

Occupational Health & Safety Program for Biosafety Program

1. References:

Advisory Committee on Immunization Practices (ACIP)

Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, 2007 (BMBL)

NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

2. **Purpose:** The purpose of this document is to provide a mechanism whereby OSU can fulfill and manage its institutional responsibility to provide a safe workplace for OSU employees working with biological hazards in research and teaching on the OSU Stillwater campus utilizing the principles of hazard identification, risk assessment, risk management, hazard/risk communication and training, and preventive medicine.

3. **Applicability:** This Occupational Health and Safety Program (OHSP) policy applies to all OSU personnel (i.e., principal investigators, faculty, staff, etc.) and students (i.e., graduate and undergraduate students) listed on the OSU-Stillwater's registration for possession, use, and/or transfer of select agents on the OSU-Stillwater campus. A risk assessment will be performed by the Institutional Biosafety Committee (IBC) to determine if personnel listed on IBC protocols are required to enroll in the OHSP.

4. Policy:

- A. All personnel listed on the University's registration for possession, use, and/or transfer of select agents and toxins shall be enrolled in and comply with the OHSP described herein.
- B. Personnel to whom this policy applies who also work with animals are subject the OHSP policy for animal handlers. For additional information on the animal handler OHSP, see IACUC policy 007.
- C. The IBC may withhold protocol approval until all personnel required to enroll in the OHSP have enrolled.

5. Responsibilities:

- A. **Occupational Health & Safety Coordinator (OHSC):** The OHSC is responsible for monitoring compliance and overall coordination of the OHSP to include providing occupational health and safety-related training to individuals enrolled in the OHSP. The OHSC is also responsible for maintaining copies of completed enrollment forms and reviewing annual questionnaires.
- B. **University Health Services Medical Director (UHSMD):** The UHSMD is the primary occupational health care provider for the OHSP and is responsible for screening occupational health questionnaires, medical consultations/exams, medical monitoring/surveillance, and coordinating delivery of medical services to individuals enrolled in the OHSP as required. USD will maintain all medical records related to the OHSP.
- C. **Biological Safety Officer (BSO):** The BSO is responsible for maintaining a current list of all select agent and toxin personnel and other personnel who are required to enroll in the OHSP and for providing an updated personnel list to the OHSC and UHSMD as changes occur.
- D. **Principal Investigator/Instructor (PI) and/or 1st Line Supervisor:** The PI and/or 1st line supervisor is responsible for insuring that personnel under their supervision are enrolled in the OHSP, are trained, and are following safe practices and procedures in the workplace. Training should include risks associated with handling the biological materials in use, including routes of transmission, and signs and symptoms of infection. Training should also include a discussion of conditions that can lead to individuals becoming immunocompromised or immunosuppressed (pregnancy, recent illnesses caused by infectious agents, chemotherapy, etc.).
- E. **Institutional Biosafety Committee (IBC):** The IBC is responsible for reviewing biological agent, toxin, and recombinant DNA protocols and assessing whether or not the personnel listed on a protocol should enroll in the OHSP. A physician from UHS serves on the committee and the OHSC serves as the physician's alternate.
- F. **The University shall bear all costs associated with the OHSP if provided by OSU.**

6. Program Description/Procedures:**A. Enrollment in OHSP:****1. Initial OHSP Enrollment:**

- **OHSP Enrollment Form:** All personnel shall complete an OHSP Enrollment Form and review it with their 1st line supervisor (or PI) to identify the occupational hazards/risks the individual will be exposed to in the workplace. The original completed OHSP Enrollment Form shall be forwarded to the OHSMD for initial occupational health screening and a copy sent to the OHSC.
- **OHSP Medical Questionnaire:** All personnel except for those in category VI-D (see below) shall also complete an OHSP Medical Questionnaire (i.e., personal medical history) and attach it to their OHSP Enrollment Form that is forwarded to the UHSMD for initial health screening and filing in their individual medical record.

2. **Annual Renewal of OHSP Enrollment:** The OHSC shall notify all applicable personnel enrolled in the OHSP to complete and return a Biosafety Annual Health Questionnaire to update their OHSP enrollment and note any change in their work or health status. The OHSC reviews the completed annual health questionnaires for significant changes in the individual's work or health status and forwards the questionnaire to the UHSMD for follow-up occupational health assessment and/or medical management as needed.

- B. OHSP Enrollment Categories:** The UHSMD will assign enrolled individuals to one of the following enrollment categories for health monitoring/surveillance based upon the information contained in the individual's health questionnaire and his/her professional medical judgment. Factors used to assign an individual to a risk category include, but are not limited to:

- Individual's health status (e.g., allergies, asthma, cardio-pulmonary health, immune system, vaccination history, pregnancy, etc.)
- Biosafety level of work being performed
- Involvement in the select agent and toxin program
- Physical/chemical/environmental hazards (e.g., radiation, toxic chemicals, noise, etc.)
- Animal species and/or potential zoonoses, if applicable

1. **OHSP Category V Enrollment:** Applies to persons working with biohazardous materials (non-select agent and/or toxin) for which enrollment in the OHSP is recommended by the IBC. Persons enrolled at this level must complete the following:

- Enrollment Form
- Initial OHSP Questionnaire
- Annual OHSP Questionnaire
- Titers may be required depending upon the agent/toxin at the discretion of the UHSMD and the IBC
- Vaccinations may be recommended depending upon the agent/toxin and the availability of the vaccination at the discretion of the UHSMD and the IBC

2. **OHSP Category VI Enrollment:** Applies to persons listed on OSU's select agent and toxin registration. There are four subcategories based upon an individual's involvement in the select agent and toxin program.

Category VI-A – This category applies to all personnel who work directly with select agents and toxins that are infectious/toxic to humans. PIs can either fall under Category VI-A or Category VI-B. Persons enrolled at this level must complete the following:

- Enrollment Form
- Initial OHSP Questionnaire
- Annual OHSP Questionnaire
- Titers may be required depending upon the agent/toxin at the discretion of the UHSMD and the IBC
- Vaccinations may be recommended depending upon the agent/toxin and the availability of the vaccination at the discretion of the UHSMD and the IBC
- Serum banking, when added and removed from the select agent and toxin registration

Category VI-B – This category applies to all personnel who enter spaces where select and/or toxin work is performed that is infectious/toxic to humans. This includes personnel on the select agent and toxin registration involved in emergency response and inventory reconciliation. Persons enrolled at this level must complete the following:

- Enrollment Form
- Initial OHSP Questionnaire
- Annual OHSP Questionnaire
- Serum banking, when added and removed from the select agent and toxin registration

Category VI-C – This category applies to all personnel involved in shipping and handling of packages containing select agent and/or toxin that are infectious/toxic to humans. This includes personnel from University Mailing Services listed on the select agent and toxin registration. Persons enrolled at this level must complete the following:

- Enrollment Form
- Initial OHSP Questionnaire
- Annual OHSP Questionnaire
- Serum banking, when added and removed from the select agent and toxin registration

Category VI-D – This category applies to all personnel listed on the select agent and toxin registration who never enter spaces where select agent and/or toxin work is performed that is infectious/toxic to humans. This includes IT personnel who are listed on the registration. This category also applies to personnel working with select agents and/or toxins that are non-infectious/toxic to humans. Persons enrolled at this level must complete the following:

- Enrollment Form

- C. **Declination Form:** Individuals may waive a recommended procedure after being apprised of the risks involved by the UHSMD. In some instances, an individual may not waive a recommended procedure if their decision will affect the health of others. A declination form that specifies the procedure that is being declined must be completed and signed by the individual. A copy of the signed declination form must be maintained by the UHSMD and the OHSC.
- D. **Treatment for exposures and injuries:** All occupational exposures and injuries must be reported to the UHSMD and the BSO. UHS maintains information such as appropriate first aid, prophylaxis options, and recommended diagnostic tests in each individual's file for each biological agent or toxin worked with. This information has also been provided to Stillwater Medical Center if a patient needs medical attention after hours.
- E. **Respirator Requirements (not covered by the OHSP):** See Appendix D of the OSU Biological Research Safety Plan and Risk Management and Environmental Health and Safety for details.