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Chapter 1: Introduction and Overview

The University of Wisconsin-Milwaukee (UWM) Department of University Safety & Assurances Biosafety Program oversees the responsible use of biological hazards in microbiology, tissue culture, recombinant DNA, molecular biology, synthetic biology, and biotechnology at all the UWM facilities. The biosafety officer (BSO) and the Institutional Biosafety Committee (IBC) evaluate and approve protocols for research experiments that work with biological hazards. This manual, in part, helps meet the goals of the UWM biological safety program, which include the following:

- **Protection**: Protect personnel, students, staff, and public from exposure to infectious agents.
- **Prevention**: Prevent environmental contamination from infectious agents.
- **Training**: Provide training and outreach to personnel as part of maintaining an excellent research institution while maintaining a safe work environment.
- **Compliance**: Comply with local, state, and federal rules and regulations.

The Principal Investigator (PI) is responsible for the implementation of procedures outlined in this manual. The PI is also responsible for maintaining a laboratory-specific biosafety manual, submitting protocols per NIH Guidelines and University Guidelines, and for the development and of lab-specific standard operating procedures (SOP). It is the responsibility of the laboratory supervisors and laboratory personnel to follow the regulations, policies, and procedures after training, understand their expectations to prevent accidents from occurring, and report any incidents to their PI and to the Biological Safety Program immediately.

Registration with the IBC is required whenever any biological materials are being used that could elicit a potential risk to humans, animals, plants, or the environment. These biological materials may include, but are not limited to: risk group 2 or higher pathogenic microorganisms, toxic chemicals used to elicit a biological response, infectious agents, viruses, viroids, prions, human tissues, human blood and bloodborne pathogens, and in-vitro construction or propagation of recombinant DNA molecules. The Biological Safety Program also asks researchers performing exempt procedures to still submit the Registration Form to for University records. All researchers are expected to follow the NIH Guidelines and any other state and federal regulation, regardless of whether they receive any kind of funding for their research. All non-exempt protocol submissions will be required to be approved the IBC. The meeting schedule is posted on the UWM Report Calendar. The BSO will evaluate and approve biosafety protocols that are exempt from IBC registration.

Biosafety Lab Inspections will help the PI and lab researchers determine if there are issues with compliance or SOPs, and provide a learning opportunity for both the researchers and the BSO. All laboratories handling any biological materials will be required to have annual biosafety inspections. In addition to handling biosafety lab inspections, the BSO also oversees the coordination of activities within the IBC and provides record of meeting minutes, approvals, etc. To learn more about the Biological Safety Program and the IBC, visit: [http://uwm.edu/safety-health/biosafety/](http://uwm.edu/safety-health/biosafety/).
Chapter 2: General Biosafety

Biohazardous Materials

A biohazardous material is any biological material capable of causing harm to humans, animals or plants, including both biohazardous agents, non-replicating materials such as toxins, and may also be used to refer to material that harbors a biohazardous agent. A biohazardous agent is a pathogen capable of replication and is a disease-causing microorganism (bacteria, chlamydia, fungi, parasites, prions, rickettsia, viruses, etc.) capable of causing diseases in humans, animals, or plants. Toxic, mutagenic, and teratogenic chemicals are not considered biohazards, but rather chemical hazards, and are addressed by the UWM Chemical Hygiene Plan.

Risk Groups

The NIH and WHO recommend four risk groups (RG) based upon the following hazardous characteristics of an agent: its ability to infect and cause disease in a susceptible human or animal host, its virulence as measured by the severity of the disease, and the availability of preventative measures and effective treatments for the disease (US DHHS, 2009). The risk group listing from the NIH Guidelines are the standard, regardless of whether there is use of recombinant DNA- see below. This can also be found in the BMBL, page 10.

<table>
<thead>
<tr>
<th>Risk Group 1 (RG1)</th>
<th>Agents that are not associated with disease in healthy adult humans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Group 2 (RG2)</td>
<td>Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available</td>
</tr>
<tr>
<td>Risk Group 3 (RG3)</td>
<td>Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk)</td>
</tr>
<tr>
<td>Risk Group 4 (RG4)</td>
<td>Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)</td>
</tr>
</tbody>
</table>

Table 1 Risk Groups (NIH, 2016, p. 47)

Determination of the appropriate risk group is the first step in determining the appropriate biosafety level (BSL) for working with the agent. The BSL is a reference to the type of containment and PPE necessary for working with the agent. The BSL typically has a parallel numbering of 1-4, thus a RG 1 agent would typically fall into a BSL-1 containment practice. This is not always true though, there are risk group 2 agents that requires some BSL-3 containment practices implemented, particularly if they have the potential to aerosolize or have a low infectious does. This manual will refer to organisms based on their risk groups, and their containment requirements by their BSL.

There is also a parallel animal biosafety level (ABSL1 through ABSL4) that specifically pertains to the safe handling of infected or potentially infected animals. See the figure below
from the BMBL for guidance. When working with animals that are recombinant, the biosafety containment levels outlined in the NIH Guidelines are required to be followed.

There is also a plant biosafety level of containment (BSL1-P through BSL4-P). Before working with any biological agent, consult the NIH guidelines, ABSA Risk Group Database, BMBL, Pathogen Safety Data Sheets from the Public Health Agency of Canada, and the BSO to determine containment needs and if protocols need to be filed with the IBC to work with the agent. Plants also have specific containment requirements, as outlined in Appendix P of the NIH Guidelines.
<table>
<thead>
<tr>
<th>Task</th>
<th>Primary Barriers</th>
<th>Secondary Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventing Exposure</td>
<td>- Personal protective equipment (PPE) use, including gowns and gloves</td>
<td>- Standard precautio ns (SPLP), including eye protection and masks</td>
</tr>
<tr>
<td>- - - -</td>
<td>- - - -</td>
<td>- - - -</td>
</tr>
<tr>
<td>Preparing Samples</td>
<td>- Use designated area for sample handling</td>
<td>- Use designated area for sample handling</td>
</tr>
<tr>
<td>- - - -</td>
<td>- - - -</td>
<td>- - - -</td>
</tr>
<tr>
<td>Disposing of Waste</td>
<td>- Use designated area for disposal</td>
<td>- Use designated area for disposal</td>
</tr>
<tr>
<td>- - - -</td>
<td>- - - -</td>
<td>- - - -</td>
</tr>
<tr>
<td>Cleaning and Disinfecting</td>
<td>- Use designated area for cleaning and disinfecting</td>
<td>- Use designated area for cleaning and disinfecting</td>
</tr>
<tr>
<td>- - - -</td>
<td>- - - -</td>
<td>- - - -</td>
</tr>
<tr>
<td>Monitoring and Surveillance</td>
<td>- Use designated area for monitoring and surveillance</td>
<td>- Use designated area for monitoring and surveillance</td>
</tr>
</tbody>
</table>

Table 3: Summary of Recommended Animal Biosafety Levels for Activities in which Experimentally or Naturally Infected Verterbrate Animals are Used
Viral vectors, even if they are rendered replication-defective, may pose recombination threats with wild-type strains and should be presumed virulent and handled as a virulent agent. When selecting a risk-group the virulent agent risk group is what is used for the agent, unless indicated otherwise in the BMBL or NIH Guidelines. Most viral vector work falls under Section III-D of the NIH Guidelines, which require IBC approval before beginning work with the vector. All viral vector work is required to be registered with the UWM IBC, regardless of the categorization under NIH Guidelines. PIs should consider requesting viral vector training through the BSO, which can be done for the entire research group in a single session.

Additional considerations need to be made for genetically-modified biological agents. Risk assessment of the wild-type organism should be done. Additionally, addressing the possibility of genetic modification, how it alters pathogenicity of the agent, and its susceptibility to antimicrobial treatments need to be discussed in the risk assessment that would then be attached to the IBC registration form. It is imperative that the PI has researched this information thoroughly and obtained an IBC approval before commencing research with GM agents. It may be possible that this information may not be available for an agent that has recently been developed, making a risk assessment incomplete or hard to complete. Assign these agents a conservative biosafety level containment to exercise the safest practices possible. Re-evaluate the agent when more information is available.

A human and/or animal cell or tissue has enormous potential to harbor potential latent infectious agents. Personnel who handle these are at risk for possible exposure to these agents. Refer to the section “Working with Cell Lines and Tissue Cultures” and refer to the UWM Bloodborne Pathogens Exposure Control Plan. All clinical/patient samples should be considered a minimum of a risk group 2 and only worked with in a BSL-2 containment or higher.

The table below outlines commonly used RG1 agents used at UWM. Note that agents not listed on Risk Groups 2, 3, and 4 are not automatically or implicitly classified in Risk Group 1. A risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

<table>
<thead>
<tr>
<th>Bacterial Agents</th>
<th>Viral Agents</th>
<th>Fungal Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus subtilis</em> (asporogenic only)</td>
<td>Adeno-associated virus (AAV) Types 1-4 Recombinant AAV</td>
<td><em>Saccharomyces cerevisiae</em></td>
</tr>
<tr>
<td><em>Bacillus lichenformis</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Escherichia coli</em> K-12</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Staphylococcus epidermidis</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Table 2: Risk Group 1 Agents Commonly Used at UWM*

RG2 agents should not be assumed to be mostly safe based on their classification alone. All organisms in RG2 have the potential to cause serious harm to the researcher and must be handled accordingly. Some organisms may best be handled in a BSL-3 containment, rather than BSL-2. Complete a risk assessment to determine the best level of containment for the pathogen. The table below identifies commonly used RG2 agents in research.

<table>
<thead>
<tr>
<th>Type of Agent</th>
<th>Organism</th>
</tr>
</thead>
</table>

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<table>
<thead>
<tr>
<th>Gram-positive Bacteria</th>
<th>Arccanobacterium haemolyticum</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bacillus anthracis</td>
</tr>
<tr>
<td></td>
<td>Trueperella pyogenes (Formerly: Actinomyces pyogenes)</td>
</tr>
<tr>
<td></td>
<td>Clostridium botulinum, C.difficile, C. chauvoei, C. haemolyticum, C. histolyticum, C. novyi, C. septicum, C. tetani- note that Botulinum neurotoxins and Botulinum producing species are Select Agents and subject to regulation from the U.S. Government.</td>
</tr>
<tr>
<td></td>
<td>Corynebacterium diphtheriae, C. pseudotuberculosis, C. renale- Note that the Diphtheria toxin is also to be considered Risk Group 2 and handled as such.</td>
</tr>
<tr>
<td></td>
<td>Dermatophilus conglobensis (note: RG 3 in animals)</td>
</tr>
<tr>
<td></td>
<td>Erysipelothrix rhusiopathiae</td>
</tr>
<tr>
<td></td>
<td>Listeria, all species</td>
</tr>
<tr>
<td></td>
<td>Mycobacterium (except those listed in RG3) including M. avium complex, M. asiaticum, M. bovis BCG vaccine strain, M. chelonei, M. fortuitum, M. kansasii, M. leprae, M. malmoense, M. marium, M. paratuberculosis, M. scrofulaceum, M. simiae, M. szulgai, M. ulcerans, M. xenopi</td>
</tr>
<tr>
<td></td>
<td>Nocardia asteroides, N. brasiliensis, N. otitidiscaviarum, N. transvalensis</td>
</tr>
<tr>
<td></td>
<td>Rhodococcus equi</td>
</tr>
<tr>
<td></td>
<td>Staphylococcus equis aureus</td>
</tr>
<tr>
<td></td>
<td>Streptococcus including S. pneumoniaae, S. pyogenes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gram-negative Bacteria</th>
<th>Actinobacillus</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Aeromonas hydrophila</td>
</tr>
<tr>
<td></td>
<td>Arizona hinshawii – all serotypes</td>
</tr>
<tr>
<td></td>
<td>Bartonella henselae, B quintana, B. vinsonii</td>
</tr>
<tr>
<td></td>
<td>Bordetella including B. pertussis</td>
</tr>
<tr>
<td></td>
<td>Borrelia recurrentis, B burgdorferi</td>
</tr>
<tr>
<td></td>
<td>Burkhholderia (except those listed in RG3)</td>
</tr>
<tr>
<td></td>
<td>Campylobacter coli, C. fetus, C. jejuni</td>
</tr>
<tr>
<td></td>
<td>Chlamydia psittaci, C. trachomatis, C. pneumoniaae</td>
</tr>
<tr>
<td></td>
<td>Edwardsiella tarda</td>
</tr>
<tr>
<td></td>
<td>Escherichia coli – all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including E. coli O157:H7</td>
</tr>
<tr>
<td></td>
<td>Fusobacterium necrophorum</td>
</tr>
<tr>
<td></td>
<td>Haemophilus ducreyi, H. influenza</td>
</tr>
<tr>
<td></td>
<td>Helicobacter pylori</td>
</tr>
<tr>
<td></td>
<td>Klebsiella - all species except K. oxytoca, which is RG 1</td>
</tr>
<tr>
<td></td>
<td>Legionella, all species</td>
</tr>
<tr>
<td></td>
<td>Leptospira interrogans - all serotypes</td>
</tr>
<tr>
<td></td>
<td>Moraxella, all species</td>
</tr>
<tr>
<td></td>
<td>Neisseria gonorrhoeae, N. meningitides</td>
</tr>
<tr>
<td></td>
<td>Pseudomonas aeruginosa</td>
</tr>
<tr>
<td></td>
<td>Salmonella including S. arizonae, S. cholerasuis, S. enteritidis, S.</td>
</tr>
<tr>
<td><strong>Mycoplasma</strong></td>
<td><strong>Bacteria</strong></td>
</tr>
<tr>
<td>----------------</td>
<td>-------------</td>
</tr>
<tr>
<td></td>
<td><em>Mycoplasma</em>, except <em>M. mycoides</em> and <em>M. capricolum</em> (USDA Select Agents)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Fungal</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Blastomyces dermatitidis</em></td>
</tr>
<tr>
<td><em>Cladosporium bantianum</em>, aka <em>C. (Xylohypha) trichoides</em></td>
</tr>
<tr>
<td><em>Cryptococcus neoformans</em></td>
</tr>
<tr>
<td><em>Dactyliaria gallopava</em> (<em>Ochroconis gallopavum</em>)</td>
</tr>
<tr>
<td><em>Epidermophytum</em></td>
</tr>
<tr>
<td><em>Exophiala (Wangiella) dermatitidis</em></td>
</tr>
<tr>
<td><em>Fonsecaea pedrosoi</em></td>
</tr>
<tr>
<td><em>Microsporum</em></td>
</tr>
<tr>
<td><em>Paracoccidioides brasiliensis</em></td>
</tr>
<tr>
<td><em>Penicillium marneffei</em></td>
</tr>
<tr>
<td><em>Sporothrix schenckii</em></td>
</tr>
<tr>
<td><em>Trichophyton</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Parasites</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Ancylostoma</em> human hookworms including <em>A. duodenale</em>, <em>A. ceylanicum</em></td>
</tr>
<tr>
<td><em>Ascaris</em> including <em>Ascaris lumbricoides suum</em></td>
</tr>
<tr>
<td><em>Babesia</em> including <em>B. divergens</em>, <em>B. microti</em></td>
</tr>
<tr>
<td><em>Brugia</em> filarial worms including <em>B. malayi</em>, <em>B. timori</em></td>
</tr>
<tr>
<td><em>Coccidia</em></td>
</tr>
<tr>
<td><em>Cryptosporidium</em>, including <em>C. parvum</em></td>
</tr>
<tr>
<td><em>Echinococcus</em> including <em>E. granulosus</em>, <em>E. multilocularis</em>, <em>E. vogeli</em></td>
</tr>
<tr>
<td><em>Entamoeba histolytica</em></td>
</tr>
<tr>
<td><em>Enterobius</em></td>
</tr>
<tr>
<td><em>Fasciola</em> including <em>F. gigantica</em>, <em>F. hepatitis</em></td>
</tr>
<tr>
<td><em>Giardia</em> including <em>G. lamblia</em></td>
</tr>
<tr>
<td><em>Heterophyes</em></td>
</tr>
<tr>
<td><em>Hymenolepis</em> including <em>H. diminuta</em>, <em>H. nana</em></td>
</tr>
<tr>
<td><em>Isospora</em></td>
</tr>
<tr>
<td><em>Leishmania</em> including <em>L. braziliensis</em>, <em>L. donovani</em>, <em>L. ethiopia</em>, <em>L. major</em>, <em>L. mexicana</em>, <em>L. peruviana</em>, <em>L. tropica</em></td>
</tr>
<tr>
<td><em>Loa loa</em> filaria worms</td>
</tr>
<tr>
<td><em>Microsporidium</em></td>
</tr>
<tr>
<td><em>Naegleria fowleri</em></td>
</tr>
<tr>
<td><em>Necator</em> human hookworms including <em>N. americanus</em></td>
</tr>
<tr>
<td><em>Onchocerca</em> filaria worms including <em>O. volvulus</em></td>
</tr>
<tr>
<td><em>Plasmodium</em> including simian species, <em>P. cynomologi</em>, <em>P. falciparum</em>, <em>P.</em></td>
</tr>
<tr>
<td>Protozoa</td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td><em>Plasmodium</em> <em>malariae</em>, <em>P. ovale</em>, <em>P. vivax</em></td>
</tr>
</tbody>
</table>
| *Sarcocystis* including *S. suï hominis* | **Alphaviruses** *(Togaviridae)* – Group A Viruses  
  ➢ Eastern equine encephalomyelitis virus  
  ➢ Venezuelan equine encephalomyelitis vaccine strain TC 83  
  ➢ Western equine encephalomyelitis virus |
| *Schistosoma* including *S. haematobium*, *S. intercalatum*, *S. japonicum*,  *S. mansoni*, *S. mekongi* | **Arenaviruses**  
  ➢ Lymphocytic choriomeningitis virus (non-neurotropic strains)  
  ➢ Tacaribe virus complex |
| *Strongyloides* including *S. stercoralis* | **Bunyaviruses**  
  ➢ Bunyamwera virus  
  ➢ Rift Valley fever virus vaccine strain MP-12 |
| *Taenia solium*, all stages | **Calciviruses** |
| *Toxocara* including *T. canis* | **Coronaviruses** |
| *Toxoplasma* including *T. gondii* | **Flaviviruses** *(Togaviridae)* – Group B Arborviruses  
  ➢ Dengue virus serotypes 1,2,3, and 4  
  ➢ Yellow fever virus vaccine strain 17D  
  ➢ Other viruses as listed in the reference source( see Section V-C, Footnotes and References of Section I through IV) |
| *Trichinella spiralis* | **Hepatitis A, B, C, D, and E Viruses** |
| *Trypanosoma* including *T. brucei brucei*, *T. brucei gambiense*, *T. brucei rhodesiense*, *T. cruzi* | **Herpesviruses** – except Herpesvirus simiae *(Monkey B virus)*  
  ➢ Cytomegalovirus  
  ➢ Epstein-Barr virus  
  ➢ Herpes simplex types 1 and 2  
  ➢ Herpes zoster  
  ➢ Human herpes virus types 6 and 7 |
| *Wuchereria bancrofti* filaria worms | **Orthomyxoviruses**  
  ➢ Influenza viruses types A, B, and C |
| *Adenoviruses*, human – all types | **Papovaviruses**  
  ➢ All human papilloma viruses |
| *Alphaviruses* *(Togaviridae)* – Group A Viruses  
  ➢ Eastern equine encephalomyelitis virus  
  ➢ Venezuelan equine encephalomyelitis vaccine strain TC 83  
  ➢ Western equine encephalomyelitis virus | **Paramyxoviruses**  
  ➢ Newcastle disease virus  
  ➢ Measles virus  
  ➢ Mumps virus |
| Parainfluenza viruses types 1, 2, 3, and 4 |
| Respiratory syncytial virus |
| Parvoviruses |
| Human parvovirus (b19) |
| Picornaviruses |
| Coxsackie viruses types A and B |
| Echoviruses – all types |
| Polioviruses – all types, wild and attenuated |
| Rhinoviruses – all types |
| Poxviruses – all types except Monkeypox virus, restricted poxviruses including Alastrim, Smallpox, and Whitepox |
| Reoviruses – all types including Coltivirus, human Rotavirus, and Orbivirus (Colorado tick fever virus) |
| Rhabdoviruses |
| Rabies virus – all strains |
| Vesicular stomatitis virus – laboratory adapted strains including VSV-Indiana, San Juan, and Glasgow |
| Togaviruses (see Alphaviruses and Flaviviruses) |
| Rubivirus (rubella) |

Table 3 List of Risk Group 2 Agents Commonly Used at UWM

The next table identifies risk group 3 and 4 agents. UWM is neither equipped to conduct research in the BSL-3 and 4 containments required for these pathogens, nor are researchers allowed to work with most of these without additional approvals by the federal government through the Select Agent and Toxin Program, the USDA/APHIS, and Dual Use Research of Concern. Please contact the Biological Safety Officer if you plan to develop a facility to study these organisms.
<table>
<thead>
<tr>
<th>Risk Group 3 (RG3) Agents</th>
<th>Risk Group 4 (RG4) Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacterial Agents</strong></td>
<td><strong>Bacterial Agents</strong></td>
</tr>
<tr>
<td><em>Bartonella</em></td>
<td>None</td>
</tr>
<tr>
<td><em>Brucella</em> including <em>B. abortus, B. canis, B. suis</em></td>
<td>None</td>
</tr>
<tr>
<td><em>Burkholderia (Pseudomonas) mallei, B. pseudomallei</em></td>
<td>None</td>
</tr>
<tr>
<td><em>Coxiella burnetii</em></td>
<td>None</td>
</tr>
<tr>
<td><em>Francisella tularensis</em></td>
<td>None</td>
</tr>
<tr>
<td><em>Mycobacterium bovis (except BCG strain), M. tuberculosis</em></td>
<td>None</td>
</tr>
<tr>
<td><em>Pasteurella multocida type B – “buffalo” and other virulent strains</em></td>
<td>None</td>
</tr>
<tr>
<td><em>Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R. sibirica, R. tsutsugamushi, R. typhi (R. mooseri) Yersinia pestis</em></td>
<td>None</td>
</tr>
<tr>
<td><strong>Fungal Agents</strong></td>
<td><strong>Fungal Agents</strong></td>
</tr>
<tr>
<td><em>Coccidioides immitis</em> (sporulating cultures; contaminated soil)</td>
<td>None</td>
</tr>
<tr>
<td><em>Histoplasma capsulatum, H. capsulatum var. duboisii</em></td>
<td>None</td>
</tr>
<tr>
<td><strong>Parasitic Agents</strong></td>
<td><strong>Parasitic Agents</strong></td>
</tr>
<tr>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td><strong>Viral Agents and Prions</strong></td>
<td><strong>Viral Agents</strong></td>
</tr>
<tr>
<td><strong>Alphaviruses (Togaviruses) – Group A</strong></td>
<td><strong>Arenaviruses</strong></td>
</tr>
<tr>
<td><strong>Arboviruses</strong></td>
<td><strong>Guanarito virus</strong></td>
</tr>
<tr>
<td>➢ Semliki Forest virus</td>
<td>➢ Lassa Virus</td>
</tr>
<tr>
<td>➢ St. Louis encephalitis virus</td>
<td>➢ Junin virus</td>
</tr>
<tr>
<td>➢ Venezuelan equine encephalomyelitis virus (except the vaccine strain TC-83, see Appendix B-II-D (RG2)</td>
<td>➢ Machupo virus</td>
</tr>
<tr>
<td><strong>Arenaviruses</strong></td>
<td>➢ Sabia virus</td>
</tr>
<tr>
<td>➢ Flexal</td>
<td>Bunyaviruses (Nairoivirus)</td>
</tr>
<tr>
<td>➢ Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)</td>
<td>➢ Ebola virus</td>
</tr>
<tr>
<td><strong>Flaviviruses (Togaviruses) – Group B</strong></td>
<td>➢ Marburg virus</td>
</tr>
<tr>
<td><strong>Arboviruses</strong></td>
<td><strong>Tick-born encephalitis virus complex including Abseterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses</strong></td>
</tr>
<tr>
<td>➢ Japanese encephalitis virus</td>
<td>Herpesvirus simiae (Herpes B or Monkey B virus)</td>
</tr>
<tr>
<td>➢ Yellow fever virus</td>
<td>Paramyxoviruses</td>
</tr>
<tr>
<td><strong>Poxviruses</strong></td>
<td>➢ Equine morbillivirus</td>
</tr>
</tbody>
</table>
Table 4 Risk Group 3 and 4 Agents

Routes of Transmission in the Laboratory and Laboratory-Acquired Infections (LAIs)

There are 4 ways in which an infectious agent may be transmitted in the laboratory:

1. **Direct transmission** through exposure to the agent. Example: splash liquid culture of *S. aureus* in eye while moving it from one bench to another.
2. **Ingestion** of the agent either by accidental ingestion of a liquid suspension or contaminated hand to mouth exposure. Example: Handling of *Cryptosporidium* culture and then failure to wash hands after handling, leading to self-inoculation of *Cryptosporidium*.
3. **Inhalation** of infectious aerosols. Example: Employee working with *M. tuberculosis* has a tear in their mask, and thus, inhales and contracts *M. tuberculosis*.
4. **Parenteral inoculation** from a syringe or contaminated sharp. Example: Researcher uses syringes to inoculate mice with *Streptococcus pneumoniae* and accidentally sticks finger with syringe after inoculating mouse, going through the glove.

There is an increased risk of transmission associated with agents that are transmitted via aerosol or droplet transmission, as well as when high-volume quantities are used in research or teaching laboratories. Both teaching and research laboratory must have appropriate protocols and SOPs in place to minimize the risk of transmission of pathogens. Teaching laboratories are at greatest risk for LAIs, as students have less training and expertise than PIs or research laboratory personnel. In 2011, the American Society for Microbiology (ASM) began developing a framework for laboratory safety in teaching laboratories in microbiology in response to Salmonella outbreaks occurring in teaching laboratories at U.S. academic institutions. The completed ASM project now provides the most current recommendations for teaching laboratories, including PPE, recommended practices, implementation of a laboratory biosafety manual, and more. To learn more, visit the [ASM Guidelines for Biosafety in Teaching Laboratories Page](#).
If the agent is an aerosol, they need to have strict protocols in place to prevent transmission. Aerosolized agents are implicated in many of the reported laboratory-acquired infections. Aerosols can spread using air currents, contaminating “clean” areas. For this reason, any agent that can aerosolize must be worked with in a biological safety cabinet (BSC) whenever possible (or fume hood if the agent is a biological toxin) to minimize the spread of the agent. Respiratory PPE, such as a mask, should be worn when handling the agent outside of the BSC.

Additional measures and considerations may be necessary to prevent laboratory-acquired infections by microorganisms that typically do not cause infection in healthy individuals but are known pathogens in immunocompromised or immunosusceptible status individuals. If there are any PIs or researchers in a lab that may have a compromised immune response and are working with agents that may be of concern to them, they will need to consult their personal physician and health care professional of their work to determine what steps would be most appropriate for their health and safety. It is the responsibility of the PI to communicate the hazards of handling the agent, proper safety practices, proper PPE, and proper disposal of the agent.

All accidental exposures must be reported as an injury that occurred at work, using the information provided through the UW System Website. Additionally, the PI must complete a First Report of Biological Exposure or Release Event Form online. It is also the responsibility of the PI (or, in a teaching lab, the laboratory manager and instructor) to ensure all personnel complete the appropriate training so they disseminate the correct information to their students in teaching and research laboratories.

Positive diagnoses of many of RG2 pathogens are required to be reported to public health agencies and will be investigated by the state and with assistance from the Safety and Assurance office. A list of notifiable diseases are available online for reference. Animal bites and scratches require additional documentation to the LAI form, located on the UWM Animal Care Program site.

The IBC can effectively carry out its designated functions only if it has adequate prior knowledge of potentially hazardous research projects. Therefore, all instructional, research, and outreach projects involving potentially pathogenic microorganisms; RG2, RG3, and RG4 infectious agents; oncogenic viruses; human tissue and blood borne pathogens; use of cell components from infectious agents RG2 and higher; and in-vitro construction or propagation of recombinant DNA molecules must be registered with and approved in writing by the Committee.

The following practices are important for disease prevention, contamination of experimental materials, and for the safety of the campus and community. Standard microbiological practices are common to all laboratories handling microorganisms. It is the responsibility of the laboratory staff and PI to develop specific procedures unique to their research facility for the safe handling and disposal of the biohazardous material(s) being utilized in the laboratory.

The following information applies to all laboratories housing biological materials. Information for specific biosafety levels are found later in this section. Most LAIs reported in the literature point to accidents during work with some type of infectious agent. These are often due
to spills, splashes, or sharps/needle stick accidents. This information should be used as a starting point for development of a laboratory specific biosafety manual for your research program or teaching laboratory. For more information, guidance, and instruction regarding any type of laboratory safety, please visit the [UWM Biosafety Page](#).

**Biological Risk Assessment**

Biological risk assessment applies biosafety principles to the available options for handling hazardous materials and agents. The following need to be considered by the PI when evaluating a potential biohazardous agent:

1. What is the capability of the biological agent to infect and cause disease in a susceptible host?
2. How virulent is the biological agent?
3. What is the concentration and suspension volume of the agent being used in the experiment?
4. What are the probable routes of transmission?
5. What is the infective dose of the agent?
6. How stable is the agent in the environment?
7. Have there been any reports of laboratory-acquired infections (LAIs) associated with this agent?
8. What is the origin of the agent?
9. What are the procedures in place to prevent the dissemination of this agent?
10. What are the most appropriate methods in place to inactivate the agent?

Prior to submission of a registration form to the IBC, the PI should complete a [biological risk assessment form](#) to help answer the questions above and to develop the protocol for the research or teaching laboratory. The completed risk assessment should be submitted to the IBC with the [IBC registration form](#) for consideration.

**Biohazard Signage**

Biohazard labels are required for all areas or equipment that house RG-2 or higher agents or in BSL-2 or higher facilities. All labels must be purchased by the laboratory and are required for biohazardous materials. A laminated (or placed in a page protector) door sign indicating the Labels should be posted at the main entrance door(s) to laboratories and animal rooms, on equipment such as freezers, refrigerators, BSCs, incubators, and transport containers. Signage templates are available online at the [UWM Safety and Health Forms Page](#).

**Roles and Responsibilities of Personnel**

The following outlines the roles and responsibilities of personnel as they pertain to biological safety at UWM. Contact the Biological Safety Program prior to initiation of a project that involves biological agents to prevent misunderstandings after work begins. This includes research, teaching, and outreach. The Biosafety Program regularly monitors research at UWM involving any of the following:

- Recombinant (transgenic) or synthetic DNA/ RNA materials, including human gene therapy
• Infectious agent research, including bacteria, viruses, fungi, prions, protozoa, and parasites, including use of proteins and other cell components from infectious agents
• Large scale propagation of cultures consisting of a volume greater than 10L or more in one vessel
• Human cells and cell culture, tissues, organs, or biological samples
• Non-human cells and cell culture, organ, or tissues, or biological samples that are infectious, potentially infectious, or recombinant
• Plants that are recombinant (transgenic), exotic, and/or grown in association with pathogenic or recombinant microbes and/or pathogenic or recombinant small animals (insects, etc.)
• Biological toxins

If the Biosafety Program is notified of biological research on-going at UWM that should have a completed registration form, they will reach out the PI and work with them to get this completed as soon as possible. Failure to have a registration form on file and approved can cause delays in research and teaching or denial of federal funding from the NIH or other governmental agencies.

Biological Safety Officer

It is the responsibility of the BSO to foster safe laboratory practices and ensure compliance with university policies, guidelines and regulations as established by university administration, Institutional Biosafety Committee (IBO), and regulatory agencies such as the NIH, CDC, and USDA.

Summary of Responsibilities of the BSO:

• Manage the biological safety program to ensure safety of the campus community, the public, and the environment to ensure against accidental release of unauthorized biological materials.
• Provide training for biosafety, recombinant DNA work, and bloodborne pathogens.
• Submission of all non-exempt registration to the NIH IBC.
• Review and approve registration (exempt and non-exempt) with the IBC as an ex-officio member.
• Manage activities and support of the Institutional Biosafety Committee, including the coordination of monthly meetings, public posting of meetings in accordance with Wisconsin Open Meetings Law, maintaining of the meeting minutes, and organizing electronic feedback from IBC personnel regarding protocol submissions.
• Work with IBC chair to appoint members, submit letters for their files, and maintain record of membership.
• Conduct annual research laboratory audits to review biological safety practices to ensure that research is conducted in a manner that protects workers and the community.
• Apply an understanding of Federal regulations and guidelines to provide education and training for UWM faculty, staff, students, and the IBC members.
• Assist with other department compliance activities, including (but not limited to): animal care, human research protections, and radiation safety.
Principal Investigator and Teaching Lead Faculty/Staff

The principal investigator (PI) is responsible for the training, supervision, and management of their laboratory personnel and equipment. It is the PI's responsibility to understand the contents of this manual and adhere to all policies set forth by UWM, the State of Wisconsin, and the U.S. Federal Government. The PI is responsible for submission of protocols for approval by the IBC, and to update their protocol every three years for re-approval by the IBC. PIs involved in teaching, research, and/or outreach activities involving biohazardous materials have the primary ethical and legal responsibility to ensure the safety of students, faculty, staff, visitors and the environment. Professors and academic staff that act as course leads are required to train their lab and teaching personnel the same as any research PI. The PI is responsible for staying up-to-date on all current policies and procedures and are required to regularly attending training offered by the Dept. of University Safety and Assurances to be able to effectively train their own personnel.

Summary of Biosafety Responsibilities of PIs/Teaching Lead Instructors/Lab Managers:

- Complete a registration form and submit for approval to the IBC and NIH before commencing any work with biological agents that fall under Sections III-A, III-B, III-C, or III-D of the NIH Guidelines.
- Complete a registration form and submit for approval to the IBC whenever working with biological agents that fall under Sections III-E of the NIH Guidelines (does not require approval prior to commencing work).
- Complete a registration form and submit for approval to the IBC whenever working with biological agents that fall under Sections III-F of the NIH Guidelines (does not require approval, only registration).
- Train all persons directly involved in potentially hazardous experiments of the potential health risks presented and the safety procedures necessary to minimize exposure.
- Attend biosafety training and stay up to date on biosafety rules and regulations.
- Be responsive and cooperative in scheduling, being present for, and following up on annual biosafety inspections. Ensure any issues addressed during inspection are corrected in a reasonable time frame to prevent a disruption of research in the facility.
- Maintain a current record of personnel training, a current inventory and safety information of biological agents being used in the laboratory, and post standard operating procedures (SOPs) for the required biosafety level.
- Establish SOPs for handling of potentially hazardous biological material in the event of a spill or contamination. Post these procedures in a prominent place in the laboratory.
- Immediately report any unusual incident, such as spill, break in containment, or overt contamination to the BSO and complete an incident report.
- Post working areas and facilities with biohazard warning signs. Standardized signs will be provided by University Safety. The PI should consult the BSO if assistance is required in placement of signs.

Laboratory Personnel: Researchers and Students
It is the responsibility of the laboratory personnel to be up to date in biosafety and chemical safety practices. Face-to-face biological safety training is required every three years and the first session is to be completed in the first semester in the laboratory. Review training is due yearly and is completed online.

Summary of Biosafety Responsibilities of Lab Personnel:

- Complete all necessary training and maintain record of the training.
- Adhere to campus, state, and federal policies and regulations.
- Understand the approved protocol(s) for research.
- Perform all tasks using established safety practices and shall comply with the safety guidelines for the work being performed
- Report any unsafe practices to PI, and if necessary, the IBC.
- Report all accidents and injuries to the PI, emergency personnel, and University Safety and Assurances.

Rules, Regulations, and Guidelines Overview

The University of Wisconsin-Milwaukee follows the rules, regulations, and guidelines set forth by local, state, and federal agencies. Links to resources below, plus additional resources regarding biosafety, can be found at the Biological Safety Resources Page. It is expected that anyone working with biohazardous materials periodically reviews these resources to keep up-to-date on the most current policies and regulations.

**National Institute of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules:** These guidelines provide guidelines for the safe use of recombinant DNA and organisms containing recombinant DNA. The most current edition was revised in April 2016. This document also provides information regarding plant biosafety levels. Use of recombinant or synthetic nucleic acid or organisms containing these are further outlined in the section called Recombinant and Synthetic Nucleic Acids. It is important to note that it does not matter if you receive funding from the NIH or not, you are required to adhere to these guidelines. The federal policy requires any institution that receives federal funding from the NIH is required to follow the guidelines in all laboratories.

**Centers for Disease Control and Prevention (CDC) and the National Institute of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories (BMBL):** The CDC and NIH have published this comprehensive guide that provides the information pertaining to biological safety. This includes standard and special microbiological practices, safety equipment, facilities maintenance and design, and provided requirements for animal biosafety levels. The most current edition is the fifth edition, published in 2009. Much of the UWM Biosafety Manual has been developed from the comprehensive information provided in this guide.

**State of Wisconsin Infectious Waste Regulations:** These are state regulations that are utilized to ensure that we comply with State Statutes 289, 299, 500.03, and NR 526.04, under the guidance of the University of Wisconsin System, the UWM Waste Management Specialists, and
contracted waste management vendors. For more information regarding waste disposal, visit the UWM Environmental Protection Page.

**Occupational Safety and Health Administration Bloodborne Pathogen Standard 1910.1030:**
In 1992, the Occupational Safety and Health Administration (OSHA) set a standard to address the occupational health risk associated with the exposure to human blood and other potentially infectious human materials. State and local government employees in Wisconsin are covered under the Department of Safety and Professional Services (DSPS) which serves as the enforcement agency for all OSHA standards. For more information about the UWM Bloodborne Pathogens Training, please visit the UWM Biological Safety Resources Page, or contact the Biological Safety Program, Engelmann Hall Room 270.

**Federal Select Agent Program:** The Federal Select Agent Program is a collaborative effort comprised of the CDC, Prevention/ Division of Select Agents and Toxins, and the and Plant Health Inspection Service/Agriculture Select Agent Services. They regulate the possession, use, and transfer of biological select agents and toxins. For more information regarding the Federal Select Agent Program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products. Refer below for more information regarding select agents and toxins.

This is the most current list of HHS and USDA Select Agents and Toxins.

| HHS and USDA Select Agents and Toxins 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73 |
|-----------------------------------------------|--|--|---|
| **HHS SELECT AGENTS AND TOXINS** | **OVERLAP SELECT AGENTS AND TOXINS** | **USDA SELECT AGENTS AND TOXINS** |
| Abrin | *Bacillus anthracis* | African horse sickness virus |
| *Bacillus cereus* Biovar *anthracis* | *Bacillus anthracis* Pasteur strain | African swine fever virus |
| Botulinum neurotoxins* | *Brucella abortus* | Avian influenza virus³ |
| Botulinum neurotoxin producing species | *Brucella melitensis* | Classical swine fever virus |
| of *Clostridium* | *Brucella suis* | Foot-and-mouth disease virus* |
| Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X₁CCX₂PACTX₆X₇CX₈X₉CX₁₀)³ | *Burkholderia mallei* | Goat pox virus |
| *Coxiella burnetii* | *Burkholderia pseudomallei* | Lumpy skin disease virus |
| Crimean-Congo haemorrhagic fever virus | Hendra virus | Mycoplasma capricolum³ |
| Diacetoxycirpenol | Nipah virus | Mycoplasma mycoides³³ |
| Eastern Equine Encephalitis virus³ | Rift Valley fever virus | Newcastle disease virus³³ |
| Ebola virus* | Venezuelan equine encephalitis virus³ | Peste des petits ruminants virus |
| *Francisella tularensis* | | |
| SARS-associated coronavirus (SARS-CoV) | Rinderpest virus* |
| Saxitoxin | Sheep pox virus |
| South American Haemorrhagic Fever viruses: | Swine vesicular disease virus |
| Chapare | |
| Guanarito | |
| Junin | |
| Machupo | |
| Sabia | |
| Staphylococcal enterotoxins A,B,C,D,E subtypes | |
| T-2 toxin | |
| Tetrodotoxin | |
| Tick-borne encephalitis complex (flavi) viruses: | |
| Far Eastern subtype | |
| Siberian subtype | |
| Kyasanur Forest disease virus | |
| Omsk hemorrhagic fever virus | |
| Variola major virus (Smallpox virus)* | |
| Variola minor virus (Ailastrim)* | |
| Yersinia pestis* | |

Table 5 HHS and USDA Select Agents and Toxins (DHHS, 2017)

*Denotes Tier 1 Agent

1 C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; “Des X” = “an amino acid does not have to be present at this position.” For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

2 A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

3 Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category. 9/10/13

These are the current DURC agents subject to additional oversight by the U.S. Government.

<table>
<thead>
<tr>
<th>Current DURC agents subject to additional oversight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avian influenza virus (highly pathogenic)</td>
</tr>
<tr>
<td><em>Bacillus anthracis</em></td>
</tr>
<tr>
<td><em>Botulinum neurotoxin</em>: For the purposes of this Policy, there are no exempt quantities of botulinum</td>
</tr>
<tr>
<td>Foot-and-mouth disease virus</td>
</tr>
<tr>
<td><em>Francisella tularensis</em></td>
</tr>
<tr>
<td>Marburg virus</td>
</tr>
<tr>
<td>Reconstructed 1918 Influenza virus</td>
</tr>
</tbody>
</table>
neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential. 

<table>
<thead>
<tr>
<th>Burkholderia mallei</th>
<th>Toxin-producing strains of Clostridium botulinum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burkholderia pseudomallei</td>
<td>Variola major virus</td>
</tr>
<tr>
<td>Yersinia pestis</td>
<td>Variola minor virus</td>
</tr>
</tbody>
</table>

| Table 6 Current DURC agents subject to additional oversight. (NIH OCP, 2017) |

Packaging, shipment and transportation requirements for infectious substances, diagnostic specimens, biological products and genetically modified organisms (GMOs):

- United Nations Dangerous Goods
- International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air
- International Air Transport Association (IATA) Dangerous Goods Regulations
- U.S. Department of Transportation 49 CFR Parts 171-177 Hazardous Materials Regulations (DOT)
- U.S. Public Health Service 42 CFR Part 72 Interstate Shipment of Etiologic Agents
- U.S. Postal Service 39 CFR Part 111 General Information on the U.S. Postal Service
- U.S. Department of Labor, OSHA 29 CFR 1910.1030 Bloodborne Pathogens
- In addition, the USDA Animal and Plant Health Inspection Service (APHIS) requires permits for importation and transportation of controlled materials, certain organisms or vectors. This includes animal and plant pathogens, certain tissue cultures and live animals. APHIS also regulates the importation, interstate movement, or environmental release of genetically engineered organisms as regulated under 7 CFR Part 340.

Personnel Training

Trained PIs and laboratory personnel will be the primary means to preventing an accident from occurring in the laboratory. Laboratory safety, biological safety, and bloodborne pathogens are required training for personnel working with RG-2 and higher agents (laboratory safety is required for anyone working in a laboratory). Contact the laboratory safety coordinator for laboratory safety training, and the BSO for biological safety training or bloodborne pathogens training.

It is the responsibility of the PI to coordinate training for handling plants, arthropods, lab equipment use, autoclave use, biological safety cabinet use, etc. It is the responsibility of the PI to coordinate training with animal care for their research team. Contact the ARC manager to arrange this training. Laboratory safety training can be coordinated through the Laboratory Safety Coordinator or the Research Safety Coordinator. Radioactive materials training can be coordinated through the Radiation Safety Officer.

<table>
<thead>
<tr>
<th>Training</th>
<th>Requirement</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Safety</td>
<td>Face-to-face: Every 3 years</td>
<td>In-Person: Biological Safety Officer</td>
</tr>
<tr>
<td></td>
<td>Renewal: online</td>
<td>Online: CITI Program</td>
</tr>
</tbody>
</table>
Recombinant DNA and Synthetic Nucleic Acids  | Before initiating a project involving these anything in the NIH Guidelines | Training: CITI Program
---|---|---
Animal Biosafety  | Initial when beginning first protocol using animals in research with biological materials Renewal: Every three years | Training: CITI Program
Dual Use Research of Concern and Select Agents  | When initiating research involving select agents or DURC | Training: CITI Program
Viral Vectors  | Before commencing new protocol with or for new researchers using viral vectors | Training: In-person with BSO
Bloodborne Pathogens  | Annual- online or in-person training | Researchers: CITI Program All other personnel: VIVID
Radiation Safety  | Annual | Radiation Safety Officer
Laboratory Safety  | Annual | Laboratory Safety Coordinator or Research Safety Manager
Animal Care and Certification  | Every 3 years | Animal Care Manager

Table 7 Training requirements for biosafety, animal care, and bloodborne pathogens at UWM.

The BSO will come to your lab per the request of the lab manager or PI and provide annual on-site training for biological safety and/ or bloodborne pathogens safe handling, or you may attend the monthly scheduled training sessions. A face-to-face session is required, at a minimum, every three years. It is encouraged that all lab personnel attend a training annually to get updates/ changes to state/ federal regulations. All face-to-face sessions will be followed up with certificates of completion for your file. A variety of biological safety trainings are available for researchers through CITI program online. Visit the Biosafety Training Page for more information about the Biosafety Training opportunities.

Medical Surveillance of Lab Personnel

It is important that personnel are regularly being monitored to identify any health concerns that could increase their risk for contracting a laboratory-acquired infection. Some agents may require vaccination prior to handling (such as personnel working in a laboratory handling blood- personnel must be offered a Hepatitis B vaccination). Accidental exposure requires an illness and injury report to be complete through the UW System HR Page by the employee and employer, as well as a follow-up with a primary-care physician for treatment for exposure.

It is the responsibility of the PI to inform their personnel and any visitors to their laboratory of risks associated with the biological materials being used in their lab- including routes of transmission, signs and symptoms of the disease, and risks for those who are
immunocompromised or immunosuppressed. It is also the responsibility of the PI to put in place restricted access policies for those at elevated risk of infection. Please contact the BSO to work with your lab to determine the best safe practices.

Whenever a vaccine is available for biological agent being studied in the laboratory, personnel should receive the vaccine prior to working with the infectious material to minimize the risk of a laboratory-acquired infection. The PI should determine these needs and set the guidelines for their research facility. The University of Wisconsin-Milwaukee cannot require vaccination, but if vaccination requirements restrict access to the lab this should be clearly communicated with personnel. Vaccine requirements must be included on the entry door to the lab to communicate the risks associated with the pathogen being studied.

**Safe Handling of Specimens and Cultures**

The following outlines the safe handling of research specimens, cultures, animals (for purposes of biosafety), and plants. Safe Practices, SOPs and more can be found online at the [Biosafety Program SOPs Page](#).

**Personal Protective Equipment (PPE)**

Personal protective equipment is used to protect laboratory personnel from contact with hazardous materials and biological agents. Appropriate lab attire also helps prevent materials from being contaminated. Safety equipment, personal protective devices, and training use of these devices must be provided by the PI or laboratory supervisor prior to use. It is the responsibility of the PI to ensure personnel are selecting and using PPE appropriately. The following is a short guide to selecting the appropriate PPE. Consultation of government resources, the BSO, and other literature regarding research with the biological agents being used will help in best determining needs for the lab personnel. Additional information can be found on the [UWM Laboratory Safety PPE Page](#).

- **Eye and Face Protection:** It is required that lab personnel wear safety glasses whenever procedures involving a possibility of a splash, work with low hazard chemicals, or impact hazard research is being conducted. These should optimally be performed in a BSC or fume hood (dependent on material), but when this is not available, the following is required for eye and face PPE:
  - Splash goggles: These are required whenever there is any probability (no matter how low) of splash may occur—including when cleaning with bleach solutions. The UWM bookstore carries a variety of splash goggles.
  - Full face protection (such as a face shield): Required whenever there is an anticipated splash or spray of hazardous materials or a high potential for aerosol generation. These are not a replacement for eye protection, so splash goggles should also be worn. These are available from the UWM bookstore.
  - Safety glasses: If the work involves an impact hazard, with low probability of splashes and chemicals that are of a low hazard, safety goggles are an appropriate choice. These are available from the UWM bookstore.
The eyes and mucous membranes are two potential routes of transmission of pathogens. Eye protection should always be worn in the laboratory. Dependent upon the other materials being handled, contact lenses may or may not be worn. Refer to the UWM Chemical Hygiene Plan for determining the best choice in protective eyewear for the laboratory. Additionally, the OSHA Lab Standard is a good reference.

Laboratory Attire: Coats, Aprons, Scrubs, Smocks, Gowns, Foot Covers

Laboratory attire includes coats, scrubs, smocks, gowns, and foot covers. The proper lab attire is important in prevention of accidental exposure or contamination. Lab coat selection should be made carefully. Aprons are not appropriate for the lab as long sleeves are necessary for arm protection. If splashes may occur, the lab coat should be resistant to liquids.

It is the recommendation of the BSO that all labs use disposable lab coats, which are disposed of in an autoclavable bag monthly (bi-monthly max.) and autoclaved prior to disposal. This minimizes the risk of accidental release of pathogens into the environment or contamination of lab personnel. They are readily available from the UWM bookstore and cost less than $10. If fabric lab coats are used, they should be autoclaved monthly and laundered by the UWM laundry service after they have been autoclaved. Both are available through the UWM bookstore. In student teaching laboratories, students handling biological agents are required to use disposable lab coats, stored in the lab for the duration of the semester, then are disposed of by the student in an autoclavable bag and autoclaved prior to disposal by the lab manager. Protective clothing must be removed and left in the laboratory before leaving for non-laboratory areas.

Do not go into non-research areas or other labs wearing lab coats worn in BSL lab facilities. Do not take lab coats home to wash, this is an accidental release risk that could expose the community and environment to pathogens. Disposable lab coats are to be made available for visitors, facilities personnel, and service workers. This is to protect them and to protect your work from contamination. Please keep extras available in the laboratory for this purpose.

Gloves

Gloves are selected by the PI and lab personnel based on the hazards involved and the type of work being done. Gloves are required whenever working with biohazards, toxic substances, hazardous chemicals. If hot materials or dry ice are being handled, temperature resistant gloves must be worn. Work that requires an elevated level of precision necessitates the use of thin-walled gloves. It is recommended that nitrile, not latex gloves, are used for this purpose, due to the high incidence of allergies associated with the use of latex gloves. Powdered gloves are banned by the U.S. Food and Drug Administration (FDA) due negative reactions to the starch powder.

If gloves are contaminated, they need to be changed immediately and hands should always be washed after removing gloves using soap and warm water for a minimum of 30 seconds. If you find that a glove has been torn or punctured while working with BSL-2 or higher pathogens, this needs to be documented and reported to the BSO as an accidental exposure. Visit
When transporting potentially infectious materials, such as cultures or waste to be autoclaved and they must leave the lab room to go to another room for this purpose, one gloved hand should be used to handle the infectious material, and the other hand should remain ungloved to touch common surfaces, such as elevator buttons or door knobs.

**Respirators**

Aerosol exposure is a continued concern in laboratories. If there is a risk of aerosol exposure that cannot be mitigated using alternative procedures or containment equipment, then respiratory protection, such as a respirator, should be considered. Respirators are selected based on the hazards the researcher will encounter and the protection required. Please contact the UWM Environmental Health, Safety, and Risk Management program for assistance in determining options and appropriate types to purchase/use in your laboratory. It is strongly recommended that you seek out training in respirator use prior to using the selected one; an error could create a very dangerous situation for the researcher wearing it. There are a variety of options, but none have been tested against any pathogens except *Mycobacterium tuberculosis*. Review [Respiratory Safety](#) under Occupational Health on the University Safety and Assurances Page for determining needs regarding respiratory protection.

**Integrated Pest Management Plan**

Having an integrated pest management plan (IPM) is a major component of protecting both the researchers in the lab and the external community. Any kind of presence of any kind of insects, whether they are pests or innocuous, is of a concern for spread of pathogens as a mechanical vector on the insect. It is necessary to make sure that if you have any kind of pest issue, including flies, cockroaches, mice, and the like, that contact the building manager, custodial staff, and professional pest controllers (if necessary) to remove the issue immediately. The best way to prevent a pest issue is to keep your laboratory facility clean, organized, and well-secured always. See [Appendix G of the BMBL](#) for more information.

**Inventory Log and Physical Inventory**

It is the responsibility of the PI and their research personnel to keep a complete inventory of chemicals and biological agents being used. A physical inventory should be available in the lab. A running log of biological agents and chemicals should be maintained electronically or written to minimize the risk of anything being taken without being noticed from the lab. The biological agents must be closely monitored always to be able to recognize if materials are missing, what those missing materials are, the quantity of the missing materials, and the potential hazard associated with those materials. Use the [Risk Group Database](#), [ATCC](#), and the [Canadian Pathogen Safety Data Sheets](#) to keep an up to date log of information regarding biological agents.
Use of Radioisotopes in Research

Some investigators may work with radioisotopes in conjunction with their work with some biohazardous agents. All work with radioisotopes conducted at UWM must be authorized through the campus Radiation Safety Program. Visit the Radiation Safety Page for more guidance, information, and training.

Aquatic Animal Special Considerations

Aquatic pathogens have different considerations than that of the terrestrial animals and their pathogens. Biocontainment necessitates a separate set of considerations, because they are a “wet” facility, which can increase the risk of spread of potential pathogens. There are no U.S. national standards set forth for aquatic biocontainment systems. There’s concern regarding generation of aerosols from water spray, improper sterilization of equipment, which could contaminate multiple tanks, centralized water that could introduce pathogens to water and recirculate throughout the facility, and outside personnel tracking in pathogens that could spread to tanks. The following are recommendations based on Canadian standards and current recommendations in literature (Bailey, 2008) (CCAC, 2005).

- Containment facility:
  - Physical separation from other holding rooms and facilities.
  - Quarantine: separate area and protocol for incoming fish from external environment to prevent spread of disease.
  - All entry and exit points have foot baths or disinfection mats and hand wash stations.
  - Controlled access into the secured entry areas.
  - Separate clothing transfer and locker area adjacent to facility for preparing for entry to lab.
  - Location and design should prevent accidental release in event of a natural disaster.
  - Pest control management plan developed for prevention of introduction of pests into facility.
  - Minimize use of materials that can withstand rigorous decontamination.
  - Immersion disinfection buckets should be available for regular sanitation of room-specific equipment.

- Water source
  - Water system should be independent and the distribution lines should be separated for zones within the fish room to minimize spread of anything through the water source.

- Tanks
  - Closures and seals should be installed and maintained to prevent spills or splashing.

- Air supply
  - Sterile air supply when possible, including use of UV air sterilizers

- General Design
Mechanical and accessory systems are accessible without having to enter the containment area from outside.

Room surfaces, including floor, walls, and ceiling, must be easy to sanitize, smooth, and impervious to moisture.

Ventilation and temperature control permits drying conditions and air mixing but prevents airborne pathogens from escaping through air movement or condensation.

Automated system to monitor ventilation and temperature.

Fail-safe backup pathogen control in event of failure of automated system.

Water collected into treatment tanks and disinfected and release meets local, state, and federal regulations.

Flood drains routed to holding reservoir to process water with disinfectant system that has an alarm system to monitor it.

Doors and walls are sealed with raised dams along doors and floors, which can hold water in containment room in the event of a leak or spill.

Plumbing prevents back flow from animal holding tanks and effluent handling systems.

Pipes are hard-plumbed with removable access points to clean and do QC checks following research studies. Exposed piping should be easily accessible for cleaning.

Electrical fixtures should be ground fault interrupted, have gaskets, be sanitized, and provided with an emergency back-up power source.

Wall switches are sealed and waterproof so they can be disinfected.

Ceiling fixtures have gaskets, are waterproof, and can be sanitized.

Outlets are positioned well above floor level and water supply lines.

Anywhere that could leave potential for water to penetrate building should be caulked, sealed, and has a gasket.

Spill kits should be stored up and away from the floor and from water sources.

- Waste Disposal
  - A means of sterile disposal of carcasses and other contaminated biological wastes including incineration, autoclaving or rendering should be considered following animal care rules, biological safety procedures, and facility safety considerations.

Use of Plants in Research or Teaching Laboratories

The use of plants in biological research only necessitates IBC approval when plants are being inoculated with plant pathogens or when transgenic plants are being researched. Plants have a system for containment unique to only plants (BSL1-P through BSL4-P) developed by the NIH, and can be found on pp. 129-138, Appendix P, of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, April 2016.

Transgenic Plants

Transgenic plants should be given consideration as well; identification on the door of the facility housing these plants should be posted to indicate need for preventing accidental release from the
facility. A customizable sign is available on the UWM Safety and Health Forms Page. The development of transgenic plants must be reported to the NIH, and requires a full approval of the IBC before commencing. Please complete the IBC registration form for approval.

**Plant Containment and Accidental Release**

Containment practices should be developed with the greenhouse director and should be approved by the IBC. If an inadvertent release of plants or spill of microorganisms must be reported to the BSO and treated immediately. Complete a First Report of Biological Exposure or Release Event Form for accidental release records. Failure to submit a report of accidental release from a greenhouse research facility may result in a review by the IBC of the research and suspension of the research until the appropriate biocontainment practices are obtained. Contact the BSO for guidance, training, discussion of facilities and greenhouse, and rules and regulations involving plants and plant biocontainment. All plant policies and procedures should be made available to all working on experiments in the greenhouse in their laboratory specific safety manual.

The following table contains the names of major plant pathogens that researchers may use in the lab. Their containment is specific to Plant Biosafety Levels, but they are a RG1 organism to humans.

<table>
<thead>
<tr>
<th>Type of Plant Pathogen</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fungi- Chytridiomycetes</td>
<td>Physoderma maydis</td>
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<tr>
<td>Fungi- Oomycetes</td>
<td><em>Albugo candida</em></td>
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<td></td>
<td><em>Peronospora sojae, P. trifoliorum, P. viticola</em></td>
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<td></td>
<td><em>Phytophthora cactorum, P. capsici, P. cinnamomi, P. citricola, P. fragariae, P. infestans, P. megasperma, P. megasperma f.sp. medicaginis, P. rubi s.sp. fragariae, P. sojae</em></td>
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<tr>
<td></td>
<td><em>Plasmodiophora brassicae</em></td>
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<td></td>
<td><em>Pythium aphanidermatum, P. arrhenomanes, P. graminicola, P. irregulare, P. ultimum</em></td>
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<td></td>
<td><em>Sclerotophthora macrospora</em></td>
</tr>
<tr>
<td>Fungi- Ascomycetes</td>
<td><em>Apiosporina morbosa (black knot), Botryosphaeria obtusa, B. ribis (B. dothidea, B. berengeriana)</em></td>
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<tr>
<td></td>
<td><em>Claviceps purpurea</em></td>
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<td></td>
<td><em>Cymodothea trifolii (sooty blotch)</em></td>
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<tr>
<td></td>
<td><em>Diaporthe phaseolorum</em></td>
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<td></td>
<td><em>Gaeumannomyces graminis</em></td>
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<td></td>
<td><em>Gibberella zeae</em></td>
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<td></td>
<td><em>Glomerella cingulate</em></td>
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<td></td>
<td><em>Leptosphaerulina trifolii</em></td>
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<td></td>
<td><em>Monilinia fructicola (Sclerotinia fructicola)</em></td>
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<tr>
<td></td>
<td><em>Nectria cinnabarina</em></td>
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<tr>
<td></td>
<td><em>Ophiostoma ulmi (Ceratocystis ulmi)</em></td>
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<tr>
<td></td>
<td><em>Pseudopeziza medicaginis</em></td>
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<tr>
<td></td>
<td><em>Pseudopeziza trifolii</em></td>
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<tr>
<td></td>
<td><em>Sclerotinia sclerotiorum (Whetzelinia sclerotiorum), S. trifoliorum</em></td>
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<td></td>
<td><em>Valsaambiens</em></td>
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<td></td>
<td><em>Venturia inaequalis (apple scab)</em></td>
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<tr>
<td></td>
<td><em>Xylaria polymorpha</em></td>
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<tr>
<td>Fungi- Powdery Mildews</td>
<td><em>Erysiphe graminis</em></td>
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<tr>
<td></td>
<td><em>Microsphaera vaccinii (on Ericaceae)</em></td>
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<td></td>
<td><em>Podosphaera clandestina (on Rosaceae)</em></td>
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<td></td>
<td><em>Sphaerotheca Asteraceae, S. cucurbitaceae, S. scrophulariaceae)</em></td>
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<tr>
<td></td>
<td><em>S. macularis (on hops and strawberry)</em></td>
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<td></td>
<td><em>Unicinula viticola</em></td>
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<tr>
<td>Coelomycetes</td>
<td><em>Colletotrichum acutatum C. coccodes, C. destructivum, .</em></td>
</tr>
<tr>
<td>Fungi</td>
<td></td>
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<tr>
<td><em>Fragariae, C. gloeosporioides, C. graminicola, C. trifolii</em></td>
<td><em>Macrophomina phaseolina (Macrophoma phaseolina, M. phaseoli, Botryodiplodia phaseoli)</em></td>
</tr>
<tr>
<td><em>Phomopsis juniperovora, P. sojae, P. viticola</em></td>
<td><em>Septoria rubi, S. tritici</em></td>
</tr>
<tr>
<td><em>Stagonospora nodorum (Septoria nodorum)</em></td>
<td><em>Stenocarpelia maydis (Diplodia zeae, D. zeae-maydis)</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hyphomycetes</th>
<th><em>Alternaria alternata, A. solani</em></th>
<th><em>Bipolaris maydis (Hemithosphorium maydis, Drechslera maydis), B. sorokiniana (Helminthosporium sorokiniana, Drechslera sorokiniana), B. victoriae (Helminthosporium victoriae, Drechslera victoriae)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Botrytis cinerea</em></td>
<td><em>Cercospora medicaginis, C. zeae-maydis</em></td>
<td><em>Cladosporium herbarum</em></td>
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<tr>
<td><em>Drechslera avenae (on oats, other grasses), D. graminea (on barley, other grasses), D. poae (on grasses), D. teres (on barley, other grasses), D. tritici-repentis (on cereals, other grasses)</em></td>
<td><em>Exserohilum turcicum (Helminthosporium turcicum, Bipolaris turcicum)</em></td>
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<tr>
<td><em>Fusarium acuminatum, F. avenaceum, F. culmorum, F. equiseti, F. graminearum, F. moniliforme, F. oxysporum, F. roseum, F. solani</em></td>
<td><em>Penicillium expansum</em></td>
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<tr>
<td><em>Rhynchosporium secalis</em></td>
<td><em>Thielaviopsis basicola</em></td>
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<tr>
<td><em>Verticillium albo-atrum, V. dahlia</em></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Fungi- Hemiascomycetes</th>
<th><em>Taphrina caerulescens</em> (leaf blister on oak, Ostrya, Rhus), <em>T. communis</em> (plum pocket on Prunus), <em>T. deformans</em> (peach leaf curl).</th>
<th></th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Fungi- Basidiomycetes</th>
<th>Wood Rotters and Root-Collar Rotters</th>
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<tbody>
<tr>
<td></td>
<td>➢ <em>Armillaria mellea</em></td>
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<tr>
<td></td>
<td>➢ <em>Ceratobasidium cerealea</em></td>
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<td></td>
<td>➢ <em>Daedaleopsis confragosa (Daedalea confragosa)</em></td>
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<td></td>
<td>➢ <em>Ganoderma applanatum (Fomes applanatus), G. lucidum</em></td>
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<tr>
<td></td>
<td>➢ <em>Hirschioporus pargamenus (Trichaptum biformis, Polyporus pargamenus)</em></td>
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<tr>
<td></td>
<td>➢ <em>Laetiporus sulphureus (Polyporus sulphureus)</em></td>
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<td></td>
<td>➢ <em>Phellinus gilius, P. robiniæ</em></td>
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<tr>
<td></td>
<td>➢ <em>Schizophyllum commune</em></td>
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<tr>
<td></td>
<td>➢ <em>Stereum ostrea</em></td>
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<tr>
<td><strong>Trametes versicolor (Polyporus versicolor, Coriolus versicolor).</strong></td>
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</tbody>
</table>

**Rusts**
- *Gymnosporangium clavipes* (cedar-quince rust), *G. globosum* (cedar-hawthorn rust), *G. juniperi-virginiana* (cedar-apple rust)
- *Puccinia coronata* (on *Rhamnaceae, Eleganaceae/Poaceae*), *P. graminis* (on *Berberis/Poaceae*), *P. recondita* (on *Ranunculaceae/Poaceae*)
- *Pucciniastrum americanum* (late leaf rust on raspberry)

**Smuts**
- *Tilletia caries* (*Tilletia tritici*), *T. laevis* (*Tilletia foetida*)

**Other Basidiomycetes**
- *Rhizoctonia solani* (*Thanatephorus cucumeris*)
- *Sclerotium rolfsii.*

<table>
<thead>
<tr>
<th><strong>Plant Pathogen Viruses</strong></th>
</tr>
</thead>
</table>
| Alfalfa mosaic  
Barley yellow dwarf  
Bean common mosaic  
Bean yellow mosaic  
Beet curly top  
Beet mosaic  
Cactus virus X  
Camellia yellow mottle  
carnation mottle  
cauliflower mosaic  
chrysanthemum mosaic  
chrysanthemum virus B  
cucumber mosaic  
cymbidium mosaic  
dasheen mosaic  
fig mosaic  
impatiens necrotic spot  
lettuce big vein  
lettuce mosaic  
lily symptomless  
maize dwarf mosaic  
odontoglossum ringspot  
papaya ringspot  
pepper mottle  
plum line pattern  
potato leaf roll  
potato virus S, X, Y  
prune dwarf |
<table>
<thead>
<tr>
<th>prunus necrotic ringspot</th>
</tr>
</thead>
<tbody>
<tr>
<td>squash mosaic</td>
</tr>
<tr>
<td>sugarcane mosaic</td>
</tr>
<tr>
<td>tobacco etch</td>
</tr>
<tr>
<td>tomato mosaic</td>
</tr>
<tr>
<td>tomato spotted wilt</td>
</tr>
<tr>
<td>turnip mosaic</td>
</tr>
<tr>
<td>watermelon mosaic virus 2</td>
</tr>
<tr>
<td>zucchini yellow mosaic</td>
</tr>
</tbody>
</table>

*Table 8 Plant Diseases Commonly Studied in Research Labs*

**Use of Animals in Research and Teaching Laboratories**

The use of animals for pathogen research poses numerous risks and require additional safety practices. Refer to the UWM Animal Care Program for details on handling animals, become certified in animal care at UWM, and to submit protocols specific to handling animals. In addition to following procedures and policies set forth by the UWM IUCUC and the IRB, additional protocols are to be submitted to the IBC for approval in the event infectious pathogens are being used in animal research. Visit the UWM IBC Page for the appropriate forms to file with the IBC.

In the event an investigator is bitten or scratched by an animal infected with a pathogen, an accidental biological release form must be filed with the IBC, in addition to the accident forms that are filed with animal care and the University. Handling bedding and animal waste must also take additional precautions and must follow the policies set forth by the animal care program, as well as policies in place for BSL-2 laboratories. All bedding from BSL-2 animal research labs must be autoclaved prior to disposal. Contact the biological safety officer and animal care to determine how to develop a protocol for handling the animals and pathogen(s) used in the laboratory.

The following list of animal etiologic agents is appended to the list of human etiologic agents. None of these agents are associated with disease in healthy adult humans; however, they are commonly used in laboratory experimental work. A containment level appropriate for RG1 human agents is recommended for their use. For agents that are infectious to human cells, e.g., amphotropic and xenotropic strains of murine leukemia virus, a containment level appropriate for RG2 human agents is recommended.
<table>
<thead>
<tr>
<th><strong>Viral Family</strong></th>
<th><strong>Examples</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Baculoviruses</td>
<td>Baculovirus</td>
</tr>
<tr>
<td>Herpesviruses</td>
<td>Herpesvirus ateles</td>
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<tr>
<td></td>
<td>Herpesvirus saimiri</td>
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<tr>
<td></td>
<td>Marek's disease virus</td>
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<td></td>
<td>Murine cytomegalovirus</td>
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<tr>
<td>Papilloma viruses</td>
<td>Bovine papilloma virus</td>
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<td></td>
<td>Shope papilloma virus</td>
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<tr>
<td>Polyoma viruses</td>
<td>Polyoma virus</td>
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<tr>
<td></td>
<td>Simian virus 40 (SV40)</td>
</tr>
<tr>
<td>Retroviruses</td>
<td>Avian leukosis virus</td>
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<tr>
<td></td>
<td>Avian sarcoma virus</td>
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<tr>
<td></td>
<td>Bovine leukemia virus</td>
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<tr>
<td></td>
<td>Feline leukemia virus</td>
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<tr>
<td></td>
<td>Feline sarcoma virus</td>
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<tr>
<td></td>
<td>Gibbon leukemia virus</td>
</tr>
<tr>
<td></td>
<td>Mason-Pfizer monkey virus</td>
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<tr>
<td></td>
<td>Mouse mammary tumor virus</td>
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<td></td>
<td>Murine leukemia virus</td>
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<tr>
<td></td>
<td>Murine sarcoma virus</td>
</tr>
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<td></td>
<td>Rat leukemia virus</td>
</tr>
</tbody>
</table>

*Table 9 Animal Viral Agents Commonly Used in Research*

**Laboratory Animal Facilities**

Animal facilities are assigned to a containment level based on their risk assessment and risk group, just like a standard biological laboratory. There are additional factors that need to be considered when working in animal facilities, including:

- Routes of transmission
- Volumes/ concentrations of agent(s) being used
- Route of inoculation
- Route of excretion of agents (if any)
- Zoonotic diseases to which the animals are susceptible and humans are susceptible
- Natural parasites that could be a problem for the animals used
- Nature of the animals (do they bite, scratch, spit, etc.)
- Possible allergen considerations
- Design features required for safety and containment
Working with Genetically Modified Animals

The National Institutes of Health (NIH) reviews all recombinant DNA research proposals that fall under their scope of approval. The University of Wisconsin-Milwaukee requires all biological research that involves genetic modifications to be filed using the IBC registration form, regardless of whether it is exempt from NIH review. As a condition for NIH funding of recombinant or synthetic nucleic acid molecule research, institutions shall ensure that such research conducted at or sponsored by the institution, irrespective of the source of funding shall comply with the NIH Guidelines (NIH, 2016, p. 10). Only a limited number of experiments are NIH exempt and only require IBC registration. Visit the IBC Page to learn more about work with Genetically-Modified Animals.

Invertebrate Research Special Considerations

Invertebrates, will still fall under the Animal Biosafety Level, but have additional considerations. Even if an arthropod is not infected with a human pathogen, they can become a risk to the external environment if they get outside of the lab, especially if they can complete a transmission cycle for a disease in which they act as a biological vector. Invertebrates can also act as mechanical vectors and transmit pathogens, such as house fly transmission of \textit{E.coli} or \textit{Salmonella} on their feet, and should also be tightly managed. Please contact University Safety & Assurances for assistance with determining the needs for working with invertebrates. Work with recombinant DNA or synthetic nucleic acid-modified arthropods requires IBC approval prior to commencing work. Visit the IBC Page to learn more about work with Genetically-Modified Animals.

\textit{Recombinant DNA and Synthetic Nucleic Acid Use in Teaching and Research}

All recombinant DNA (rDNA) research proposals, regardless of funding sources, require the PI to determine the physical and biological containment level, complete an IBC registration form, and receive approval from the IBC prior to commencing research. There are six categories of experiments covered by the NIH guidelines. The following is a summary based on these guidelines. The comprehensive \textit{NIH Guidelines for Research Involving Recombinant DNA or Synthetic Nucleic Acid Molecules} was most recently updated in April 2016.

Research that Requires NIH Approval (and IBC)

\textit{Section III-A: Human Gene Transfer Experiments and Intentional Drug Resistance in Microorganisms}

Per Section III-A of the NIH Guidelines, experiments falling under this category require the approval of the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov, the publication of the proposal in the Federal Register for 15 days of comment, review by the NIH Recombinant DNA Advisory Committee (RAC), and approval by specific NIH prior to commencing the research. Experiments that fall in this category include those that involve human gene transfer experiments and the transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally from their
environment, specifically if this could compromise the ability to control the disease agent (NIH, 2016).

The UWM IBC will not approve a protocol that falls in this category until it has received approval from the NIH, which should be submitted with the IBC Registration Form. After reading and reviewing the NIH Guidelines, contact University Safety & Assurances if your research falls in this category for assistance.

Section III-B: Cloning of Toxin Molecules

Per Section III-B of the NIH Guidelines, research that falls in this category cannot be initiated without submission of relevant information on the proposed experiment to NIH/Office of Biotechnology Activities (OBA). Review the NIH Guidelines for exceptions. Experiments in this category include experiments involving the cloning of toxin molecules, including botulinum toxins, tetanus toxin, diphtheria toxin, and \textit{Shigella dysenteriae} neurotoxin (NIH, 2016).

The UWM IBC will not approve a protocol that falls in this category until it has received approval from the NIH, which should be submitted with the IBC Registration Form. After reading and reviewing the NIH Guidelines, contact University Safety & Assurances if your research falls in this category for assistance.

Section III-C: Use of Human Subjects for rDNA or Synthetic Nucleic Acid Trials

Section III-C experiments cover human subjects. In addition to having IBC approval, these experiments require Institutional Review Board (IRB) approval and NIH/OBA registration approval. In some cases, they may also need NIH RAC approval as well. These include all experiments that involve the deliberate transfer of rDNA or synthetic nucleic acid molecules, or DNA/RNA derived from rDNA or synthetic nucleic acid molecules to one or more human research subjects (NIH, 2016).

See the IRB page for more details regarding IRB approvals. An IBC registration form needs to be approved, even after it has been approved by the NIH/OBA. After reading and reviewing the NIH Guidelines, contact University Safety & Assurances if your research falls in this category for assistance.

Section III-D: RG2/3/4 Pathogens, Infectious viruses, Helper viruses in tissue culture, and Cultures > 10 L

Section III-D covers whole animal or plant experiments, experiments involving the use of infectious DNA or RNA viruses, or use of defective DNA or RNA viruses in the presence of a helper virus in tissue culture, experiments involving DNA from Risk Group 2, 3 or 4 agents, experiments involving greater than 10 liters of culture, and experiments involving Influenza viruses. Prior to the commencing an experiment in this section, the PI must submit a Registration Form to the Institutional Biosafety Committee. The IBC reviews and approves all experiments in this category prior to initiation. Additionally, IACUC will require filing of appropriate documentation for approval for animal experiments.
Research that Does Not Require NIH Approval (Exempt) but Requires IBC Approval

Section III-E: Require Approval Concurrent with Research

Section III-E experiments include experiments that do not fall under the section III-A, III-B, III-C, III-D, or III-F, and fall in one of the following: Experiments that involve forming rDNA or synthetic nucleic acids containing no more than two-thirds of the genome of any eukaryotic virus, genetically modified plants, transgenic rodents (ABSL-1 only), breeding of transgenic rats (ABSL-1 only). The Institutional Biosafety Committee reviews and approves all such proposals, but Institutional Biosafety Committee review and approval prior to initiation of the experiment is not required (NIH, 2016). When the PI is going to begin this experiment, a registration form should be submitted for approval.

Section III-F: Does not Require IBC Approval, Does Require IBC Registration

Section III-F experiments are exempt from the NIH Guidelines however; they must still be registered with the IBC who will verify the exempt status of the registration. It is the responsibility of the PI to file the paperwork in a timely manner in accordance with NIH Guidelines. See the IBC Page for the appropriate registration forms.

Transport and Shipping of Biological Materials

The proper packaging, labeling, and transportation methods are essential in minimizing an accidental exposure or release of biological material on campus during transport. The following should be considered when transporting and shipping biological materials around campus.

Transportation of Biological Materials

- Primary containment: Select an appropriate primary container that is designed for transporting the material. Do not use food containers or other containers that have not been designed for the explicit use as a laboratory storage container.
- Primary sample containers should be placed in a secondary container for transport. For example, if a bag full of inoculated culture plates need to be transported to the autoclave for disposal, they should be placed in a plastic bag housed in a labeled biohazard container. Do not use red biohazard bags for disposal unless necessary- they cannot go in the regular garbage and must go through medical waste.
- Bubble wrap, newspaper, etc. may be used inside the secondary containment to act as shock-absorbers and to stabilize the primary containers from rupturing due to shifting around in the secondary containment.
- Secondary containers should be clearly labeled with a description of contents and an emergency contact name and phone number. If it is a biohazard, a biohazard label should also be affixed to the container.
• If the material must be transferred to another part of campus that is further than walking distance and must be transported in a vehicle, a UWM vehicle should be used for transport so the driver and their personal car environment is not exposed to potential hazards. When transporting in a vehicle, secure the container using bungee cords, belts, or other means.

Shipment of Biological Materials

Shipping hazardous materials requires training for shipping the materials and fall under U.S. Department of Transportation (DOT), International Air Cargo Organization (IACO), and International Airport Transport Association (IATA) federal regulations. Contact the Department of University Safety and Assurances to determine training needs and safe handling practices.

If the material being moved off-campus is biohazardous waste, it must be handled by approved vendors or the Waste Management Specialist. It should not be moved by researchers or PIs from the laboratory. Please contact Waste Management for additional assistance.
Chapter 3: BSL-1 Laboratory Procedures

The following are some key techniques and safety considerations based on each biosafety level 1. Remember that risk group organisms generally fall into the same number of containment, so if it is an RG1 organism, it most likely needs a BSL-1 level of containment. It is the responsibility of the PI to determine the appropriate BSL and submit a complete IBC registration form.

**BSL-1 Standard Microbiological Technique and Hygiene**
(UW Biosafety, 2017)

The following are recommendations based on the BMBL 5th edition recommendations for BSL-1 labs. Please note that there may be additions to this list, and it is only intended to be a starting point for determining safety needs in the laboratory. A registration form should be filed with the IBC for BSL-1 to ensure there is a record of research with UWM.

✓ Do not eat, drink, chew gum, use tobacco, apply cosmetics, or handle contact lenses in the laboratory.
✓ Do not store food for human consumption in the laboratory.
✓ Do not store items such as coats, handbags, dishes, or other personal items in the laboratory.
✓ Wash hands frequently after handling infectious materials, after removing personal protective equipment (PPE), and always before leaving the laboratory.
✓ Keep hands away from mouth, nose, eyes, face, and hair.
✓ Do not pipet by mouth.
✓ Wear pants and close-toed shoes in the laboratory.
✓ Wear the appropriate PPE for BSL-1 containment: at a minimum- a lab coat; with gloves, eye protection, respiratory protection, face protection, etc. used when appropriate.
✓ Keep laboratory doors closed and locked.
✓ Aerosol generating procedures should not be performed in equipment corridors not located in the laboratory suite.
✓ Plants or animals not associated with the research being conducted are not permitted in the laboratory.

**ABSL-1 Facility**

Most stock animals will fall into this level after quarantine. In addition, any animals inoculated with Risk Group 1 (RG1) agents fall in this level of containment. The following are items that must be followed in an ABSL-1 lab:

- Approval from the UWM Institutional Animal Care and Use Committee (IACUC) and the Animal Care Program.
- Training with safe handling of animals, coordinated through animal care (visit their [UWM page](#) for more information).
• Research lab specific biosafety manual (separate from this manual), containing: specific PPE, location of supplies, training requirements for personnel, waste handling practices, autoclave procedures, operation and decontamination of equipment used in facility, disinfectants to use in lab (appropriate concentration, contact time and shelf life), and any of the SOPs for research. It’s the responsibility of the PI to coordinate training with the on-site veterinarian and animal care manager and to ensure that personnel have been adequately trained in biosafety practices. PIs and their personnel are required to follow the policies set forth by the UWM Animal Care Program. You will not be allowed to do animal research in the animal facility without IACUC and Animal Care approvals.
• All lab personnel handling animals must go through the Animal Care Program training. Contact the Animal Care Manager for more information and to coordinate the training. The PI must ensure that all lab personnel have additional training in laboratory safety, biological safety, and bloodborne pathogens. Contact the Department of University Safety and Assurances to set up training.
• All personnel involved in animal research are required to complete an Occupational Health Animal Care Program Questionnaire. This is available on the Animal Care Occupational Health Page.
• Door signage: Entrances to all animal areas must have signage that indicates restricted access, applicable occupational health requirements, PPE, contact information for the PI or their lab manager, and any specific procedures to follow for entry and exit.
• The animal facilities are tightly controlled. Animals used in research at UWM are housed in approved Animal Research Facilities that are closely monitored by the campus veterinarian. The access to these facilities is restricted and are to remain locked always.
• PPE: Please contact the Animal Care Program to learn about PPE options that they have set forth for use in research facilities.
• Minimize splashes and aerosols through using safety features on equipment, mechanical pipettors, use of a biological safety cabinet, etc. No mouth pipetting is allowed.
• Handwashing must be done before leaving the laboratory or touching any common use surfaces.
• Sharps must be disposed of in approved containers and removed for disposal through coordination with the Waste Management Specialist. Contact the Dept. of University Safety and Assurances for coordination of sharps removal.
• Work surfaces must be decontaminated after work is complete to minimize the risk of accidental release. Work with the Animal Care Program to select an appropriate disinfectant.
• No plants or animals that are not part of the research should be in the facility.
• Contact the Dept. of University Safety and Assurances if there are ever issues with pest management.
• All cultures, stocks, animal wastes, etc. are to be decontaminated before disposal. The Animal Care Program will coordinate use of the autoclave. If additional assistance is needed, contact University Safety & Assurances. Any time materials are being moved out of a room, they need to be contained in a leak proof secondary container and preferably only moved using a cart.
• A biological safety cabinet (BSC) is not generally required in an ABSL-1 lab. But, risk is minimized if one is available for use. The Animal Care Program has specific requirements for entry and exit of animal research facilities. Long hair must be tied back.
Goggles must be worn when there’s a splash risk. If lab personnel wear contact lenses, safety glasses or other eye protection should be worn to prevent airborne particles from encountering the eyes. Gloves are required and should only be disposed of in the animal room.

- Secondary barriers:
  - Located in area of a building not open to unrestricted personnel.
  - Self-closing, self-locking external doors.
  - Doors should remain closed (do not prop open).
  - Sink must be available for handwashing with soap and paper towel available.
  - Floors- slip-resistant, impervious to liquids, chemical resistant.
  - Bench tops- impervious to water, easy to clean, non-porous, chemical resistant.
  - Chairs- non-porous material, easily cleaned and disinfected.
  - Windows- if the facility has windows, they must be break resistant. If they can open, screens must be put on them to prevent accidental release.
  - Airflow- inward flow of air without recirculation of exhaust air. Contact Animal Care for details.
  - Proper lighting is necessary to keep animals comfortable and to keep the research area safe when working in it.
  - Floor drain traps should be filled with water or disinfectant.
  - Cages- see Animal Care for details. There are automatic cage washers available.
  - Eyewash stations and chemical shower must be readily available.

**BSL-1 P Facility Overview**

BSL1-P is designed to provide a moderate level of containment for experiments for which there is convincing biological evidence that precludes the possibility of survival, transfer, or dissemination of recombinant DNA into the environment, or in which there is no recognizable and predictable risk to the environment in the event of accidental release.
Chapter 4: BSL-2 Laboratory Procedures

BSL-2 Standard Microbiological Practices
(UW Biosafety, 2017)

Many laboratories should be operating at a BSL-2. Any research requiring this level of containment requires a filed and approved registration form with the IBC.

✓ A site-specific laboratory manual containing SOPs, activities performed, and a copy of this manual should be available on site.
✓ Employees and students should be trained and informed of biohazards.
✓ Plan and organize materials and equipment before starting work.
✓ Keep laboratory doors closed; limit access to necessary personnel.
✓ Post a biohazard sign at the laboratory entrance when RG2 pathogens are being used. Identify the agent in use, and the appropriate emergency contact personnel.
✓ A lab coat and eye protection are required at a minimum for laboratory entry. A fully fastened lab coat, gloves, and eye protection are required when working with all RG2 organisms, human blood, fluid, or tissues, or human cells.
✓ Remove all protective clothing, including gloves, before exiting the laboratory and wash hands thoroughly.
✓ When practical, perform aerosolizing procedures in a certified biological safety cabinet (BSC). Some equipment cannot be handled in a BSC, because it will disturb the air curtain, so this may not always be an option.
✓ Centrifuge materials in unbreakable, closable tubes. Used a rotor with a sealed head or safety cups, and load it in a BSC. After centrifugation, open the rotor and tubes in a BSC.
✓ Avoid using hypodermic needles whenever possible. If they must be used, discard in approved sharps containers without removing or re-capping needles. Refer to the bloodborne pathogens plan for more information.
✓ Cover countertops where biohazardous materials will be used with plastic-backed disposable paper to absorb spills; discard after work session.
✓ Routinely wipe work surfaces with an appropriate disinfectant after experiments and immediately after spills. Routinely decontaminate all infected materials by appropriate methods before disposal.
✓ Report all accidents and spills to the PI or laboratory safety manager. All laboratory personnel should be familiar with the emergency spill protocol, where/how to clean up equipment, and how to report the incident.
✓ Good housekeeping practices are essential in laboratories engaged in work with infectious microorganisms. Establish a habit of weekly cleaning.
✓ Be sure to advise custodial staff of hazardous areas and places they are not to enter. Use appropriate warning signs.

ABSL-2 Facility

All procedures and protocols mentioned in the ABSL-1 facility above are required in ABSL-2 facilities. Animals infected with RG2 pathogens require ABSL-2 containment. In addition to what’s listed above, additional components include the following:
• Door signage: Entrances to all animal areas must have signage that indicates restricted access, applicable occupational health requirements, PPE, contact information for the PI or their lab manager, and any specific procedures to follow for entry and exit. Additionally, the lab entrance must have an Animal Biosafety Level 2 door sign. Signs must include any occupational health requirements, PPE requirements, contact information, and entry/exit procedures.
• Medical surveillance of animals, lab personnel, and support personnel is required.
• A currently certified biological safety cabinet (BSC) is required when there is any potential for creating infectious aerosols, including (but not limited to): pipetting, centrifuging, sonicating, blending, mixing, shaking, opening of container, intranasal inoculation of animals, and harvesting any tissues. Centrifugation can be done outside of a BSC if it has safety cups or sealed rotors.
• All wastes must be disinfected— including all cultures, stocks, wastes, carcasses, tissues, bedding, feed, sharps, etc. before moving for disposal and transported in a secondary container with a biohazard label.
• Lab equipment must be decontaminated after every procedure.
• A Biological Spill Kit must be housed in the lab facility. This includes: disinfectant, waste container(s), PPE, tools for picking up broken glass (tongs, dustpan, broom), spill-cleanup procedures, and barrier tape.
• In addition to a BSC, it is required that cages are washed in a cage washer, windows must be sealed (cannot open to outside), and an autoclave available in the facility (not necessarily in the room).

BSL2-P Overview

BSL2-P is designed to provide a greater level of containment for experiments involving plants and certain associated organism for which there is a recognized possibility of survival, transmission, or dissemination of recombinant DNA-containing organisms, but the consequence of an inadvertent release has a predictably minimal biological impact.

Chapter 5: BSL-3 and 4 Recommendations

BSL-3 Recommendations

There are currently no RG3 organisms necessitating a BSL-3 facility at UWM, however, RG2+ organisms (those that are considered RG2, but may have strains that place them in a borderline RG3 category) may necessitate BSL-3 containment. If RG3 organism(s) are found to be used on campus, the UWM biosafety manual will be updated to reflect BSL-3 policies and procedures. It is the responsibility of a PI’s home Department or School/College to provide BSL-3 facilities.

Some key elements to keep in mind regarding BL-3 are as follows:
- Special consideration for all sharps required.
- Elimination or reduction of use of glassware in laboratory.
- Hazard communication and training for microbes handled in laboratory.
- A special BSL-3 laboratory-specific manual is required.
- All procedures for infectious materials must be done within a BSL-3 approved BSC.
Researchers are required to wear solid-front gowns, scrub suits, or coveralls that are not worn outside of the laboratory. Eye and face protection is worn for anticipated splashes. Gloves are always worn in the laboratory and disposed of in the laboratory. The laboratory doors must be self-closing and have restricted access. The laboratory has a ducted ventilation system and personnel must be able to identify direction of airflow. Facility design will include decontamination, engineering controls, operational parameters, SOPs, and manuals specific to the BSL-3 laboratory space.

ABSL-3 Facility Guidelines

ABSL-3 facilities are suited for animals infected with RG3 agents. Currently there are no active ABSL-3 facilities at UWM. Should an ABSL-3 facility be needed and is developed by the PI in coordination with University Safety & Assurances more specific guidelines to be developed. In addition to ABSL-1 and ABSL-2 requirements, ABSL-3 facilities include the following:

- Door signage for ABSL-3: Entrances to all animal areas must have signage that indicates restricted access, applicable occupational health requirements, PPE, contact information for the PI or their lab manager, and any specific procedures to follow for entry and exit.
- Very controlled access (minimal entry/exit by personnel).
- Lab coats/gowns/uniforms required, face protection and splash goggles required when there’s any potential for splash, respirators must be worn as appropriate, hair should be up in a hair net. Disposable PPE should be disposed of in an appropriate biohazard container. Two pairs of gloves should be worn as appropriate. Reusable PPE should be decontaminated after each use.
- Containment caging systems should be used to reduce the risk of infectious aerosols from encountering animals and bedding. They must be ventilated to prevent escape of microbes from the cage.
- Exhaust systems should be sealed and HEPA filtered with an alarm system for malfunctions.
- Wastes are to only be decontaminated in the facility and transported to waste disposal using an approved secondary container labeled “BIOHAZARD” with a biohazard symbol.
- Secondary Barriers:
  - Entry is through a double-door entry.
  - Showers should be considered, determine need through doing a risk assessment prior to set-up of facility.
  - Sinks are to be hands-free or automatically operated and stocked with soap and water, located near the exit. If there are segregated areas for manipulation of infected animals or materials, there needs to be a sink available at that exit. Sink traps must be filled with water or disinfectant.
  - External windows are discouraged. If there are windows, they must be break-resistant and sealed.
Ventilation requires careful monitoring - must be inward flow without recirculation of exhaust air, exhaust must be dispersed away from air intake or occupied areas, or it must be HEPA filtered.

- Design and operational procedures must have written documentation, and facility must be tested prior to commencing research, and annually thereafter to verify that all ABSL-3 parameters are being met.

**BSL3-P and BSL4-P Overview**

BSL-3 and BSL4-P describe additional containment conditions for research with plants and certain pathogens and other organisms that require special containment because of their recognized potential for significant detrimental impact on managed or natural ecosystems (UW Biosafety, 2017). UWM currently does not have any facilities for working in BSL3-P or BSL4-P containment.

**BSL-4 Recommendations**

UWM does not allow RG4 organisms or biohazardous materials requiring BSL-4 containment or facilities on the campus or at any of its outlying units or off campus locations. There are a limited number of approved and certified BSL-4 facilities within the U.S., such as those at the Centers for Disease Control and Prevention in Atlanta, GA and the U.S. Army Medical Research Institute into Infectious Diseases (USAMRID) in Fort Detrick, MD. See Table 2 for additional information. Refer to the select agents table for more information.

See the next section for more information regarding animal BSL labs and plant BSL labs.
Chapter 6: Equipment and Facility Management

Laboratory Design

As a pathogen increases in its virulence, its physical containment level also increases. In addition to PPE, it is imperative to have proper safety equipment, as this provides the primary means of containment of a pathogen. The laboratory design is secondary to the equipment. Please contact the BSO and University Safety and Assurances when developing renovations, additions, or new facilities. Additional information can be found in the BMBL, 5th Edition.

Laboratory Ventilation

Be sure you know the differences between chemical fume hoods, clean benches, biological safety cabinets, and isolators (UW Biosafety, 2017). Several types of ventilation provide distinct types of protection. These protections include:

- **Product protection**: Protection of product/ experiment.
- **Personal protection**: protection of personnel working in laboratory.
- **Environmental protection**: protection of the environment outside of the laboratory.

Please contact University Safety & Assurances to determine your laboratory facility needs. You may require both a chemical fume hood and a biological safety cabinet. This can be determined through risk assessment.

Laboratory air pressure must be lower than that in adjacent spaces for laboratory containment to be effective. Negative air pressure is what ensures that air stays in the lab, and doesn’t carry pathogens into hallways or adjacent spaces. The primary way to effectively maintain this pressure is keep the doors to the laboratory closed. Ensure that exhaust air from biohazardous laboratories are not recirculating in the building, but rather ducted to the outside only and leaving through a stack remote from the building air intake. The use of HEPA filters may be employed in particularly hazardous facilities. Table 3 overviews facility standards recommended for BSL-1, BSL-2, and BSL-3.

Chemical Fume Hoods

Chemical fume hoods are not typically used for biological agents. They are intended for work with chemical hazards. Fume hoods may be used for work with biological materials when the prevention of laboratory exposure is a concern and sterility is not a concern only. They exhaust air to the outside, do not filter air, and directly draw air from the laboratory environment. Do not use a chemical fume hood in place of a biological safety cabinet. For more details on chemical fume hoods, refer to the UWM Chemical Hygiene Plan or contact the laboratory safety coordinator.

Clean Benches, Clean Air Devices

Clean benches and clean air devices provide product protection. The airflow from benches and devices go through a HEPA filter, and discharged air will then flow back across the
work surface and directly into the work from. They are appropriate choices for working with products that are not hazardous but need to remain contaminant free, when preparing nonhazardous mixtures and biological media, and for particulate-free assembly of sterile equipment and electronic devices. They are not appropriate for working with pathogens and should never be used for work with potentially hazardous biological or chemical materials.

**Biological Safety Cabinet**

Biological Safety Cabinets (BSC) are designed to work with biological hazards and allow for the handling of products in a clean environment. BSCs are designed with an inward flow to protect the researcher, HEPA-filtration exhaust to protect the surrounding environment, and HEPA-filter supply air for protection of the product (except for Class I) (UW Biosafety, 2017).

There are three classes of BSCs: Class I, Class II (Type A1/ A2/ B1/ B2), and Class III (glove box, isolator). BSCs are the primary means of containment in working with infectious microorganisms. Pages 290-325 of the Biosafety in Microbiological and Biomedical Laboratories, 5th Edition outlines the selection, installation, and use of Biological Safety Cabinets. If a BSC is being used in a laboratory, it should be certified. It is required to be certified annually if it is used for BSL2 or BSL3 agents. Development of a SOP for the BSC used in your research facility is required and will be requested when registering research with the IBC. A template is available for use on the UWM Safety and Health Forms Page.

**Handling of Environmental, Clinical, and Pathological Specimens**

Every environmental, clinical, and pathological specimen taken from a human, animal, or plant should be considered a biological hazard and handled following guidelines for their safe handling. In laboratories that handle human blood or body fluids, Universal Precautions must be followed. All personnel handling human blood or body fluids are required to complete bloodborne pathogen training, and are advised to possess the HBV vaccine.

Laboratories working with human blood or other potentially infectious materials (PIM) must have a written exposure control plan in place (UW Biosafety, 2017). PIM include semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva, and any other body fluids that may be mixed in origin. Additionally, any unfixed human tissues, organs, primary cell cultures, cultures containing HIV or HBV, human stem cells, and experimental animals infected with HIV or HBV are included in these regulations. Contact the Biological Safety Officer for more information regarding regulations and regulatory requirements for the safe handling of PIM.

**Cultures**

Aerosol formation from culture samples continues to be an area of concern when performing routine procedures in the laboratory. The following are means by which cultures could be released via aerosol formation (UW Biosafety, 2017):

- Removing stoppers from culture vessels
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- Opening vessels after vortexing or shaking
- Flame-sterilizing utensils
- Electroporation
- Centrifugation
- Sonication, homogenization, blending or grinding tissues
- Expelling final drop from pipette

Cultures should be handled carefully to avoid aerosols. When using centrifugation, ensure that the tubes and rotors are gasket-sealable. Microplate lids need to be sealed with tape or use an adhesive backed Mylar film in place of the lid. Use a fume hood or BSC to load, remove, and open tubes, plates and rotors. Take care to minimize risk of accidental spilling on benches, floors, and during transport.

Research equipment used to manipulate infectious materials need to be evaluated to best determine secondary containment, as well as issues one may encounter with decontamination. Development of a SOP for disinfection of each item of equipment may be necessary, and should be included in the laboratory safety manual for the research facility. It is the responsibility of the PI to train their personnel in safe use of all equipment.

Use of human or animal cell cultures have an additional set of considerations necessary, and protocols should be included in the laboratory safety manual for their safe handling. Cell or tissue cultures typically have few biohazards on their own, but when inoculated with a pathogen, they are classified and handled at the same biosafety level as the agent. At UWM, BSL-2 containment is required for all cell lines of human origin and for all human clinical material, no exceptions to this rule. Any cell lines exposed to oncogenic viruses, primate cell cultures originating from lymphoid or tumor tissues, and all nonhuman primate tissues are to be handled using BSL-2 practices. Do not use a laminar flow cabinet to perform manipulations that could create aerosols, only a certified BSC. Post a labeled biohazard symbol at the door to the laboratory. The PI is required to ensure all proper containment and training occurs before handling of these types of cultures.

Long-Term Storage of Cultures

Some laboratories maintain cultures and/or archival samples of biohazardous agents. In these instances, a “generic” registration for maintenance and storage of reference or other samples/cultures should be submitted to the biosafety program office. An inventory of agents should be attached and updated whenever significant changes are made, either additions or deletions. Significant changes include additional species or additional strains of inventoried agents that demonstrate a need for more stringent containment. Please complete a Storage Registration Form for IBC submission to review.

Equipment

Centrifuge Equipment
Centrifuges are commonly used in laboratories that handle biohazardous materials. Centrifuges can create aerosols if there is a mechanical failure. Aerosols can be generated in the process of filling centrifuge tubes, removing the supernatant from the centrifuge, and suspending pellets. The greatest concern with centrifugation is if a tube breaks during the centrifugation process. These risks can be minimized by using sealed tubes and safety buckets that are sealed with O-rings, filling tubes rotors, and accessories inside of a BSC, balancing the buckets, tubes, and rotors, and working in a BSC to decant supernatant or re-suspending sediment. The following are procedures that should be implemented and documented in the laboratory-specific biosafety manual. These procedures will help minimize the risk of injury or accidental exposure from use of a centrifuge.

- Review the operating manual before using the centrifuge. Keep the manual with the biosafety manual in lab.
- Do not deviate from the manufacturer instructions- maintain and operate the centrifuge following these instructions.
- Examine the centrifuge on a regular basis for damage or poor maintenance, and keep a log of use and maintenance.
- All users should be trained by the PI prior to first use and an SOP should be made available for the lab.
- Post operating instructions that include safety precautions on the unit.
- Keep the vendor information handy in case an issue arises so they can be contacted quickly.

The PI or laboratory manage must document safety training for use of a centrifuge. In this documentation, include the following:

Possible routes of exposure of material used in centrifuge (skin, eyes, inhalation)
Proper PPE and engineering controls
Safe use
SOP
Date researcher(s) received training
Name of researcher(s)
Signature of researcher(s)

**Autoclaves**

Autoclaving, or steam sterilization, is the use of a pressurized steam machine to kill infectious agents. This form of “wet heat” is the most effective means for sterilizing standard laboratory equipment and decontaminating biohazardous waste generated in our teaching and research laboratories. Autoclave use should only be performed by those trained in the use of the autoclave. This should be the responsibility of the PI to ensure that all lab personnel know how to properly use the autoclave for their facility. Lab managers need to sure teaching assistants know how to use the autoclave properly as well.

Safe use of an autoclave includes steam pressure of about 15 psi to and a temperature of 121°C for 30-60 minutes, depending on the material being autoclaved. In addition to proper function of
the autoclave, preventing entrapment of air is important to ensure all the material is properly being sterilized. A SOP needs to be in place for labs that use an autoclave. Each autoclave on campus is required to maintain an autoclave use log. The autoclave log should include the columns indicated in Figure 1 below. A Word version and fillable PDF of this form is available under Biological Forms on the University Safety and Assurances Page.

![Autoclave Log](image)

**Figure 1 Sample Autoclave Log.**

All autoclave materials should be in approved bags (no red biohazard bags - they cannot be disposed of in regular trash, use orange or clear) and a rigid, autoclavable secondary container. Follow the guidelines provided by the manufacturer for setting cycle time. Keep a log for each autoclave. Check the autoclave monthly using a sterilizing indicator (biological or chemical). If the waste is a large bag of plates from a teaching or research laboratory, add a cup of water to the bag and keep the bag slightly open, otherwise the steam will not penetrate the waste completely, leaving potential pathogens alive. After the cycle has been completed, let the waste cool before removing. If autoclaved waste is in a bag, seal it after removing from the autoclave. Treated autoclave bags should go into an opaque black garbage bag and then be moved to the general trash.

Wear heat-resistant gloves when loading and unloading the autoclave. Under the heat-resistant gloves, wear fluid-resistant gloves before autoclaving to prevent hands from being contaminated from untreated waste. Wear a lab coat to protect clothing, and splash goggles if a
splash hazard is present. A general standard operating procedure (SOP) for autoclave use that may be used in your facility can be found on the Biosafety SOP Page.

Flow Cytometers

Teaching and research laboratories utilizing flow cytometers should operate under the same containment conditions in which the cells would normally be handled. For example, if human cells are being sorted in a flow cytometer, they need to be handled at a BSL-2 containment. If the cells being sorted are potentially infectious unfixed cells, potentially infectious aerosols will be generated when using a flow cytometer, particularly if the cell sorter fails to operate in a normal manner. The higher speed, the higher the number of aerosols generated. Wear the proper PPE when working with a flow cytometer. A general standard operating procedure (SOP) for flow cytometry that may be used in your facility can be found on the Biosafety SOP Page.

Pipettes and Pipetting Aids

Pipetting must be done by mechanical means, never by mouth. Ideally, pipet work should be done in a BSC. If one is not available, minimize hazard by using cotton-plugged pipettes and pipette tips, do not use suction and propulsion pipettes with biohazardous materials, and store used pipettes for disposal in approved sharps container that fits the pipette in its entirety. Use plastic over glass whenever possible. The use of a plastic garbage bag is not acceptable for collection of pipettes and pipet tips. When the waste container of pipettes become full, it may be autoclaved and handled as sharps waste.

Sharps

The use of sharps should be restricted as much as possible. The only times sharps should be used is when injections, phlebotomy techniques, and fluid aspiration are performed. Some sharps may be used when doing dissections as well- in these cases disposable sharps should be considered for scalpels, biopsy punches, etc. to minimize accidental exposure hazards. If researchers are using sharps in their research, they are required to complete bloodborne pathogens training (to review needle stick injuries) in addition to biosafety training.

PIs and lead instructors are responsible for training their respective personnel in the safe handling practices for sharps and safe disposal practices. The sharps containers should be situated closely to where the sharps are being used. Sharps may be disposed of in a hard-sided container that can be completely sealed. If a container designed for sharps disposal is not used, deface all labels and clearly label as a sharps container, including a biohazard symbol, prior to using for sharps disposal. Never overfill a sharps container- when it is 2/3 full, seal the container and request a pick-up. Never try to push waste down to make space for more waste, as this increases the risk of a needle stick injury. Request pick-up of sharps containers using the online form. Refer to the disposal section for more information.
Any research facility that uses sharps runs a risk of needlestick injury and will need to complete bloodborne pathogens training, as well as maintain a Bloodborne Pathogens Exposure Control Plan following the UWM Bloodborne Pathogens Exposure Control Plan template.

Loop Sterilizers and Bunsen Burners

The sterilization of a loop or needle in an open flame generates aerosols that can contain viable microbiological agents. It is strongly encouraged that laboratories use a shielded electric incinerator or a hot bead sterilize to minimize the risk of aerosol production while sterilizing a loop or needle. Another recommended option is to use disposable (one-time use) loops and needles for culture work and collecting the waste loops and plastic needles in a sharps container that fits them in their entirety. They can be autoclaved and disposed of after autoclaving in general waste in non-red autoclave bag. The use of a continuous flame gas burner such as a Bunsen burner, in a BSC is prohibited, as they can produce turbulence that interferes with the airflow of the cabinet and can damage the HEPA filter.

Biohazardous Waste Disposal

The following biohazardous waste disposal guidelines are intended to protect the public, the environment, laboratory personnel, custodial personnel, waste haulers, and landfill/incinerator operators. Workers that generate biohazardous waste in the laboratory need to follow the appropriate labeling, packaging, and intermediate disposal of waste that conforms to guidelines set forth by the Biological Safety Program to ensure the safety of all that may encounter the waste. Signage templates are available on the UWM Safety and Health Page for any facilities that have biohazardous materials.

The following materials require decontamination prior to disposal. Note that decontamination means reducing the number of disease-producing microorganisms and rendering an object safe for handling. Please note, if the waste is mixed, containing both chemical hazards and biological hazards, the hazardous chemical or radioactive materials take precedence over the biological hazards and need to be handled by the Waste Management Specialist for disposal.

Biohazardous waste must be stored in a secondary container until it is moved for decontamination. The secondary container must be hard-sided (cannot leak through), possess a secure fitting lid, and possess the following symbol (or similar):
The following are examples of biohazardous materials that must go through the proper decontamination prior to disposal:

- Microbiological Laboratory Wastes, including
  - Cultures derived from clinical specimens and pathogenic microorganisms
  - Laboratory equipment that has encountered microbiological waste
- Human materials: tissues, liquid blood, cells, body fluids
- Animal materials: tissues, liquid blood, cells, body fluids from an animal carrying an infectious agent that can be transmitted to humans
- Animal or human pathogen containing materials
- Plants:
  - Exotic/invasive plants
  - Virulent plant pathogens
- Contaminated sharps
- Animal bedding/waste as pre-determined by animal care.

Infectious and Medical Waste Disposal

Contaminated materials from teaching labs, research laboratories, and animal research facilities must be decontaminated prior to disposal or washing for reuse. These include all cultures, tissues, media, plastics, glassware, instruments, and laboratory coats. Materials should be collected in leak-proof containers containing the universal biohazard symbol. Use only an autoclavable biohazard bag for waste, contained in an autoclavable secondary container for autoclaving purposes. See figure 3 for the proper symbol to affix to the biohazard container.
After waste has been decontaminated, place decontaminated waste in a regular black trash bag with a label that states “OK TO TRASH” to notify custodians and waste management that the material has been decontaminated. For reusable materials, after autoclaving, they may be washed (i.e. plastics, glassware, and instruments that are reusable) normally and reused. Laboratory coats should be autoclaved weekly to minimize the risk of accidental exposure, or disposable laboratory coats should be used and disposed of monthly.

Sharps must be collected in an approved medical sharps container. These include syringes with needles, lancets, and razor blades. It does not matter what they were used for, they must be disposed of as medical waste. It is recommended that autoclavable sharps containers are used in laboratories handling biological materials, and then autoclaved prior to the Waste Management Specialist coordinating removal of the container. This minimizes the risk of accidental release from the container to the environment during removal. The Waste Management Specialist handles the processing for the medical waste through the University of Wisconsin System contracted vendor Madison Environmental Resourcing, Inc. (MERI) and is not handled by general custodial services. Please contact the Waste Management Specialist to coordinate removal of sharps containers.

Fragile glass, glass slides, cover slips, pipettes, and pipette tips that have encountered infectious materials should be disposed of in an approved biohazard bag that has a hard-sided secondary labeled containment. This bag can then be autoclaved, double bagged, and disposed of in the regular trash. If the risk of puncturing a bag is still high after double-bagging, place in a box and seal before disposing of in the trash.

**Liquid Waste**

Any liquid waste, such as cultures or media, that have been contaminated/ inoculated with biological agents or toxins must be rendered safe through chemical or autoclave treatment. It is preferred that autoclaving the liquid waste is done (except in cases where hazardous chemicals are also present- they take precedence over the biological materials). A SOP for inactivating the agent is required in the registration form that is to be submitted to the IBC for all biological materials.

**Animal Waste**

Animal waste (i.e. bedding, feces, urine, etc.) may require disinfection or inactivation and will be outlined in the approved IBC protocol. Disinfected waste can be disposed of in the trash or by other approved means after disinfection. Animal waste that does not require disinfection/ inactivation may be disposed of in the regular trash or other approved means. It is the responsibility of the PI to coordinate appropriate waste disposal with animal care.

Animal carcasses that contain recombinant or synthetic nucleic acid molecules or a recombinant or synthetic nucleic acid molecule-derived from another organism are required to be disposed of in an approved means to prevent its use as food by human beings or wild animals (regular trash prohibited). Carcasses are sent for disposal via incineration through our contracted
medical waste service. Contact the BSO or Campus Research Veterinarian/Associate Director to determine disposal means prior to IBC approval based on the animals being used in research.

Animal carcasses from preserved dissection specimens should be disposed of according to chemical hazard first. If they contain less than the 2% threshold of formalin, they may be carefully double bagged and handled according to the preservation company instructions.

Noninfectious Waste

There are items in the laboratory that may fall under noninfectious waste, but do require containment. These items can be placed in plastic garbage bags and disposed of in the regular trash, unless they have been contaminated with any infectious waste. If they have been contaminated with any kind of infectious waste, then they must be treated as such. The following are a list of items that may fall under noninfectious waste (UW Biosafety, 2017):

- Items that are soiled or spotted with human blood or body fluids not known to be infected with any infectious agents. Examples include gowns, gloves, dressing, and surgical drapes.
- Laboratory equipment, non-fragile waste glass, containers, packaging materials, and any other materials that did not have any contact with blood, body fluids, clinical cultures, or infectious agents.
- Noninfectious animal waste, including feces, bedding, tissues, blood, body fluids, or cultures not suspected to be carrying an infectious agent transmissible to humans.
- Fragile glass, glass slides, cover slips, pipettes, and pipette tips that have not encountered blood, body fluids, clinical cultures, or infectious agents. These items should be disposed of in a hard-sided container, that, when full, is dumped into a trash bag.

Choosing a Method of Decontamination

Determination of the appropriate method for decontaminating your materials may be challenging. There may be multiple SOPs in place for your research laboratory as there may be multiple means of decontamination based on the type of material being decontaminated and what equipment is available. Work with the BSO to determine what methods of decontamination may work best for your needs.

If you are working with biological waste that contains any volatile, toxic or carcinogenic chemicals, radioisotopes, or explosive substances, these take precedence over the biological material. These should not be autoclaved, and need to be handled as hazardous or radioactive waste. Contact the Laboratory Safety Coordinator to determine how to handle the material, and contact the Radiation Safety Officer for radioactive materials safe-handling.

Biohazardous Waste Disposal Decision Tree

The following is a decision tree that can help guide you in determining the best way to handle the biohazardous waste you generate in your lab. See figure 2. Please remember the following when disposing of hazardous waste:
Autoclavable bags that you want to throw in the trash after decontamination cannot be red. The reason for this is because they will be considered regulated medical waste by the waste management contractor vs. general waste. There are a variety of other colors available. Red bags should only be used for items that cannot be autoclaved/decontaminated.

All sharps go into sharps containers. The best way to determine if something should go in a sharps container is to think about whether it may be able to puncture a garbage bag. If it could puncture a garbage bag, it should go in the sharps container.

**Autoclave Use**

Steam sterilization by means of a properly functioning autoclave is the ideal method for decontamination of materials contaminated with biohazardous waste. To ensure that the autoclave is effectively decontaminating materials, they are to be tested monthly using a biological (Geobacillus stearothermophilus spore test) or chemical indicators that can verify adequate times being used to decontaminate a full load containing biohazards. The use of indicator tape is advised whenever using an autoclave to ensure that the load has been autoclaved for the proper amount of time. Please note that the bigger the load, the longer the exposure time necessary to properly decontaminate the biohazards. The key is to remember that larger loads of solid waste should be autoclaved at a minimum of one hundred twenty-one degrees Celsius at fifteen PSI for one hour.

**Chemical Disinfection**

If an autoclave is unavailable or not appropriate for the material, the alternative is to use a chemical disinfectant that has been freshly prepared at a concentration known to be effective against the biohazards that need to be inactivated (UW Biosafety, 2017). This is a complex subject, to best determine what will fit your needs, discuss this with the Laboratory Safety Coordinator and the BSO. Consideration of level of resistance should be considered as well (see pg. 56). The chart below has a brief overview of options available, but ultimately additional references should be sought out to determine what will fit your facility needs. It is recommended that teaching laboratories use 10% (1:10 bleach: water) solution for routine lab bench disinfection after handling biological agents.
BIOLOGICAL & MEDICAL WASTE DECISION TREE

Is it Sharp?
(needles, razor blades, scalpels)

Yes

No

Sharps Container

Don’t Know

Is it Infectious?

No

Yes

Can the material be autoclaved or chemically decontaminated?

No

Don’t Know

Yes

Decontaminate

Picked up bimonthly by University Safety & Assurances Hazardous Waste Staff or by request at: http://uwm.edu/environmental-protection/pickup-request/

Dumpster
(No un-treated redbag waste may be put in the dumpster)

July 2017

Figure 3 Biohazard Decision Tree
**Most Resistant**

- Prions
- Coccidia (*Cryptosporidium*)
- Bacterial Spores (*Bacillus*, *Clostridium* sp.)
- Mycobacteria (*M. tuberculosis*, *M. avium*, *M. leprae*)
- Protozoan Cysts (such as *Giardia*)
- Small, naked viruses (such as *Polio* virus)
- Protozoan Trophozoites (such as *Acanthamoeba*)
- Gram-Negative Bacteria (Non-spore forming) (*Pseudomonas*, *Providencia*)
- Fungi (*Candida*, *Aspergillus*)
- Large, Non-enveloped Viruses (*Enterovirus*, *Adenovirus*)
- Gram-Positive Bacteria (*Staphylococcus*, *Enterococcus*, *Streptococcus*)
- Large, Enveloped Viruses (HIV, HBV)

**Least Resistant**

*Figure 4 Descending level of germicidal resistance of pathogens*
<table>
<thead>
<tr>
<th>Chemical</th>
<th>Best Used for Inactivation Of…</th>
<th>Applications</th>
<th>Level of Activity</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol Ethanol Isopropanol</td>
<td>Vegetative bacteria, Mycobacteria, vegetative fungi, enveloped viruses</td>
<td>Instruments, surfaces that have low organic burden, lightly soiled hands if handwashing isn’t readily available</td>
<td>Intermediate</td>
<td>Flammable, does not penetrate protein-rich materials, rapid evaporation, ineffective against naked viruses and spores</td>
</tr>
<tr>
<td>Aldehydes Cidex Wavicide-01</td>
<td>All microorganisms</td>
<td>Non-porous surfaces</td>
<td>High</td>
<td>Very toxic to animals and humans</td>
</tr>
<tr>
<td>Peroxygen Compounds Ethylene oxide Virkon</td>
<td>Wide range of bacteria, viruses, and fungi; variable against bacterial spores and Mycobacteria</td>
<td>Heat-sensitive equipment</td>
<td>High</td>
<td>Ethylene oxide is a human carcinogen, and restricted use</td>
</tr>
<tr>
<td>Halogens Clidox Clorox Other household bleach</td>
<td>Vegetative bacteria, enveloped viruses</td>
<td>Benchtop surfaces, blood spills</td>
<td>Medium-High</td>
<td>Inexpensive, highly effective in decontaminating large spills</td>
</tr>
<tr>
<td>Iodophors Povidine Bentadine</td>
<td>Mycobacteria, viruses, fungi, most fungi, varying for fungal and bacterial spores</td>
<td>Antiseptic</td>
<td>Medium-High</td>
<td>Low toxicity, Low irritant</td>
</tr>
<tr>
<td>Phenolic Compounds</td>
<td>Vegetative Bacteria (Gram-Positive), Enveloped viruses</td>
<td>In combination with detergents, excellent choice for cleaning benchtops, general purpose surfaces</td>
<td>Medium-High</td>
<td>Can be used with detergents</td>
</tr>
<tr>
<td>Quaternary ammonia disinfectants</td>
<td>Most fungi, vegetative Gram-positive bacteria</td>
<td>Added to handwashing compounds</td>
<td>Low-Medium</td>
<td>Low toxicity, but ineffective against mycobacteria, spores, and most viruses Can cause contact dermatitis</td>
</tr>
</tbody>
</table>

*Table 10 Chemical Methods of Microbial Control*

**Incineration**

The ultimate means of sterilization of medical and microbiological waste is incineration. Animal carcasses treated with preservatives such as formalin, medical sharps, etc. are examples of materials that are shipped for incineration. Contact the waste management specialist to determine the needs for your laboratory.

**UV Treatment**
UV light is not recommended as a primary means of disinfection because there several factors that could influence the efficacy of its ability to disinfect materials. UV light does not penetrate organic material well, and works best when used on surfaces that it encounters. Because UV light can cause erythema (sunburn) and eye injury, personnel that are using UV light (such as in a cabinet) should avoid exposure. This includes the use of UV light in a biosafety cabinet as a means of disinfection— it is neither recommended or an acceptable means of disinfection as a standalone. It is recommended that 70% ethanol be used as a primary means of biosafety cabinet disinfection, or other stainless-steel safe decontaminant agents.

*Equipment Malfunction*

In the event of a mechanical malfunction, systems breakdown or shutdown of any nature, or preventive maintenance of primary containment equipment or components, the BSO must be notified immediately. In the case of an unplanned event and if Physical Plant mechanical staff is not already on the scene, the BSO will notify appropriate Physical Plant staff. Proper precautions must be taken immediately. All experiments must be halted and the biological agents secured (e.g., containers sealed or containers placed in freezer or refrigerator). The area must be cordoned off during the entire time of the shutdown. No further activities will be allowed until University Safety and Assurances staff certify that the facility is safe to use.

*Food and Drink Guidelines*

Food and drink used for human consumption are not allowed in any research or teaching laboratories at any time. This includes at student work desks. Even if there is a line where nothing can cross in a laboratory, this does not mean an aerosol or radioactive chemical can’t cross this line. The only acceptable barrier is a physical wall and door separating the non-lab work space from the lab work space. Students are required to find a safe area to consume their food and drink outside of the laboratory. It is the responsibility of the PI to ensure lab personnel and students are not eating or drinking anything in the laboratory, and will be enforced.

In addition to food and drink, gum chewing, applying cosmetics, smoking, and taking medication are strictly prohibited in teaching and research laboratories handling biological agents. Water bottles are included in this guideline— all water bottles need to be stored out of the research/ teaching facility in a backpack or separate room. All backpacks should be housed in cubbies or on shelves, never on the floor. PIs should set the example; they too should not be eating/ drinking in the lab facilities and they need to enforce this in their labs. The chemical hygiene plan is required to reflect your food and drink policy. This will be checked by the lab safety coordinator and the biological safety officer during inspection that it is included in the chemical hygiene plan and clearly posted in the laboratory.

*Housekeeping*

Laboratory personnel and the PI are expected to maintain good housekeeping in their facilities. BSL-2 labs should NEVER have a custodial staff member entering to clean the lab. Laboratory personnel should move all non-hazardous waste to be disposed of outside of the lab. Regular decontamination of benches, washing of glassware, and keeping the lab free of clutter...
are important in minimizing additional risks of contamination or injury in the lab. Contact the laboratory safety coordinator to help evaluating your lab to ensure it is safe and orderly.

Chapter 7: Emergency Management and Biosecurity

Biosecurity

When an experiment is in progress, lab doors should be closed. If there is no one present in the lab, the doors are to remain locked. Unauthorized/unapproved people are not permitted in the laboratory. If anyone requests access to the laboratory and the personnel do not know who the person is, request identification (Panther Card ID or Driver’s License) and their purpose for entering the facility. This is for your safety and their safety. Unauthorized personnel should never be in the research or teaching laboratories, as it exposes an accidental release hazard and threatens the biosecurity of UWM. If you feel that your unauthorized personnel are trying to gain unapproved access to your lab facility, contact the UWM Public Safety immediately at 9911 on a campus phone and (414) 229-9911 from a cell phone or other non-campus phone.

The University of Wisconsin-Milwaukee is committed to protecting their students, employees, and public from any possible bioterrorism agents or accidental release of biological agents. The following identifies the list of steps taken by UWM to prevent biosecurity incidents. There is also discussion of Select Agents and Dual Use Research of Concern (DURC) in this section. Ways that biosecurity measures are taken by University Safety and Assurances are listed below.

- Inspection: The BSO conducts annual biosafety inspections, and the laboratory safety personnel conduct lab safety inspections. These identify any areas of concern and address them so corrective actions can be taken.
- Security of biologically sensitive materials: access controls, including locked doors, restricted animal facilities, and key card access (some labs) help restrict non-authorized personnel from entering facilities. Materials are locked up and stored securely by PIs to prevent theft.
- Inventory: each PI is responsible for maintaining a biological and chemical inventory for their lab, and holds their personnel accountable for tracking usage, transfer, and decontamination of biological materials. Visit the UWM Safety and Health Forms page for a sample of an inventory log that can be used in research labs.
- Transport of biological agents: PIs and laboratory personnel follow state and federal regulations regarding the transport and shipment of biological agents. See the section below for more information regarding transport.
- Approval of Use: All research and teaching labs containing the use of any kind of biological material must be registered and approved by the IBC. Visit the IBC Page for more information.
- Reporting: If an accidental release occurs, University Safety & Assurances and emergency personnel are contacted immediately and an accidental release form is submitted.
- Training: providing up to date biosafety training helps the University ensure staff and students are trained properly to handle biohazardous materials.
Select Agents

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107–188 requires the Department of Health and Human Services (HHS) to establish and regulate a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety (DHHS, 2017). In addition, it is required that under the Agricultural Bioterrorism Protection Act of 2002 that that USDA establishes and regulates a list of biological agents that pose a severe threat to animal health and safety, plant health and safety, and/or to the safety of animal or plant products (DHHS, 2017). Table 2 outlines the current Select Agents and Toxins. Work with any of these select agents requires special registration and inventory. Please visit www.selectagents.gov for more information, or contact the BSO to discuss your research if you believe it may fall into this category of research.

Dual Use Research of Concern (DURC)

The University of Wisconsin-Milwaukee is subject to the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC). Thus, the UWM Biological Safety Program must review all potential dual use research to determine whether it meets the criteria outlined in this policy for DURC. Dual Use Research of Concern (DURC) is life sciences research that could be utilized to provide knowledge, information, products, or technologies that could be intentionally misused to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security (NIH OCP, 2017). Refer to Table 3 for a list of current DURC agents subject to additional oversight.

Even if your laboratory does not receive federal grant funds from the U.S. Government, you still need to have a protocol approved by the IBC. If you think that you may have research that could potentially be dual research, contact the biological safety program. Review the DURC policy to help determine your needs.

Emergency Plans

There are emergency plans implemented by the Safety and Industrial Hygiene Program focused on the safe handling of chemicals, good laboratory practices, and other general safety that you may need education/training in to work safely on campus. Each laboratory should have their own emergency plan that has been developed through working closely with the University Safety & Assurances Department and through biosafety protocol development.

General Emergency Plan

The key information that should be included regarding biological hazards include (but are not limited to) the following (UW Biosafety, 2017):

- If a spill occurs, leave the affected area immediately. Even if the spill is small, aerosols may be generated that could expose the community to the pathogen. If it is
clothing that is contaminated, remove clothing if possible. Exposed skin should be washed for 15+ minutes with soap and water. A splash to the eyes should be treated using an eyewash station for at least 15 minutes.

- If the spill may be dangerous to people in and out of the lab and staff cannot contain it, the spill needs to be reported to UWM police.
- Close the laboratory door, and mark it with a “NO ENTRY” sign. Notify the PI (if not present) and the biological safety officer.
- Seek medical treatment for anyone who has been exposed.
- If necessary, call 9-1-1.
- Complete an accidental release/ exposure form within 24 hours of the incident.
- Do not reenter the room until any aerosols have settled (minimum 30 minutes) and the extent of the hazard and its dissemination has been determined.
- Each person who enters the laboratory for cleanup should wear (at a minimum) a lab coat, gloves, and eye protection.
- Use an appropriate concentrated disinfectant to decontaminate. Ensure that a supply of stock disinfectants is always readily available in the laboratory.
- Decontaminate anything used in cleanup.

BSL-3 facilities have a different plan to follow. If a BSL-3 facility is developed at UWM, new plans will be implemented to reflect additional safety procedures necessary.

**Exposure Response**

PIs are asked to consider what the consequences of exposure the biological hazards they are working with may have and have a developed response procedure for this potential exposure on file with their protocol and/or registration form. Complete the First Report of Biological Exposure or Release Event Form online. Information that should be kept on file in case of accidental exposure should include the following (UW Biosafety, 2017):

- A description of the pathogen(s), including signs and symptoms of an infection from this pathogen.
- Distinct characteristics of the strain(s) used in the laboratory, including antibiotic resistance, transmissibility, atypical tissue tropism, foreign genes that alter pathogenicity, etc.
- Recommendations for treatment, including effective medications, quarantine, etc.
- A detailed record of a history of exposure to the agent(s) in question for some pathogens from start of employment (work with BSO to determine need for this)
- Completion of an accidental exposure/release form within 24 hours of the incident, submitted to the BSO. This form must be used when any of the following occur:
  - Potential exposures or releases of organisms or biological toxins on the UWM campus and UWM off-site facilities.
  - Reporting must be completed within 24 hours of the event, and is the responsibility of the Principal Investigator to report the event.
  - Potential exposures include needle sticks, animal bites, aerosol exposures, and other incidents potentially resulting in disease.
  - Potential releases include spills outside of primary containment as well as potential releases to the environment.
Unauthorized releases of transgenic animals or plants should also be reported on this form.

- After completing this form, select “Submit” at the bottom of this form. The information on this form will be sent to designated individuals at the UWM Biological Safety Program.
- Information on this form is used to determine how our offices may help you and your laboratory and for mandatory federal reporting purposes.
- The submitter will be contacted for incident follow-up.
- If you need assistance completing this form or reporting an incident, please call the BSO at 414-588-4261.

**Spills Inside a BSC**

A properly functioning and up-to-date BSC should contain potentially hazardous biological aerosols from spills within its unit on its own. Therefore, it is extremely important to have your biosafety cabinet checked annually. It is the responsibility of the PI to have a well-developed SOP in place for operation and cleanup of a BSC, as well as spill procedures, which are required in any approved research protocol.

**Recommended Clean-Up Materials for Lab Facilities**

The following should be kept in the laboratory, and all personnel should be trained in where it is housed, how to use it, and provide the plan in place for accidental spills.

- **Disinfectants**: Selection should be made based on the biological agent(s) it would be used against (See Table 4). If dilutions are made, such as with bleach, fresh solutions should be made on a schedule depending on the materials used and the manufacturer’s recommendations.
- **Absorbent materials**: There should be, at a minimum, a sufficient quantity of paper towels on hand to soak up the maximum volumes handled in the laboratory. There are other absorbent pads available, but paper towel will suffice.
- **Extra PPE**: This is dependent upon the biological agent, but when handling a spill, a gown, gloves, and eye protection should always be worn to prevent additional accidental exposure from occurring.
- **Signage**: Signage available for posting until aerosols have settled after a spill.

**Volunteers and Minors in the Laboratory**

In general, children or adult volunteers should refrain from entering the laboratory facilities unless the appropriate paperwork has been filed and approved. This includes a volunteer application, agreement for assumption of risk, indemnification, release, and consent for emergency treatment; volunteer action plan completed by PI, signed laboratory safety sheets, and SOPs for the lab facility.

Additionally, minors must have a letter sent to their legal guardian(s), and there needs to be a completed background check on anyone working near the student in question. For more information regarding volunteers in the laboratory, please contact University Safety &
Assurances. Note that minors and volunteers must complete biosafety training if working in BSL-2 facilities as well, and they are not permitted in any lab that is deemed a high hazard by the University Safety and Assurances staff. Please visit the Laboratory Forms on the UWM site to view and complete forms for minors to work in laboratories.
Chapter 8: Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) is charged by the University Chancellor to formulate guidelines and procedures related to the use of biohazardous agents, including: human, animal, and plant pathogens, other infectious agents, toxins, and recombinant DNA (rDNA). As mandated by the NIH, experiments involving human gene therapy, formation of transgenic animals or plants, and the generation and/or use of rDNA must be registered and approved by the IBC. UWM also requires IBC registration and approval for use of Risk Group 2 or higher biohazardous agents. Roles and duties specific to the NIH Guidelines can be found in the Section IV-B-2 of the NIH Guidelines (NIH, 2016).

The Chancellor, upon the recommendation of the Vice Chancellor for Research and Dean of the Graduate School, will appoint members to the IBC and designate one member to serve as chairperson. To provide the quality of input needed for in depth consideration of research activities presenting real or potential hazards, the membership shall be composed of the following:

- **Faculty**: A minimum of five (5) faculty members shall be appointed for rotating three year terms. Faculty shall be selected based on experience and expertise in infectious disease research, experience and expertise in rDNA technology, and the capability to assess the safety of biological research and to identify any potential risk to public health or the environment. Research academic staff with PI status are considered faculty for this guideline.
- **Community Members Not Otherwise Affiliated with the University**: A minimum of two outside members who represent the interest of the surrounding community with respect to health and protection of the environment (e.g. 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) shall be appointed. These will be three (3) year membership appointments.
- **Laboratory Staff**: A minimum of one member representing laboratory research staff such as a research associate/research assistant, medical technologist, or laboratory technician shall be appointed. This will be a rotating 3-year membership.
- **Continuing Members**: The following will be continuing (ex-officio) committee members.
  - Asst. Director, University Safety and Assurances
  - Biological Safety Officer
  - Campus Veterinarian
  - Campus Medical Officer

The IBC has the responsibility of assessing risks and potential environmental impacts associated with investigations involving biological agents and making recommendations for safe conduct of such studies. It also functions on behalf of the institution to ensure that the experimental work is performed in compliance with current policies and guidelines promulgated by government granting and regulatory agencies. The Committee does not monitor activities which are appropriately the concern of other established programs, e.g., Radiation Safety
Program or Animal Care Program; however, it will closely interact with these groups in a concerted effort to minimize health risks to University personnel, students, and the public.

The current registration forms, information out the UWM IBC, and more can be found at the UWM IBC Page. Registrations approved by the IBC will be active for 3 years from the date of approval. Written notification that the registration will expire will be sent out at least 30 days prior to the expiration date. The PI will then be required to submit an updated registration application for review and approval by the IBC. The IBC will meet monthly to conduct business during the year. Registration forms/protocols will be discussed and determination of approval/rejection will be decided at these times.

IBC Meeting Procedures and Protocol Reviews

The review of registration forms and biosafety protocols are evaluated based on risk assessment in accordance with NIH guidelines. Regardless of the status of the project (NIH exempt or non-exempt) it is expected that all protocols adhere to state and federal regulations and recommendations. The following are the actions the IBC will take regarding a protocol, following Robert’s Rules of Order.

- **APPROVE**: 51%+ of the IBC approves the protocol as submitted.
  - Biological Safety Officer (BSO) sends final electronic copy with approval to PI to be printed- the original must be sent/brought to the BSO at Engelmann Hall 270.
  - Committee chair signs the approved protocol, an electronic copy is generated by the BSO and saved, and the original is returned to the PI. Work can begin.
- **APPROVE WITH CONTINGENCY(IES)**. The PI is required to complete additional steps as outlined by the IBC before the protocol is to be approved. A revised protocol must then be submitted for approval.
- **TABLE**. If the IBC is unable to come to a majority approval, it will be tabled and deficiencies will be addressed by the PI and re-submitted.
- **REJECT**. This action is only taken when there are significant issues with the protocol. A new protocol must be developed and include recommendations provided from the BSO and IBC.

The following projects must have a protocol approved and on file before commencing, as noted in the NIH Guidelines of this Biosafety Manual and the document itself.

- Recombinant (transgenic) or synthetic DNA/RNA materials, including human gene therapy, proteins, and enzymes of infectious biological agents
- Microbes and disease-causing agents including bacteria, viruses, fungi, prions, protozoa, and parasites
- Large scale propagation consisting of a volume greater than 10L or more in one vessel
- Human cells and cell culture, organs or tissues, or biological samples
- Non-human cells and cell culture, organ or tissues, or biological samples that are infectious, potentially infectious or recombinant
- Animals (vertebrate and/or invertebrate) that are recombinant (transgenic), exotic, and/or grown in association with pathogens and/or recombinant materials
• Plants that are recombinant (transgenic), exotic, and/or grown in association with pathogenic or recombinant microbes and/or pathogenic or recombinant small animals (insects, etc.)
• Biological Toxins (this does not include toxic chemicals or antibiotics)
• Select Agents and Toxins
• Dual Use Agents of Concern

A summary of all III-E protocols is also reviewed and submission of a protocol is required when initiating the research. The researcher does not have to wait for an approval from the IBC, but does require submission. These include experiments that involve the formation of recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus, experiments involving whole plants that do not already fall under III-A, III-B, III-D, or III-F, or experiments involving transgenic rodents. These projects must fall under BSL-1 containment.

Protocols that are submitted to the BSO that do not require IBC review include:
• Non-recombinant DNA protocols
• NIH exempt protocols
• Personnel amendments
• Grant additions

All other protocols must be approved by the IBC. All projects must be registered for teaching and research, even if they do not require an approval.

All approved protocols are required to be re-submitted for review every three years to the IBC. If a change is made to the experiment in which NIH Guidelines apply or differ from what was previously approved, this will also be reviewed and approved by the IBC. Protocol changes that require significant changes to safety precautions, such as PPE, administrative or engineering controls, will also be reviewed and approved by the IBC (UW Biosafety, 2017). If there are smaller changes, such as personnel additions/ deletions then the approval can be done by the BSO who can then notify the IBC.

The BSO and the Dept. of University Safety and Assurances withhold protocols from IBC agenda that are deemed not ready for review. PIs may be asked to attend the meeting to clarify their protocol information and answer questions during protocol review. If a PI is unable to attend, and the IBC is unable to understand the protocol, it may be tabled until the PI can attend a meeting. If a protocol is tabled, the research cannot be conducted during that time that pertains to that specific protocol. A PI can send a lab manager or researcher in their place to answer questions, but only the PI can complete and submit the registration form and the PI is responsible for its content.

Meetings may be digitally recorded so there is an accurate record of the meeting on file and so the BSO can accurately prepare minutes for review. All meetings are conducted following Robert’s Rules of Order. Thus, the IBC cannot act on a protocol without a quorum present, which is one more than half of the voting members. Therefore, it is important for IBC members to attend meetings regularly to ensure that the IBC will meet quorum; otherwise, the meeting will be cancelled and all protocols scheduled to be approved at that session will be held until the next
scheduled meeting. If a protocol is left unapproved, the research cannot be conducted during that time that pertains to that specific protocol.

The IBC is subject to the Wisconsin Open Meetings Law. Actions may only be taken at meetings that have been announced and are open to the public. Notices will be posted in advance at https://uwm.edu/news/ under open meetings. Some sessions may go to closed session. Protocols that contain information that must be protected due to confidentiality agreements, disclosure, safety and security, DURC, select agents/ toxins, protocol violations, or repeated biosafety violations in the research laboratory will be discussed in closed session pursuant to Wisconsin Statues sections 19.85(1)(d) and 19.85(1)(e). More details can be found on the IBC page at the UWM Biosafety Page. Meetings are held monthly, typically during the last week of the month. These meetings are held on campus and will last 1-3 hours, depending on the number of protocols submitted and other items that need to be discussed. Agendas are made available to the public upon request and can be obtained through the BSO, who acts as the UWM Contact and Recorder for the IBC.

Protocol Review Questions

The PI and the IBC must concur on all matters relating to containment requirements, safe practices, and handling and disposal procedures for biohazardous agents. In event of non-concurrence, the recommendations of the Committee shall prevail until they are modified or rescinded by appellate decision of an administrative review which may include outside reviewers. Questions relating to recombinant DNA studies that are not covered by the NIH Guidelines will be referred to the NIH Office of Recombinant DNA Activities for resolution.

The IBC will use an evaluation form to review the criteria found on the IBC registration form. All comments will be compiled and used to discuss the protocol at a formal meeting. Personnel involved in the submitted protocol are invited to discuss their submission at the meeting.

Visit the UWM IBC Page for more information.

Teaching Laboratories and IBC Registration

The University of Wisconsin-Milwaukee offers a variety of teaching laboratories that work with recombinant DNA, animals, animal or human cells/ tissues, and biological agents. It is part of the biosafety program to keep all the teaching laboratories that handle agents that fall under NIH guidelines on file for the safety of the students, staff, and public. The UWM IBC Page has a registration form for teaching laboratories to complete and submit for IBC approval. The IBC is not responsible for how the content is taught, simply for evaluating the safety and efficacy of using biological agent(s) in the course as outlined in the registration form.

Termination of Unsafe Research

The Biological Safety Officer, with concurrence from the Chair of the IBC, or with concurrence of three (3) members of the IBC if the Chair is unavailable, may stop any work with
microbial agents or any hazardous research project that creates an unreasonable hazard to personnel or involves experiments prohibited by the institution. The entire IBC then will review the problem and will complete the review within a working week then forwarding written recommendation(s) to the Vice Chancellor for Research and Dean of the Graduate School and the Provost for final action. It is required that any unlawful research is reported to the federal government.

*Standard Operating Procedures (SOPs)*

The UWM Biosafety Program has developed generally accepted standard operating procedures (SOPs) for general research practices on the [UWM Biosafety SOP Page](https://www.selectagents.gov). Anyone working with a biohazardous agent or biohazardous material at any facility of UWM is expected to follow these SOPs. PIs should work with the BSO to develop specific SOPs for their research facility. A general blank SOP is available for use on the [UWM Biosafety SOP Page](https://www.selectagents.gov).

*Bibliography*
