73.8, access cards will be issued to individuals by the Responsible Official. [to be done]
3. 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.
4. 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 §73.8 and who are performing a specifically authorized function during hours required to perform the defined job.

5. Personnel not approved under §73.8 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 §73.8. Personnel not approved under §73.8 must sign the entry log, and the escort must sign also. Any containers, bags, etc. must be inspected by a person approved under §73.8 before being brought into the area.
6. 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.
7. Protocol for changing access codes following staff changes or following loss or compromise of keys, passwords, combinations, etc. [to be done]
8. Procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of select agents or toxins, or alteration of inventory records. [to be done]
9. Procedures for reporting and removing unauthorized persons [to be done]
10. All packages must be inspected before entry to and exit from the area. The Principal Investigator must develop written procedures for the inspection of all packages prior entry to and 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 §73.8, such as maintenance workers, inspectors, etc.
11. Intra-entity transfers of select agents and toxins, including provisions for ensuring that the packaging, and movement from a laboratory to another laboratory or from a laboratory to a shipping place, is conducted under the supervision of an individual approved under §73.8. [to be done]

Cyber Security

1. Individuals not approved under §73.8 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 www.uky.edu/FAIT/Security/).

3. Individuals given electronic access to sensitive data are prohibited from sharing their password with anyone else.

Other Policies

1. Principal Investigators must hold a Ph.D., Pharm.D., or M.D. degree in order to be permitted by the University of Kentucky to obtain, possess, use, ship or receive any select agent or toxin. Any exception to this policy requires approval by the UK Institutional Biosafety Committee, who will review the research protocol and credentials of the Principal Investigator. The IBC will develop criteria to evaluate such requests.
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 section and each Principal Investigator's security plan at least annually and after any incident.
4. Individuals approved under §73.8 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.