

UWSP BIOLOGICAL SAFETY MANUAL



University of Wisconsin–Stevens Point

**Risk Management, Environmental Health & Safety,**

**& the Institutional Biosafety Committee**

**Stevens Point, Marshfield, & Wausau, WI**

**Note: This is a living document and may be updated without notice. Contact** [**biosafety@uwsp.edu**](mailto:biosafety@uwsp.edu) **to ensure you have the most updated copy.**

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**CONTACT** **LIST**

***NOTE:*** *Contact information changes frequently; for a current contact list, please refer to the* [***UWSP biosafety website***](https://www3.uwsp.edu/acadaff/orsp/Pages/What-is-IBC.aspx)*.*

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**DEFINITIONS** **OF KEY TERMS**

**Biological Agents:** Biological agents include bacteria, viruses, fungi, other microorganisms and their associated toxins, which have the ability to directly threaten the health and safety of individuals, animals, and plants, or pose risks to animal or plant products. Their ability to adversely affect human, animal, and plant health can occur in a variety of ways, ranging from mild conditions (i.e., allergic reactions, treatable diseases, or tissue irritation / damage) to serious conditions (i.e., incurable disease, crop decimation, or death). Such biological agents are widespread in the natural environment; they are found in water, soil, plants, and animals. Because many microbes and viruses reproduce rapidly, sometimes requiring minimal resources to do so, they represent a potential danger in numerous settings.

The Occupational Safety and Health Administration (OSHA) recognize a list of biological agents of varying risk groups, found at <https://www.osha.gov/SLTC/biologicalagents/index.html>. Many of these biological agents are not appropriate for use at UWSP campuses. An additional list of *select* biological agents and toxins (with some overlap of agents) is also recognized by the United States Department of Health and Human Services (HHS) and Department of Agriculture (USDA), found at <https://www.selectagents.gov/SelectAgentsandToxinsList.html>. Most of the select biological agents on this list are not appropriate for use at UWSP campuses.

**Biological Materials:** Biological materials are broadly defined as any biological entity, containing any organisms, viruses, or portions thereof, dead or alive. The focus on biological materials for the purpose of biosafety is restricted to those materials that have the potential to cause disease in humans, animals, plants, and pose risks to animal or plant products. The key distinction between a biological agent (select or otherwise) and a biological material in this document is that a *potential* risk *may* exist in a biological material, but that risk is unknown or unlikely without further isolation, enrichment, or other alteration of that material. Biological agents carry known risks. In some instances, a biological material (like a soil sample or human blood) may contain a biological agent (and even a select biological agent), but without isolation, enrichment, and expansion of the agent from within that biological material is unlikely to pose a direct risk to humans, animals, plants, or animal or plant products. Such cases will depend on the nature of the biological material, the manipulation of that material, and the potential biological agent(s) contained therein.

**Recombinant Nucleic Acids (recDNA/RNA):** Recombinant forms of ribonucleic acids (RNA), deoxyribonucleic acids (DNA), and similar synthetically created constructs (collectively abbreviated here as recDNA/RNA) are commonly used in science and academia, as their utility spans a large number of topics. The reason such constructs receive federally-mandated regulation is that they may pose a significant risk to humans, animals, plants, or animal or plant products depending upon the sequences generated and their potential introduction into an organism, virus, or potentially infectious vector.

**Risk Group:** Risk groups are used to describe a biological agent, biological material, or recDNA/RNA and its ability to cause disease, as well as whether or not treatments are available. Four levels of increasing associated risks are recognized. The following information about risk groups is provided below from guidelines developed by the National Institutes of Health (NIH), within *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

**Risk Group 1 (RG1):** Risk group 1 describes biological materials / recDNA/RNA which are not associated with disease in healthy adult humans / animals / plants. They represent no or little risk to individuals, animals, and plants, or to the community or environment.

**Risk Group 2 (RG2):** Risk group 2 describes biological agents (although relatively few) / biological materials / recDNA/RNA that are associated with human / animal / plant disease which is rarely serious and for which preventive or therapeutic interventions are often available. They represent a moderate risk to an individual, animal, or plant, but a low risk to the community or environment.

**Risk Group 3 (RG3):** Risk group 3 describes biological agents / biological materials / recDNA/RNA that are associated with serious or lethal human, animal, or plant diseases for which preventive or therapeutic interventions may be available. They represent a high risk to an individual, animal, or plant, but a low risk to the community or environment.

**Risk Group 4 (RG4):** Risk group 4 describes biological agents (most select agents and several others) / biological materials / recDNA/RNA that are likely to cause serious or lethal harm to humans, animals, or cause plant diseases for which preventive or therapeutic interventions are not usually available. They represent a high risk to the individual, animal, or plant, and they pose a high risk to the community or environment.

**Biological Safety Level:** The primary risk criteria used to define the four ascending levels of containment, referred to as biosafety levels-1 (BSL-1) through -4, are infectivity, severity of disease, transmissibility, and the nature of the work being conducted. Biosafety levels are not directly correlated with risk group levels, even though they both have 4 tiers. As an example, an RG1 biological material may require biosafety level-2 containment if it is modified or manipulated in a way which increases its infectivity, or increases the risk that personnel might become infected by the material. Another important risk factor for biological agents / biological materials / recDNA/RNA that cause moderate to severe disease is its origin; as an example, a plant virus indigenous to a region poses a lower threat to the environment than if it is exotic to that region, requiring different practices (and biosafety levels) at different universities. Each level of containment describes the microbiological practices, safety equipment, and facility safeguards for the corresponding level of risk associated with handling a particular biological agent / biological material / recDNA/RNA. The basic practices and equipment used (BSL-1 and -2) are appropriate for procedures common to most research and clinical laboratories. Facility safeguards help protect personnel, the community, and the environment.

**Personnel:** In this manual, personnel are broadly defined as anyone taking part in research, an instructional activity, biological shipping/receiving and disposal, or other aspect of any project involving biological agents / biological materials / recDNA/RNA. Examples of personnel range from faculty to staff, students, collaborators, etc.

**Biosafety-Related Activities:** These activities are broadly defined in this document to include any research, instructional activity, collaborative project, etc., either at UWSP campuses, UWSP-related facilities, or off-site involving UWSP-supervised / sanctioned excursions, which include the use of biological agents, biological materials, or recDNA/RNA.

**Principal Investigator:** A principal investigator is broadly defined as the lead individual on an approved biosafety protocol application. Examples of principal investigators include: 1) faculty or academic staff member for a research laboratory; 2) faculty or academic staff member or instructor on an instructional activity (courses taught by multiple faculty and staff are advised to have co-principal investigators); 3) faculty or academic staff member at multi-use facilities either on or off campus; 4) faculty or academic staff member supervising off-site excursions; and 5) other faculty / staff in a supervisory role warranting the oversight of biosafety-related activities. Such individuals must be designated as an appropriate principal investigator, will serve as the contact person for any biosafety concerns and/or reports, and will have their contact information posted where biosafety-related activities are conducted or available during the excursion when biosafety-related activities are conducted.

**Institutional Biosafety Committee (IBC):** This committee consists of a group of faculty, staff, and non-university affiliated members of the general public appointed by the university to oversee biosafety documentation of related practices on UWSP campuses (or associated sites). This committee is responsible for reviewing and approving proposed biosafety protocols *before* activities may be conducted with various biological agents, biological materials, or recDNA/RNA. More information regarding the IBC is found in a separate section of this document.

**Biological Safety Officer (BSO):** The BSO inspects classrooms, labs, and other spaces where activities with biological agents, biological materials, or recDNA/RNA take place. More information regarding the BSO is found in the same section outlining roles of the IBC.

**Visitors:** Visitors are broadly defined as anyone entering a research space or classroom in which biosafety-related activities are conducted who is not listed on the biosafety protocol, and not an IBC member. Different categories of visitors may be recognized and are subject to different levels of training and/or notification of the biosafety-related risks, particularly as they relate to the heightened risks involving biosafety level-2 procedures. Anyone who wishes to work on biosafety-related activities, even if they are considered a collaborator, must be included in the Personnel Training Form, complete any necessary training, and must be made aware of the risks associated with these activities.

Additionally, regardless of the biosafety level practices which take place in a given laboratory / space, and regardless of the type of visitor entering such spaces, visitors must be made aware of the specific hazards associated with these areas. Biohazard communication is the first line of hazard notification. Facility Services will inform the department / division chair when scheduled contract work is to be performed in one of these spaces. The PI is responsible for notifying the IBC of any work or maintenance scheduled to be done in the lab spaces. The IBC or designee will then provide the necessary site-specific training or information as necessary to the contractor / service provider in coordination with Facility Services.

**Emergency Personnel:** Emergency personnel include any immediate responders to specific situations including fire, medical emergency, criminal activity, etc. Such individuals will not need direct consent by the principal investigator to enter the space hosting biosafety-related activities when emergency situations are taking place. It is the responsibility of the principal investigator to maintain proper signage alerting emergency personnel to the potential risks of entering such spaces, and it is the responsibility of any personnel on the biosafety protocol to comply with emergency procedures to post pre-made signage to specific equipment (i.e., biosafety cabinet) to further alert emergency personnel of risks associated with contacting that equipment when experiments are going on.

**Service Providers & Contractors:** Multiple individuals may need to enter the space hosting biosafety-related activities in order to service equipment, computers, building ventilation, broken equipment, etc. Such individuals will only be permitted entry into biosafety level-2 spaces with direct consent of the principal investigator, under their supervision, when no biosafety-related activities are taking place. Specific precautions should be taken prior to permitting entry for service providers (i.e., pre-decontamination of surfaces and equipment), and these procedures must be listed in the biosafety protocol. Spaces where only biosafety level-1 practices are needed do not require supervision and pre-decontamination prior to the entry of service providers.

**Visiting Observer:** Principal investigators may invite individuals to observe biosafety-related activities, or consent to the observation of such activities by individuals who are not listed on the biosafety protocol and/or who have not completed biosafety training. If a principal investigator wishes to invite a visitor to observe a biosafety level-2 activity, it will require prior approval by the IBC, which may require training and will require documentation of the visit.

**IBC Standard Operating Procedures (SOP):** This document summarizes the activities that require NIH oversight and aids PIs and instructors in determining the extent to which the Biosafety Protocol Application must be completed. The SOP also describes the process of submission, review, and approval of applications.

**Biosafety Protocol Application (BPA):** This document is the biosafety protocol application for all research or instructional laboratory techniques that pose a biosafety hazard to students, staff, or the environment. All protocols involving recombinant DNA/RNA or biological agents or materials that are classified as Risk Group 2 or higher must complete portions of this application form. Prior to beginning a teaching or research protocol involving a biosafety hazard, a PI or instructor must complete the appropriate sections of the application and have the protocol approved by the IBC. For determining which sections of the BPA apply to your work, consult the IBC SOP, NIH Guidelines, and/or BMBL, 5th ed.

**Personnel Training Form:** This document is designed to identify all personnel who will be working on the project. This includes the principal investigator, co-principal investigators, collaborators, staff, students, and others. Training completion dates and certificates must be provided with this document, in addition to who is responsible for training personnel. This form must be submitted with each biosafety protocol application. Changes in personnel (other than the PI) do not require resubmission of the BPA; instead, this personnel training form must be updated and resubmitted.

**Personal Protective Equipment (PPE):** PPE is any attire appropriate for the biosafety-related activity to be conducted which keeps personnel safe. There is no one set standard for PPE, as the nature of the activity dictates the appropriate PPE to be used. In most biosafety-related activities, latex or non-latex gloves are required.

**Biological Safety Cabinet (BSC):** A BSC is specifically designed to create a sterile working environment for biological agents, biological materials, or recDNA/RNA, particularly if they belong to a higher risk group. It contains a high-efficiency particulate air (HEPA) filter to prevent contamination of the internal environment, as well as to prevent exposure of personnel to the biological agent / biological material / recDNA/RNA. BSC class and type designation depends on its design; appropriate class and type BSCs for biosafety level-2 practices are minimally Class II, type A2 (standard laminar flow hoods are inappropriate) which must be certified annually.

**INTRODU****CTION**

Biological research and teaching is accompanied by inherent risks. The goal of a biological safety program is to minimize biological risks to the lowest level possible. This risk mitigation is accomplished through a combination of facility and equipment safeguards, proper guidelines for personal protective equipment (PPE), appropriate safety practices, relevant policies, and training recommendations. The effectiveness of a biological safety program is only as good as the training provided to individuals working with biological materials and their subsequent ability to follow best practices.

The University of Wisconsin-Stevens Point (UWSP) Biological Safety Manual is intended as a resource to provide its personnel (researchers, faculty, staff, students, collaborators, etc.) with the best practices for working with biological agents / biological materials / recombinant nucleic acids (recDNA/RNA). Complying with best practices helps ensure these activities are conducted in a safe and secure manner in accordance with all applicable regulations and guidelines. Adhering to this resource will help protect personnel, as well as visitors, the public, and the environment from exposure to biological agents / biological materials / recDNA/RNA utilized for all laboratory, research, teaching, and support activities conducted at UWSP campuses, at facilities maintained or supervised by UWSP, and off-site where UWSP activities may take place. This biosafety manual is largely based on the guidelines set forth by the Centers for Disease Control and Prevention (CDC) as outlined within *Biosafety in Microbiological and Biomedical Laboratories* (or BMBL, 5th Ed., <https://www.cdc.gov/biosafety/publications/bmbl5/>) and guidelines developed by the National Institutes of Health, within *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (<https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html>, referred to as *NIH Guidelines)*.

Use of biological agents, biological materials, or recDNA/RNA at UWSP campuses / UWSP supervised locations will require the completion of a biosafety protocol application. Any work (research, instructional, or other) involving biological agents, biological materials, or recDNA/RNA will require review by the IBC. Applications should outline best practices and must be adhered to by all personnel. Failure to comply with these guidelines may result in intervention by the IBC, which could result in enforced cessation of the activity in question (outlined in the section on biological compliance & enforcement).

**RISK ASSESSMENT**

**All principal investigators and instructors planning to conduct and/or oversee a biosafety-related activity MUST perform an initial risk assessment.** Answer the EACH of following questions to determine if you need to submit a biosafety protocol application, and to what degree this application must be completed.

1. Are you working with biological materials (bodily fluids, tissues, etc.), biological specimens, or samples likely to contain biological materials or specimens (wastewater, soil samples, natural water samples, etc.)?

Yes – proceed to #2

No – no IBC oversight is required (if remaining questions do not apply)

I do not know – consult the IBC chair

1. Are you working with recombinant DNA or RNA (recDNA/RNA) that can replicate within a cell (excluding PCR products and PCR primers) or working with cells or organisms carrying recombinant DNA?

Yes – proceed to #3

No – proceed to #4

I do not know – consult the IBC chair

1. Is your recDNA/RNA work exempt from IBC oversight as described in NIH Guidelines Section III-F or Appendix C?

Yes – complete the first two sections of the Biosafety Protocol Application for an exempt protocol

No – complete all relevant sections of the Biosafety Protocol Application for a non-exempt protocol

I do not know – consult the IBC chair

1. Is your biological specimen classified as a Risk Group 2 pathogen by the NIH Guidelines Appendix B or are your samples likely to contain Risk Group 2 agents? *Please note that Risk Group 1 agents can be elevated to Risk Group 2 status based on the specific protocols being used. It is better to err on the side of caution and use additional precautions to reduce risk of a borderline hazard. It is the* ***responsibility of the PI/instructor*** *to perform the risk assessment and correctly identify the proper risk group.*

Yes – complete all relevant sections of the Biosafety Protocol Application for a non-exempt protocol

No – no IBC oversight is required

I do not know – consult the IBC chair

1. If so far your responses indicate either no oversight or partial completion of the Biosafety Protocol Application, *but* a part of your planned activities have the potential to be used for nefarious purposes, also known as Dual Use Research of Concern (DURC), you must still complete all relevant sections of the BPA.

**BIOSAFETY COMPLIANCE** **& ENFORCEMENT**

As defined previously, a biosafety-related activity taking place at UWSP campuses, UWSP-facilities, or off-site with UWSP supervised / led activities will require oversight by the IBC. Select activities may also require post-approval monitoring by the IBC. The following list indicates steps to ensure biosafety compliance, or steps required to re-instate compliance.

* Biosafety protocols must be developed by the principal investigator of the biosafety-related activity (laboratory supervisor, instructor, lead supervisor of the shared facility, etc.) which then must be submitted to the IBC for approval *before* any work with biological agents, biological materials, or recDNA/RNA can be prepared or conducted.
  + The receipt of biological agents, biological materials, or recDNA/RNA will be prohibited until the biosafety protocol is approved.
    - Principal investigators are not permitted to purchase such items, request the transfer of such items from outside labs (either on campus or off-site), or personally transport such items prior to biosafety protocol approval.
    - It is possible to request the approval of a biosafety protocol restricted to archiving and storage if the principal investigator successfully demonstrates intent to comply with biosafety training and compliance, and that the circumstances involving the timing and/or receipt of such items is of a sensitive nature. However, failure to subsequently generate an approved biosafety protocol involving such items will result in their appropriate destruction and disposal. The IBC must pre-approve their receipt.
* Before a biosafety protocol can be approved, the principal investigator and any personnel working with this investigator (either in a collaborative capacity or in a lesser role) on activities involving biological agents, biological materials, or recDNA/RNA, must complete the specified training prior to conducting these activities. Personnel working in the lab when such activities are taking place must also review the biosafety manual and biosafety protocol(s) prior to working on the project.
  + The Biosafety Protocol Application and the Personnel Training Form must be submitted to the IBC; these documents indicate that all personnel have read necessary biosafety documents, completed required training, and guarantee that they will uphold the guidelines set therein.
    - A signed copy of the biosafety protocol and personnel training form must be submitted to the IBC.
  + Training is provided through the [Collaborative Institutional Training Initiative (CITI) Program](https://about.citiprogram.org/en/homepage/), and is valid for three (3) years. Additional in-person training may be required by the IBC.
* Modifications to the Personnel Training Form can be submitted to biosafety@uwsp.edu.
* To modify an existing biosafety protocol, i.e., introduction of new biological materials, incorporation of new equipment and/or facilities requiring containment practices, alteration of experiments which may alter the inherent risks to personnel, federally-altered biosafety status of the items worked with, etc.), the principal investigator must submit a Biosafety Protocol Application form with the “Modification Form” box marked. The PI should copy the unmodified information from the original approved Biosafety Protocol Application to the new Biosafety Protocol Application. In Section 2B of the Biosafety Protocol Application, the PI should clearly indicate how the protocol is being modified and identify the specific sections that contain modifications.
* Biosafety protocols expire after three (3) years. If PI’s wish to continue working on the project after expiration, they can submit a new biosafety protocol for *de novo* review.
* The safe practices outlined in this biosafety manual, and as outlined by any approved biosafety protocol, will require periodic inspection by the IBC. A written summary of the inspection will be provided to the principal investigator.
  + No action is required if all personnel have demonstrated safe practices in their activities, if all biological agents / biological materials / recDNA/RNA are appropriately stored, manipulated, or processed for decontamination, if all spaces are appropriately maintained to minimize risks for loss of containment, risks to personnel, or risks to animals, plants, or animal or plant products, and if all other biosafety-related activities outlined in the biosafety protocol are upheld.
  + Should a minor lack of compliance be observed at inspection:
    - The IBC will record and review minor acts of non-compliance. Appropriate actions will then be outlined by the IBC, and these actions will be put forth to the principal investigator. If repeat offenses occur, then actions recommended by the IBC may be increased as outlined in the previous bullets.
  + Should a major lack of compliance be observed at inspection:
    - The IBC, in consultation with the department chair or equivalent, EH&S officer, or protective services representative, has the authority to suspend laboratory activities in part or whole if deficiencies in laboratory procedures or equipment pose a significant safety threat.
      * Infractions of this nature may also entail the pursuance of disciplinary actions against the principal investigator and personnel as set forth per the University Handbook.
      * If suspension of laboratory operations is necessary, a written report including a description of the nature of the hazard and remedial actions necessary to resume activities will be filed with the Dean of the College, the protective services director, the IBC , the EH&S officer, and the Office of Research and Sponsored Programs.
    - Written appeal under this procedure should be made to the IBC and EH&S officer for consideration by the suspending authorities.
      * The IBC should conduct periodic inspections of their applicable labs and enact necessary corrective actions.
      * The BSO has the responsibility to conduct periodic laboratory inspections. Inspections shall be conducted while the laboratory is in use so that the operating procedures will be verified as being followed by all personnel.
      * The schedule of all inspections, checklists, and reports will be kept in each department office, and the Office of Research and Sponsored Programs.
      * Inspection results and checklists used shall be communicated to the principal investigator after completion of the inspection.
  + Should the IBC receive notification of a lack of compliance or unexpected event:
    - The IBC will investigate the incident, and report findings to the Institution. It is the responsibility of the IBC to ensure adherence to Institutional and Federal policies and guidelines.
    - The IBC is committed to the safe use of institutional spaces, staff and students, and the environment. Safe practices are recommended and enforced to prevent non-compliance due to negligence and/or human error. Non-compliance places everyone at risk of exposure to potentially biohazardous sources.
      * The IBC works to ensure safe practices of biological teaching and research activities for UW-Stevens Point campuses / UWSP supervised locations. If you see something, say something! No aversion toward paperwork or potentially inconvenient training schedules should *ever* be a priority over the safety of personnel, the public, or the environment.

**BIOSAFETY LEVELS AND RISK GROUPS**

Risk identification in the field, in the classroom, and in the laboratory is essential to the protection of personnel, the public, and the environment. A risk assessment is a subjective process that identifies the risks associated with handling and/or manipulating a specific biological agent, biological material, or recDNA/RNA that could potentially cause harm to humans, animals, or plants. When performing a risk assessment, multiple factors must be considered including its origin (i.e., human derivation, viral construct, plant pollinator genome, etc.), infectivity, transmissibility, severity of disease, availability of potential treatments, and the nature of work associated with the biological agent, biological material, or recDNA/RNA being handled. The results of the risk assessment provide guidance for the appropriate biosafety level, laboratory practices and procedures, PPE, safety equipment, and facility design to protect all parties from potential exposure or release. When risk is unknown, a conservative approach is best and safeguards should be incorporated into biosafety procedures until more information is available. Personnel training can mitigate some risks and, in some cases, additional training may be warranted to safely conduct the work necessary.

How a biological agent, biological material, or recDNA/RNA might infect / inoculate a human, animal, or plant in a controlled laboratory setting (even settings off-site) could be different than in nature, so biosafety procedures should consider the location of the work being conducted. Potential routes of exposure in the laboratory are direct eye, skin, or other mucosal membrane exposure, contact with compromised skin (i.e., cut / wound / sore), sharps injury, animal or arthropod bite, ingestion, and aerosol exposure. Atypical exposure or infection routes may be viable in the laboratory / classroom / off-site work station because biological materials manipulated in such settings are often used in concentrations much higher than found in nature, making non-traditional exposure routes, like through aerosolization of biological materials, possible. Examples of biological material manipulation which can generate aerosols include pipetting, centrifuging, sonicating, vortexing, changing animal bedding, and performing necropsies, among others. Practices, procedures, safety equipment, PPE, and training are used to mitigate these risks.

Biosafety level and risk group are not always defined the same. Risk groups describe a biological agent, biological material, or recDNA/RNA based on its ability to cause disease and available treatments, whereas biosafety levels are a combination of laboratory practices, techniques, facilities, and safety equipment appropriate for the risks posed by the biological agent, biological material, or recDNA/RNA and the associated laboratory procedures. One risk group of biological agent, biological material, or recDNA/RNA could be used at a higher or lower biosafety level depending on how they are being used, or if alterations were made to them rendering them more hazardous (i.e., incorporating virulence factors or resistance markers into microbes capable of infecting humans / animals / plants), or less hazardous (i.e., chemically-inactivating and fixing pathogenic tissues or samples).

Risk group 1 biological materials, or recDNA/RNA are not associated with disease in healthy adults, plants, or animals; all biological agents belong to a risk group higher than 1. Risk group 2 biological agents, biological materials, or recDNA/RNA are associated with human, animal, or plant diseases that are rarely serious, and for which preventative or therapeutic interventions are often available. Biological agents, biological materials, or recDNA/RNA which cause serious diseases in healthy adults, animals, or plants for which there are no preventative or therapeutic interventions belong to higher risk groups; most risk group-3 and 4 agents are not allowed at UWSP campuses / facilities (particularly if they require biosafety level-3 or 4 practices) without prior inactivation via an approved inactivation method, which lowers their overall risk. You may be able to determine the risk group for a particular biological entity by reviewing the American Biological Safety Associations’ risk group database: <https://my.absa.org/Riskgroups>; you may also consult the IBC/BSO if you are uncertain as to the risk a preserved sample may pose.

Biosafety level 1 (BSL-1) is the basic level of protection and the building block for all the additional levels. The biological materials / recDNA/RNA used at BSL-1 are not known to cause disease in healthy adults, animals, and/or plants. BSL-2 practices build upon those outlined in BSL-1. The biological agents / biological materials / recDNA/RNA used at BSL-2 are capable of causing disease in healthy adults, animals, or plants, with the route of exposure commonly occurring through skin or mucous membranes in a lab-like setting. Both risk groups and biosafety levels do not take into account instances where an individual, animal, or plant may have increased susceptibility. While personnel working with such biological agents / biological materials / recDNA/RNA do not have to disclose information regarding their altered susceptibility of infection to their institution, it is essential that the institution provide training to help them determine if they are at an increased risk due to pre-existing conditions, decreased immunity, their use of certain medications, organ transplantation, pregnancy or breast-feeding, and/or other circumstances. Training is discussed in a subsequent section of this document. Personnel can discuss any of the concerns they might have with their personal physician or the UWSP Occupational Health Providers (e.g., student health services, or Ministry Health’s contracted medical surveillance program, as examples). Any animals or plants which may become infected with specific pathogens must not be removed from containment to safeguard the environment from similar exposures, and appropriate actions should be taken with the IBC and IACUC for remediation.

**GENERAL BUILDING** **SECURITY**

Business hours for buildings at UWSP campuses are determined based on classroom usage; therefore, buildings do not have set hours of accessibility. Access to research laboratories, classrooms where biosafety level-2 activities may take place, and similar areas, is controlled to prevent unauthorized laboratory entry. UWSP’s policy for access to laboratories (teaching or research) with biosafety-related activities is determined on a departmental or college basis, and must be made available in that department’s handbook. At minimum, doors will not be propped open, students will maintain identification, and any suspicious activities, persons, or packages will be reported to Protective Services.

If working with biological agents, biological materials or recDNA/RNA is conducted after business hours, personnel must notify the principal investigator, and be approved by the appropriate parties prior to commencing activities. Laboratory door and key policies are determined by principal investigators in consultation with facilities services, departments, and/or colleges. An individual’s keys are collected as part of the off-boarding process. Additional access control based upon biosafety level is discussed in the next section. If incompatible projects are planned for the same space, the IBC, department, and college will determine responsibility and usage.

**BIOLOGICAL SAFETY** **BEST PRACTICES**

The two best resources for assistance with conducting risk assessments are *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) and *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*). Below is a compilation of the standard practices and procedures from both resources for BSL-1 and BSL-2, as well as for animal BSL-1 (ABSL-1) and animal BSL-2 (ABSL-2), encompassing research with biological agents / biological materials both naturally occurring, synthetically created (including recDNA/RNA), and those modified in the laboratory. Additional information pertinent to good large scale practices (GLSP) on Page 67 and large scale biosafety level-1 (LSBSL-1) practices is indicated in Appendix B on Page 68. Additional information pertinent to plant biosafety levels-1 and -2 (PBSL-1 and PBSL-2), is indicated in Appendix C, Pages 69 and 70, respectively. The following requirements are the minimum requirements for conducting research at UWSP campuses. Additional safety practices and policies might be required based upon their risk assessment and IBC recommendations.

**Biological Safety Level****-1**

BSL-1 is appropriate for well characterized biological materials / recDNA/RNA generation methods (i.e., PCR of non-hazardous sequences) that do not consistently cause disease in healthy adults / animals / plants and present minimal hazards to personnel and the environment. Laboratory personnel have been appropriately trained to work in the laboratory and often work on open bench tops using aseptic technique and other standard microbiological practices. Containment equipment is not warranted unless the risk assessment states otherwise.

BSL-1 Standard Practices

* Principal investigators must enforce the institutional policies and any additional policies outlined in their biosafety protocol that control access to the laboratory.
* Personnel must wash their hands after working with potentially biohazardous materials and before leaving the laboratory.
* Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
* Mouth pipetting is prohibited; mechanical pipetting devices must be used.
* Policies for the safe handling of sharps (e.g., needles, scalpels, pipettes, and broken glassware) must be developed and implemented. Whenever practical, principal investigators should adopt improved engineering and work practice controls that reduce the risk of sharps injuries. The following precautions must always be followed with sharp items:
  + Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, directly recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
  + Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
  + Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
  + Broken glassware must not be handled directly. Instead it must be removed using a brush and dustpan, tongs, or forceps. Plasticware should be substituted for glassware whenever possible.
  + Compromised glassware (e.g., chipped or cracked slides, coverslips, and containers) must not be used with biological materials.
* Personnel must perform all procedures in a manner which minimizes the creation of splashes and/or aerosols.
* Personnel must decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious biological material with appropriate disinfectant.
* Personnel must decontaminate all cultures, stocks, and other potentially infectious biological materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:
  + Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof, covered container and secured for transport.
  + Materials to be removed from the facility for decontamination must be packed in accordance with applicable state and federal regulations.
* A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious biological materials are present. The sign may include the name of the material(s) in use, as well as the name and phone number of the principal investigator. Biological material information should be posted in accordance with institutional policies.
* An effective pest management program is required (described in Appendix A-Facilities Pest Management, Page 62).
* The principal investigator must ensure that personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and applicable exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual’s susceptibility to infection or their ability to receive immunizations or prophylactic interventions. Therefore, all personnel should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify with the institution’s healthcare provider for appropriate counseling and guidance.

BSL-1 Safety Equipment

* Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.
* Protective eyewear must be worn when conducting procedures that have the potential to create splashes of microorganisms or other hazardous biological materials. Personnel who wear contact lenses in the laboratory should also wear eye protection. Eyeglasses also may not provide adequate side protection from splashes.
* Gloves must be worn to protect hands from exposure to hazardous biological materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Wash hands prior to leaving the laboratory. In addition, personnel working at BSL-1 should:
  + Change gloves when contaminated, when glove integrity is compromised, or when otherwise necessary.
  + Remove gloves and wash hands when work with hazardous biological materials has been completed and before leaving the laboratory.
  + Avoid washing, reusing, or sharing disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

Additional BSL-1 Requirements for Working with Recombinant Nucleic Acids

* Work surfaces must be decontaminated immediately after any spills of viable materials, in addition to routine decontamination after working with biological materials for the day.
* Personnel must wash their hands: (i) after they handle materials involving organisms containing recombinant or synthetic nucleic acid molecules, and (ii) before exiting the laboratory.
* In the interest of good personal hygiene, facilities (e.g., hand washing sink, shower, changing room) and protective clothing (e.g., uniforms, laboratory coats) shall be provided that are appropriate for the risk of exposure to viable organisms containing recombinant or synthetic nucleic acid molecules.

**Biological Safety Level****-2**

BSL-2 is appropriate for biological agents / biological materials that pose a moderate risk to healthy adults / animals / plants and the environment. Personnel must be periodically monitored, undergo specific training, and be competent when handling pathogenic biological agents / biological materials. Containment equipment is regularly used to contain potential aerosols when working at BSL-2. In addition, access to the laboratory is restricted by the principal investigator, as well as other personnel. BSL-2 builds upon the BSL-1 practices and procedures described above. The BSL-2 practices and procedures described below are *in addition* to those BSL-1 practices.

BSL-2 Special Practices

* All personnel or approved visitors (e.g., emergency personnel and service providers) entering the laboratory must be advised of the potential biohazards through appropriate signage and/or verbal notification and meet specific entry/exit requirements (i.e., potential health hazard and required PPE).
* Personnel must be provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory (services provided through a contract with Ministry Health).
* Each institution should consider the need for collection and storage of serum samples from at-risk personnel.
* A laboratory-specific biosafety protocol must be prepared and adopted as policy. The biosafety protocol and this biosafety manual must be available and accessible within each laboratory, classroom, shared facility, off-site facility, etc., in which BSL-2 work practices are conducted.
  + Personnel Training Forms must also include copies of up to date information regarding all personnel training.
* The principal investigator must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with biological agents / biological materials requiring BSL-2 practices.
* Potentially infectious biological agents / biological materials must be placed in a durable, leak proof, covered container during collection, handling, processing, storage, or transport within a facility. The transport container must have a universal biohazard label.
* Laboratory equipment should be routinely decontaminated after spills, splashes, or after other potential contaminations occur, as well as for general lab cleanliness.
  + Spills involving infectious biological agents / biological materials must be contained, decontaminated, and cleaned up by personnel properly trained and equipped to work with infectious biological agents / biological materials.
  + Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
* Incidents that may result in exposure to infectious biological agents / biological materials must be immediately evaluated and treated according to procedures described in this biosafety manual the laboratory’s biosafety protocol. All such incidents must be reported to the principal investigator (immediately) and IBC within 24 hours. Medical evaluation, surveillance, and treatment should be provided and appropriate records of potential exposure events must be maintained.
* Animals and plants not associated with work performed in the laboratory must not be permitted in the laboratory.
* All procedures involving the manipulation of infectious biological agents / biological materials that may generate an aerosol should be conducted within a biological safety cabinet (BSC) or other physical containment devices.
  + Rotors should be opened inside of BSCs.
  + Small centrifuges can be placed inside of a BSC if a rotor cannot be removed.
  + Additional containment devices, such as centrifuge safety cups, can be moved into a BSC before opening.
* Biological agents / biological materials received by an approved supplier (confirmed by the IBC) must be opened only within a BSC by trained personnel in case any interior containment of the biological agent / biological material has become compromised during shipping.
* Security-sensitive biological agent / biological material information should be posted in accordance with the institutional policy. Advance consideration should be given to emergency and disaster recovery plans, as a contingency for man-made or natural disasters.

BSL-2 Safety Equipment

* Properly maintained BSCs, other appropriate PPE, or other physical containment devices must be used under the following circumstances:
  + When procedures with a potential for creating infectious aerosols or splashes are conducted, including pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious biological agent / biological material, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
  + When high concentrations or large volumes of infectious biological agents are used. Such biological agents / biological materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
* Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous biological agents / biological materials. Protective clothing must be removed before leaving the laboratory to access non-laboratory areas (e.g., cafeteria, library, other classrooms, and administrative offices). Protective clothing must be appropriately disposed of as biohazardous waste, or decontaminated and laundered by an appropriate facility at the university. It is recommended that laboratory clothing not be taken home.
* Eye and face protection (goggles, mask, face shield or other splatter guard) should be used for anticipated splashes or sprays of infectious or other hazardous biological agents / biological materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Personnel who wear contact lenses in laboratories should also wear eye protection. Eyeglasses also may not provide adequate side protection from splashes.
* Eye, face, and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

Additional BSL-2 Requirements for Work with Recombinant Nucleic Acids

* While uncommon, select recombinant nucleic acids may be directly infectious in their nascent state. Work conducted with such constructs must be carried out in a BSC with appropriate decontamination after work is completed.
* When the organisms containing recombinant or synthetic nucleic acid molecules in use in the laboratory require special provisions for entry (e.g., vaccination), a warning sign incorporating the universal biohazard symbol must be posted on the door(s) accessing the laboratory work area. The biohazard warning sign identifies the agent, lists the name and telephone number of the principal investigator, and indicates the special requirement(s) for entering the laboratory.
* Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules must be immediately reported to the IBC and the National Institutes of Health’s Office of Science Policy (NIH OSP). Reports to the NIH OSP shall be sent, preferably by e-mail to: [NIHGuidelines@od.nih.gov](mailto:NIHGuidelines@od.nih.gov); additional contact information is also available on the OSP website (<http://www.osp.od.nih.gov/>) and through the UWSP risk management website (<http://www.uwsp.edu/rmgt/Pages/ehs/default.aspx>). Medical evaluation, surveillance, and treatment are provided as appropriate, and written records are maintained.
* Considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel may be collected and stored. Additional serum specimens may be collected periodically depending on the agents handled or the function of the facility. This service is optional and provided through a contract with Ministry Health.
* A biosafety protocol is prepared or adopted for each laboratory conducting research at biological safety level-2. Personnel are advised of special biohazards and required to read and follow instructions on practices and procedures in the biosafety protocol and this manual.
* If high concentrations or large volumes of organisms containing recombinant or synthetic nucleic acid molecules are used, biological agents / biological materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used and if they are opened only in a BSC.

**Animal Biological Safety Level****-1**

Animal research presents unique challenges because the activities of the animals pose hazards to personnel. For example, they can scratch, bite, create aerosols, and may be infected with a pathogenic agent. The use of animals for research is approved by the UWSP Institutional Animal Care and Use Committee (IACUC) on an individual protocol basis (separate from a biosafety protocol).

ABSL-1 is used for research with animals that also involve biological materials that are not known to cause disease in healthy adults / animals / plants and present minimal hazards to personnel and the environment. All personnel must have specific training for the animal facility and have knowledge of potential risks and animal procedures or be supervised by an individual with such knowledge. In addition, the facility should be separate from general building traffic.

ABSL-1 Standard Practices

* The animal facility director establishes and enforces policies, procedures, and protocols for institutional policies and emergencies.
* Each institute/organization must assure that worker safety and health concerns are addressed as part of the animal protocol review (separate from a biosafety protocol).
* Prior to beginning a project, animal protocols also must be reviewed and approved by the IACUC (separate from a biosafety protocol) and the IBC.
* A biosafety protocol specific to the animal facility must be prepared or adopted in consultation with the laboratory animal manager and appropriate safety professionals. The biosafety protocol and this manual must be available and accessible. Personnel are advised of potential biohazards and are required to read and follow instructions on practices and procedures.
* The principal investigator must ensure personnel receive appropriate training regarding their duties: animal care, animal husbandry procedures, potential biohazards, manipulations of infectious biological materials, necessary precautions to prevent exposures, and hazard/exposure evaluation procedures (physical hazards, splashes, aerosolization, etc.). Personnel must receive annual updates and additional training when procedures or policies change. Records are maintained for all biohazard evaluations, personnel training sessions, and their attendance.
* An appropriate medical surveillance program is in place, as determined by risk assessment. The need for an animal allergy prevention program should be considered.
* Facility supervisors should ensure that medical staff is informed of potential occupational biohazards within the animal facility, including those associated with research, animal husbandry duties, animal care and manipulations.
* Personal health status may impact an individual’s susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all personnel and particularly women of childbearing age should be provided information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify with the institution’s healthcare provider for appropriate counseling and guidance.
* Personnel using respirators must be enrolled in an appropriately constituted respiratory protection program provided through Environmental Health & Safety.
* A sign incorporating safety information and the universal biohazard symbol must be posted at the entrance to the areas where infectious biological materials and/or animals are housed or are manipulated. The sign must include the animal biosafety level, general occupational health requirements, PPE requirements, the principal investigator’s name (or other responsible personnel), telephone number, and required procedures for entering and exiting the animal areas. Identification of specific infectious biological materials is recommended when more than one biological material is being used within an animal room.
* Access to the animal room must be limited. Only those personnel required for program or support purposes are authorized to enter the facility.
* All personnel including facility personnel, service providers, and visitors are advised of the potential biohazards (natural or research pathogens, allergens, etc.) and are instructed on the appropriate safeguards.
* Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.
* Gloves should be worn to prevent skin contact with contaminated, infectious and biohazardous materials, and when handling animals.
* Gloves and other PPE should be removed in a manner that minimizes transfer of infectious biological materials outside of the areas where infectious biological materials and/or animals are housed or are manipulated.
* Personnel must wash their hands after removing gloves, and before leaving the areas where infectious biological materials and/or animals are housed or are manipulated.
* Eye, face, and respiratory protection should be used in rooms containing infected animals, as dictated by the risk assessment.
* Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside of the laboratory in cabinets or refrigerators designed and used for this purpose.
* All procedures are carefully performed to minimize the creation of aerosols or splatters of infectious biological materials and waste.
* Mouth pipetting is prohibited. Mechanical pipetting devices must be used.
* Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware, must be developed and implemented. When applicable, principal investigators should adopt improved engineering and work practice controls that reduce the risk of sharps injuries. Precautions must always be taken with sharp items, including:
  + Use of needles and syringes or other sharp instruments in the animal facility is limited to situations with no alternative for such procedures as parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.
  + Disposable needles must not be bent, sheared, broken, directly recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. Used disposable needles must be carefully placed in puncture-resistant containers used for sharps disposal. Sharps containers should be located as close to the work site as possible.
  + Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
  + Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plasticware should be substituted for glassware whenever possible.
  + Equipment containing sharp edges and corners should be avoided.
* Equipment and work surfaces are routinely decontaminated with an appropriate disinfectant after work with an infectious biological material, and after any spills, splashes, or other overt contamination.
* Animals and plants not associated with the work being performed must not be permitted in the areas where infectious biological materials and/or animals are housed or are manipulated.
* An effective integrated pest management program is required.
* All wastes from the animal room (including animal tissues, carcasses, and bedding) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional, local and state requirements.
* All potentially infectious biological materials must be decontaminated using an effective method before disposal.

ABSL-1 Safety Equipment

* A risk assessment should determine the appropriate type of PPE required.
* Special containment devices or equipment may not be required as determined by appropriate risk assessment.
* Protective laboratory coats, gowns, or uniforms may be required to prevent contamination of personal clothing.
* Protective outer clothing should not be worn outside areas where infectious biological materials and/or animals are housed or manipulated. Gowns and uniforms are not worn outside the facility.
* Protective eyewear should be worn when conducting procedures that have the potential to create splashes of microorganisms or other biohazardous materials. Personnel who wear contact lenses should also wear eye protection when entering areas with potentially high concentrations of airborne particulates. Eyeglasses also may not provide adequate side protection from splashes.
* Gloves should be worn to protect hands from exposure to biohazardous materials.
* A risk assessment should be performed to identify the appropriate glove for the task and alternatives to latex gloves should be available.
* All personnel must change gloves when they are contaminated, when integrity of the gloves is compromised, or when otherwise necessary.
* Gloves must not be worn outside the animal rooms.
* Gloves and other PPE should be removed in a manner that prevents transfer of infectious biological materials.
* Do not wash, reuse, or share disposable gloves. Dispose of used gloves with other contaminated waste.
* Personnel must wash their hands after handling animals and before leaving the areas where infectious biological materials and/or animals are housed or are manipulated. Hand washing should occur after the removal of gloves.

Additional ABSL-1 Recombinant Nucleic Acid Requirements

* The containment area shall be patrolled or monitored at frequent intervals.
* All genetically engineered neonates shall be permanently marked within 72 hours after birth, if their size permits. If their size does not permit marking, their containers should be marked. In addition, transgenic animals should contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among non-transgenic animals.
* A double barrier shall be provided to separate male and female animals unless reproductive studies are part of the experiment or other measures are taken to avoid reproductive transmission. Reproductive incapacitation may be used.
* The containment area shall be in accordance with state and federal laws and animal care requirements.
* Animals shall be confined to securely fenced areas or be in enclosed structures (animal rooms) to minimize the possibility of theft or unintentional release.
* When an animal containing recombinant or synthetic nucleic acid molecules or a recombinant or synthetic nucleic acid molecule-derived organism is euthanized or dies, the carcass shall be disposed of to avoid its use as food for human beings or animals unless food use is specifically authorized by an appropriate federal agency.
* A permanent record shall be maintained for the experimental use and disposal of each animal or group of animals.

**Animal Biological Safety Level****-2**

ABSL-2 is used to work with animals that are infected with pathogens, or that also involve biological agents / biological materials that pose a moderate risk to healthy adults / animals / plants and the environment. The ABSL-2 practices and procedures described below are *in addition* to ABSL-1 practices and procedures described above. Access to the animal facility is restricted. All personnel must have the appropriate training to handle infectious biological agents / biological materials and/or animals that are infected with pathogens or be supervised by someone who is trained. Lastly, BSCs or other primary containment equipment must be used when infectious biological agents / biological materials are manipulated or there is potential for aerosols or splashes.

ABSL-2 Standard Practices

* A biosafety protocol specific to the animal facility prepared and adopted in consultation with the animal facility director and appropriate safety professionals is available for reference.
* This biological safety manual and the laboratory biosafety protocol must also be available and accessible. Personnel are advised of potential biohazards and required to read and follow instructions on practices and procedures.
* Consideration should be given to specific biohazards unique to the animal species and biosafety protocol in use.
* A sign incorporating the universal biohazard symbol must be posted at the entrance to areas where infectious biological agents / biological materials and/or animals are housed or manipulated if infectious biological agents / biological materials are present. The sign must include the animal biosafety level, general occupational health requirements, PPE requirements, the principal investigator’s name and names of other responsible personnel, telephone number, and required procedures for entering and exiting the animal areas. Identification of all infectious biological agents / biological materials is necessary when more than one biological agent / biological material is being used within an animal room.
* Security-sensitive biological agent / biological material information and occupational health requirements should be posted in accordance with the institutional policy. Advance consideration should be given to emergency and disaster recovery plans, as a contingency for man-made or natural disasters. The emergency contingency plan should be printed and available in the Animal Care Facility.
* Access to the animal room is limited. Only personnel required for program or support purposes are authorized to enter the animal facility and the areas where infectious biological agents / biological materials and/or animals are housed or manipulated.
* All persons including facility personnel and approved visitors are advised of the potential hazards (physical, naturally occurring, or research pathogens, allergens, etc.) and are instructed on the appropriate safeguards.

ABSL-2 Special Practices

* As indicated by the risk assessment, all personnel are recommended to enroll in a medical surveillance program with appropriate immunizations for biological agents / biological materials handled or potentially present, before entry into animal rooms. When appropriate, a baseline serum sample should be stored**.**
* Procedures involving a high potential for generating aerosols should be conducted within a biosafety cabinet or other physical containment device. When a procedure cannot be performed within a biosafety cabinet, a combination of PPE and other containment devices must be used.
* Restraint devices and practices that reduce the risk of exposure during animal manipulations (e.g., physical restraint devices, chemical restraint medications) should be used whenever possible.
* Decontamination by an appropriate method (e.g., autoclave, chemical disinfection, or other approved decontamination methods) is necessary for all potentially infectious biological agents / biological materials and animal waste before they are moved outside the areas where infectious biological agents / biological materials and/or animals are housed or are manipulated. Such infectious biological agents / biological materials include potentially infectious animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse.
* A method for decontaminating routine husbandry equipment, sensitive electronics, and medical equipment should be identified and implemented.
* Biological agents / biological materials to be decontaminated outside of the immediate areas where infectious biological agents / biological materials and/or animals are housed or are manipulated must be placed in a durable, leak proof, covered container and secured for transport. The outer surface of the container must be disinfected prior to moving biological agents / biological materials. The transport container must have a universal biohazard label.
* An appropriate waste disposal program must be developed and implemented in compliance with applicable institutional, local and state requirements. Autoclaving of content prior to incineration is recommended.
* Equipment, cages, and racks should be handled in a manner that minimizes contamination of other areas.
* Equipment must be decontaminated before repair, maintenance, or removal from the areas where infectious biological agents / biological materials and/or animals are housed or are manipulated.
* Spills involving infectious biological agents / biological materials must be contained, decontaminated, and cleaned up by personnel properly trained and equipped to work with infectious biological agents / biological materials.
* Incidents that may result in exposure to infectious biological agents / biological materials must be immediately evaluated and treated according to procedures described in the biosafety protocol and this safety manual. All such incidents must be reported to the animal facility supervisor, the principal investigator, and the BSO. Medical evaluation, surveillance, and treatment should be provided where appropriate, and appropriate records of potential exposure events must be maintained.

ABSL-2 Safety Equipment

* When personnel are conducting procedures with a potential for creating aerosols, splashes, or other potential exposures to hazardous biological agents / biological materials, properly maintained BSCs, PPE (e.g., gloves, laboratory coats, face shields, respirators, etc.) and/or other physical containment devices or equipment should be used. Such procedures include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, intranasal inoculation of animals, and injection of animals with biological agents / biological materials.
* When indicated by risk assessment, animals should be housed in primary biosafety containment equipment appropriate for the animal species, such as solid wall and bottom cages covered with filter bonnets for rodents or other equivalent primary containment systems for larger animal cages.
* A risk assessment should determine the appropriate type of PPE to be utilized.
* Scrub suits and uniforms should be removed before leaving the animal facility. Reusable clothing is appropriately contained and decontaminated before being laundered. Laboratory and protective clothing should never be taken home.
* Gowns, uniforms, laboratory coats and PPE should be worn while in the areas where infectious biological agents / biological materials and/or animals are housed or manipulated and removed prior to exiting. Disposable PPE and other contaminated waste should be appropriately contained and decontaminated prior to disposal.
* Eye and face protection (mask, goggles, face shield or other splatter guard) should be used for manipulations or activities that may result in splashes or sprays from infectious or other hazardous biological agents / biological materials and when the animal or microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Personnel who wear contact lenses should also wear eye protection when entering areas with potentially high concentrations of airborne particulates. Eyeglasses also may not provide adequate side protection from splashes.

Additional ABSL-2 Recombinant Nucleic Acid Requirements

* While uncommon, select recombinant nucleic acids may be directly infectious in their nascent state. Work conducted with such constructs must be carried out in a BSC with appropriate decontamination after work is completed.
* The containment area shall be controlled and have a locking access.
* Animals of the same or different species, which are not involved in the work being performed, shall not be permitted in the animal area.
* Any incident involving spills and accidents that result in environmental release or exposures of animals or laboratory workers to organisms containing recombinant or synthetic nucleic acid molecules shall be reported immediately to the Animal Facility Director, IBC, National Institutes of Health’s Office of Science Policy (NIH OSP), and other appropriate authorities (if applicable). Reports to the NIH OSP shall be sent, preferably by e-mail to: [NIHGuidelines@od.nih.gov](mailto:NIHGuidelines@od.nih.gov); additional contact information is also available on the OSP website (<http://www.osp.od.nih.gov/>) and through the UWSP risk management website (<http://www.uwsp.edu/rmgt/Pages/ehs/default.aspx>). Medical evaluation, surveillance, and treatment shall be provided as appropriate and written records maintained. If necessary, the area shall be appropriately decontaminated.
* When appropriate and given consideration to the biological agent / biological material handled, baseline serum samples shall be collected and stored for animal care and other at-risk personnel. Additional serum specimens may be collected periodically depending on the biological agent / biological material handled and the function of the animal facility.
* Biological agents / biological materials removed from the animal containment area in a viable or intact state shall be transferred to a non-breakable sealed primary container and then enclosed in a non-breakable sealed secondary container. All containers, primary and secondary, shall be disinfected before removal from the animal facility. Advance approval for transfer of biological agents / biological materials shall be obtained from the Animal Facility Director. Packages containing viable agents may only be opened in a facility having an equivalent or higher level of physical containment unless the agent is biologically inactivated or incapable of reproduction.
* Needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles, or similarly approved biosafety-related activity. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant or synthetic nucleic acid molecules. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Following use, needles shall not be bent, sheared, directly replaced in the needle sheath or guard, or removed from the syringe. Needles and syringes shall be promptly placed in a puncture-resistant sharps container and decontaminated, preferably by autoclaving.
* Appropriate steps should be taken to prevent horizontal transmission or exposure of laboratory personnel. If the agent used as a vector is known to be transmitted by a particular route (e.g., arthropods), special attention should be given to preventing spread by that route. In the absence of specific knowledge of a particular route of transmission, all potential means of horizontal transmission (e.g., arthropods, contaminated bedding, or animal waste, etc.) should be prevented.
  + Animals shall be contained within an enclosed structure (animal room or equivalent) to minimize the possibility of theft or unintentional release and to avoid arthropod access. The special provision to avoid the entry or escape of arthropods from the animal areas may be waived if the biological agent / biological material in use is not known to be transmitted by arthropods.
  + If arthropods are used in the experiment or the biological agent / biological material under study can be transmitted by an arthropod, interior work areas shall be appropriately screened (52 mesh). All perimeter joints and openings shall be sealed and additional arthropod control mechanisms used to minimize arthropod entry and propagation, including appropriate screening of access doors or the equivalent.

**SHARP****S**

The appropriate use of sharps is described in the previous sections discussing the requirements for the BSLs. The safe use of sharps in the laboratory is essential to help limit potential exposures to infectious biological agents / biological materials in the laboratory, so further discussion is warranted. The term sharps include syringes, razor blades, scalpels, scissors for necropsies, glass Pasteur pipettes, broken slides or glassware, and other items that could puncture or cut the skin. These items should only be used with potentially infectious biological agents / biological materials when there are no other options and engineering controls are used. A risk assessment will be conducted to determine if additional engineering controls are needed to make the use of sharps safer.

* All sharps are discarded in labeled, puncture-resistant sharps containers
* Sharps containers should never be filled past the fill line (~⅔ of the container)
* Needles must not be directly recapped, bent, sheared, broken, removed from disposable syringes, or otherwise manipulated
* When possible, use needles with engineering controls such as safety glides
* Do not pick up broken glass by hand
* Do not use glassware if its integrity has been compromised (e.g., chipped or cracked)

**BIOLOGICAL SAFETY CABINET (****BSC)**

BSCs provide the primary containment when working with potentially infectious biological agents. UWSP has various BSC models produced by various manufacturers. In general, the BSCs at UWSP campuses are Class II, which means air is pulled into the front grill and the air is then exhausted through a certified HEPA filter before being circulated back onto the work surface and into the room. Since air is recirculated back into the room, the BSCs at UWSP campuses cannot be used with chemicals that create hazardous vapors unless the BSC is fitted with a charcoal filter, other filter capable of capturing the vapors, or a canopy exhaust. Maintenance of BSCs is described in Appendix A entitled Facilities, Safety Equipment, and Maintenance, on Page 62. If a BSC is not functioning properly, it may not provide an effective protection for personnel. If this happens, do not continue to use the BSC and call Environmental Health and Safety immediately. It is essential that work practices do not compromise the containment of a BSC.

To ensure maintenance of containment the following practices must be followed:

* Cabinet blowers should be operated at least 3 to 5 minutes before beginning work
* Gauges should be within the operable range listed on the face of the BSC
* The work surface, interior walls, and interior surface of the window should be wiped with appropriate disinfectant (typically either 10% bleach or quaternary Lysol)
* If disinfectant is corrosive or leaves a film, all surfaces must be rinsed with sterile water
* Equipment and supplies needed within the BSC during operation must be sprayed with appropriate disinfectant before placing them in the BSC to maintain sterility
* Do not place any equipment, supplies, or papers on the front grill of the BSC
* All operations should be performed on the work surface at least 4 inches from the inside edge of the front grille
* Equipment that causes turbulence (e.g., vortexes) should be placed in the back ⅓ of the work surface
* Clean items should be kept separate from contaminated items
* Once work commences:
  + Movements of others near/around the BSC must be kept to a minimum to maintain the air barrier of the BSC
  + Limit arm movement across the air barrier of the BSC
  + Move arms in and out slowly, perpendicular to the sash of the BSC
  + All materials, equipment, and containers must be surface decontaminated with appropriate disinfectant before being removed from the BSC
  + Any solid wastes generated in the BSC must be collected and sealed in an appropriate container or biohazard bag, which is then sprayed with disinfectant before being removed from the BSC to place in biohazardous waste collection
  + Any liquid wastes generated in the BSC must be aspirated through a vacuum flask (or similar) containing disinfectant, followed by aspiration of decontaminant to clear the aspiration tubing; an appropriate in-line filter must be installed between the flask and vacuum equipment to prevent contamination of mechanics; wastes must contact the disinfectant an appropriate amount of time before the vacuum flask is emptied, which also requires surface decontamination upon removal from the BSC
* Disinfect the work surface, interior walls, and interior surface of the sash with appropriate disinfectant when all equipment has been removed and all work is complete
* Check the drip pan under work surface for cleanliness; decontaminate as needed
* Lower the sash, turn off the blower, and turn on the UV-light timer (if applicable)

**BIOHAZARDOUS SPILL** **PROTOCOLS**

Spills involving potentially infectious biological agents / biological materials / recDNA/RNA must be contained, decontaminated, and cleaned up by personnel properly trained and equipped to handle them. Spills can be small or large, and with low or elevated risk group designations. All potentially biohazardous spills must be remedied in adherence to EPA and Federal guidelines, regardless of size or risk group. The information below includes the general spill cleanup procedures for UWSP campuses. Laboratory / classroom / alternate area-specific modifications to these procedures must be justified and approved by the IBC. Disinfectants are specific to each laboratory / classroom / alternate area and based upon the biological agents / biological materials in use. A table of recognized disinfectants is included at the end of this section for reference. Each laboratory / classroom / alternate area must have a spill kit for efficient cleanup and procedures posted around the laboratory. This kit must have an appropriate disinfectant, absorbent material, PPE, and spill notification signage.

**Spills involving a low risk group material requiring BSL-1 practices**

* Alert fellow personnel if they are working in the same laboratory at the time of the spill, as they may be able to provide assistance
* Disinfect and change gloves if they are potentially contaminated; replace PPE as needed
* Cover the spill with paper towels or other absorbent material to absorb the spill (minimizes aerosolization and spread)
* Pour appropriate disinfectant gently over the covered spill, working from the outside inwards in a circular fashion
  + **NOTE:** Pouring disinfectant *directly* over a biohazardous liquid generates aerosols which may still remain infectious and increase the area of contamination.
* Wait at least the minimum contact time (usually 10-20 minutes) for the given concentration and type of disinfectant used to penetrate through the contained spill
* Remove the absorbent materials and place them in a biohazard bag for disposal
* Rinse the area with water if disinfectant is corrosive or leaves a film (ethanol is **not** an EPA-approved spill cleaner in many cases). It is recommended that a 10% bleach solution or quaternary ammonium be used for spill cleanups, and wipe down with water afterward to prevent corrosion/film.
* After properly removing PPE, wash hands with soap and water before exiting the laboratory
* Notify the principal investigator of the spill, as a possible exposure may have occurred. The incident should be reported to the IBC within 24 hours.
* \**If the spill occurred within a BSC, follow the procedures of additional BSC clean-up outlined on the next page, including decontamination of the drip-tray.*

**Blood spills or spills with high organic content which are *not known* to harbor pathogens**

* Wear gloves and other appropriate personal protective equipment (PPE); change them if they are potentially contaminated to minimize spread
* Absorb blood with paper towels or disinfectant soaked towels and place in a biohazard bag
  + Collect any sharp objects with forceps or other mechanical device and place in a sharps container
* Spray the spill site with 10% household bleach and allow to air-dry for 15 minutes
* Wipe the area with disinfectant soaked paper towels
* Discard all disposable materials used to decontaminate the spill and any contaminated PPE into a biohazard bag
* Decontaminate any reusable items with disinfectant
* Wash hands and exposed skin areas with antiseptic soap and water
* Notify the principal investigator of the spill, as a possible exposure may have occurred, and report the incident to the IBC within 24 hours.

**Biohazardous spill inside a BSC requiring BSL-2 practices**

* + Alert fellow personnel if they are working in the same laboratory at the time of the spill, as they may be able to provide assistance
  + Disinfect and change gloves if they are potentially contaminated; replace PPE as needed
  + Keep the BSC running
  + Cover the spill with paper towels or other absorbent material to absorb the spill (minimizes aerosolization and spread)
    - *\*If necessary, flood the area, and later the drip-tray with appropriate disinfectant and allow the disinfectant to sit for 15-30 minutes.*
  + Pour appropriate disinfectant gently over the covered spill, working from the outside inwards in a circular fashion
  + Wait at least the minimum contact time for the concentration and type of disinfectant used to penetrate through the contained spill (typically 15-30 minutes)
  + Remove the absorbent materials and place them in a biohazard bag for disposal
  + Clean the area again with disinfectant, allowing it to air dry for 20 minutes
  + Check the drip pan for liquid; if present, repeat disinfection steps
  + Rinse the area with water if disinfectant is corrosive or leaves a film
  + After properly removing PPE, wash hands with soap and water before exiting the laboratory
  + Notify the principal investigator of the spill, as a possible exposure may have occurred, and report the incident to the IBC within 24 hours.

**Spill inside a centrifuge requiring BSL-2 practices**

* + If upon opening a centrifuge a spill is suspected, close the lid again and alert fellow personnel to evacuate the room for at least 30 minutes to allow aerosols to settle
    - Place signage on the laboratory door indicating that a spill has occurred and entry is temporarily prohibited
  + If instead a spill is suspected DURING operation of the centrifuge, select the emergency break (if the instrument has one) then/or unplug the machine and carry out the evacuation with temporary signage as indicated in the previous bullet
  + Replace any PPE as it may be contaminated
  + Upon re-entry, transfer the rotor or safety cups to the BSC for submersion in a non-corrosive disinfectant for 30 minutes
  + Use a forceps or tongs to remove any sharps that may have been generated in the centrifuge and transfer them to a sharps biohazardous waste container
  + Spray the inside of the centrifuge with a disinfectant, allow it to air dry for 10-20 minutes, then wipe the inside and outer surfaces of the centrifuge with disinfectant-treated paper towels
  + Carefully open the rotor or safety cups and transfer leaked containers into the disinfection for further submersion (contact time per disinfectant type and concentration)
    - Aspirate off any liquids that may still be in the rotor or safety cup, followed by some disinfectant to clean the line, then re-submerge the rotor or safety cup to complete the disinfection
  + If the disinfectants leave a film, clean off all surfaces with sterile water
  + Notify the principal investigator of the spill, as a possible exposure may have occurred, and report the incident to the IBC within 24 hours.

**Biological spill outside of a BSC requiring BSL-2 practices**

* + Alert fellow personnel if they are working in the same laboratory at the time of the spill, as they may be able to provide assistance, or they may be advised to leave and deter other personnel from entering the space (minimizes cross-contamination and spill spread)
    - Evacuate the area for at least 15 minutes (30 minutes if involving a biological agent or human-derived materials containing potentially infectious substances) along with other nearby personnel and post signs indicating the biological spill clean-up is in progress, warning that entry is temporarily prohibited
      * If the biological materials spilled are not fully characterized, err on the side of caution and vacate the area for the full 30 minutes.
    - You may contact the principal investigator if you are uncertain if you can properly contain the spill on your own
      * If this is the case, you must alert other personnel in the area to leave the area, properly remove contaminated PPE, post signage not to enter the space due to the spill, and wash your hands before leaving the laboratory
  + Disinfect and remove any contaminated PPE and place them in a biohazard bag; replace PPE as needed
  + Cover the spill with paper towels or other absorbent material to absorb the spill (minimizes aerosolization and spread)
  + Pour appropriate disinfectant gently over the covered spill, working from the outside inwards in a circular fashion
  + Wait at least the minimum contact time for the concentration and type of disinfectant used to penetrate through the contained spill (typically 15-30 minutes)
  + Remove the absorbent material and place in a biohazard bag for disposal
    - If there are any sharps potentially in the spill, use a forceps or tongs to manipulate the absorbent material during clean-up
  + Spray the area and surrounding area again with disinfectant and allow it to air-dry for 15 minutes
  + Wipe down the area with disinfectant-soaked absorbent towels
  + Rinse the area with water if disinfectant is corrosive or leaves a film
  + After properly removing PPE, wash hands with soap and water before exiting the laboratory
  + Notify the principal investigator of the spill, as a possible exposure may have occurred, and report the incident to the IBC within 24 hours.

In the event of gross biological contamination in a laboratory, the laboratory must be secured and appropriate signage placed at the entrances for at least 30 minutes. After aerosols have settled, a large surface disinfection must be performed with the assistance of Risk Management and Environmental Health and Safety. If surface disinfection is not a viable option, Risk Management will work with an outside consultant or company (e.g., Veolia, CPR restoration, UW-Laboratory of Hygiene) to perform a gas decontamination of the space.

Sample disinfectants are indicated below; other disinfectants may be plausible. Contact the IBC for questions or alternatives. Feel free to also review this information via the CDC: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/disinfection-methods/chemical.html>.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Example Disinfectants & Their Properties**  [obtained through CITI training modules on biosafety, decontamination, as well as information available through the EPA and CDC] | | | | | |
| Options for Types of Disinfectant | | Effective Concentration | Recommended Duration / Contact Time | Range of Action  *[Target Microorganisms, Biomolecules, Etc.]* | General Notes & Solution Drawbacks |
| 1) | Chlorine [i.e., household bleach] | Minimum of 500 ppm | As low as 5, as high as 30, depending upon the substance treated *AND* how freshly made the bleach solution is | Broad Spectrum, Including:  Vegetative bacteria  Enveloped (lipid viruses)  Non-enveloped (non-lipid)  viruses  Bacterial Spores | Corrosive  Inactivated by organic material  Does not have a long shelf-life  Loses concentration with exposure to light and air, thus working solutions don't have a long shelf-life |
| 2) | Iodine | 75 to 1600 ppm | Seconds to minutes, but leaves significant residue | Broad Spectrum, Including:  Vegetative bacteria  Enveloped (lipid viruses)  Non-enveloped (non-lipid) viruses  Bacterial Spores | Longer shelf life  Inactivated by organic material  Concentrated solutions are less effective as Iodine will be bind to itself or carrier molecules |
| 3) | Alcohol | 70 to 85 percent (some species of microbes as low as 30%, but not common) | Dependent upon species targeted, anywhere from 10 seconds to 1 hour | Limited Spectrum, Including:  Vegetative bacteria  Enveloped (lipid) viruses  Some non-enveloped (non-lipid) viruses | Ethyl Alcohol  Isopropyl Alcohol  Flammable  Evaporation rate due to vapor pressure may require repeated application |
| 4) | Quaternary Ammonium Compounds [i.e., Lysol] | 0.1 to 2.0 percent | As low as 10 minutes, or select cases 5 seconds, but if be used >10 minutes, will require rinsing to reduce films | Limited Spectrum, Including:  Vegetative bacteria  Enveloped (lipid viruses) | Low-level disinfectant  Long shelf life  Inactivated by organic material  Modern formulations combined with other disinfectants are more effective |
| 5) | Phenol | 1.0 to 5.0 percent | Generally 10 minutes depending upon the solution concentration | Limited Spectrum, Including:  Vegetative bacteria  Enveloped (lipid) viruses  Some non-enveloped (non-lipid) viruses | Long shelf life  Corrosive  Can leave residue  Tuberculocidal and fungicidal  Hard water can affect effectiveness |
| 6) | Formaldehyde | 0.2 to 8.0 percent | Approximately 15 minutes at lower concentrations to disinfect but as a sample fixative >24 hours | Broad Spectrum, Including:  Vegetative bacteria  Enveloped (lipid viruses)  Non-enveloped (non-lipid) viruses  Bacterial Spores | Effective in presence of organic material  Sterilant, fixative  Diminished activity in colder temperatures  Non-corrosive  Suspect carcinogen, toxic at low levels |
| 7) | Hydrogen Peroxide | 3.0 to 25.0 percent | As low as 1 minute, usually up to 10 minutes, fairly reactive solution | Broad Spectrum, Including:  Vegetative bacteria  Enveloped (lipid viruses)  Non-enveloped (non-lipid) viruses  Bacterial Spores | Higher concentrations are sporicidal  Strong oxidizer, higher concentrations can burn skin |

**TRANSPORT** **OF BIOLOGICAL AGENTS / BIOLOGICAL MATERIALS / recDNA/RNA**

Transport of biological agents, biological materials, and recDNA/RNA can take several forms. Transport can refer to the process of transporting biohazardous waste to an autoclave, moving biological agents or samples between laboratories, or even shipping materials. When moving biohazardous trash, biological agents, biological materials, or recDNA/RNA, the outer surfaces of the container or bag must be disinfected; then the container/bag should be placed in a leak proof, covered container labeled with a biohazard symbol for transport to the desired destination. After being autoclaved, sharps containers are sealed, collected in a hard-walled box for transfer to a designated chemical or biological stockroom and/or autoclave facility, and disposed of through Veolia contract agents.

The transport (shipment) of infectious biological agents, or biological materials suspected to contain biological agents, is regulated by the United States Department of Transportation, the International Civil Aviation Organization (ICAO), the International Air Transport Association (IATA), and by foreign countries. Biological agents (or biological materials suspected to contain them) are regulated as biohazardous substances and must meet specific shipping criteria. These regulations are designed to protect workers, first responders, the general public, and the environment from exposure by using strict packaging, labeling, package marking, and shipping paperwork requirements. The applicable regulations are:

* US Postal Service- 39 CFR Part 3 and 20
* OSHA- 29 CFR Part 1910. 1030
* ICAO- Technical Instructions for the Safe Transport of Dangerous Good by Air
* IATA- Dangerous Goods Regulations
* Public Health Service- 42 CFR Part 72
* US Department of Agriculture- 7 CFR Part 340
* US Department of Transportation 49 CFR 171-179

In addition to these requirements, there are also country specific transfer, import, and export requirements. In the United States there are multiple categories of permits that might be required to import, export, or transfer biological agents or biological materials (possibly also recDNA/RNA). While some of the regulations use the term importation, they are also for the transport of items between states, locations, and principal investigators (even at the same institution).

* Importation of Etiological Agents of Human Disease- 42 CFR Part 71
* Importation of Etiological Agents of Livestock, Poultry and Other Animal Diseases and other Materials Derived from Livestock, Poultry and Other Animal- 9 CFR Part 121
* Importation of Plant Pests- 7 CFR Part 330
* Export of Etiological Agents of Human, Animal, and Plant Related Materials- 5 CFR Parts 730-799, 49 CFR 171-179

**SHIPPING, RECEIVING****, AND STORAGE**

Due to the requirements for transport of biological agents and biological materials, it is essential that the personnel performing the packaging, labeling, and receiving duties for a laboratory are appropriately trained. All individuals shipping potentially infectious biological agents / biological materials must be certified to ship biohazardous substances. This training is provided through the University of Wisconsin-Stevens Point, Risk Management, and periodic recertification is required. Additional training is required with the online [CITI Program](https://about.citiprogram.org/en/homepage/). Very limited shipping of biological agents / biological materials is authorized on campus; anyone wishing to complete this training or requiring assistance with biohazardous shipments off-site should coordinate with Walter Clark, the director of Risk Management and Environmental Health and Safety and the IBC. Specific packing requirements for shipment types can be found in Appendix C of BMBL.

* Shipping
  + Determine if any permits are required for the biological agents / biological materials being shipped
  + Obtain relevant permits and training certification
  + Determine shipping category
  + Acquire appropriate shipping containers and labels
  + Locate courier service
  + Notify recipient of your intent to ship
  + Fill out shipping paperwork and set pickup time
  + Package the materials appropriately; include permits and a description of contents
  + Send tracking number to the recipient
  + Confirm the receipt of materials by the recipient
* Receiving
  + Add biological agents / biological materials to the biosafety protocol, with approval from the IBC and describe its use if new research is conducted with this biological agent / biological material **(must be done prior to receiving any materials.)**
  + Obtain any required permits before the biological agents / biological materials are purchased, or if no fees are charged, before the shipment is sent
  + Request a tracking number from the shipper
  + Obtain the package and open inside a BSC if it contains potentially infectious biological agents / biological materials
  + Verify the contents of the package and send confirmation to shipper
  + Log materials in laboratory inventory system

All bacteria, viruses, cell lines, samples, and materials should be logged in a laboratory specific inventory. This inventory can be in electronic or a paper format. At minimum, this inventory should include the recipient’s name, the substance’s name, amount of the substance received, the date, descriptive information including applicable biosafety protocol information (title, protocol number), antibiotic resistances, and name of the individual who entered it into the inventory.

**ABBREVIATED LABORATORY MOVES****, CLOSURES, AND DECOMMISSIONING POLICIES**

UWSP is committed to the health and safety of its students, faculty, staff, and visitors, as well as the surrounding community and environment in which UWSP personnel conduct their studies, scholarship, and work. The goal of these policies is to ensure safe and compliant transitions in laboratory occupancy. More specifically, in order to protect others when a principal investigator vacates laboratory spaces, these policies require that none of the principal investigator’s research materials may be left behind in the laboratory. Further, these policies require that the investigator assures that proper laboratory decommissioning has been conducted, e.g., that all laboratory equipment, fixtures, furniture, and spaces are properly cleaned and decontaminated.

Principal investigators, departments, and project managers are equally responsible for complying with advanced notification and other requirements. These overlapping requirements are necessary because—depending on the situation—only one of these entities will have the ability to comply with these policies.

These policies will be administered by Environmental Health and Safety (EH&S). A checklist for laboratory moves and closures is available on the [UWSP Biosafety website](https://www3.uwsp.edu/acadaff/orspdev/Pages/What-is-IBC.aspx), along with the Potential Contaminants Of Concern (PCOC) Declaration Form and appropriate biosafety notice of decontamination signs.

Laboratory Move Guidelines—Biosafety

***Note:*** *The following guidelines are a portion of the overall laboratory move guidelines available through EH&S. They can also be accessed on the* [*UWSP Biosafety website*](https://www3.uwsp.edu/acadaff/orspdev/Pages/What-is-IBC.aspx)*.*

* Use the move as an opportunity for housecleaning with reduction of biohazardous materials prior to the move. Include materials left behind by previous researchers in your determination of what will be disposed of and what will be moved.
  + Biological materials left behind:
    - Dispose of biological wastes (infectious and potentially infectious materials) as was done routinely for that location through autoclaving, chemical disinfection, etc. The chemical disinfectant needs to be efficacious for the materials to be disinfected and appropriate contact times must be used.
    - Render recombinant organisms (even those requiring BSL-1 practices) inactive prior to disposal (usually through autoclaving or chemical disinfection).
    - Clean and decontaminate surfaces (lab benches, sinks, etc.) with an efficacious disinfectant.
    - Empty all materials from equipment (e.g., biosafety cabinets, incubators, freezers) and decontaminate equipment thoroughly with an efficacious disinfectant. Affix decontamination biosafety notices over biohazardous materials labels.
    - Dispose of biological sharps through usual collection containers for the building; decontaminate non-medical sharps (if potentially infectious) and package appropriately.
    - Cover biohazard signage on equipment that has been decontaminated and remove door signs when biohazards are no longer present.
    - It is optimal to have a walk-through with the building manager / EH&S / BSO as part of a lab close-out and complete a decommissioning checklist.
  + Vehicles and equipment used for move:
    - Personal vehicles are not allowable.
    - If commercial handlers or vehicles are used, the federal (DOT) regulations for hazardous materials shipping apply.
    - Use of UW vehicles by UW personnel on campus is exempt from the DOT regulations, but safe transport is still the primary concern. Use the precautions outlined below for safe transport of biological materials.
    - For short distances between buildings, moving materials on carts *might* be appropriate. Use carts with sides or lips to prevent packages, boxes, etc. from sliding off.
* Use this time to create or curate an inventory of materials. Identify all biological materials stored in labs and other locations (e.g., cold rooms, storage areas, shared equipment and spaces).
  + Biological materials to be moved:
    - Use hazard communication including signage on each container or piece of equipment with hazardous contents (e.g., biohazard stickers on containers with infectious and potentially infectious materials). An itemized list of contents is recommended.
    - Include a spill kit (e.g., absorbent, disinfectant, personal protective equipment) with each load and have a spill protocol that details how spills should be handled.
    - For infectious or potentially infectious materials, use leak-proof primary and secondary containers, sufficient absorbent material to soak up all liquids present, and apply surface disinfection on containers and hazard signage. Packaging that meets the DOT HazMat regulations is preferred for these materials and is required if commercial carriers or vehicles are utilized. Persons preparing the packages for transport by commercial carriers must be trained and certified for HazMat shipping.
    - Transfer biological samples in durable plastic screw-cap tubes whenever possible. Glass tubes or snap-cap microfuge tubes can be placed inside larger plastic screw-cap tubes to minimize chances of breakage or leakage.
    - Examples of packaging material include petri plates, tubes, and tubes in racks which can be placed in plastic Ziploc bags surrounded by generous amounts of absorbent material (e.g., paper towels, cotton batting) within secondary leak-proof containers (e.g., plastic or Styrofoam boxes or coolers) that are sealed with tape. Package materials tightly enough with absorbent or partitioning materials (to separate inner containers) to minimize shifting of contents.
    - To maintain cold temperatures in coolers, cold packs are preferred over dry ice since containers with dry ice cannot be sealed tightly. Explosions and injuries can result if containers holding dry ice are taped tightly closed instead of being vented.
    - Empty and drain all equipment such as water baths, incubators, etc., and disinfect them prior to the move. Decontaminate centrifuges (chamber and rotors) and remove rotors for the move. In general, follow the manufacturer’s recommendations for moving equipment safely.
    - Biosafety cabinets (BSCs) and laminar flow hoods used for BSL-1 and BSL-2 materials must be decontaminated and certified before any of these hoods can be serviced, relocated, reused, or surplussed.
    - Freezers and refrigerators should optimally be emptied of their contents, but moving this equipment intact is possible over short distance. All contents must be in sealed unbreakable containers and the unit must remain closed, locked if possible, and sealed (e.g., with cables). All loose items must be placed in boxes or fixed in position to avoid shifting of contents that could result in breakage and spills. **Note: freezers and refrigerators containing regulated biological materials may not be transported intact if commercial carriers are used since this method does not meet the DOT requirements for packaging.**
    - Animal transportation should be determined with conferral of the IACUC.
    - Select biological agents (and/or their toxins) require all of the precautions as outlined above in addition to security requirements for safe transport. Only authorized users can handle these agents/toxins and authorized users must accompany them at all times. Chain of custody forms need to be completed.
  + Move into the new location:
    - Check for spills and equipment damage as you unload and move into new lab spaces.
    - Post new signage with startup and use of materials in new locations.
    - Principal investigators will need to update locations by amending their biosafety protocols. See the [UWSP Biosafety website](https://www3.uwsp.edu/acadaff/orspdev/Pages/What-is-IBC.aspx) for guidance and additional information on amending lab-specific biosafety protocols.

Applicability of these Policies:

* Research and teaching laboratories owned by UWSP campuses or occupied by UWSP students, faculty, or staff require adherence to these policies.
* Laboratories that use chemicals, radioactive materials, biologicals, human pathogens, controlled substances, compressed gases, large equipment, mercury containing monitors, etc. require adherence to these policies.
* Laboratories or ancillary research spaces (e.g., cold rooms, freezers in hallways) that are vacated by a principal investigator require adherence to these policies.
* Laboratory space that is to be reused by a different principal investigator, as well as laboratory space that is to be converted for another use, requires adherence to these policies.
* Movement of safety critical equipment requires adherence to these policies.

Background on Policy Necessity:

* EH&S oversight of laboratory decommissioning and transfer ensures transportation and licensing compliance. If EH&S is not contacted in advance of a laboratory closure, there is a high risk of unsafe and/or noncompliant transport of research materials.
* The U.S. Environmental Protection Agency (EPA) generally requires:
  + Removal of all chemicals within three days of vacating a laboratory.
  + Prior to vacating a laboratory, laboratory personnel (who are most knowledgeable) must properly label and/or identify all remaining chemicals, samples, and containers.
* The U.S. Nuclear Regulatory Commission requires removal of all radioactive materials and waste prior to vacating a laboratory. No radioactive material or waste may be unsecured.
* The U.S. Drug Enforcement Agency (DEA) and the State of Wisconsin requires removal of all controlled substances prior to vacating a laboratory. No controlled substance may be unsecured.
* The State of Wisconsin requires removal of all human pathogens and infectious waste from research with human pathogens prior to vacating a laboratory.
* Laboratory equipment, fixtures, furniture, and space that has not been properly cleaned and decontaminated may pose a hazard to EH&S staff, movers, construction and renovation personnel, and future occupants.
* Research materials (e.g., chemicals, biologicals, radioactive materials, needles) left in a vacated laboratory pose hazards to EH&S staff, hazardous waste contractors, construction and renovation personnel, and future occupants. These are extreme hazards when such materials are unlabeled, unidentified, unstable, improperly stored, contaminated, or improperly contained. When unsecured in a vacant laboratory, these research materials are also at risk of theft, diversion, and misuse.
* Research materials that are not promptly removed from a vacated laboratory are ineligible for redistribution or recycling, making disposal the only viable option. Disposal costs are dramatically more expensive than recycling/redistribution costs due to extra characterization and necessarily conservative handling.
* To ensure safety, safety critical equipment must be certified in place. Prior to use, EH&S must recertify all safety critical equipment that has been moved.

The principal investigator and his/her laboratory personnel are primarily responsible for complying with this policy because they are the most knowledgeable (and may have the only knowledge) of the identity, characteristics, and hazard of materials and contamination in their laboratory / space.

Principal Investigator Responsibilities

* **30 Day Notification of Laboratory Vacancy**
  + To ensure proper characterization and disposition of research materials and decontamination of laboratory equipment, fixtures, furniture, and space, principal investigators must notify EH&S 30 days prior to vacating laboratory spaces. EH&S notification is required even if only a single room is to be vacated, and even if the space is to be used by another principal investigator.
* Ensure the safety of materials and equipment, including the safety and compliance of materials and equipment left behind in a vacated laboratory, even if the laboratory is to be used by another principal investigator.
* Adhere to established EH&S procedures for safe and compliant disposal and decontamination of research materials. If these procedures are not followed, EH&S will arrange for the proper disposal and decontamination, as deemed necessary. The costs of these activities, including labor charges to properly segregate and label hazardous materials, will be charged directly to the principal investigator.
* Ensure that research material cleanouts are performed by staff knowledgeable of hazards and trained in all required safety disciplines.
* Notify EH&S whenever they plan to move any of the following safety critical equipment, even if the move is across a room or from one room to another:
  + autoclaves, automated film processors, biological safety cabinets, clean benches (horizontal or vertical laminar flow), compressed gas manifold delivery systems, electron microscopes, ethylene oxide sterilizers, fume hoods, gamma counters (or gamma detectors), glove (isolation) boxes, high magnetic field equipment, lasers (class IIIb or IV), liquid scintillation counters (LSC), refrigerators, freezers, X-ray equipment
* Notify IBC of applicable biosafety protocols requiring closure.

Department / Division Chairs & Building Manager Responsibilities

* **30 Day Notification of Laboratory Vacancy**
  + To ensure proper disposal of research materials and decontamination of laboratory equipment, fixtures, furniture and space, departments must notify EH&S 30 days prior to vacating laboratory space. EH&S notification is required even if only a single room is to be vacated, and even if the space is to be used by another principal investigator.
* Absorb the costs of decontamination and disposal of research materials in situations where there has been a failure to meet the requirements listed in the principal investigator responsibilities sub-section, if those costs cannot be recovered from the principal investigator.
* Secure written approval from EH&S and the office of the Dean before reassigning vacated laboratory spaces.
* Secure written approval from EH&S before initiating construction or renovation of vacated laboratory spaces.
* Ensure that research material cleanouts be performed by staff knowledgeable of hazards and trained in all required safety disciplines, including temporary hires on an as needed basis.

Biosafety-Related Activity Manager Responsibilities—Facility Services

* **60 Day Notification of Laboratory Vacancy:**
  + To ensure proper disposal of research materials and decontamination of laboratory equipment, fixtures, furniture, and spaces, biosafety-related activity managers must notify EH&S 60 days prior to vacating laboratory spaces. EH&S notification is required, even if only a single room is to be vacated, and even if the space is to be used by another principal investigator.
* Absorb the costs of laboratory renovation projects that relate to decontamination and research material disposal.
* Ensure that vacated laboratory space is not re-occupied without prior written approval from EH&S.
* Ensure that construction or renovation does not commence in vacated laboratory spaces without prior written approval from EH&S.

EH&S Responsibilities

* When a principal investigator vacates laboratory spaces, EH&S is responsible for verifying that the space is free of hazardous materials and contamination. EH&S will complete this verification in a timely manner, and will provide a written approval to the department (for new occupancy) or project manager (for space to undergo construction/renovation).
* EH&S staff will provide detailed instructions and guidance to principal investigators and their staff in advance of all laboratory moves, closures, and decontamination, including requirements for labeling and identification of research materials.
* EH&S staff will evaluate and provide guidance for the movement of research materials. If the materials in question are to be moved on city streets and lab staff are not trained to properly package and/or ship these items, EH&S will assist in this process. Each principal investigator will be responsible for the cost of the shipping containers as well as all incurred shipping charges.
* EH&S staff will pay for the removal and ultimate disposal of all properly labeled and classified research materials. If research materials are inappropriately left after the space is vacated, EH&S will arrange for the proper disposal and decontamination. The costs of these activities, including labor charges to properly segregate and label hazardous materials, will be charged directly to the principal investigator.

Additional Resources & References

* ANSI/AIHA Z9.11-Laboratory Decommissioning Guidelines from NIH
* Biosafety in Microbiological and Biomedical Laboratories, 5th Edition
* Committee on Prudent Practices for Handling, Storage, and Disposal of Chemicals in Sciences, Mathematics, and Applications, National Research Council, 2007. Prudent Practices in the Laboratory: Handling and Disposing of Chemicals, National Academy Press: Washington, D.C.
* EPA Environmental Management System Standard-40 CFR 262.105(b)(8)
* OSHA Laboratory Standard 1910.1450 (Occupational Exposure to Hazardous Chemicals in the Lab)-1910.1450

**HEALTH MANAGEMENT** **PROGRAM**

A safe and healthy working environment is essential when conducting biosafety-related activities. This environment is created collaboratively between the institution, principal investigator, personnel, and the Environmental Health and Safety Department. In the event of an incident, personnel must be provided optional medical surveillance, as appropriate, and offered available immunizations for biological agents / biological materials handled or potentially present in the laboratory / classroom / alternate site. Additional services may also be provided at student health services; preventative health equipment assessment is also available as coordinated through Environmental Health and Safety.

Personal health status may impact an individual’s susceptibility to infection or their ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel, particularly women of childbearing age, should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution’s healthcare provider (a confidential resource) for appropriate counseling and guidance.

Recognizing if an incident could result in a potential exposure is a critical evaluation when conducting biosafety-related activities. A potential laboratory exposure occurs when any potentially infectious biological agents / biological materials / recDNA/RNA come into contact with the eyes, mouth, other mucous membranes, or non-intact skin (i.e., wounds, cuts, etc.). Examples of activities which may result in a potential exposure include, but are not limited to, needle sticks, cuts, animal bites, aerosol exposure, mucosal exposure, ingestion, PPE failure or removal error, BSC failure, or a spill outside of primary containment. In the laboratory, classroom, or alternate site, personnel may be working with high concentrations of biological agents / biological materials / recDNA/RNA, and it is possible for them to be infected through a different route than what would normally occur in nature. The principal investigator and the IBC should be notified as soon as possible after any exposure incident occurs in the laboratory / classroom / alternate site. Biosafety Incident Report forms are available on the biosafety website.

It is important that personnel understand the necessary actions that should be taken following a potential laboratory exposure. Knowledge of these steps helps ensure that the appropriate medical treatment, prophylaxis, and/or post-exposure evaluations are utilized to prevent infection.

* In the event of a needle stick, cut, animal bite, or similar sharps exposure:
  + Stop work immediately
  + Provide immediate first-aid, if trained
  + Squeeze wounds to flush blood (decreases, but does not eliminate, the entrance of the biological agent / biological material / recDNA/RNA)
  + Wash the affected areas with disinfectant/soap for 15 minutes
  + Stop the bleeding
  + Report the incident to the principal investigator and IBC
  + Seek medical follow-up as warranted
  + Complete medical surveillance to evaluate whether or not symptoms develop
* In the event of a liquid-to-eye or other mucous membrane exposure:
  + Stop work immediately
  + Proceed to an eyewash station to flush the eyes for 15 minutes
    - If oral contact occurred, continuously rinse the oral cavity instead, taking care not to ingest any solution
  + Report the incident to the principal investigator and IBC
  + Seek medical follow-up as warranted
  + Complete medical surveillance to evaluate whether or not symptoms develop
* In the event of an aerosol exposure:
  + Stop work immediately
  + Leave the laboratory using the proper exit procedures
  + Report the incident to the principal investigator and IBC
  + Seek medical follow-up as warranted
  + Complete medical surveillance to evaluate whether or not symptoms develop

It is essential for you to know the signs and symptoms of the potentially infectious biological agents, biological materials, or recDNA/RNA you are working with. Each laboratory must train their personnel on this information. Any potential exposure to infectious biological materials must be immediately evaluated and treated according to the procedures described in the corresponding biosafety protocol; minimally, all exposure events must include the items listed below. All such incidents must be reported to the principal investigator and IBC. Medical evaluation, surveillance, and treatment will be provided, and appropriate records of such incidents must be maintained.

* Development of symptoms
  + Notify the principal investigator and IBC immediately
  + Seek medical treatment

**EMERGENCY** **RESPONSE**

It is up to each principal investigator to ensure that their personnel are appropriately trained to deal with an emergency. Below are basic emergency procedures when working in the laboratory / classroom / alternate site should biosafety level-2 practices be warranted. However, they should be modified for each laboratory to address the unique nature of the work being performed. The emergency procedures should be posted inside the laboratory / classroom / alternate site in multiple areas for reference alongside an emergency contact list. Incident Report forms should be completed following the emergency response and submitted to the IBC within 24 hours of the incident.

* Fire
  + In the event of a fire in the laboratory, stop all work and call 911
  + If you are trained to use a fire extinguisher and feel comfortable putting out the fire, do so using the closest fire extinguisher; then call 911 (you may not be trained to see all risks which may still be present, even if the fire is no longer visible)
  + If a fire alarm sounds, suspend work in the laboratory
  + If you are working in a BSC when a fire alarm sounds:
    - Stop working
    - Lower the sash
    - Attach a sign to the cabinet to keep the sash closed to protect emergency response personnel from potential exposure if there is time
  + Remove PPE before leaving the laboratory if there is time
  + Exit the laboratory and building quickly yet safely
  + Meet at your laboratory’s designated meeting spot outside the building and perform a headcount
* Loss of Power
  + In the event of a power outage in the laboratory, stop working and exit the laboratory using the standard procedure, and wait for the power to be restored
  + If you are working in a BSC during a power outage:
    - Stop working
    - Lower the sash
    - Attach a sign to the cabinet to keep the sash closed to protect service providers from potential exposure if there is time
    - If a complete failure prevents lowering the sash, attach a sign to the BSC all the same
* Medical Emergencies
  + Provide immediate first-aid, if trained
  + Stop the bleeding of wounds (flush blood first if bleeding results from a biohazardous sharp) and wash the affected area with disinfectant/soap
  + If the individual is unconscious, or there is an emergency, call 911 and locate the nearest automated external defibrillator (AED) if needed
  + If possible, decontaminate and remove any PPE they might be wearing
* Building Evacuation Notice
  + If there is a building evacuation notice, stop working, remove PPE, and exit the building
  + Meet in the laboratory’s designated spot and take a head count
  + If you are working in a BSC:
    - Stop working
    - Lower the sash
    - Attach a sign to the cabinet to keep the sash closed to protect emergency response personnel from potential exposure if there is time
* Criminal Activity
  + If you observe criminal behavior or a suspicious person, do not intervene
  + Get to a safe location and notify Protective Services immediately

**BIOHAZARD** **COMMUNICATION**

Signs communicating the risks inside a laboratory / classroom / alternate site should be posted at the entrance to alert personnel and visitors of the potential risks found in these areas. These risks could be chemical, radiological, or biological in nature. This sign should incorporate the universal biohazard symbol when potentially infectious biological agents / biological materials / recDNA/RNA are used or stored in that space. The information on the sign should include the name and phone number of the principal investigator, and include information regarding the biological agents, biological materials, and/or recDNA/RNA components used in accordance with the requirements of the UWSP IBC. The sign must also indicate appropriate lines of communication in the event of an incident. In addition, equipment, waste containers, refrigerators, and freezers storing/used with potentially infectious biological agents / biological materials / recDNA/RNA should be labeled with a biohazard sticker. Notices of decontamination are available on the [UWSP biosafety website](https://www3.uwsp.edu/acadaff/orspdev/Pages/What-is-IBC.aspx) for laboratory moves / closures / decommissioning / etc. The IBC has provided templates for communicating biohazardous materials in lab spaces, classrooms and approved sites, which can be viewed on the [UWSP biosafety website](https://www3.uwsp.edu/acadaff/orspdev/Pages/What-is-IBC.aspx).

**TRAINING** **REQUIREMENTS**

All personnel conducting biosafety-related activities will complete biological safety training provided at the University of Wisconsin-Stevens Point through the Collaborative Institutional Training Initiative (CITI) Programs’ online biosafety modules found at their website: <https://about.citiprogram.org/en/homepage/>. Training is valid for three (3) years. Initial training courses include “Biosafety Introduction and Risk Assessment, and Risk Management. Additional applicable training modules will depend on the work being conducted. Each activity is different, and may require different biosafety training. Be aware that other training modules not related to biosafety may be required more generally for research and other purposes at UWSP campuses, such as research integrity, IRB training, and work with animals, etc., depending on what other activities you plan to conduct. CITI Program courses available for biosafety-related activities include:

* Biosafety Introduction and Risk Assessment (required)
* Risk Management (required)
* OSHA Bloodborne Pathogens (required for research or teaching activities involving human-derived materials, which must comply with OSHA Bloodborne Pathogen Standard)
* Recombinant DNA Research (required if research or teaching activities involve recombinant DNA, recombinant RNA, or synthetic nucleic acids)
* Animal Biosafety (required if research or teaching activities involve working with vertebrate or invertebrate animals; work with vertebrate animals will require IACUC approval as well)
* USDA Permits (research or teaching activities involving Plants and/or Soils)
* Select Agents, Toxins, Biosecurity and Bioterrorism [required if research or teaching activities involve working with select agents or toxins defined by the US Department of Health and Human Services (DHHS), US Department of Agriculture (USDA) and Animal Plant Health Inspection Service (APHIS)]
* Shipping and Transportation of Biological Materials (required if faculty or staff that will be shipping regulated biological materials)

The principal investigator must ensure that personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposure, and exposure evaluation procedures. Personnel are responsible for updating their training certification in the event of expiration or when procedural or policy changes occur. In addition, the principal investigator must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with biological agents / biological materials / recDNA/RNA requiring BSL-2 practices. Training must be documented and accessible for laboratory inspections or biosafety protocol reviews.

Each laboratory / classroom / alternate site, the biological agents / biological materials / recDNA/RNA they house, and the various biosafety-related activities performed therein will have a corresponding biosafety protocol. Therefore, principal investigators are responsible for ensuring personnel or select visitors receive specific training corresponding to their specific space / potentially biohazardous components used / biosafety-related activities performed *before* these individuals enter the laboratory / classroom / alternate site. This training provides these individuals with knowledge about the risks posed by the biological agents / biological materials recDNA/RNA in the laboratory / classroom / alternate site.

Note: If working with human subjects or live animals, additional training may be required.

Proper compliance with procedures outlined in biosafety-related training doesn’t just protect personnel listed on the biosafety protocol; compliance also protects emergency personnel in the event of an incident, service providers in the event of routine maintenance, visiting observers during collaborations, facility services and custodial staff tending to specific building needs and routine cleaning, additional personnel present in the building, and it even protects the community and environment with proper containment procedures. Therefore, campus staff from other work departments must be informed by the responsible department of any special hazards to which they might be exposed while working temporarily in the laboratory. This awareness must be coordinated in combination with facility services and the department or unit. Staff performing routine cleaning in labs or information technology maintenance must also be informed by the department of any unusual hazards. This can be accomplished with the use of hazard signage posted in the space at points of entry and on all applicable containers/storage. The IBC may provide templates for researchers and staff to customize their laboratories.

**INSTITUTIONAL BIOSAFETY COMMITTEE (****IBC) RESPONSIBILITIES AND FUNCTIONS**

Institutions are required to ensure that research / teaching / other biosafety-related activities conducted at (or sponsored by) that institution follow the requirements of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (<https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html>). However, the *NIH Guidelines* are not all encompassing and will never be complete due to rapidly changing technology and emerging organisms / viruses. Best practices and good judgment must be used to evaluate biosafety-related activity risks to ensure protection of personnel, the public, and the environment. Therefore, before biosafety-related activities may be conducted by personnel at UWSP campuses, at UWSP-associate facilities, etc., a risk assessment and subsequent biosafety protocol must be conducted and approved by the UWSP IBC prior to the initiation of the experiments.

Principal investigators working with biological materials or agents must complete a biosafety protocol application. Using the risk assessment starting on Page 11, identify and complete the appropriate portions of the application for the intended work. If you are unsure of how much of the which portions to complete after performing this risk assessment, contact [biosafety@uwsp.edu](mailto:biosafety@uwsp.edu). Additional assessments for animal work will be carried out in conjunction with the Institutional Animal Care and Use Committee (IACUC). Work involving human subjects will likewise need to be carried out in conjunction with the Institutional Review Board (IRB).

The *NIH Guidelines* set requirements for the IBC, as well as for principal investigators, and the institution. The applicable requirements for UWSP, based on current biosafety-related activities, are indicated below. For the exact language and additional requirements, see the *NIH Guidelines*.

**Institutional** **Responsibilities**

* Establish and implement policies that provide for the safe conduct of recDNA/RNA biosafety-related activities and ensure compliance with the *NIH Guidelines*
* Establish an Institutional Biosafety Committee, whose responsibilities need not be restricted to recDNA/RNA biosafety-related activities
* Appoint a Biological Safety Officer (BSO), who is a member of the IBC
* Appoint at least one individual with expertise in plants, plant pathogens, or plant pest containment principles
* Appoint at least one individual with expertise in animal containment principles
* Ideally appoint persons with expertise in recDNA/RNA technology, biological safety, and physical containment methods
* Assist and ensure compliance with the *NIH Guidelines* by principal investigators conducting biosafety-related activities
* Ensure appropriate training for the IBC Chair and members, BSO, and other containment experts when applicable, as well as principal investigators and other laboratory personnel regarding safety and implementation of the *NIH Guidelines*
  + The IBC Chair is responsible for ensuring that IBC members are appropriately trained
  + A principal investigator is responsible for ensuring that laboratory personnel are appropriately trained and training is documented
  + The institution is responsible for ensuring that each principal investigator has sufficient training; however, this responsibility may be delegated to the IBC
* Determine the necessity for health surveillance of personnel involved in connection with individual recDNA/RNA biosafety-related activities
* Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH OSP within thirty days, unless the institution determines that a report has already been filed by the IBC
* The institution shall file an annual report with NIH OSP which includes:
  + A roster of all IBC members, clearly indicating the Chair, contact person, BSO, plant expert, animal expert, or *ad hoc* consultants
  + Biographical sketches of all IBC members (including community members)
  + The institution is ultimately responsible for the effectiveness of the IBC, and may establish procedures that the IBC shall follow in its initial and continuing review and approval of applications, proposals, and activities
* When possible, and in consistent protection with privacy and proprietary interests, the institution is encouraged to open its IBC meetings to the public
* Upon request, make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies, the latter of which are required to be made available to the public
* If public comments are made on IBC actions, the institution shall forward both the public comments and the IBC’s response to the NIH OSP

**IBC Review** **and Approval Process**

* The IBC will be comprised of no fewer than five members who collectively have experience and expertise in recDNA/RNA technology and the capability to assess the safety of recDNA/RNA biosafety-related activities and to identify any potential risk to public health or the environment.
  + At least two members shall not be affiliated with the institution (apart from their membership on the IBC)
    - These individuals should represent the interest of the surrounding community with respect to health and protection of the environment
    - Suggested examples of these individuals include officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community
  + Include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles
  + Include at least one individual with expertise in animal containment principles
  + Ideally include persons with expertise in recDNA/RNA technology, biological safety, and physical containment
  + Ideally include persons to have as consultants, persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment
  + Include at least one member representing the laboratory technical staff
* The IBC will determine a meeting schedule prior to the start of each semester, and will meet ad hoc to conduct business as needed
* No member of an IBC may be involved in the review or approval of a project in which he/she has been engaged or expects to be engaged, except to provide information requested by the IBC at the beginning of the meeting
* No member of an IBC may be involved in the review or approval of a project in which he/she has a direct financial interest
* IBC meetings will be conducted by the IBC Chair. In the event the IBC Chair cannot be present at the meeting or if the Chair’s Biosafety Protocol Application is being reviewed by the IBC, the meeting will be conducted by the IBC member with the highest campus seniority that is present at the meeting
* At minimum, the IBC will review recDNA/RNA biosafety-related activities conducted at or sponsored by the institution for compliance with the *NIH Guidelines* as specified in Section III, *Experiments Covered by the NIH Guidelines*, and approving those research projects that are found to conform with the *NIH Guidelines*, including:
  + Independent assessment of the containment levels required by the *NIH Guidelines* for the proposed biosafety-related activities
  + Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recDNA/RNA biosafety-related activities
  + Ensure compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*
* Notify the principal investigator of the results of the IBC’s review and approval
  + If the IBC review requires changes subsequent to approval, the principal investigator will be notified in writing, and allowed 30 days to provide necessary documentation of changes.
* Lower containment levels for certain experiments as specified in Section III-D-2-a in the *NIH Guidelines, Restricted Agents Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems*
* Determine containment levels as specified in Sections III-D-4-b and III-D-5 in the *NIH Guidelines*
* Periodically review recDNA/RNA biosafety-related activities conducted at the institution and all applicable sites, to ensure compliance with the *NIH Guidelines* post-approval.
* Develop and distribute emergency plans covering accidental spills and contamination / exposure of personnel resulting from recDNA/RNA biosafety-related activities
* Report any significant problems with (or violations of) the *NIH Guidelines* and any significant biosafety-related activity accidents or illnesses to the appropriate institutional official and NIH OSP within 30 days.
* May not authorize initiation of experiments which are not explicitly covered by the *NIH Guidelines* until the NIH (with the advice of the Recombinant DNA Advisory Committee, or RAC, when required) establishes the containment requirement
* May not authorize restricted experiments without prior approval from NIH OSP with advice of the RAC
* Perform other functions as may be delegated to the IBC under Section IV-B-2 in the *NIH Guidelines*
* Shall read, sign, and understand the UWSP IBC non-disclosure agreement (NDA) as applicable
* During meetings shall provide opinions and review consistent with the *NIH Guidelines* and BMBL
* IBC members must not use e-mail communication regarding IBC business as a replacement for meetings due to open records laws

**Biological Safety Officer (****BSO) Responsibilities and Duties**

* Conduct initial and periodic inspections to ensure that laboratory standards are rigorously followed in the laboratory, classroom, or alternate sites
* Enforce suspension of biosafety-related activities deemed to be carried out in a non-compliant manner and maintain records of these violations as described in the section on Biosafety Compliance & Enforcement
* Report to the IBC and the institution any significant problems, violations of the *NIH Guidelines*, and any significant biosafety-related accidents or illnesses of which the BSO becomes aware
* Develop emergency plans for handling accidental spills and contamination / exposure of personnel and investigating laboratory accidents involving recDNA/RNA biosafety-related activities
* Provide advice on laboratory security
* Provide technical advice to principal investigators and the IBC on research safety procedures
* Additional duties as assigned by the institution and the IBC

**Principal Investigator** **Responsibilities and Duties**

* Responsible for full compliance with the *NIH Guidelines* in the conduct of recDNA/RNA biosafety-related activities
* Refrain from initiating or modifying recDNA/RNA without IBC approval
* Complete the appropriate Biosafety Protocol Application for any research or teaching activities for IBC review and approval
* Report any problems, violations of the *NIH Guidelines*, or any research-related accidents and illnesses to the IBC within 24 hours
* Report any new information bearing on the *NIH Guidelines* to the IBC
* Be adequately trained in good microbiological techniques
* Adhere to IBC approved emergency plans for handling accidental spills and contamination / exposure of personnel
* Comply with shipping requirements for recDNA/RNA, biological agents, and biological materials
* Make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*
* Select appropriate microbiological practices and laboratory techniques to be used for biosafety-related activities
* Remain in communication with the IBC throughout the conduct of the biosafety-related activity
* Make available to all laboratory personnel this biosafety manual and all lab-specific biosafety protocols that describes the potential biohazards and the precautions to be taken
* Instruct and train laboratory personnel (and select visitors as deemed necessary by the IBC) in the practices and techniques required to ensure their safety and ensure they understand the procedures for dealing with biosafety-related accidents. Maintain training documentation within the laboratory.
* Maintain all biohazard communication notices and be available to explain the nature of the hazards present in the laboratory / spaces to service providers or contractors as needed in coordination with facility services
* Verify biosafety training and training renewal of all personnel (complete and submit the Personnel Training Form to the IBC)
* Inform personnel of the reasons and provisions for any precautionary medical practices advised / recommended (e.g., vaccinations or serum collection)
* Supervise the performance of personnel to ensure that the required safety practices and techniques are employed
* Investigate and report any problems pertaining to the operation and implementation of containment practices and procedures in writing to the IBC within 24 hours
* Correct work errors and conditions that may result in the release of recDNA/RNA, which are reportable to the IBC
* Ensure the integrity of the physical containment (e.g., biological safety cabinets) and biological containment (e.g., purity and genotypic and phenotypic characteristics)

**APPENDIX A****–FACILITIES, SAFETY EQUIPMENT, and MAINTENANCE**

This appendix describes the various facility requirements for different BSLs, as well as required decontamination, laboratory safety equipment, and general maintenance.

**Decont****amination**

Multiple methods of decontamination/disinfection for biohazardous waste, laboratories / classrooms / alternate sites, work surfaces, and equipment must be available (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method). Chemical disinfection is appropriate for liquid research waste, laboratories / classrooms / alternate sites, work surfaces, and equipment when chemicals are proven effective again the biological agents / biological materials / recDNA/RNA being used. An autoclave should be available for personnel working with potentially pathogenic biological agents or biological materials (i.e., cell lines, blood, tissues, etc.), particularly those potentially containing bloodborne pathogens, for the purposes of decontaminating solid laboratory waste. Autoclave cycle times ensuring decontamination will vary depending on the type and size of the load as well as the potential pathogens. Autoclaves are validated each run and weekly by using combination pressure/temperature indicator strips and Getinge Assure Accufast Biological Indicators (*Geobacillus stearothermophilus*) with subsequent inoculation and incubation to verify loss of biologic viability.

**Eyewashes** **and Safety Showers**

Areas where biosafety-related activities requiring BSL-2 practices must have both eyewashes and safety showers, which must be maintained for use in the event of a splash to the face, eyes, or a spill on clothing / skin. An eyewash station must be readily available where biosafety-related activities requiring BSL-1 practices are conducted. Eyewash stations will be flushed weekly with a log kept at each eyewash station. The chemical hygiene plan designates responsibility for weekly flushing and log maintenance. Safety showers are flushed on an annual basis, also via the chemical hygiene plan, and records are kept at the safety shower.

**Biological Safety Cabinets (****BSC)**

BSCs serve as primary containment when working with potentially pathogenic biological agents or biological materials requiring BSL-2 practices. BSCs provide protection for the personnel and the experiment, while also protecting the environment. There are multiple, different models of BSCs at UWSP campuses. They are certified on an annual basis by CSI Testing, Class One Air, or other approved service providers. It is critical that BSCs be functioning properly for them to provide adequate protection. Do not use a BSC that has failed a certification or that is not functioning properly.

**Pest** **Management**

Wil-Kil is in charge of managing pests in UWSP campus and branch campus buildings. They use NUVAN pro strips to control pests and provide service on a quarterly basis. If you notice pests in your laboratory, contact the appropriate building manager, departmental / unit chemical hygiene officer, or BSO to set up an onsite assessment and resolution plan.

Specific facility requirements are needed depending upon the level of biosafety required in a laboratory / classroom / alternate site. Below are the basic requirements for biosafety-related activities at UWSP campuses. A risk assessment might determine that additional facility items are required for a specific set of experiments.

**BSL-1** **Facilities**

* Laboratories / classrooms / alternate sites should have doors for access control
* Laboratories / classrooms / alternate sites should have sinks for hand washing
* The laboratory / classroom / alternate site should be designed so that it can be easily cleaned; carpets and rugs in laboratories / classrooms / alternate sites are not appropriate
* Laboratory / classroom / alternate site furniture must meet specific criteria:
  + All furniture must be capable of supporting anticipated loads and uses
  + Spaces between benches, cabinets, and equipment should be accessible for cleaning
  + Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals
  + Chairs used in biosafety-related activities must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant
* Laboratory windows that open to the exterior should be fitted with screens to prevent arthropod-based containment breach; alternatively, the window may be locked, with a sign indicating that opening is prohibited

**BSL-2** **Facilities (in addition to BSL-1 requirements)**

* Access to BSL-2 facilities are restricted; doors must not be propped open and personnel should maintain identification
* Laboratory / classroom / alternate site doors should ideally be self-closing and minimally have locks in accordance with the institutional policies
* Laboratories / classrooms / alternate sites must have a sink for hand washing
  + The sink may be manual, hands-free, or automatically operated
  + A sink should be located near the exit door
* The laboratory / classroom / alternate site should be designed so that it can be easily cleaned and decontaminated; carpets and rugs in the laboratories / classrooms / alternate sites are not permitted
* Laboratory / classroom / alternate site windows that open to the exterior are not recommended
  + The window should be locked, with a sign indicating that opening the window is prohibited
* BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations
  + BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, or other sources of possible air flow disruptions
* Vacuum lines should be protected with liquid disinfectant within the traps and maintain an in-line HEPA filter
* An eyewash station must be readily available
* There are no specific requirements for ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to the spaces outside of the laboratory. Confirm that the physical plant does monitor airflow and that air flows into the laboratories / classrooms / alternate sites.
* HEPA filtered exhaust air from a Class II BSC can be safely recirculated back into the laboratory / classroom / alternate site environment if the cabinet is tested and certified at least annually and operated according to the manufacturer’s recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection, preferably with in-line charcoal adsorption. Provisions to assure proper biosafety cabinet performance and air system operation must be verified.
* A method for decontaminating all biohazardous wastes should be available to the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method)

**ABSL-1** **Facilities**

* The animal facility is separated from areas that are open to unrestricted personnel traffic within the building. External facility doors are self-closing and self-locking.
* Access to the animal facility is restricted; personnel using the facility should maintain identification.
* Doors to areas where infectious biological materials and/or animals are housed open inward, are self-closing, are kept closed when experimental animals are present, and are never propped open. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.
* The animal facility must have a sink for hand washing.
* Sink traps are filled with water and/or appropriate liquid to prevent the migration of vermin and gases.
* The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors and ceilings) are water resistant. Floors must be slip resistant, impervious to liquids, and resistant to chemicals.
* It is recommended that penetrations in floors, walls and ceiling surfaces be sealed, including openings around ducts, doors, and doorframes to facilitate pest control and proper cleaning.
* Cabinets and bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
* Chairs used in animal areas must be covered with a non-porous material that can be easily cleaned and decontaminated. Furniture must be capable of supporting anticipated loads and uses. Sharp edges and corners should be avoided.
* External windows are not recommended; if present, windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that can open, they must be fitted with screens, and ideally kept locked with a sign indicating it cannot be opened. The presence of windows may impact facility security and therefore should be assessed by security personnel.
* Ventilation should be provided in accordance with the *Guide for Care and Use of Laboratory Animals* (<https://www.ncbi.nlm.nih.gov/books/NBK54050/>). No recirculation of exhaust air may occur. It is recommended that animal rooms have inward directional airflow.
* Ventilation system design should consider the heat and high moisture load produced during the cleaning of animal rooms and the cage wash process.
* Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas to facilitate cleaning and minimize the accumulation of debris or fomites.
* If floor drains are provided, the traps are filled with water, and/or appropriate disinfectant to prevent the migration of vermin and gases.
* Cages are washed manually or preferably in a mechanical cage washer. The mechanical cage washer should have a final rinse temperature of at least 180°F. If manual cage washing is utilized, ensure that appropriate disinfectants are selected.
* Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
* Emergency eyewash and shower stations are readily available; their location is determined by risk assessment.

**ABSL-2** **Facilities (in addition to ABSL-1 Requirements)**

* A hand-washing sink is located at the exit of the areas where infectious biological agents / biological materials and/or animals are housed or are manipulated. Additional sinks for hand washing should be located in other appropriate locations within the facility.
* If the animal facility has segregated areas where infectious biological agents / biological materials and/or animals are housed or manipulated, a sink must also be available for hand washing at the exit from each segregated area.
* Sink traps are filled with water, and/or appropriate disinfectant to prevent the migration of vermin and gases.
* The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors and ceilings) are water resistant.
* Penetrations in floors, walls, and ceiling surfaces are sealed, including openings around ducts, doors, and doorframes to facilitate pest control and proper cleaning.
* Floors must be slip-resistant, impervious to liquids, and resistant to chemicals.
* Cabinets and bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
* Furniture should be minimized. Chairs used in animal areas must be covered with a non-porous material that can be easily cleaned and decontaminated. Furniture must be capable of supporting anticipated loads and uses. Sharp edges and corners should be avoided.
* External windows are not recommended; if present, windows must be sealed and resistant to breakage. The presence of windows may impact facility security and therefore should be assessed by security personnel.
* Ventilation should be provided in accordance with the *Guide for Care and Use of Laboratory Animals*. The direction of airflow into the animal facility is inward; animal rooms maintain inward directional airflow compared to adjoining hallways. A ducted exhaust air ventilation system is provided. Exhaust air is discharged to the outside without being recirculated to other rooms.
* Ventilation system design should consider the heat and high moisture load produced during the cleaning of animal rooms and the cage wash process.
* Cages should be autoclaved or otherwise decontaminated prior to washing. A mechanical cage washer should have a final rinse temperature of at least 180°F. The cage wash area should be designed to accommodate the use of high-pressure spray systems, humidity, strong chemical disinfectants and 180°F water temperatures during the cage/equipment cleaning process.
* If BSCs are present, they must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.
* HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer’s recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly to the outside through an independent, hard connection, preferably with in-line charcoal adsorption. Provisions to assure proper safety cabinet performance and air system operation must be verified. BSCs should be recertified at least once a year to ensure correct performance.
* All BSCs should be used according to the manufacturer’s specifications to protect the worker and avoid creating a hazardous environment from volatile chemicals and gases.
* If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an in-line HEPA filter placed as near as practical to each use point or service cock. Filters are installed to permit in-place decontamination and replacement.
* An autoclave should be present either in the animal facility or close by (requiring proper transfer procedures described elsewhere) to facilitate decontamination of infectious biological agents / biological materials and their associated wastes.
* Emergency eyewash and shower stations are readily available; their location is determined by risk assessment.

**APPENDIX B****–LARGE SCALE RESEARCH**

The IBC will determine the appropriate containment level for experiments with 10 liters or greater of viable organisms containing recDNA/RNA. The *NIH Guidelines* explains the criteria for the different containment levels, but only addresses the biological hazards and not properties of the products or risks of the downstream processes. For purposes of large-scale research or production, four physical containment levels have been established based on the degree of biohazard posed to the health of personnel and the environment. However, currently, only two apply to the biosafety-related activities at UWSP campuses. In the future, the third level could potentially apply.

The three biosafety levels of large-scale physical containment potentially used at UWSP campuses are referred to as Good Large Scale Practice (GLSP), Large Scale BSL-1(LSBSL-1), and Large Scale BSL-2 (LSBSL-2). Good Large Scale Practice is recommended for large-scale biosafety-related activities involving viable, non-pathogenic, and non-toxigenic recDNA/RNA-containing strains derived from host organisms that have an extended history of safe, large-scale use. Large Scale BSL-1 is recommended for large-scale research or production of viable organisms containing recDNA/RNA that require BSL-1 containment at the laboratory scale and that do not qualify for Good Large Scale Practice. Large Scale BSL-2 is recommended for large-scale research or production of viable organisms containing recombinant or synthetic nucleic acid molecules that require BSL-2 containment at the laboratory scale. Research falling under this level is not currently being conducted at UWSP campuses.

**Good Large Scale Practices (****GLSP)**

* Institutional codes of practice shall be formulated and implemented to assure adequate control of health and safety matters.
* Written instructions and training of personnel shall be provided to assure that cultures of viable organisms containing recDNA/RNA are handled prudently and that the laboratory / classroom / alternate site be kept clean and orderly.
* In the interest of good personal hygiene, facilities (e.g., hand washing sink, shower, changing room) and protective clothing (e.g., uniforms, laboratory coats) shall be provided that are appropriate for the risk of exposure to viable organisms containing recDNA/RNA.
* Eating, drinking, smoking, applying cosmetics, and mouth pipetting must be prohibited in the laboratory / classroom / alternate site.
* Cultures of viable organisms containing recDNA/RNA shall be handled in facilities intended to safeguard health during work with microorganisms that do not require containment.
* Discharges containing viable recDNA/RNA-containing organisms shall be handled in accordance with applicable government and environmental regulations.
* Addition of materials to a system, sample collection, transfer of culture fluids within/between systems, and processing of culture fluids shall be conducted in a manner that maintains an individual's exposure to viable organisms containing recDNA/RNA at a level that does not adversely affect the health and safety of personnel.
* The facility's emergency response plan shall include provisions for handling spills.

**Large Scale Biological Safety Level-1 (****LSBSL-1)**

* Spills and accidents which result in overt exposures to organisms containing recDNA/RNA are immediately reported to the principal investigator. Medical evaluation, surveillance, and treatment are provided where appropriate, and written records of these events are maintained.
* Cultures of viable organisms containing recDNA/RNA shall be handled in a closed system (e.g., closed vessel used for the propagation and growth of cultures) or other primary containment equipment (e.g., biological safety cabinet containing a centrifuge used to process culture fluids) which is designed to reduce the potential for escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system or other primary containment equipment provided all physical containment requirements specified in [Appendix G-II-A of the NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948438), *Physical Containment Levels—Biosafety Level 1*, are met.
* Culture fluids (except as allowed in [Appendix K-III-D of the NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948483)) shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recDNA/RNA have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one which has been demonstrated to be effective using the organism that will serve as the host for propagating the recDNA/RNA. Culture fluids that contain viable organisms or viral vectors intended as a final product may be removed from the primary containment equipment by way of a closed system for sample analysis, further processing, or final fill.
* Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be conducted in a manner which minimizes the release of aerosols or contamination of exposed surfaces.
* Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to high efficiency particulate air (HEPA) filters or by other equivalent procedures (e.g., incineration) to minimize the release of viable organisms containing recDNA/RNA into the environment.
* A closed system or other primary containment equipment that has contained viable organisms containing recDNA/RNA shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure except when the culture fluids contain viable organisms or vectors intended as a final product as described in [Appendix K-III-C of the NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948483), described above. A validated sterilization procedure is one which has been demonstrated to be effective using the organism that will serve as the host for propagating the recDNA/RNA.

**Large Scale Biosafety Level-2 (****LSBSL-2)**

*Contact the IBC and BSO if you are considering biosafety-related activities warranting LSBSL-2 practices.*

Emergency plans required by Sections IV-B-2-b-(6), *Institutional Biosafety Committee*, and IV-B-3-c-(3), *Biological Safety Officer*, shall include methods and procedures for handling large losses of culture on an emergency basis.

**APPENDIX C****–PLANT RESEARCH**

Biosafety-related activities with recombinant plants may be conducted at UWSP campuses. The safety practices below are the requirements from the *NIH Guidelines* that pertain to such biosafety-related activities. Please note that work with recDNA/RNA in plants or any work with plant pathogens must also comply with regulations set forth by the United States Department of Agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA).

**Plant Biological Safety Level-1 (****PBSL-1)**

* PBSL-1 Standard Practices
  + Access to the greenhouse shall be limited or restricted, at the discretion of the greenhouse director, when experiments are in progress.
  + Prior to entering the greenhouse, personnel shall be required to read and follow instructions on PBSL-1 greenhouse practices and procedures. All procedures shall be performed in accordance with accepted greenhouse practices that are appropriate to the experimental organism.
  + A record shall be kept of experiments currently in progress in the greenhouse facility.
  + Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.
  + A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens), by methods appropriate to the organisms and in accordance with applicable state and federal laws.
  + Arthropods and other motile macroorganisms shall be housed in appropriate cages. If macroorganisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.
  + Experiments that involve other organisms requiring containment levels lower than PBSL-1 may be conducted in the greenhouse concurrently with experiments that require PBSL-1 containment, provided that all work is conducted in accordance with PBSL-1 greenhouse practices.
* PBSL-1 Facilities
  + The term “greenhouse” refers to a structure with walls, a roof, and a floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth.
  + The term “greenhouse facility” includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas, and is considered part of the confinement area.
  + The greenhouse floor may be composed of gravel or other porous material. At a minimum, impervious (e.g., concrete) walkways are recommended.
  + Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to contain or exclude pollen, microorganisms, or small flying animals (e.g., arthropods and birds); however, screens are recommended.

**Plant Biological Safety Level-2 (****PBSL-2)**

* PBSL-2 Additional Requirements
  + Personnel shall be required to read and follow instructions on PBSL-2 practices and procedures. All procedures shall be conducted in accordance with accepted greenhouse practices that are appropriate to the experimental organisms used.
  + A record shall be kept of experimental plants, microorganisms, or small animals that are brought into or removed from the greenhouse facility.
  + The principal investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the greenhouse director, IBC, NIH OSP, and other appropriate authorities immediately (if applicable).
  + Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.
  + Decontamination of run-off water is not necessarily required. If part of the greenhouse is composed of gravel or similar material, appropriate treatments should be made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel.
  + A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens) by methods appropriate to the organisms and in accordance with applicable state and federal laws.
  + Arthropods and other motile macroorganisms shall be housed in appropriate cages. If macroorganisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.
  + Experiments that involve other organisms requiring containment levels lower than PBSL-2 may be conducted in the greenhouse concurrently with experiments that require PBSL-2 containment, provided that all work is conducted in accordance with PBSL-2 greenhouse practices.
  + A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following:
    - The name of the responsible individual (i.e., the principal investigator)
    - The plants in use
    - Any special requirements for using/entering the area
  + If organisms are used that have a recognized potential for causing serious, detrimental impacts on managed or natural ecosystems, their presence shall be indicated on a sign posted on the greenhouse access doors.
  + If there is a risk to human health, a sign shall be posted incorporating the universal biohazard symbol.
  + Materials containing experimental microorganisms, which are brought into or removed from the greenhouse facility in a viable or intact state, shall be transferred in a closed, non-breakable container.
  + A greenhouse biosafety protocol shall be prepared or adopted. This biosafety protocol shall:
    - Advise personnel of the potential consequences if such practices are not followed
    - Outline contingency plans to be implemented in the event of the unintentional release of organisms
* PBSL-2 Facilities
  + A greenhouse floor is composed of material impervious to the biological agent requiring containment. Concrete is recommended, but gravel or other porous material under benches is acceptable unless propagules of experimental organisms are readily disseminated through gravel. Soil beds are acceptable unless propagules of experimental organisms are readily disseminated through soil.
  + Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to exclude pollen or microorganisms; however, screens are required to exclude small flying animals (e.g., arthropods and birds).
  + An autoclave shall be available for the treatment of contaminated greenhouse materials.
  + If intake fans are used, measures shall be taken to minimize the ingress of arthropods. Louvers or fans shall be constructed such that they can only be opened when the fan is in operation.
  + PBSL-2 greenhouse containment requirements may be satisfied by using a growth chamber or growth room within a building provided that the external physical structure limits access and escape of microorganisms and macroorganisms in a manner that satisfies the intent of the foregoing clauses.