



Biosecurity

Select Agent Program
2016

Biosecurity

- The **ODHL Biosecurity Plan** is designed to safeguard the select agent or toxin against unauthorized access, theft, loss or release.



Biosecurity

1. Definitions

- General Definitions: See section 73.1 of the 42 CFR Select Agent Rule - **Appendix A**



Biosecurity

2. Key Roles and Responsibilities

- RO – Responsible Official
 - Ensures compliance with select agent regulations
 - Investigates security breaches
 - Perform annual review of plans
 - Ensures performance of an annual compliance inspection
 - Report the identification and final disposition of any select agent or toxin recovered from samples or proficiency testing
- Steve York- RO, Supervisor, Quality Assurance and Compliance/Laboratory Safety Officer



Biosecurity

2. Key Roles and Responsibilities

- ARO – Alternate Responsible Official –
 - Tammy Bannerman, Laboratory Director
 - Kevin Sohner, Special Microbiology Supervisor
 - Takes over when RO is absent



Biosecurity

2. Key Roles and Responsibilities

- PI – Principal Investigator – Larry King, General Microbiology Supervisor
 - Provide scientific and technical direction to the ODHL Select Agent Program
 - Adopt the ODHL Biosecurity Plan procedures
 - Assure timely completion and submission of select agent ID and transfer forms
 - Maintain an up-to-date select agent registration
- Laboratory personnel
 - Maintain security of select agents while in their possession
 - Report all incidents and breaches in security or biosafety to the PI and/or the RO/ARO



Biosecurity

3. Restricting Access to Select Agents & Toxins/Security

- Authorized Individuals
 - Only individuals authorized by the RO have access to the exclusion areas
 - Security Risk Assessment or SRA –
 - Individuals must be cleared by the U.S. Department of Justice
 - Maintain a valid SRA to remain on ODHL SA Registration - 3 year renewal cycle
 - Background checks



Biosecurity

4. Security

- Site-Specific Risk Assessment
 - Agent-Specific Risk Assessment: A description of the ODHL select agent related assets is found in **Appendix B**. ODHL is not a Tier 1 lab.
 - The overall agent-specific risk for ODHL is considered to be **Moderate**



Biosecurity

4. Security

- Site-Specific Risk Assessment
 - Threat Assessment: Considers the risks posed by insider individuals, outsider individuals, individuals that may desire to do harm, natural and man-made disasters
 - Probability of occurrence: Man **Low**, Nature **Low**, Incident **Low**
 - Consequence of occurrence: Man **Low**, Nature **Moderate**, Incident **Moderate**
 - Vulnerability Assessment: This considers security weaknesses and deficiencies of the facility
 - The overall vulnerability of the ODHL is considered to be **Moderate**



Biosecurity

4. Security

- Mitigation (Protection Strategy)
 - Exclusion/Secure Areas
 - BSL3 – rooms 104, 105, 105A, 105B, 105C
 - Access to these areas are limited to staff listed on the ODHL Select Agent Registration
 - All other individuals are not permitted access/entry to these areas unless escorted and monitored by an authorized staff member
 - Tailgating is prohibited into any exclusion area
 - Doors are fitted with locksets
 - Key use is controlled



Biosecurity

4. Security

- Physical Security
 - Entry into the ODH Laboratory is strictly controlled
 - Gated entry after hours with controlled by Proximity Card
 - Entrances are locked at all times or monitored by personnel
 - All entrances and corridors are monitored by video-surveillance equipment
 - Entry into BSL III is controlled by key pad security system administered by RO and ARO/LSO
- Operational Security
 - Intrusion Detection, Access Control, Closed Circuit TV and Emergency Power Systems at ODHL- [Appendix C](#)



Biosecurity

4. Security

- Key control
 - Keys are not required to access the facility.
 - Emergency key access is limited to Security Risk Assessment approved individuals
 - Only the RO/ARO are able to sign out keys to authorized SRA-approved staff if access is needed to Exclusion/Secure areas
 - Issued keys are responsibility of staff receiving key
 - Key to be returned daily to issuer (RO or ARO)



Biosecurity

4. Security

- Inventory Control
 - An inventory is performed quarterly by QA/QC
 - The formal inventory is a computerized file with restricted access
 - Any security breach to the inventory will be reported to the Select Agent Program
- Information and Electronic Systems Security
 - Information Security includes procedures and protocols for information systems control such as electronic storage and hardcopy records.
 - See **Appendix E** for the Information System Security Features



Biosecurity

5. Access control

- BSL3 Laboratory – Entry
 - Rooms 103 & 104 – Requires agency issued ID/Proximity Badge
 - Room 105 – Requires personal Security Code
 - Rooms 105 A, B, C – Requires agency issued ID/Proximity Badge
- Electronic Records
 - ID/Proximity Badge system – Records date and time that badge activates entry system
 - Security Code system – Records date and time security code entered into key pad
 - Systems are independent



Biosecurity

5. Access control

- Activity Log Book
 - Legible Writing (**Print - Required**)
 - Accurate - extremely important to accurately log in and out (BSL3)
 - BSL3 (Rooms 104, 105, 105 A, B, C) – record date, time in & time out, name, check whether working with infectious agents (requires full PPE) or not working with infectious agents (does not require full PPE; appropriate for cleaning, service or routine maintenance)
 - Entry records are stored for a minimum of 3 years in the office of the PI.



Biosecurity

5. Access control

- BSL3 Suite
 - Rooms (104, 105, 105A, 105B, 105C) Activity Log (**Appendix G**)

ENTRY DATE	TIME IN	TIME OUT	NAME RO Authorized Personnel	NAME Non-authorized Personnel (visitors / housekeeping / maintenance / service) [Informational Handout for Visitors, Maintenance, Service and Housekeeping Personnel on file]	CHOOSE ONLY ONE EXPLANATION	
					Work with infectious agent or material (v)	Not working with infectious agent or material / Housekeeping / Maintenance / Service / Repair (v)
Date	Time In	Time Out				



Biosecurity

6. Provisions for Routine Cleaning, Maintenance and Repairs

- Visitors to the ODHL
 - Prior to visitor arrival, host employees are to notify front office staff of scheduled visitors
 - Enter through the main entrance: Building 4, Stackhouse Laboratory
 - Visitor Log - Sign in prior to entry
 - Personal visitors must also adhere to the sign in/sign out protocol
 - Show Picture ID
 - Sign Ohio Department of Health Visitor Confidentiality and Non-Disclosure Agreement
 - Display ODHL-supplied Temporary ID Badges (name, agency/company)
 - Exception - State Agency personnel may display state issued ID badge
 - Escort to and from laboratory or office area by host staff
 - Host staff to monitor visitor activity
 - Visitor Log - Sign Out on leaving



Biosecurity

6. Visitors

- Visitors to exclusion/secure areas
 - Visitors or other unauthorized individuals, including unauthorized ODH employees, requiring access to an exclusion / secure area within the ODHL must be informed of safety/hygiene by signing a copy of a document entitled Informational Handout for Visitors, Maintenance, Service and Housekeeping Personnel and Ohio Department of Health Visitor Confidentiality and Non-Disclosure Agreement (**Appendix H**)
 - The blank forms are kept in a binder on a shelf in Room 103
 - Applies to visitors entering Rooms 104, 105, 105A, 105B, 105C



Biosecurity

6. Visitors

- Visitors to exclusion/secure areas
 - SRA-Approved Staff check the Informational Handout Binder
 - Required to sign on an annual basis
 - If the guest is in the binder and 1 year has not passed they can enter with an escort
 - If the guest is not in binder or 1 year has passed they must complete a new Informational Handout before entering the secure area with an escort
 - File signed copy in Binder
 - Activities of visitors and other un-authorized individuals are to be monitored by an SRA approved ODHL staff member at all times



Biosecurity

7. Reporting/Removing Unauthorized or Suspicious Persons

- Unauthorized Person
 - Any individual who is not SRA-approved
- Suspicious Person
 - Any individual not associated with the entity that has no valid reason to be in the areas where select agent or toxins are possessed, used or transferred
 - Attempts by “unauthorized” ODHL individuals to intentionally access registered areas containing a select agent or toxin
 - Individuals representing themselves as government personnel attempting to gain access to the facility or obtain sensitive information that cannot or will not present appropriate identification
 - Use of fraudulent documents or identification to request access



Biosecurity

7. Reporting/Removing Unauthorized or Suspicious Persons

- Suspicious activities
 - Indirect threats against the entity received by email, letter, telephone or website postings
 - Attempts to coerce entity personnel into a criminal act
 - Intimidation of entity personnel based on their scientific work
 - Requests for access to laboratories for no apparent legitimate purpose, or for purposes that don't seem legitimate
 - Unauthorized attempts to probe or gain access to proprietary information systems particularly access control systems

Immediately report any of the above to RO/ARO



Biosecurity

8. Loss or Compromise of Keys, Passwords, Combinations

- Security Breach
 - Report to RO/ARO and refer to procedure entitled 'Reporting and Investigating a Security Breach' ([Appendix I](#))
 - Access to select agents controlled by electronic means is changed immediately, locks are replaced immediately and a select agent inventory is conducted
 - Personnel Access changes take place when an individual is re-assigned or requires access to different select agents
 - Temporary badges to secure areas are available and need to be signed in and out each day of use from the RO or ARO



Biosecurity

9. Loss, Theft or Release of Select Agents or Toxins

- The loss or theft of a select agent or toxin may be observed directly or discovered through review of inventory control records
 - Immediately report to the RO/ARO
- Refer to Appendix I 'Reporting and Investigating a Security Breach'
- CDC Form 3 will need to be completed (**Appendix K**)



Biosecurity

10. Compliance with Security Procedures by SRA-approved Staff

- All staff authorized to work with Select Agents must meet or exceed the minimum education and experience requirements
 - Refer to **Appendix F**
- Training is conducted that addresses the needs of the individual for the work they will perform.
 - Refer to **Appendix O** for a complete description of the ODHL Select Agent Program Curriculum



Biosecurity

11. Means of Securing Select Agents and Toxins

- Select Agent Activity Log
 - Records are kept anytime a select agent is accessed
 - Recorded on 'Select Agent Activity Log' – **Appendix D**
 - Daily/weekly approval needed from RO/ARO or PI



Biosecurity

12. Provisions and Policies for Shipping, Receiving and Storage of Select Agents and Toxins

- Packaging of a Select Agent or toxin is performed only by an SRA-approved staff member that is certified to package and ship
 - Please refer to the shipping PowerPoint for details on shipping instructions
- CDC Form 2 is used for transferring select agents – **Appendix J**
- Unexpected receipt of a Select Agent
 - SRA staff takes possession of the package, initiates COC, secures the package in evidence locker
 - Notifies the RO/ARO and PI



Biosecurity

13. Destruction of Select Agents

- All submitted specimen materials, select agent isolates, and waste are destroyed per the 'Select Agent Destruction Protocol' ([Appendix L](#))
- Upon identification of a select agent or toxin, the RO/ARO submits a completed APHIS/CDC Form 4 'Report of the Identification of A Select Agent or Toxin in a Clinical or Diagnostic Laboratory' ([Appendix N](#)) to the CDC SAP for documentation of the disposition of the select agent or toxin.
- All Tier 1 agents must be destroyed



Biosecurity

14. Inspection of Packages

- All packages, containers, carts, and bags that appear to be of suspicious nature that are brought in to or removed from a secure area are must be inspected by a SRA staff member
- Refer to **Appendix M** on guidelines on recognizing suspicious packages

15. Intra-Entity Transfers

- Occurs when a select agent or toxin is transferred from one SRA-approved individual to another within the same entity under the same registration.



Biosecurity

16. Reporting Requirements Following the Identification of a Select Agent or Toxin

- A immediate notification to the CDC SAP is required upon the identification of a select agent from a submitted isolate, recovered from a clinical or environmental sample, or proficiency testing.
- Report using APHIS/CDC Form 4, 'Report of the Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory'. ([Appendix N](#))
- The identification of the following must be **immediately reported** by telephone, fax or email: *Bacillus anthracis*, Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium*, *Burkholderia mallei*, *Burkholderia pseudomallei*, *Francisella tularensis*, Ebola viruses, Marburg virus, Variola major virus, Variola minor, or *Yersinia pestis*



Biosecurity

16. Reporting Requirements Following the Identification of a Select Agent or Toxin

- The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within seven (7) calendar days after identification.
- A copy of the completed APHIS/CDC Form 4 must be maintained for 3 years.
- The identification and final disposition of select agents received as part of a proficiency testing challenge must be reported by submission of APHIS/CDC Form 4 within 90 days of receipt.
- Temporary exemption
 - If necessary the RO/ARO must contact the CDC SAP to request an exemption from the 7 day destruction requirement
 - Exemption can be requested for up to 30 days



Biosecurity

18. Drills and Exercises

- Drills and exercises are conducted on an annual basis to satisfy the requirements of the Biosafety, Security and Incident Response Plans.
- Each SRA-approved individual must undergo annual “refresher” training.
- Should an individual not complete annual training, the RO will removed the individual from the SA registration and access to SA areas will be revoked.



Biosecurity

19. Records

- All records are maintained with secure and controlled access
- Complete obliteration, destruction or alteration of any record related to any use of select agents is not permitted and is considered a breach of protocol that will result in notification and investigation by the RO/ARO.
- The proper method to make changes to hard-copy records is to make a single line through the incorrect existing record, handwrite the correction adjacent to the lined-out record, initial and date.



Biosecurity

Please take the quiz online: Passing grade is 80%

Questions?

Please send an email to:

Eric St Germain, BT Coordinator

Steve York, RO, LSO

Tammy Bannerman, ARO

Larry King, PI

Kevin Sohner, ARO

