



## STEM CELL LABORATORY (STCL)



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Biological Safety - Biosafety Levels

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**BIO SAFETY LEVELS** Four biosafety levels (BSLs) are summarized in the table below for proper handling of biohazardous materials. BSLs consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed the documented or suspected routes of transmission of the infectious agents, and for the laboratory function tor activity.

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause diseases in immunocompetent adult humans	Standard microbiological practices	None required	Open bench top, sink required
2	Associated with human disease. Hazard: percutaneous injury, mucous membrane exposure, ingestion	BSL-1 practices plus: • limited access • biohazard warning signs • sharps precautions • biosafety manual defining waste decontamination or medical surveillance policies	Primary barriers: Class I or II biosafety cabinets or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPE: laboratory coats, gloves, face protection as needed	BSL-1plus: • non-fabric chairs and other furniture easily cleanable • autoclave available • eyewash readily available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practices plus: • controlled access • decontamination of all wastes • decontamination of lab clothing before laundering • baseline serum	Primary barriers: Class I or II biosafety cabinets or other physical containment devices used for all manipulations of agents; PPE: laboratory coats, gloves, respiratory protection as needed	BSL-2 plus: • physical separation from access corridors • hands-free handwashing- sink • self-closing double door access • exhaust air not recirculated • negative airflow into laboratory • eyewash readily available in lab
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practices plus: • clothing change before entering • shower on exit • all material decontaminated on exit from facility	Primary barriers: All procedures conducted in Class III biosafety cabinets or Class I or II biosafety cabinets in combination with full-body, air supplied positive pressure suit	BSL-3 plus: • separate building or isolated zone • dedicated supply/exhaust, vacuum and decon system  <b>There are no BSL-4 labs at Duke</b>

Summarized from **Biosafety in Microbiological and Biomedical Laboratories**, 5th Edition, 2007.  
<http://www.cdc.gov/od/ohs/biosfty/bmbI5/bmbI5toc.htm>

### Classification of Agents According to Risk

Biological agents are assigned to biosafety levels (BSL) based on the risk they pose to human health and the environment. Such factors as severity of disease caused by the agent routes of exposure, and virulence are used when determining the most appropriate BSL. The partial list below is provided to assist laboratories in making preliminary decisions on the appropriate

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biosafety level for particular agents. Ultimately, the Occupational and Environmental Safety Office (OESO) will make the final BSL assignment. If a particular agent is not listed below, or if further assistance is needed in interpreting BSL requirements, contact the OESO-Biological Safety Division at 684-8822. There are no Biosafety Level 4 labs at Duke.

### Biohazard Warning Signage

A sign incorporating the universal biohazard symbol **must be posted** at the entrance to the laboratory when infectious agents are present.

**Biosafety Level 1 (BSL-1):** The sign may include the name of the agent (s) in use, and the name and phone number of the laboratory supervisor or other responsible personnel.

**BSL-1** is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. All bacterial, parasitic, fungal, viral, rickettsial, and chlamydial agents which have been assessed for risk but do not belong to a higher risk group can be safely handled at BSL-1. Be aware that many agents not ordinarily associated with disease are opportunistic pathogens and may cause infection in the young, the aged and immunocompromised individuals. Examples of agents handled at BSL-1 include: *Bacillus subtilis*, *Eschericia coli* -K12, *Naegleria gruberi*, etc.

**Biosafety Level 2 (BSL-2):** Posted information on the sign must include the name of the agent(s), laboratory's biosafety level, supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory.

**BSL-2** builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that: 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

### **BSL-2 Viral Agents:**

Adenovirus	HTLV types I and II
Creutzfeld-Jacob agent	Human Blood & Blood Products
Cytomegalovirus	Kuru
Eastern equine encephalitis	Monkeypox virus
Epstein-Barr virus	SIV
Hepatitis A, B, C, D, E	Spongiform encephalopathies
Herpes simplex viruses	Vaccinia virus

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HIV

VSV (lab adapted strains)

**BSL-2 Bacterial/Rickettsial Agents:**

Campylocacter fetus, coli, jejuni  
Chlamydia psittaci, trachomatis  
Clostridium botulinum, tetani  
Corynebacterium diphtheriae  
Legionella spp  
Neisseria gonorrhoeae  
Neisseria meningitidis  
Pseudomonas pseudomallei  
Salmonella spp

Shigella boydii, dysenteriae,  
flexneri, sonnei  
Treponema pallidum  
  
Vibrio cholera  
(including El Tor)  
Vibrio parahaemolyticus  
Vibrio vulnificus  
Yersinia pestis

**BSL-2 Fungal Agents:**

Blastomyces dermatitidis  
Cryptococcus neoformans  
Microsporum spp  
Exophiala dermatitidis (wangiella)

Fonsecaea pedrosoi  
Sporothrix schenckii  
Trichophyton spp

**BSL-2 Parasitic Agents:**

Entamoeba histolytica  
Cryptosporidium spp  
Giardia spp  
Naegleria fowleri  
Plasmodium spp

Strongyloides spp  
Tania solium  
Toxoplasma spp  
Trypanosoma spp

**Biosafety Level 3 (BSL-3):** Posted information on the sign must include the name of the agent(s), laboratory's biosafety level, supervisor's name (or other responsible personnel), telephone number(s), and required procedures for entering and exiting the laboratory.

**BSL-3** is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures. All procedures involving the manipulation of infectious materials must be conducted within BSCs or other physical containment devices. A BSL-3 laboratory has special engineering and design features.

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**BSL-3 Viral Agents:**

Valley	VSV exotic strains (Piry)
Rift Valley Fever (Zinga)	Yellow fever (wild type)

**BSL-3 Bacterial/Rickettsial Agents:**

Bacillus anthracis	Mycobacterium bovis
Francisella tularensis	Rickettsia rickettsii
Mycobacterium tuberculosis	Yersenia pestis (resistant strains)

**BSL-3 Fungal Agents:**

Coccidioides immitis	Histoplasma capsulatum
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