Institutional Biosafety Committee (IBC) Policy on Appropriate Containment for Select Opportunistic and Borderline Pathogens

1.0 Purpose: The purpose of this Institutional Biosafety Committee (IBC) policy is to require BSL-2 precautions in laboratories working with opportunistic and borderline pathogens which are not known to cause infection in healthy individuals but are known pathogens of persons who have been compromised in various ways including, but not limited to, open wounds, cuts, antibiotic therapy, persons with immune systems rendered deficient.

2.0 Scope: This policy applies to all UW-Madison Principal Investigators (PI), and UW-Madison employees and staff, along with applicable employees and staff of external agencies having agreements with UW-Madison, all members of the UW-Madison IBC, and UW-Madison Office of Biological Safety (OBS).

3.0 Related Documents/Resources:

- UW-Madison, Office of Biological Safety - **Institutional Biosafety Committee (IBC) Handbook**; found on the OBS website (www.ehs.wisc.edu/biosafety).
- UW-Madison, Office of Biological Safety - **Biohazard Recognition and Control Handbook**; found on the OBS website (www.ehs.wisc.edu/biosafety).
- U.S. Department of Health and Human Services, **Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) - Biosafety in Microbiological and Biomedical Laboratories (BMBL**), current version and/or any subsequent revisions.
- U.S. Department of Health and Human Services, **National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,** current version and/or any subsequent revisions. (Organisms are in Appendix B of the guidelines)

4.0 Definitions:

Opportunistic Pathogens: Organisms which are not known to cause infection in healthy individuals but are known pathogens of persons who have been compromised in various ways including, open wounds, cuts, antibiotic therapy, persons with immune systems rendered deficient via infection, acquired or congenital condition or via therapy (e.g. HIV+, diabetes, complement deficiencies, severe asthma, organ transplant, chemotherapy or long-term steroid treatment) and persons with immunocompromised, immunosuppressed or susceptible immune status (e.g. pregnant women, very young or old, diabetes, individuals on steroid therapy).

Risk Group 1: Agents not associated with disease in health adult humans.

Risk Group 2: Agents associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available.

The Current version of this Policy is retained at the Office of Biological Safety and posted to biosafety.wisc.edu
Printed copies may not be relied upon as current, active IBC policy

Risk Assessment: A critical exercise focused on the prevention of laboratory acquired infections whereby the facilities, equipment and practices are considered. The assessment may take into account laboratory conditions and engineering controls, as well as expertise of the person handling the agent, available therapies, and immunizations, presence of vectors, quantity (volume and/or titer), economic and environmental effects.

5.0 Roles and Responsibilities: Not Applicable.

6.0 Policy: Based on risk assessments, the IBC has determined that Biosafety Level 2 (BSL-2) precautions are appropriate for handling the following microorganisms:

Adeno-associated virus (AAV): The wildtype virus is generally considered RG1 because it usually requires another virus for replication. BSL-1 laboratory precautions are acceptable for gutted AAV vectors (e.g., missing the *rep* and *cap* genes) unless higher hazard transgenes (e.g., oncogenes) are expressed or high titers and/or large volumes of virus are handled, in which case BSL-2 should be used.

***Aspergillus flavus* and *A. fumigatus*:** May cause opportunistic infections in the immunocompromised individual.

Bacillus anthracis (Sterne): A vaccine strain and is missing an important virulence factor. There are some reports of pathogenicity of this strain in animals. Furthermore, per guidance from CDC, BSL-2 practices will avoid contamination of the lab, which could cause problems in confounding detection of anthrax.

Bacillus cereus: A foodborne pathogen produces toxin and causes cutaneous infections inhealthy adults.

***Candida albicans*:** An opportunistic pathogen with significant consequences for individuals with stressed immune systems.

***Clostridum difficile*:** The "new" epidemic strain (B1/NAP-1) of this bacterium has substantial clinical consequences, is usually resistant to some antibiotics such as fluoroquinolones, and can infect healthy adults.

Enterococcus faecalis* and *E. faecium: All vancomycin resistant strains are included. Furthermore, containment will minimize contamination of surfaces in the lab, which is important because this pathogen is extremely hardy in its ability to survive for weeks on environmental surfaces.

The Current version of this Policy is retained at the Office of Biological Safety and posted to biosafety.wisc.edu
Printed copies may not be relied upon as current, active IBC policy

***Pneumocystis jiroveci* (*P. carinii* f.sp. *hominis*):** Causes opportunistic infections in the immunocompromised individual.

***Pseudomonas aeruginosa*:** Causes eye infections, especially in contact lens wearers, chronic respiratory infections among cystic fibrosis patients and may be invasive in persons taking antibiotic therapies.

***Salmonella typhimurium LT2*:** There is evidence that this strain may cause disease in healthy adults as well as immunocompromised individuals.

***Stenotrophomonas maltophilia*:** Has been implicated in infrequent ocular infections, primarily in patients with ocular compromise. Of particular concern is that treatment is limited by resistance to common antibiotics.

Additional information:
Most wet labs will meet the standards for a BSL-2 facility. Some of the practices utilized under BSL-2 containment are:

- Work with microorganisms in the laboratory setting may create situations whereby the normal route of transmission is circumvented. In the lab, the concentration and volume are typically higher than encountered outside of the lab and procedures provide "opportunities" to infect in an abnormal manner such as splash to mucosa or needle stick injury.
- Biohazard signs are posted on the door to the laboratory when work with the microorganism is in progress.
- Individuals who may be exposed are informed of the potential risks to their health posed by the pathogen.
- Exposures are treated with first aid and reported to the PI with medical evaluation as deemed prudent.
- The lab is under negative air pressure relative to the corridor and the lab door is kept closed to maintain negative pressure.
- Many procedures can be conducted at the open lab bench under BSL-2 containment, but activities involving high concentrations and/or large volumes or that generate aerosols need to be avoided or done in containment.
- Use of a biological safety cabinet is preferred but is not required; alternative containment equipment may be acceptable.
- Disinfectants are chosen that are effective against the pathogens handled.
- Submission of a biosafety protocol is required.

The Current version of this Policy is retained at the Office of Biological Safety and posted to biosafety.wisc.edu
Printed copies may not be relied upon as current, active IBC policy

Original signed & dated Policies are retained by the Office of Biological Safety

Signature	Date
Professor Susan West, IBC Chair	05/07/2014

The Current version of this Policy is retained at the Office of Biological Safety and posted to biosafety.wisc.edu
Printed copies may not be relied upon as current, active IBC policy