NAME OF INSTITUTION

Occupational Health Program for High-Risk Pathogens and Toxins

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1. POLICY

1.1. (*Name of Institution*) shall maintain an Occupational Health Program for High-Risk Pathogens and Toxins to promote and maintain a safe and healthy workplace by limiting opportunities for exposure, promptly detecting and treating exposures, and using information gained from work-related illnesses and near-misses to further enhance safety precautions.

2. PURPOSE

2.1. The purpose of this plan is to establish comprehensive medical surveillance and response protocols for recognizing and responding to exposure incidents, releases, and symptoms involving high-risk pathogens and toxins and to provide guidance to medical personnel in the prophylaxis and management of suspected or known illnesses. It also establishes the occupational health requirements for employees with access to Tier 1 Select Agents and Toxins.

3. APPLICABILITY AND SCOPE

3.1. This document specifically applies to all personnel at risk for occupational exposure to high-risk pathogens and toxins. High-risk pathogens and toxins are those pathogens and toxins determined to be of high-risk to individual human health and/or communicable with significant risks to public health (*See Section 6 – Definitions*). The following agents have been determined to meet the definition of "high-risk":

(Example agents to consider for management under high-risk occupational health protocols)

1) Tier 1 Select agents and toxins (*Access to the list of agents is restricted, contact the Responsible Official or Select Agent-approved Principal Investigators for specific agents if necessary*.
2) Non-Tier 1 Select agents and toxins (*Access to the list of agents is restricted, contact the Responsible Official or Select Agent-approved Principal Investigators for specific agents if necessary*.
3) Other Risk Group 3/Biosafety Level 3 agents of concern handled at BSL-3.

3.2. **Operations/Employees Covered by this Plan**

3.2.1. The requirements of this document apply to all laboratories and other functional units where employees are at risk for *occupational exposure* to high-risk pathogens and toxins.

Each Supervisor/Principal Investigator must determine which employee(s) are at risk for *occupational exposure* as defined in Section 6.7 of this plan.

3.2.2. The occupational health program for Tier 1 Select Agents is administered by the EH&S Office, whereas implementation of the program, along with all medical determinations, is performed by Occupational Health Services.

4. REFERENCES

4.1. *Biosafety in Microbiological and Biomedical Laboratories* (U.S. Department of Health and Human Services – Centers For Disease Control / National Institutes of Health, 6th Edition)

4.2. 42 CFR Part 73 Possession, Use, and Transfer of Select Agents and Toxins, Final Rule.

5. RESPONSIBILITIES

5.1. The **Principal Investigator/Supervisor** is responsible for:

5.1.1. Identifying individuals at risk for *occupational exposure*, as defined in this policy, and ensuring that they are properly trained on, and comply with, this program.;

5.1.2. Ensuring that pre-placement and annual medical evaluations are completed for all individuals requiring access to Tier 1 select agents and toxins in accordance with *Section 7 – Pre-Placement and Ongoing Medical Evaluations*;

5.1.3. Ensuring that *BSL-3 Medical Questionnaire* information is updated by all individuals enrolled in the occupational health program for Tier 1 Select Agents and Toxins and submitted to Employee Health Services at least every 12 months or immediately upon change in health status or agent exposure risk;

5.1.4. Contacting at-risk individuals that are absent from the workplace for three unplanned, consecutive work days to assess and rule out an unreported illness requiring a risk assessment response;

5.1.5. Immediately reporting any *events* or *symptoms* to the Biosafety Officer and Division Director in accordance with *Section 9 – Managing Events and Symptoms* and initiating an investigation of the accident;

5.1.6. Participating on the Risk Assessment Team as described in *Section 8 – Risk Assessment Team*; and

5.1.7. Maintaining records in accordance with Section 11 - *Recordkeeping*.

5.2. **Occupational Health Services** is responsible for:

5.2.1. Performing pre-placement and ongoing medical evaluations for all employees with access to Tier 1 Select Agents and Toxins in accordance with *Section 7 – Pre-Placement and Ongoing Medical Evaluations*.

5.3. **Employees, students, and volunteers** are responsible for:

5.3.1. Complying with all applicable elements of this program if they are at risk for *occupational exposure* to high-risk pathogens and toxins.

5.4. The **EH&S Office** is responsible for:

5.4.1. Overseeing the overall implementation and management of this program;

5.4.2. Ensuring that the provisions of the program are being met;

5.4.3. Reviewing the program periodically and evaluating the effectiveness of the program;

5.4.4. Immediately investigating all reported *events* involving high-risk pathogens and toxins and evaluate exposure risk in conjunction with the Supervisor/Principal Investigator in accordance with Section 9 – *Managing Events and Symptoms*.

5.4.5. Consulting with the designated infectious disease specialist as needed.

5.4.6. Coordinating pre-placement and ongoing medical evaluations for all employees with access to Tier 1 Select Agents and Toxins, as well as other required medical evaluations, surveillance and vaccination programs;

6. DEFINITIONS

6.1. **High-risk pathogens and toxins –** Any select agent, overlap select agent, or Tier 1 select agent or toxin, all pathogens in risk group 4 as specified in the National Institute of Health's Guidelines for Research Involving Recombinant DNA Molecules or recommended for biosafety level 4 in Biosafety in Microbiological and Biomedical Laboratories (BMBL) published by the US Centers for Disease Control and Prevention and the National Institutes of Health (NIH), and any other pathogen or toxin identified by the (insert institution's name) as high-risk to employees and/or communicable with significant risks to public health. The Biosafety Officer shall compile and update, as necessary, a list of high-risk pathogens and toxins in Section 3 of this document.

6.2. **Events –** Any unplanned, undesired occurrence (e.g., break in protocol, equipment failure,

major mechanical malfunction, etc.) which resulted in, or could have resulted in, an *exposure incident*, *release*, or other *minor event*.

6.3. **Exposure incident –** Any event where an employee or another person present in the laboratory may ingest, inhale, absorb through the skin or eyes, or otherwise come into contact with high-risk pathogens or toxins. Any event that results in the activation of a post-exposure medical surveillance/ prophylaxis protocol would be considered an *exposure incident*.

6.4. **Release –** Any event involving a discharge of a high-risk pathogen or toxin, including those designated as select agents, outside primary containment devices (e.g., biological safety cabinet, centrifuge safety cup, etc.) or secondary containment barriers (e.g., HEPA exhaust systems).

6.5. **Minor event –** Any event, which in the judgment of the person(s) involved, increases the potential for exposure and does not meet the definition of an *exposure incident* or *release*.

6.6. **Symptoms** – Symptoms of disease consistent with the case definition of a laboratory pathogen(s) or toxin. Agent Specific Exposure Response and Treatment Resources are provided in Appendix C. Note: A high index of suspicion for potential occupational exposures should be maintained during any unexplained illness among at-risk workers.

6.7. **Occupational exposure** – Potential for skin, eye, mucous membrane, respiratory, or parenteral contact with high-risk pathogens or toxins that may result from the performance of an employee's duties.

6.8. **Risk Assessment Team –** A local institutional response team established to review and assess individual and public health risk associated with reported exposure incidents, releases, and symptoms. The team will consist of an infectious disease medical provider, an epidemiologist from the state or local health department, two scientists (i.e., the individual's immediate supervisor plus another scientist with relevant experience working with infectious agents), a senior member of institutional leadership, and the EH&S Director and Biosafety Officer**.**

6.9. **Tier 1 Select Agent and Toxin** – A biological agent or toxin included in 42CFR Part 73.3 or 73.4 designated as a Tier 1 select agent and toxin and, therefore, subject to additional requirements (e.g., occupational health requirements) as listed in the regulation.

7. PRE-PLACEMENT AND ONGOING MEDICAL EVALUATIONS

7.1. Pre-placement medical evaluations are required for all employees with access to Tier 1 select agents and toxins. The guidelines for entry requirements to each Tier 1 select agent registered

space are developed with input from the Principal investigator, EH&S Office, Occupational Health Services, and other experts with knowledge of the agent or associated infectious disease. Federal guidelines from the CDC, NIH, or American Practitioners of Infection Control regarding occupational health for specific Tier 1 Select Agents, or other applicable agents, will be considered.

7.2. These evaluations, which are coordinated through the EH&S Office, explore the agent hazards and personal risk factors associated with the employee's proposed activities. The healthcare provider reviews the individual's personal medical and immunization history to determine whether the worker can assume the duties of the position. The healthcare provider also provides work-related health and safety advice, administers appropriate vaccines, and coordinates with the EH&S Office to ensure the individual is enrolled in applicable surveillance programs (e.g., TB screening, periodic serological testing, etc.).

7.3. All at-risk employees, including both new employees and those switching duties, must be enrolled prior to receiving access to Tier 1 select agents and toxins utilizing the following procedure:

7.3.1. Complete the *BSL-3 Medical Questionnaire (See Appendix D)* and provide to Occupational Health Services at the medical exam appointment. Based on the answers provided on the *BSL-3 Medical Questionnaire* and during the in-person assessment, Occupational Health Services may require additional information or testing.

7.3.2. Occupational Health Services will provide the EH&S Office with an indication of the individual's "clearance" or approval to enter the intended Tier 1 Select Agent and Toxin registered space using the *BSL-3 Medical Approval Form (See Appendix D)*.

7.3.3. Upon receipt of the *BSL-3 Medical Approval Form*, the EH&S Office will notify the individual and laboratory director of their clearance status and coordinate any required tests, vaccinations, or screening applicable to the facility in which the individual seeks entry, such as the collection of serum for baseline testing of antibody levels; the offering of required or recommended vaccinations; respirator medical clearance tests, and/or the implementation of applicable screenings (e.g., tuberculosis). Results of any tests and/or screenings will be communicated to the employee in a confidential manner.

7.3.4. Laboratory supervisors are responsible for communicating the following information

when administering lab-specific training involving high-risk pathogens: 1) applicable agent risks and symptoms of disease; 2) the worker's responsibilities following a laboratory incident or accidents involving high-risk pathogens; 3) reporting procedures in the event that the worker develops symptoms suggestive of an occupationally acquired infection; and 4) the availability and appropriate use of medical supplies (e.g., thermometer, surgical masks, etc.) if indicated.

7.4. The *BSL-3 Medical Questionnaire* information must be updated and submitted to Occupational Health Services at least every 12 months or immediately upon change in health status or agent exposure risk. Examples of change in health status include pregnancy, medical conditions or drug therapies that impact the immune system, changes in physical capabilities, and any change that affects respirator fitting. Annual updates of the *BSL-3 Medical Questionnaire* will be coordinated and tracked by the EH&S Office.

7.5. ***Prophylactic Immunization***

7.5.1. Certain licensed vaccines (i.e., those in which the benefits clearly exceed the risks such as influenza, yellow fever, smallpox, anthrax, and rabies vaccines) will be offered to at-risk employees where medically appropriate. Employee participation in prophylactic immunization programs is highly encouraged where medically appropriate and recommended by the CDC's Advisory Committee on Immunization Practices (ACIP). In some cases, employees can be restricted from working with or around specific high-risk pathogens if they elect to decline a vaccine that is a condition of the work assignment.

7.5.2. The *(Institution's name*) will integrate the recommendations of the U.S. Public Health Service Advisory Committee on Immunization Practices into any written Agent Specific Exposure Response and Treatment References where appropriate. Refer to Agent Specific Exposure Response and Treatment Resources provided in Appendix C for more information.

7.6. ***Considerations for Employees At Increased Risk of Infection***

7.6.1. *Compromised Immunodefenses*. In addition to implementation of good microbiological practices and the use of appropriate safety equipment, employees at risk of occupational

exposure to high-risk agents should have unimpaired immune systems. Therefore, special attention will be paid to those with immunological impairment to determine whether additional precautions or other accommodations (e.g., transfer or re-assignment) should be made. Accommodations will be determined on a case-by-case basis with input from the employee, Principal Investigator, EH&S Office, Occupational Health Services (or a contracting agency's equivalent), and the employee's private physician, as necessary. Conditions that may impair immune defenses include: chronic dermatitis, eczema, psoriasis, lymphadenopathy, hepatospenomegaly, asplenia, and complement or antibody defects. Treatment with radiation, chemotherapy, and corticosterioids may also impair immune response.

7.6.2. Pregnancy. Special attention will also be paid to pregnant laboratory employees and employees attempting to become pregnant since certain high-risk agents (e.g., *Brucella abortus*) can infect the fetus, either in utero or during delivery, and cause congenital or neonatal infections. Employees with access to high risk agents known to affect the fetus and who are planning a pregnancy are encouraged to discuss this with the Principle Investigator and/or Occupational Health Services.

8. RISK ASSESSMENT TEAM

8.1. The Risk Assessment Team will consist of an infectious disease medical provider, a epidemiologist from the state or local health department, two scientists (i.e., the individual's immediate supervisor plus another scientist with relevant experience working with infectious agents), a senior member of institutional leadership, and the EH&S Director and Biosafety Officer**.**

8.2. Appropriate members of the Risk Assessment Team may be activated by EH&S or senior leadership as follows:

- A potential exposure event has occurred such that there may be a moderate-to-high risk of exposure of an individual or the environment to the pathogen.
- An individual working with high-risk pathogens or toxins develops symptoms consistent with the case definition of agents being handled (Refer to Agent Specific Exposure Response and Treatment Resources provided in Appendix C).

- An individual working with high-risk pathogens or toxins requests testing for evidence of high-risk pathogen infection or toxin exposure.
- When abnormal test results requiring investigation are available.
- Following resolution of symptoms in an ill worker, to advise on removal of isolation practices (if applicable), and to authorize return to work (if applicable). Laboratory workers may be asked to be seen by the Infectious Disease Medical Provider prior to his/her return to work.

8.3. The Risk Assessment Team will take all information into account to determine whether there is moderate-to-high or low risk of exposure and to determine what level of testing and isolation may be required and, if applicable, what environmental clean-up is necessary. Risk assessment criteria may include:

- Was there a documented occupational exposure, release, or other event?
- Is there evidence of symptoms consistent with infection or exposure?
- Are there medical examination/laboratory data supporting a diagnosis of a work-related illness?
- Did the individual work with or around a high-risk pathogen or toxin within a time period prior to onset of symptoms that is compatible with pathogen's incubation period?
- Did the individual use a laboratory procedure likely to cause aerosols?
- Is there illness in other laboratory workers?
- Is there a high prevalence of respiratory disease in the community?

8.4. Agent-specific exposure questionnaires will be developed by the Risk Assessment Team to facilitate the assessment. The Risk Assessment Team, in coordination with the Principal Investigator, will determine and include all high-risk procedures and methods that are used in the laboratory in each questionnaire which will be used to assess exposure risk.

9. MANAGING EVENTS AND SYMPTOMS

9.1. **Events**

9.1.1. ***Documenting***

9.1.1.1. All individuals entering a BSL-3 laboratory to work with high-risk pathogens

must, at a minimum, record the date and time of entry. This may be achieved by using a log book or electronic access system. (Note that this requirement does not apply to BSL-2 labs working with high-risk pathogens or toxins).

9.1.1.2. As much as possible, work with high-risk pathogens at BSL-3 should be performed with two personnel present. In some circumstances, it may be necessary to work alone, but this is only permissible for experienced individuals (as determined by the Principal Investigator). A responsible individual should be informed of the work plan if an individual is working alone.

9.1.1.3. All *events* involving high-risk pathogens or toxins, i.e., *exposure incidents, releases,* and other *minor events* must be documented in the Event Log (Appendix A), which will be maintained in the accessible entry area of the BSL-3 (or BSL-2 if applicable) laboratory. Events may include, but are not limited to, spills inside or outside a biological safety cabinet, equipment failures, and breaches in protocol (e.g., accidental use of expired disinfectant).. All events must be reported to the Supervisor/Principal Investigator (See Reporting).

9.1.2. ***Reporting***

9.1.2.1. All events resulting in e*xposure incidents* or *releases* must be reported to the Supervisor/Principal Investigator within one hour, whereas all other events must be reported by the employee to the Supervisor/Principal Investigator upon exiting the laboratory.

9.1.2.2. All events involving high-risk pathogens or toxins will be assessed by the Supervisor/Principal Investigator in conjunction with the Biosafety Officer to initially evaluate the exposure risk and need for notification of senior leadership. Those judged to have a moderate-to-high risk of exposure must be immediately reported to the appropriate senior leadership and an incident report submitted to the EH&S Office by the Principle Investigator.

9.1.2.3. If senior leadership considers it warranted, the Risk Assessment Team will be activated to assess the exposure event. Any external communications regarding an incident must be cleared through senior leadership prior to such communication.

*9.1.3. **Exposure Assessment***

9.1.3.1. All events involving high-risk pathogens and toxins, including *exposure incidents*, *releases*, and other *minor events*, must be immediately investigated and assessed to determine root causes. An initial risk assessment will be performed for each event based on the assessed procedural risk and the nature of the breach, i.e. exposure potential. Initial determination of exposure risk after the reporting of an event will be performed in-house by the Supervisor/Principal Investigator and Biosafety Officer, and if determined appropriate, the Risk Assessment Team will be activated by senior leadership. Criteria used for risk assessment are described in *Section 8 – Risk Assessment Team*.

9.1.3.2. Periodic reviews of events will be performed by the Biosafety Officer and/or Institutional Biosafety Committee (IBC) to assess for trends. Prevention efforts, such as addressing knowledge deficits or workload issues that may have contributed to the breach, must be undertaken, and any changes in protocol must be evaluated for efficacy.

9.1.3.3. The protocols that will be implemented following a low-risk and high-risk event are as follows:

<u>Low-Risk Protocol</u>: Initial in-house risk assessment of an event by the Supervisor/Principal Investigator and the Biosafety Officer determines there is a low risk of exposure.

Example Scenario: A biological safety cabinet fails while high-risk pathogens are being handled while wearing approved respiratory protection.

Required Action:

1. An Incident Report will be completed by the employee and supervisor and forwarded to EH&S for review and follow-up.
2. The employee may continue to work and no further action is necessary. The Risk Assessment Team need not be convened.

3. The employee should be reminded to report any symptoms to the Supervisor/Principal Investigator as per the standard protocol.

<u>High-Risk Protocol</u>: Initial in-house risk assessment of an event by the Supervisor/Principal Investigator and the Biosafety Officer determines there is a moderate-to-high risk of exposure.

Example Scenario: An employee ingests, inhales, absorbs through the skin or eyes, or otherwise comes into contact with a high-risk agent.

Required Action:

1. Appropriate senior leadership will be immediately notified an Accident Report will be filed by the employee and supervisor.
2. The Risk Assessment Group will be notified that a potential exposure incident has occurred as appropriate.
3. The state and local health departments will be notified as appropriate.
4. A Symptom Monitoring Log (Appendix B) will be developed and implemented for at-risk personnel. The Log will be monitored daily by the Supervisor/Principal Investigator. At-risk individual(s) will report the presence or absence of symptoms (Refer to Appendix C - *Agent-specific Exposure Response and Treatment Resources*).
5. If there is evidence of symptoms within a time period that is compatible with a pathogen's incubation period, laboratory personnel must follow Illness Response Protocol #3.

9.2. **Symptoms**

9.2.1. The following procedures are required as a means to monitor and detect potential occupational exposure (i.e., lab-acquired infection) to high-risk pathogens or toxins as quickly as possible.

9.2.1.1. ***Reporting***

9.2.1.1.1. Personnel must immediately report any suspect *symptoms* to their Supervisor/Principal Investigator. If the individual has worked with or around

any high-risk pathogen within a time period prior to onset of *symptoms* that is compatible with a pathogen's incubation period, the Supervisor/Principal Investigator will, in turn, immediately notify the Biosafety Officer who will notify appropriate senior leadership.

9.2.1.1.2. The Risk Assessment Team will be notified of the illness and any relevant events in the laboratory as appropriate.

9.2.1.2. ***Exposure Assessment***

9.2.1.2.1. Upon onset of suspect *symptoms*, the employee will immediately make initial contact with the Supervisor/Principal Investigator. If at home and the potential pathogen(s) of concern involve communicable agents, the employee will not report to work pending further evaluation and instruction. If at work, the applicable *Agent Specific Exposure Response and Treatment Resources* in Appendix C should be reviewed and Infectious Disease Medical Provider on the Risk Assessment Team consulted. Should onset of symptoms occur while the employee is in travel status, the Supervisor/Principal Investigator will collect supporting information and contact appropriate senior leadership immediately to gain guidance on response. If a moderate-to-high risk occupational exposure event has occurred within a time period that is compatible with pathogen's incubation period prior to work-related travel, the Risk Assessment Team will determine if travel should be cancelled based on potential risk to the individual and/or public.

9.2.1.2.2. When an illness is reported to the Supervisor/Principal Investigator and/or the Risk Assessment Team has been activated, they will use all available information to determine the level of exposure risk and then follow the Agent Specific Exposure Response and Treatment Resources (Appendix C) that may include medical monitoring, serum collection and/or testing, other laboratory testing, and isolation or quarantine.

<u>Symptom Response Protocol #1</u>: Symptoms with no exposure risk

Example scenario: An employee has not worked with high-risk pathogens or in a BSL-3 laboratory within a time period that is compatible with any relevant pathogen's incubation period, but has now developed symptoms consistent with the case definition of high-risk pathogen(s). The employee calls their supervisor from home indicating he/she has relevant symptoms.

Required Action:

1. The laboratory entry log will be reviewed by the Supervisor/Principal Investigator and/or Biosafety Officer to determine the last day the employee worked with high-risk pathogens or in a BSL-3 facility. It should be confirmed that the employee has not worked with high-risk pathogens within the pathogen's expected incubation period.
2. The employee may report to work if feeling well enough unless the potential pathogen(s) of concern involves a communicable agent. Or, the employee may opt to remain home on sick leave.
3. Surveillance will be enhanced for other respiratory and/or febrile illness among laboratory workers to determine if the laboratory may have been contaminated. If no other illness is identified, no further action is necessary. Employees who are not well enough to work will remain at home on sick-leave, and will be seen by a personal physician at their own discretion. If illnesses are identified in other laboratory staff working with high-risk pathogens, the Risk Assessment Team should be consulted to determine further action.

Symptom Response Protocol #2: Symptoms with low exposure risk

Example scenario: An employee has worked with high-risk pathogens or in a BSL-3 laboratory within a time period that is compatible with any relevant pathogen's incubation period, and has now developed symptoms consistent with the case definition of a high-risk pathogen(s). In this scenario, given no known exposure incidents or releases, a non-work-related illness should be strongly considered.

Required Action:

1. The entry log will be reviewed by the Supervisor/Principal Investigator to determine the last day the employee handled high-risk pathogens and/or worked in the BSL-3 laboratory, and the Event Log will be checked for documentation of events for the time period that is compatible with pathogen's incubation period. The Biosafety Officer and appropriate senior leadership will be notified.
2. The employee may report to work if feeling well enough unless the potential pathogen(s) of concern involves a communicable agent. Or, the employee may opt to remain home on sick leave.
3. If the employee's symptoms are compatible with the agent(s) involved, the Risk Assessment Team will be notified as appropriate through senior leadership.
4. The Risk Assessment Team may require the employee to remain at home and monitor symptoms using the Symptom Monitoring Log (Appendix B). The log should be reviewed daily with the Supervisor/Principal Investigator.
5. The state and local health departments will be notified as appropriate.
6. If symptoms resolve within 72 hours, the employee, after consultation with the Supervisor/Principal Investigator, will return to work. Monitoring will continue for the remainder of the suspected incubation period.
7. If symptoms persist or worsen, the employee will be referred for further medical evaluation as appropriate (at designated Medical Center if hospitalization is needed).
8. Transport to any healthcare facility for testing or medical evaluation should be arranged such that the employee does not use public transportation. Additionally, EMS personnel should be notified of the suspect pathogen(s) involved and need for isolation precautions.

<u>Symptom Response Protocol #3</u>: Symptoms with high exposure risk

Example scenario: A documented exposure incident or release has already occurred. The Risk Assessment Team, and state or local health departments as appropriate, will be

notified that an exposure incident or release has occurred. The development of symptoms has been monitored using the Monitoring Log (Appendix B).

Required Action:

1. If symptoms appear after an exposure incident or release, the Risk Assessment Team will be consulted and the employee will be referred for further medical evaluation as appropriate (at designated Medical Center if hospitalization is needed).
2. Transport to any healthcare facility for testing or medical evaluation should be arranged such that the employee does not use public transportation. Additionally, EMS personnel should be notified of the suspect pathogen(s) involved and need for isolation precautions.

10. MEDICAL RESPONSE PROCEDURES

10.1. Agent-Specific Exposure Response and Treatment References.

10.1.1. Links to Agent-Specific Exposure Response and Treatment Resources are provided in *Appendix C*. These protocols define clinical features, treatment options, potential post-exposure prophylaxis options, recommended diagnostic tests, and in-patient precautions.

10.2. Procedures for Exposure Incidents Involving High-Risk Pathogens and Toxins

10.2.1. The adequacy and timeliness of wound cleansing or other response after an occupational exposure occurs may be the most critical determinant in preventing infection. The following procedures must be applied following any laboratory *exposure incident* (e.g., accidental needlestick or other sharps exposure, loss of integrity of respiratory protection, animal or insect bite or scratch, splash to the mucous membranes, etc.) involving high-risk pathogens and toxins:

1. Attend to the exposure or wound site with first aid if applicable. If the injury is severe or if risk of exposure to a toxin is significant, call 911 or go to the nearest Hospital Emergency Room or Urgent Care Facility. First Aid kits are available at designated locations in each facility.

a. ***Intact skin exposure***: Remove contaminated clothing, then immediately go to the sink and thoroughly wash the skin with soap and water. Decontaminate any exposed skin surfaces with soap and water or an antiseptic scrub solution for 5 minutes. Do not abrade skin.

b. ***Broken, cut or damaged skin, or puncture wound***: Remove contaminated clothing, then immediately go to the sink and vigorously wash the wound with soap and water for 15 minutes.

c. ***Splash to eye(s), nose, or mouth***: Remove contaminated clothing, then immediately flush the area with running water for at least 5-10 minutes.
   i. <u>For splashes to the eyes</u>, flush eyes for at least 15 minutes with water, preferably using an eyewash. If no eyewash is available, pour water on the eye(s) for 15 minutes, rinsing from the nose outward to avoid contamination of the unaffected eye. Hold eyelids away from your eyeball and rotate your eyes so that all surfaces may be washed thoroughly.

d. ***Ingestion or Inhalation***: Remove contaminated clothing, then immediately seek medical attention. Do not induce vomiting unless advised to do so by a healthcare provider.

2. Notify Supervisor/Principal Investigator & Biosafety Officer
   a. Be prepared to describe:
      i. Who was exposed
      ii. Date and time of exposure;
      iii. Agents/specimens involved;
      iv. Nature of exposure/event;
      v. PPE in use at time of exposure; and
      vi. Response measures taken (i.e., first aid).

b. Senior leadership will be notified and the Risk Assessment Team assembled as indicated in this document.

3. Seek post-exposure medical evaluation and follow-up at Occupational Health Services or other designated medical provider.
    a. Bring applicable Agent-Specific Information, if available, including the results of any known drug resistance testing.

4. Advise any non-affiliated medical providers that the bill for your medical services should be submitted as a Workers Compensation claim.

5. Complete any required accident report forms.

11. ABSENTEEISM

11.1. Any at-risk employee that is absent from the workplace for three (3) unplanned, consecutive work days shall be contacted by their Principal Investigator/Supervisor at home to assess and rule out an unreported injury or illness requiring a risk assessment response. If the supervisor has a reasonable suspicion that the employee's illness may be work-related, the Principal Investigator/Supervisor shall implement the appropriate Illness Response Protocol.

12. EDUCATION AND TRAINING

12.1. Training on the procedures described in this plan is required for all at-risk employees an shall be completed by the Principle Investigator or training designee during lab-specific training activities.

12.1.1. **At-risk Employees**

12.1.1.1. Education and training for employees with *occupational exposure* to high-risk pathogens, regarding the details and implementation of this protocol, must be provided prior to admission to the laboratory and must include discussions of the following:

1. Specific implementation details of this plan.
2. Applicable Agent-Specific Exposure Response and Treatment Protocols
3. Reporting mechanisms and requirements
4. Communication pathways between employee, supervisor, director and/or biosafety officer

12.1.1.2. An important component of the training program is the verification of understanding. Therefore, employee competency will be tested and/or assessed by designated lab personnel in order to gauge their level of understanding of these topics.

12.1.2. **Risk Assessment Team**

12.1.2.1. Training on this plan must be provided to all core members of the Risk Assessment Team. This training will be coordinated by the EH&S Office. Initial training content will include:

1. The roles and responsibilities of the Risk Assessment Team.
2. Basic awareness training for all high-risk agents described in Section 3.
    a. Infectious dose, infectious routes, symptomology, incubation period, treatment/vaccine options, restrictions.
    b. Examples of high-risk laboratory procedures (to assist in determining risk of exposure and urgency for treatment/vaccination).
3. Specific implementation details of this plan.
4. Agent-Specific Exposure Response and Treatment Protocols (Appendix C).
5. Reporting mechanisms and requirements.
6. Communication considerations.

13. MEDICAL COSTS AND LEAVE

13.1. Medical Costs

13.1.1. Prompt and accurate reporting of events or symptoms will ensure employee safety,

containment of disease, and protection of the public health. To facilitate and encourage prompt reporting, (*Institution's name*) has systems in place to manage medical costs for the evaluation and treatment of employees, students, and volunteers with suspect or known symptoms requiring follow-up (as per approved agent-specific exposure response and treatment resources). This system includes a combination of paid leave benefits, workers compensation, and/or health insurance benefit coverage, dependent on the particular circumstances of the incident and on each individual's affiliation.

13.1.2. Additionally, systems are in place to provide for both initial and routine medical assessment and surveillance such as medical clearance for respirator use. Periodic serological screening of staff may also be performed, as indicated in approved Agent-Specific Exposure Response and Treatment Resources (Appendix C), for evidence of previous or current infection even in the absence of reported exposure events or compatible illness. These services are provided on work time and at no charge to the employee, student, or volunteer.

13.1.3. Laboratory testing will be performed by Occupational Health Services or an approved testing laboratory when warranted. For these assays, there will be no cost to the individual(s) involved.

13.1.4. Samples required for laboratory testing will be collected by licensed healthcare staff and tested in accordance with the Agent-Specific Exposure Response and Treatment Protocol Resources provided in Appendix C.

13.2. **Leave**

13.2.1. For lost time due to suspected work-related illness, employees will be placed on administrative leave at full pay without charge to leave credits until absence is no longer deemed necessary by the Risk Assessment Team or until a work-related diagnosis is made. Once a determination is made regarding whether the illness is work-related, the employee will be placed on sick leave or workers' compensation leave retroactive to the date the employee became ill. Students and volunteers will also be placed on worker's compensation for work-related illnesses.

14. RECORDKEEPING

14.1. **Medical providers** shall maintain relevant employee medical records.

14.2. **Principal Investigators/Supervisors** responsible for employees who are at risk for occupational exposure to high-risk pathogens shall maintain up-to-date records of the following:

- A current version of this document;
- Access logs (3 years);
- Event logs (3 years); and
- Records of lab-specific training (retainable for one year after the employee, student or volunteer leaves service).

14.3. EH&S shall maintain up-to-date records of the following:

- Copies of all accident or incident reports involving high-risk pathogens (retainable for 5 years after the incident); and
- Materials used for training of Risk Assessment Team members;
- Records of training provided by the EH&S Office.
- All documentation related to the Risk Assessment Team activities and communications.

15. PROGRAM REVIEW

15.1. This plan will be reviewed by EHS& on a periodic basis and upon all significant applications of the plan. A summary of each review will be communicated to the Institutional Biosafety Committee (IBC) as appropriate.

15.2. The Risk Assessment Group will be convened periodically to review this plan and provide any recommendations for modifications of the plan.

16. APPROVALS AND REVISION RECORD

This document has been reviewed and approved by the individuals listed below and is approved for internal publication.

Document approved by EH&S Director (*or Biosafety Officer*)

Signature: _____ Date: _____

Document approved by Director for Administration

Signature: _____ Date: _____

When signed, this document shall be scanned and retained in the EH&S Office Policy files with the original document for future reference.

Revision Record(s):

Revision	Date	Responsible Person	Description of Change

17. APPENDICES

Appendix A: High-Risk Agent Event Log

Appendix B: Daily Symptom Monitoring Log (Template)

Appendix C: Agent-Specific Exposure Response and Treatment Protocol Response References

Appendix D: BSL-3 Medical Questionnaire and Medical Approval Forms

Appendix A – High Risk Agent Event Log

RULES FOR USE

1. All Events must be properly recorded in this event log, including the date of log entry, name of person making the log entry, time of log entry, description of event, type of event and person(s) notified and when. **All events** resulting in e*xposure incidents or releases m*ust be reported to the Supervisor/Principal Investigator within one hour, whereas all other events must be reported by the employee to the Supervisor/Principal Investigator upon exiting the laboratory. Events involving select agents must be immediately reported to the Responsible Official as well. Events are defined as:

   - **Exposure incident:** Any event where an employee or another person may ingest, inhale, absorb through the skin or eyes, or otherwise come into contact with high-risk pathogens. Any event that results in the activation of a post-exposure medical surveillance/ prophylaxis protocol would be considered an *exposure incident*.

   - **Release:** Any event involving a discharge of a high-risk pathogen, including those designated as select agents, outside primary containment devices (e.g., biological safety cabinet, centrifuge safety cup, etc.) or secondary containment barriers (e.g., HEPA exhaust systems).
   - **Theft:** Unauthorized removal of select agent or toxin.
   - **Loss:** A failure to account for a select agent or toxin.

2. **Minor event:** Any event, which in the judgment of the person(s) involved, increases the potential for exposure and does not meet the definition of *exposure incident* or *release*.
3. Once completed, the event log must be kept on file for a period of three (3) years from the last dated entry.
4. The event log must be maintained and protected in accordance with the information protection policy regarding access to control documents.
5. All entries must be made using permanent blue or black ink.

DATE	NAME	TIME	DESCRIPTION OF EVENT	PERSON(S) NOTIFIED/TIME	*TYPE OF EVENT

**** Exposure Incident, Release, Theft, Loss, or Minor Event***

Appendix B – Daily Symptom Monitoring Log (Template)

Date: (time)*	__/_ _/__	__/_ _/__	__/_ _/__	__/ __/__	__/_ _/__
Temperature in ^{0}F**					
Pulse**					
Respirations**					
Chills					
Sweats					
Fatigue/Malaise					
Skin lesion/rash***					
Cough (productive?)					
Headache					
Stiff neck					
Vision changes					
Joint pains(s)					
Muscle pain					
Swollen Lymph Nodes					
Chest pain					
Back pain					
Anorexia					
Abdominal pain					
Nausea/Vomiting					
Diarrhea					
Altered mental status****					
Medications taken***					

* Note the time of each observation.
** Vital signs should be taken at least every 4 hours.
*** For any skin lesion/rash, describe color, if raised, where it started, if possible take photo with ruler beside lesion and note date and time of photo
**** Describe, e.g., disorientation, confusion, restlessness, drowsiness, etc.
***** List all medications and the dose, including over the counter medications such as Tylenol, Aspirin, anti-diarrheal medications (*Use reverse side of this form if needed*).

NOTE: ***This information is being requested for the principal purpose of enabling a healthcare professional to monitor and evaluate the status of your health following a potential exposure incident involving a high risk pathogen or toxin.***

Appendix C - Agent-Specific Exposure Response and Treatment Resources

Updated (*Insert date)*

AGENT	REFERENCE

Appendix D – BSL-3 Medical Questionnaire/Medical Approval Forms

BSL-3 Medical Questionnaire

Version: (*date)*

REQUIREMENT

Federal select agent regulations require that all individuals with access to Tier 1 Biological Select Agents and Toxins (BSAT) be enrolled in an Occupational Health Program (OHP). Medical evaluation of employees working at BSL-3 may be required by the institution for other agents as well. Enrollment is intended to ensure the availability of appropriate medical evaluation and treatment in the event of a laboratory acquired infection. The OHP must include an initial and periodic medical evaluation of such employees. The OHP is also designed to provide employees working with high risk agents with counseling on available and appropriate vaccines.

PURPOSE OF THIS MEDICAL QUESTIONNAIRE:

The purpose of this form is to obtain relevant information about your current personal health and medical history and your work-related exposure risks. This information will be used by Occupational Health Services (OHS) to make an accurate assessment of your ability to safely work in a BSL-3 laboratory with high risk pathogens and toxins. The OHS medical professional will evaluate the information on this form and document for you and your supervisor any work restrictions or protective medical measures to be followed. If restrictions and/or protective measures (such as immunization) are required, it is expected that you will comply as a condition of working in the registered BSL-3 laboratory space. The questionnaire also requests information that may expedite medical evaluation and appropriate treatment in the event of a laboratory exposure/infection.

You will be asked to complete the *BSL-3 Medical Questionnaire* prior to an initial medical evaluation and at least annually. You are also required to update the questionnaire when there has been a change in your health status that could affect your ability to work safely with high risk agents.

PRIVACY OF YOUR MEDICAL RECORDS

OHS will maintain your personal health and treatment information in a confidential medical record to ensure your privacy. OHS will not release confidential information about you without your written consent, except as required by law. OHS will, however, notify your supervisor and the EH&S Office of required work restrictions or protective measures and of the status of your clearance to work with Tier 1 BSAT or other BSL-3 agents as appliable (Only the Medical Approval Form will be forwarded to the EH&S Office).

DIRECTIONS

Please fill out the enclosed questionnaire and bring it with you to your initial OHS appointment. If you have questions about any requested information, leave it blank and discuss it with the OHS medical care provider. Use the last page of the questionnaire to provide further information if it does not fit in the allotted field. If you have questions regarding this form or your OHS visit, please contact the EH&S Office.

PARTICIPANT INFORMATION		
Name (Last, First, M.I.):	Date:	Date of Birth:
Division/Unit:	Principal Investigator/Phone Number:	
E-mail address:	Work Phone:	
Job Title:	Gender: ☐ Male ☐ Female	
Home Address: Street _____ City/State/Zip Code _____ Home Phone (____)_____ Cell Phone (____)_____ Home email: _____	Work Address: Building:_____ Office: _____ Lab: _____	
☐ Check here if you live alone. Emergency Contact Name:_____ Phone: _____		

Emergency Contact Address:	
Primary Care Provider Name:_____ Address:_____ Phone: _____ Fax: _____	Pharmacy Name:_____ Address:_____ Phone: _____

OCCUPATIONAL HISTORY

1. Describe your current laboratory activities.

2. Describe any previous employment involving infectious agents.

3. Have you ever had your serum banked? If yes, please indicate where and when below.

4. Do you currently work with or have you ever worked with, or have you been immunized against or treated for any of the agents listed below:	**Work With**	**Immunized or Treated for***	(agent list continued)	**Work With**	**Immunized or Treated for***

***If yes, provide any available information on where you were immunized or treated and immunization/booster dates and titers.**

MEDICAL HISTORY

***NOTE*: If you do not know the answer to a question, please discuss with the occupational health physician. Conditions are not necessarily disqualifying but the information may be important if treatment for a laboratory infection is required.**

5. Do you have any of the following conditions?

- ☐ Chronic respiratory/lung disease
- ☐ Asthma
- ☐ Chronic cough
- ☐ Tuberculosis
- ☐ HIV/AIDS
- ☐ Other chronic infectious disease
- ☐ Any condition affecting you immune system
- ☐ Autoimmune disease, e.g., lupus or rheumatoid arthritis
- ☐ Removal of your spleen
- ☐ Skin condition resulting in breaks in the skin
- ☐ Hives
- ☐ Anaphylactic reaction
- ☐ Allergic rhinitis
- ☐ Cancer (e.g. leukemia, lymphoma, cancer treatment, etc.)
- ☐ Organ transplant
- ☐ Coronary heart disease with angina or previous myocardial infarction.
- ☐ Cardiac arrhythmia
- ☐ Valvular heart disease/artificial heart valve
- ☐ Vascular graft
- ☐ Diabetes
- ☐ Hypoglycemia
- ☐ Dizziness/vertigo
- ☐ Syncope (fainting) in the past 5 years
- ☐ Seizure disorder
- ☐ Sleep disorder
- ☐ Psychosis
- ☐ Bipolar disorder
- ☐ Claustrophobia
- ☐ Chronic renal disease
- ☐ Chronic liver disease
- ☐ Uncorrected vision problems

6. List any other past or current conditions requiring treatment:

7. Have you ever had any problems wearing required personal protective equipment (e.g., respirator, gloves, etc)?
☐ Yes ☐ No

If yes, please describe:

8. Do you have any current medical complaints or symptoms? ☐ Yes ☐ No

If yes, please describe:

9. Have you completed any foreign travel in the past 12 months? ☐ Yes ☐ No

10. Do you smoke or have a history of smoking? ☐ Yes ☐ No

11. Do you consume alcohol? ☐ Yes ☐ No If yes, approximately how many drinks per week? _____/week.

12. Do you currently use or have a history of using recreational drugs? ☐ Yes ☐ No

13. Do you currently have or have a history of substance abuse/dependence? ☐ Yes ☐ No

14. What prescription and/or over-the-counter medications are you currently taking?

15. What additional prescription medications have you taken in the last 6 months?

16. Did you receive an influenza vaccination this season? ☐ Yes ☐ No

17. What was the date of your last TB test? _____ (Contact the Medical Monitoring Coordinator at 473-8034) Result: Positive/Negative (circle)

18. Do you have any environmental allergies? ☐ Yes ☐ No

If yes, please describe:

19. Do you have any allergies to medications or therapeutic agents? ☐ Yes ☐ No

If yes, please describe:

20. Have you ever had an adverse reaction to a medication? ☐ Yes ☐ No

If yes, please describe:

21. Do you have any animals at home? ☐ Yes ☐ No

If yes, please list:

22. Do you have any other animal exposures? ☐ Yes ☐ No

If yes, please describe:

23. Do you have any external medical device (e.g., insulin pump) that cannot be removed or decontaminated with immersion if it were potentially contaminated? ☐ Yes ☐ No

If yes, do you have a readily available replacement for the device? ☐ Yes ☐ No

24. Are you pregnant or planning to become pregnant within the next 18 months? ☐ Yes ☐ No

25. Are you breast feeding at this time? ☐ Yes ☐ No

26. Would you like to discuss pregnancy concerns with an EHS occupational health physician at this time? ☐ Yes ☐ No

27. Do you have any concerns or questions about occupational health and safety issues related to your duties in a BSL-3 laboratory? ☐ Yes ☐ No

If yes, please describe:

Additional information: _____

EMPLOYEE ACKNOWLEDGEMENT

I certify that I fully understand all requests for information contained on this form and that the information supplied by me on this form is complete and correct to the best of my knowledge.

Employee Signature: Date:

BSL-3 MEDICAL APPROVAL FORM

Employee name:	Date:

Medical evaluation is for:

☐ Initial Clearance ☐ Annual Review ☐ Other

Medical Recommendations:

The above employee is:

☐ Cleared for work with Tier 1 BSAT facilities (if applicable)

☐ Cleared for work with Tier 1 BSAT with the following restrictions, *vaccinations, and/or additional protective medical measures (if applicable):

☐ Cleared for work at BSL-3.

☐ Cleared for work at BSL-3 with the following restrictions, *vaccinations, and/or additional protective medical measures:

_____

_____

☐ Not Cleared for work with Tier 1 BSAT and/or at BSL-3 at this time. (*Please indicate if it is expected that the employee may be able to return to BSL-3 work in the future, after medical re-evaluation*)

Comments: _____

Additional Comments: _____

_____

* **Vaccine Policy**

- *Anthrax vaccine is recommended for laboratory personnel at risk for repeated exposure to fully virulent B. anthracis spores (e.g., handle environmental samples that might contain powders and are associated with anthrax investigations.) See ACIP 2009 recommendations.*
- *All laboratory personnel conducting variola PCR testing **must be** vaccinated against smallpox and revaccinated every three years.*
- *Influenza vaccine is recommended for all laboratory personnel working with high-risk pathogens.*

Medical Practitioner (print):	
Medical Practitioner (signature):	Date:

Distribution: Original: Occupational Health Services (all pages)
Copy: EH&S Office (this page only)