Biological and Select Agent Safety Policy

**POLICY**

All possession, use, and transportation of biological agents hazardous to human, animal, and plant health must conform to regulations and guidelines established by federal, state, and local agencies. Biological agents include infectious organisms, recombinant DNA molecules, oncogenic viruses, viroids, prions, transgenic organisms, and select agents.

**PURPOSE**

This biological safety policy provides faculty, staff, and students at WSU and the surrounding community with guidelines for managing risks associated with the use or control of biological agents, including infectious agents, recombinant DNA molecules, oncogenic viruses, viroids, prions, transgenic organisms, and select agents.

This policy assists the University, the Institutional Biosafety Committee (IBC), University departments, Extension, and principal investigators involved in research, teaching, and/or diagnostics in identifying and implementing appropriate safeguards.

The University Biological Safety Officer, the Office of Research Assurances (ORA), the Office of Research Support and Operations (ORSO), and Environmental Health and Safety (EH&S) have copies of the federal and state guidelines available for reference.

**DEFINITIONS**

**Appropriate Biosafety Levels**

*Appropriate biosafety levels* (i.e., BSL and ABSL) are levels appropriate to the biologic agent and protocol in use and in conformance with regulations or guidelines from federal, state, and local agencies including, but not limited to:

- Centers for Disease Control and Prevention (CDC)
- National Institutes of Health (NIH)
- United States Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS)

**Infectious Agents**

*Infectious agents* are all infectious organisms (e.g., bacteria, fungi, parasites, prions, viruses, and viroids) that can cause disease in humans, animals, or plants, or cause significant environmental or agricultural impact.

**Infectious Materials**

*Infectious materials* are materials that may harbor infectious organisms, such as tissues, fluids (including blood), and cells or cell cultures.

**Oncogenic Viruses**

*Oncogenic viruses* are viruses capable of inducing neoplasms in their hosts.
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Prions

Prions are infectious proteinaceous particles associated with transmissible spongiform encephalopathies in animals and humans.

Recombinant DNA

Recombinant DNA is spliced DNA formed from two different sources.

Select Agents

Select agents are agents listed in the Code of Federal Regulations (including, but not limited to, 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121) and are capable, if released, of generating a serious public health crisis or are high-consequence livestock pathogens. Transfer of select agents is limited and controlled by the National Centers for Disease Control and Prevention (CDC).

Transgenic Organisms

Transgenic organisms are animals, plants, or microbes that have been modified by genetic engineering. Genetic engineering is the transfer of DNA between living cells.

ORGANIZATIONAL STRUCTURE

In order to ensure that the requirements of the biosafety program are met, a collective and interactive effort between various University organizations, departments, and individuals at all University campuses is required. Figure 1 illustrates the primary responsibilities for biosafety in relationship to the current University organizational structure. It is intended that the administrators, principal investigators, and employees at each campus work in cooperation with the specified safety groups to support the University biosafety program.

RESPONSIBILITY

Comprehensive Protection Program

The comprehensive protection program includes EH&S, the Radiation Safety Office (RSO), the ORA, including the biosafety officer, the Office of the Campus Veterinarian, and elements within the ORSO.

These offices work collaboratively to ensure a comprehensive, integrated protection program that ensures that risks associated with the use of animals, radioactive materials, human research subjects, recombinant DNA, and genetically-modified organisms do not exceed the benefits accrued from the University activities. These specific elements are governed by a variety of state and federal laws and regulations. Many of these offices coordinate activities with Presidential committees including the Radiation Safety Committee, the Institutional Review Board for Human Subjects Research, the Conflict of Interest Review Board, the Institutional Animal Care and Use Committee, and the Institutional Biosafety Committee.
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### Offices of Research and Finance and Administration

The Office of the Vice President for Research and the Office of the Senior Associate Vice President for Finance and Administration implement the Biological and Select Agent Safety Policy. The biosafety function is part of the comprehensive protection program.

The Vice President for Research or representative and the Senior Associate Vice President for Finance and Administration or representative are jointly responsible to:

- Review the biological safety policy at least once a year and report University activity, as required, to federal and state agencies.
- Ensure compliance with applicable regulations and guidelines from federal, state, and local agencies.
- Identify funding mechanisms for IBC-recommended biosafety-related capital projects.

### Office of Research Assurances

The Office of Research Assurances:

- Assists the Vice President for Research in administering and implementing a comprehensive biosafety program.
- Ensures that all University investigators, including those at regional campuses, Extension, and research stations, conduct activities with biological agents at appropriate biosafety levels. Coordinates with the Institutional Animal Care and Use Committee (IACUC) for housing of laboratory animals at appropriate biosafety levels. See the definition for Appropriate Biosafety Levels.

### Institutional Biosafety Committee (IBC)

The University's Institutional Biosafety Committee (IBC):

- Reports to the University President through the Vice President for Research regarding compliance with federal and state regulations and biosafety needs.
- Approves all University protocols (i.e., BioSafety Approval Forms) to conduct activities with biological agents or house laboratory animals at appropriate biosafety levels. University protocols include protocols used at regional campuses and research stations. See the definition for Appropriate Biosafety Levels.

IBC approval to conduct research is required regardless of funding source or submission of a BioSafety Approval Form (BAF).
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IBC (cont.)

To obtain copies of the BAF and instructions, select the Forms and Templates link on the Biosafety website at:

www.bio-safety.wsu.edu/biosafety/

- Reviews research protocols for compliance with standards. (See above.)
- Reviews health surveillance measures.
- Reviews all recombinant DNA research conducted at WSU for compliance with guidelines established by the National Institutes of Health (NIH).
- Recommends assessment of biosafety facilities, procedures, and practices by WSU Biological Safety Officer and EH&S.
- Recommends training for personnel involved with biological and select agent activities.
- Establishes and implements policies for WSU biosafety and select agent activities.
- Advises the Vice President for Research in the resolution of conflicts that arise with interpretation of biological safety standards.
- Approves inspection checklists for approval of BSL and ABSL laboratories and procedures.
- Assists in prioritizing and administering minor and major capital funds for biosafety needs.

WSU Biological Safety Officer (BSO)

The WSU Biological Safety Officer (BSO):

- Develops, directs, and manages the WSU biological safety program, in compliance with federal, state, and institutional guidelines.
- Serves as a biosafety resource, including providing technical advice on biosafety procedures and monitoring biosafety trends and regulatory changes, for the following University groups:

  Institutional Biosafety Committee (IBC)
  Institutional Animal Care and Use Committee (IACUC)
  University Health and Safety Committee (UH&S)
  Human Subjects Institutional Review Board (IRB)
  Environmental Health and Safety (EH&S)
  Facilities Services, Operations
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BSO (cont.)

- Assists research investigators and staff with all biological safety issues including the following:
  
  - Interpretation of regulations
  - Biocontainment practices
  - Biosafety risk assessment
  - Development of standard operating procedures (SOPs)
  - Development of the laboratory biosafety manuals
  - Use of biocontainment equipment

- Assists investigators regarding management and safety of transgenic organisms.

- Reviews biosafety manuals and standard operating procedures (SOPs) for biological agents. Coordinates with EH&S regarding specific details for laboratory approval and inspection when warranted by the nature of a biological agent.

- Develops and maintains the database of biological agents at WSU. The database includes a current inventory of select agents on all University campuses in compliance with 42 CFR Part 73 and Public Law 107-188, "Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

- Acts as a resource when questions arise regarding appropriate decontamination of facilities and equipment.

- Develops, implements, and maintains biological safety training and educational programs for academics, investigators, and staff. This training is in addition to the bloodborne pathogen training provided by EH&S.

- Provides advice about response plans in coordination with the affected WSU units’ emergency response plans and the principal investigator (PI).

- Serves as a resource to provide biosafety consultation to incident commanders (i.e., WSU Police Services, and/or local police and fire services) during emergency responses.

- Coordinates with Facilities Services, Operations and EH&S for corrections, modifications, and/or repairs to physical facilities.

- Coordinates with Facilities Services, Capital on planning and design criteria for major capital projects.

- Provides advice about biohazard waste management in coordination with Facilities Services, Operations.
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<tr>
<th>Environmental Health and Safety (EH&amp;S)</th>
<th>The Department of Environmental Health and Safety serves as a biosafety resource for laboratory, public health, and occupational settings.</th>
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<tr>
<td>Laboratory Biosafety</td>
<td>Environmental Health and Safety:</td>
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<td></td>
<td>• Inspects physical facilities and containment equipment initially and at regular intervals for compliance with general CDC, NIH, USDA, and other federal agency guidelines. Environmental Health and Safety conducts inspections in accordance with laboratory inspection checklists developed in coordination with the Biological Safety Officer (BSO) and the IBC.</td>
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<td></td>
<td>• Coordinates with Facilities Services, Operations and the BSO for corrections, modifications, and/or repairs to physical facilities.</td>
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<td></td>
<td>• Assists the BSO in review of laboratory biosafety manuals and standard operating procedures (SOPs) for compliance with biological safety guidelines for BSL and ABSL procedures.</td>
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<td>• Develops and maintains the biosafety cabinet certification program for the University, including inspection of biosafety cabinets and maintenance of a biosafety cabinet database (see <em>SPPM 4.22</em>).</td>
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<td>• Provides general guidance about health and safety standards, and assists the BSO and the IBC in reviewing research proposals.</td>
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<td>• Provides advice about response plans in coordination with the affected WSU units’ emergency response plans and the PI.</td>
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### Biological and Select Agent Safety Policy

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<tr>
<th>Public Health Biosafety</th>
<th>The following <em>SPPM</em> sections provide policies and procedures regarding public health biosafety issues:</th>
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<tbody>
<tr>
<td><strong>Hantavirus</strong></td>
<td>See <em>SPPM</em> 6.33.</td>
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<tr>
<td><strong>Bird and Bat Waste</strong></td>
<td>See <em>SPPM</em> 6.35.</td>
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<td><strong>Food Safety and Sanitation</strong></td>
<td>See <em>SPPM</em> 6.20.</td>
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<tr>
<td><strong>Sewage Spills</strong></td>
<td>See <em>SPPM</em> 6.70.</td>
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<tr>
<td><strong>Occupational Health</strong></td>
<td>See <em>SPPM</em> 2.44 regarding the bloodborne pathogen safety policy and procedures.</td>
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<tr>
<td><strong>Facilities Services, Operations</strong></td>
<td>See <em>SPPM</em> 4.24 regarding the disposal of biohazard wastes.</td>
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<td></td>
<td>See <em>SPPM</em> 5.40 regarding the transport and shipment of hazardous materials, biological materials, and dangerous goods.</td>
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<tr>
<td><strong>Central Receiving and Delivery</strong></td>
<td>Central Receiving and Delivery monitors shipments of dangerous goods; e.g., infectious, biohazardous, diagnostic; to ensure that Department of Transportation regulations 49 <em>CFR</em> and select agent regulations 42 <em>CFR</em> Part 72.6 and Appendix A are followed for all packages shipped from and received at Central Receiving and Delivery.</td>
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<td>Central Receiving and Delivery is not held responsible for dangerous goods shipments picked up directly by carriers from University departments (see <em>SPPM</em> 5.40).</td>
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<td><strong>Departmental Administrators</strong></td>
<td>Departmental administrators supervise their employees, students, and visitors with regard to biological risks. The department chair:</td>
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<td>• Reviews laboratory accident reports.</td>
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<td>• Takes appropriate steps to avoid accidents.</td>
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<td>• Coordinates the development of emergency management plans.</td>
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<td>• Approves control methods.</td>
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<td><strong>Principal Investigator</strong></td>
<td>WSU assigns primary responsibility for enforcing rules and procedures for proper control of biologically hazardous agents to the principal investigators and supervisors. These duties include:</td>
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<td>• Operating in conformance with all applicable regulations and guidelines from federal, state, local, and University policies.</td>
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**Principal Investigator (cont.)**

- Implementing a laboratory biosafety manual including standard operating procedures and emergency procedures for managing biologically hazardous agents for any such research under the investigator's supervision.

- Training employees in safety practices, correcting work errors, identifying defective working conditions, and developing a positive attitude among employees toward accident prevention.

- Responding to small spills and releases.

- Properly decontaminating equipment and facilities as needed.

- Investigating and reporting each accident or unintentional release, initiating corrective action, and recommending improvements to ensure maximum safety for WSU laboratory workers. The investigator also sends a copy of each report to the IBC, BSO, and EH&S.

- Ensuring that operations involving using or storing select agents are conducted according to 42 CFR Part 73 and the U.S. Patriot Act of 2001. This includes taking steps to ensure that no "restricted person," as defined by the Patriot Act, has access to select agents under the principal investigator's control.

- Ensuring compliance with all import, export, and material transport permit requirements (see SPPM 5.40).

**Employees**

Employees assigned to work with biologically hazardous materials are responsible for complying with safety rules and procedures. These duties include:

- Reporting each accident or spill resulting in human exposure or breach of containment or any action or condition, which may cause such a breach to the principal investigator or supervisor.

- Reporting any relevant medical profile change to the principal investigator who then includes the change in the employee's medical surveillance records.

- Maintaining proficient, safe working techniques and containment practices.

- Attending training sessions and safety orientations as directed.