THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Principles of Biosafety (BSL2 Training)

Department of Research Safety

September 2017

This course is intended to provide researchers with information necessary to comply with the requirements of the CDC Biosafety in Medical and Biological Laboratory (BMBL) and NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). It addresses work with moderate-risk biohazardous agents that are present in the community and associated with human disease of varying severity. This self study is to be completed in conjunction with supervisor-provided in-person training specific to the agents that you will be handling.

Objectives

Upon completing this course you should be able to:

- Identify facility design, work practices, and PPE required for work at the BSL2/ABSL2 level.
- Employ standard precautions for BSL2 agents while handling these materials.
- Properly use a biological safety cabinet (BSC).
- Demonstrate proper clean-up procedure for an infectious material (BSL2) spill.
- Identify the role of the Institutional Biosafety Committee (IBC), responsibilities for compliance with the NIH Guidelines, and potential consequences for non-compliance.

Review of Introduction to Biosafety (BSL1) Information

BIOSAFETY BASICS

The International Biohazard Symbol

All pathogenic or potentially pathogenic biological material (micro-organisms, viruses, prions, toxins) are considered biohazardous and must be handled with special care to avoid exposure or release of the material. As such, biohazardous material must be readily recognizable.

The International Biosafety Symbol was developed by the Dow Chemical Company in 1966 for labeling their containment products.

It was designed to be easily recognizable from all angles.

Following its publication in the journal Science in 1967, the symbol was immediately adopted by the US Centers for Disease Control and Prevention (CDC), the Occupational Safety and Health Administration (OHSA),

and the National Institutes of Health (NIH), and it quickly became the internationally accepted symbol for Biohazardous Material.

•Biosafety is a combination of containment principles, technologies and operational practices that, together, help prevent exposure to, or release of, infectious material or toxins that can cause harm to humans or animals.

•Biosafety applies to pathogenic or potentially pathogenic biological materials or toxins. A pathogen is a microorganism, nucleic acid, or protein that is capable of causing disease in humans or animals. When the pathogen can cause disease in humans and animals (when it is transmissible between the two) it is considered a zoonotic pathogen.

•Using a pathogen risk assessment process, pathogens are assigned to a risk group (RG) category based on the risk to the individual/animal and the risk to public health or animal populations. These categories range from risk group 1 to 4.

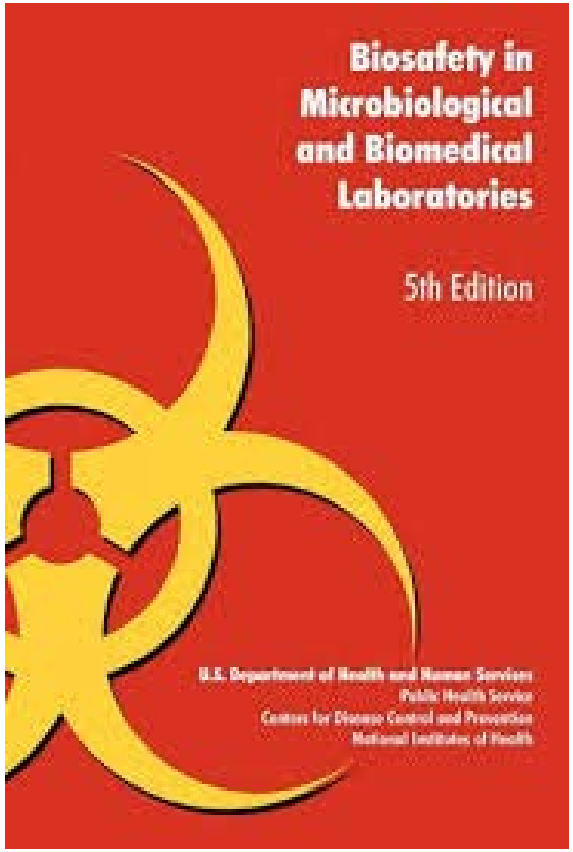
•Containment levels refers to the minimum physical containment and operational practices required for handling infectious material and toxins safely in laboratory and animal work environments. In a manner similar to risk group classifications, laboratories are also classified into biosafety containment levels (BSL) from 1 to 4.

CDC Biosafety in Medical and Biological Laboratories (BMBL)

The BMBL is the national guideline for work with biohazardous agents. All organizations that receive NIH funding must comply with the BMBL.

It includes information related to:

- Biosafety levels
- Containment,
- Decontamination and disinfection
- Transportation,
- Disposal
- Hazards associated with specific biological agents.



Risk Group Comparison

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	Risk Group 1	Risk Group 2	Risk Group 3	Risk Group 4
Characteristics	Does not cause disease in healthy adults	Can cause infection of varying severity; Rarely lethal	gents associated with moderate to evere disease outcome; Can be thal	Capable of causing severe disease with lethal outcome
Availability of Treatment	Not applicable	Treatment usually available or host immune system is capable of controlling the infection	reatment may not be av	Treatment is generally not ible
Routes of Transmission	Not applicable	Ingestion, through the skin and via facial mucous membranes	ame as Risk Group 2 plus	
Disease Severity to Individual	None in healthy adults	Low to moderate	Moderate to high; igher mortality and mor	this
Community Risk	Low	Low	ow to moderate	High
Infectious Dose	Not applicable	Generally high (variable)	ower doses capable of infection	Can be as low as 1 organism
Example Agents	Non-conjugative strains of E. coli, rodent cell lines, Saccharomyces cerevisiae	**Parasites (Plasmodium, Trypanosomes, Leishmania)** **GI pathogens (Salmonella, Shigella)** **Bloodborne Pathogens (HBV, HCV, Borrelia)**	Mycobacterium tuberculosis, West ile Virus, Yellow Fever Virus, ickettsia rickettsii	Ebola virus, Marburg virus, Sabia virus, Equine Morbillivirus
Gwladys Caspar's Quick Guide and Associated Safe Practices	Don't drink it Never eat, drink, o smoke in the laboratory	Don't touch it Wear gloves, decontaminate work surfaces, avoid touching your face, make sure wounds are covered, wear face protection, and work behind a shield	on't breathe it ecause of inhalation risk, perform ll work inside of a biosafety cabinet; Vear respiratory protection if eeded	Don't do it (in your state unless you have a federally approved BSL4 laboratory); Risk Group 4 agents require significant containment

Risk Group 2 agents present a moderate risk to human health and low risk to the community at large.

Biosafety Containment Levels

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	Biosafety Level 1	Biosafety Level 2	Biosafety Level 3	Biosafety Level 4
Practices	Basic foundational work practices	Level 1 practices plus safe sharps work practices	evel 2 work practices, with all work erformed inside primary containment levices	Same as Level 3
Protective Clothing	Gloves and Lab coat recommended	Gloves and lab coat required; Face protection added if potential for splash or splatter	ame as Level 2; espiratory protection added if varranted after risk asse	Supply airline respirator and fully encapsulating protective)
Containment Equipment	None required	Biosafety cabinet to contain aerosols based on risk assessment; Centrifuge safety buckets and other primary	ame as Level 2	is et lab. All work performed in sealed glove boxes
Lab Design Features	General lab, easy to clean surfaces, sink, and door	Same as Level 1, with recommendation of controlled airflow into the lab and biosafety cabinet for aerosol containment	ame as Level 2 with requirement of ontrolled airflow into the lab, dedicated VAC system, no recirculation of xhaust, airflow monitoring devices at ntry, two-door separation from general raffic, and fan failure alarms	Same as Level 3, with many more advanced features; Level 4 is a building within a building approach; All systems for lab separated from non Level 4 areas
Other			HEPA filters for exhaust air may be required	Double HEPA filtered exhaust air; HEPA filtered supply air; Effluent decontamination system

BSL2 practices are required for handling Risk Group 2 agents.

BSL-2 precautions are suitable for work involving agents that pose moderate hazards to personnel and the environment. They are appropriate when work is done with any human-derived blood, body fluids, tissues, or primary human cell lines where the presence of an infectious agent may be unknown.

BSL2 FACILITY REQUIREMENTS

Risk = Hazard + Exposure

What is considered when determining the containment level?

1. *Aerosol generation* –Equipment or procedures which may produce aerosols can expose personnel to infectious aerosols.
2. *Quantity* – Large scale processes (e.g. industrial fermentation, vaccine production) may have different containment requirements than laboratory scale work using the same pathogen.
3. *Concentration of pathogen* – Certain types of work (e.g. pure cultures) may entail a higher concentration of pathogens than others (e.g. diagnostic specimens).
4. *Type of proposed work* – The nature of the work may have inherent risks associated with it which need to be considered (e.g. the type of animal and the inherent risks associated with that animal when undertaking *in vivo* work).
5. *Shedding (specific to animals)* - Pathogens may be present in the saliva, urine or feces, and may also be exhaled by the animal.

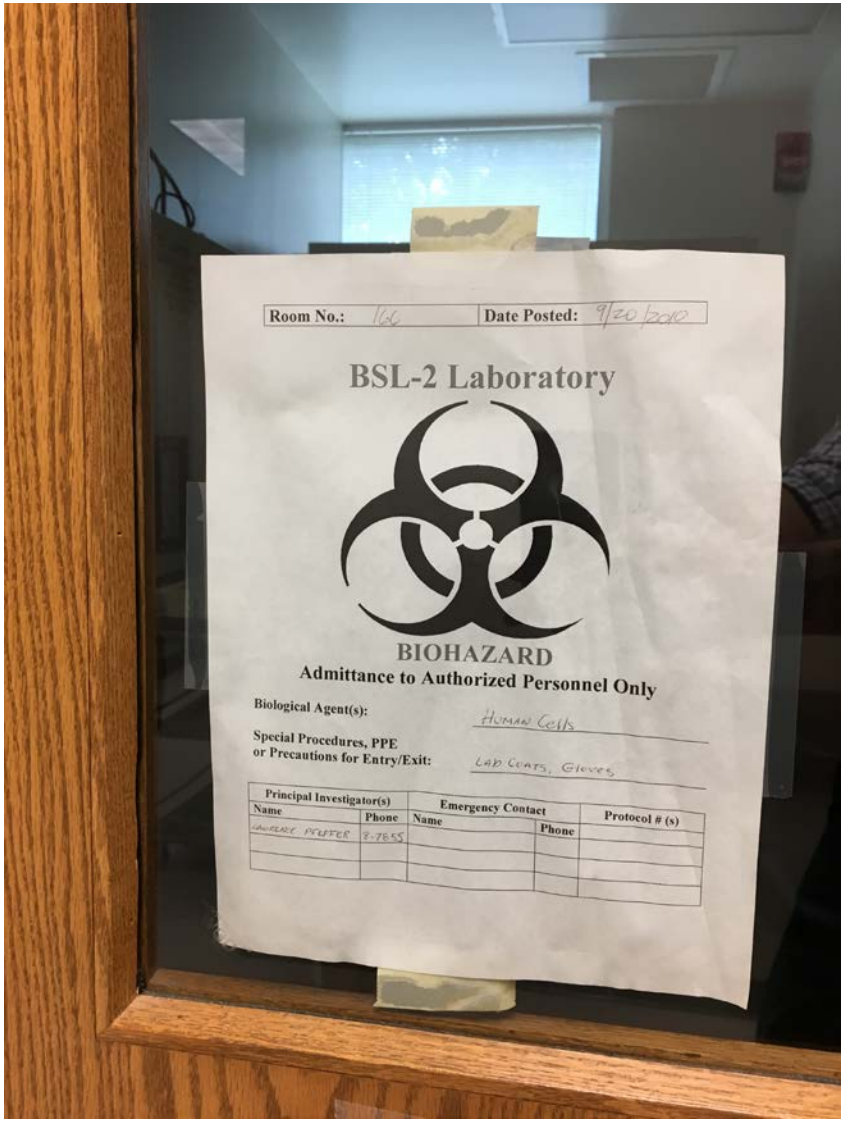
BSL2 facilities include a wide variety of laboratories and animal work areas, including diagnostic and health-care laboratories (public health labs, clinical or hospital-based) and many biological research laboratories in universities.

BSL2 is primarily required for risk group 2 pathogens, whose mode of transmission is **ingestion, inoculation, and through contact with mucous membranes**. These organisms are not generally transmitted by the airborne route, but you must take care to avoid splashes and the generation of aerosols.

When animals are housed in a space where the room itself provides the primary containment, the requirements for these types of zones are referred to as ABSL2.

BSL2 Facilities must have the following features:

- BSL2 work areas must be separated from public access. (While BSL1 work may be done in an open floor plan lab, BSL2 labs must have a door to limit access.)
- Signage outside of BSL2 labs must identify the following:
  - Hazardous agent(s) being handled.
  - Necessary precautions (e.g. PPE).
  - Vaccines available or required (e.g. Hep B) for entry.
  - Contact information.
- Handwashing facilities.
- Vacuum lines protected with filters or liquid disinfectant traps.
- Eyewash station must be readily available and easily accessible.
- Plants and animals not associated with work prohibited in BSL2 laboratories!



Physical requirements for BSL2

Physical containment requirements are proportional to the risks associated with the agents handled in them.
BSL2 facility containment features include facility design (e.g. location, surface finishes, access control) and biosafety equipment, such as primary containment devices (e.g., BSCs) for certain activities.

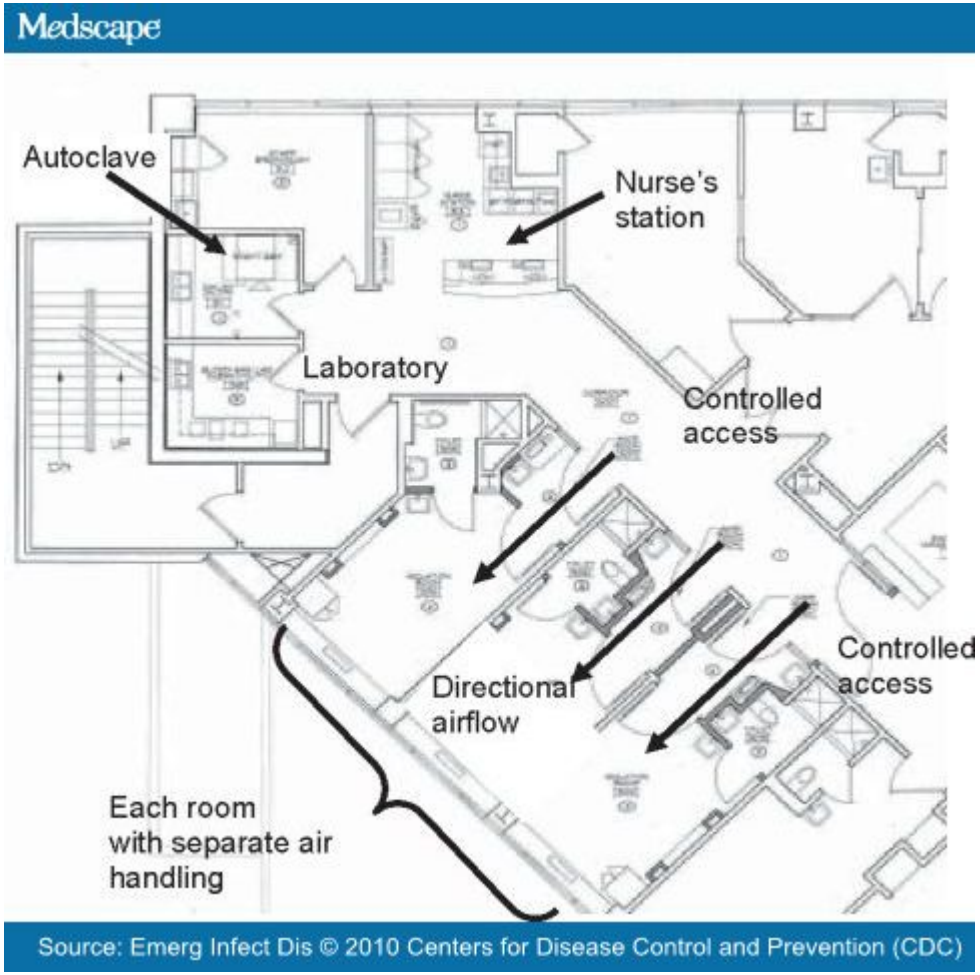
Operational practice requirements for BSL2

Operational practice requirements for BSL2 include administrative controls (e.g., biosafety program management, training) and procedures (e.g., work practices, PPE use, decontamination) that mitigate the risks associated with the pathogens and toxins handled.

BSL2 Facilities

If the work performed presents a risk of infection from aerosol inhalation facilities require:

- **Directional airflow (typically into lab)**
- **Primary containment**
  - **Biological safety cabinet**
  - **HEPA filters**



As required by the CDC BMBL

BSL2 PPE

BSL2 PPE: Lab Coat

- Lab coats (or equivalent) must be worn while working with hazardous materials.
  - Remove before leaving work area.
  - Dispose of appropriately
  - Do not take home
- Lab coat must be closed (i.e. buttoned)
- Lab coat sleeves should be tucked into the top of gloves.

Gloves and Eye Protection

- Gloves must be worn while working at the BSL2 level.
  - Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
  - Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
  - Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

- Eye and face protection is required when there is anticipated potential for splash or spray of infectious material.
- Decontaminate eye and face protection after use or discard as contaminated waste.
- Eye and face protection recommended whenever working with infected animals.
- Any materials handled within the BSC while BSL2 agents are being handled should be considered contaminated and must be discarded as infectious waste.

BSL2 standard practices build upon BSL1 practices by providing requirements for controlling lab access, the use of containment equipment to control aerosols, and requirements for hazard and work practice training specific to the agents being handled.

BSL2 STANDARD PRACTICES

Review of Standard Microbiological Practices for BSL 1

- Proper technique for donning and doffing of gloves.
- Wash hands after removing gloves.
- No eating, drinking, smoking, handling contact lenses, applying cosmetics.
- No food stored in lab.
- No mouth pipetting.

- Work practices to minimize splash and aerosol creation.
- Decontaminate work surfaces at least once a day or after spills.
- Decontaminate cultures, stocks, etc. before disposal.
- Complete necessary training and immunizations if available.

BSL2 Standard Practices

- Restrict access to lab when work is being conducted.
- Everyone working at BSL2 must be informed of hazards and meet entry/exit requirements.
- Specific training required for the handling of pathogenic agents. This must be obtained from the PI or Office of Research Safety.
- Work must be supervised by scientists competent in handling infectious agents and associated procedures.

BSL2 Standard Practices

- Use only durable, leak proof containers for material handling, processing, storage, and transport of infectious materials.
- Aerosol or splash procedures must be conducted in BSCs or physical containment.
- Personnel provided medical surveillance, as appropriate, and offered available immunizations for agents handled.
- Exposure incidents or suspected exposure must immediately be evaluated and treated.

- Equipment must be routinely decontaminated after use.
- Equipment must be decontaminated before repair, maintenance, or removal.
- All incidents must be reported lab supervisor.
- Injuries and exposures must be reported to your supervisor and called into Corvel.

Sharps Handling

- Do not use bent, sheared, or broken needles.
- Do not recap needles.
- Used needles discarded in puncture resistant, FDA approved sharps container.
- No direct handling of broken glass.
- Secure sharps including razor blades, scalpels and similar materials when not in use.

BSL2 Supervisor Responsibilities

- Enforce the institutional policies that control access to the laboratory.
- Ensure that laboratory personnel receive appropriate training regarding their duties including precautions to prevent exposures and exposure evaluation procedures.
- Provide updates or additional training when procedural or policy changes occur.
- Ensure proficiency in standard and special microbiological practices.

- Report incidents to IBC, IACUC or the Office of Research Safety when necessary.
- **Provide supervision at a level sufficient to do the following:**
  - Enforce requirements for PPE use.
  - Enforce work practice requirements such as proper use of BSCs and decontamination of work surfaces.
  - Ensure compliance with IBC and IACUC protocol requirements.

OOOoooPPPppppSSSSssss

BIOHAZARDOUS MATERIAL SPILL CLEANUP

In the event a spill of a BSL2 material:

- Exit the spill area.
- Close the door,
- Post warning sign,
- Wait 30 minutes for aerosols to settle,
- Return wearing PPE
- **Clean spill by:**
  - Covering with paper towels or rags
  - Pouring 1-10% solution of household bleach
  - Waiting 10 minutes for bleach to work
  - Discard material as **biohazardous waste**
  - Use tongs to handle broken glass and sharp materials.

https://www.youtube.com/watch?v=aGrPG3zla2I

(Click link to watch video)

Factors Affecting Chemical Decontamination:

1. Organism or material being treated
2. Activity of chemical disinfectant
3. Concentration of disinfectant
4. Concentration of disinfectant
5. Contact time
6. Presence of organic material
7. Humidity

Disinfectant Selection:

	Chlorine Compounds	Alcohols	Phenolics	Quats
Bacteria	Very good	Good	Good	Good for gram positive
Envelope Viruses	Very good	Good	Good	Good
Non-envelope Viruses	Very good	Fair**	Fair**	Not effective
Fungi	Good	Fair	Good	Fair
Bacterial Spores	Good with high concentration	Not effective	Not effective	Not effective
Protozoal Parasites*	Moderate with high concentration and long contact time (hours)	Not Effective	Not Effective	Fair (some quats at high concentration)

*** hydrogen peroxide most effective**
**** check disinfectant susceptibility for individual virus**

Chemical Components in Common Disinfectant Products:

Spor Klenz (Best): Hydrogen peroxide, peracetic acid, acetic acid

Clorox/Bleach: Hypochlorite/Chlorine

Ethanol or Isopropanol: Ethanol or isopropanol. (Doesn't work well in the presence of organic materials. Not appropriate for soiled surfaces, biohazard spills, etc.)

Table 2. Activity Levels of Selected Liquid Germicides[a]

Procedure / Product	Aqueous Concentration	Activity Level
Sterilization		
glutaraldehyde	variable	
hydrogen peroxide	6 – 30%	
formaldehyde	6 – 8%	
chlorine dioxide	variable	
peracetic acid		
Disinfection		
glutaraldehyde	variable	high to intermediate
ortho-phthalaldehyde	0.5%	high
hydrogen peroxide	3 – 6%	high to intermediate
formaldehyde [b]	1 – 8%	high to low
chlorine dioxide	variable	high
peracetic acid	variable	high
chlorine compounds [c]	500 to 5000 ml/L free/available chlorine	Intermediate
alcohols (ethyl, isopropyl) [d]	70%	Intermediate
phenolic compounds	0.5 to 3%	intermediate to low
iodophor compounds [e]	30 – 50 mg/L free iodine up to 10,000 mg/L available iodine 0.1 – 0.2%	intermediate to low
quaternary ammonium compounds		low

Centrifuge Safety

- Centrifuge must be labeled with biohazard sticker if used for infectious materials.
- Only use centrifuges with safety cups and lid.
- Inspect tubes, bottles and rotors for cracks and deformities before each use.
- Allow 10 minutes after run to allow aerosols time to settle.
- In case of emergency (e.g. spill in centrifuge, broken tube, rotor failure) stop the unit and wait at least 30 minutes for aerosols to settle.
- Decontaminate with 10% bleach for 30 minutes followed by 70% ethanol and let air dry.

Biological Safety Cabinets (BSCs) are engineering structures designed to provide protection to the worker, materials being handling on the work surface, and the environment. Failure to follow proper work procedures may introduce contamination into the cabinet or potentially expose workers in the lab. Understanding the principles of BSC operation can help maximize safety and the quality of your work.

BIOLOGICAL SAFETY CABINETS

Biological Safety Cabinets

Engineered device certified to contain potentially hazardous biological agents.

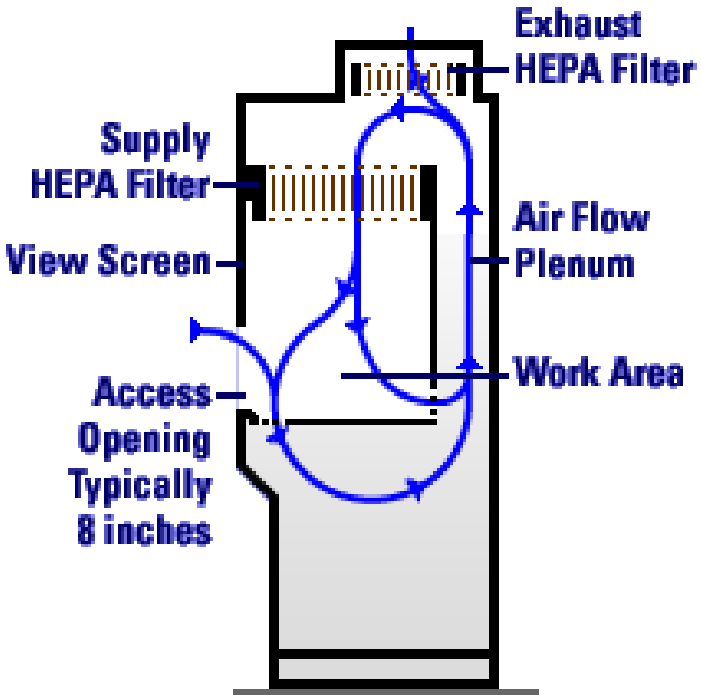
Use HEPA filters and directional airflow to provide protection to:

- Personnel
- Product being handled (i.e. the work surface)
- Environment

Biological Safety Cabinets

Effective performance depends on:

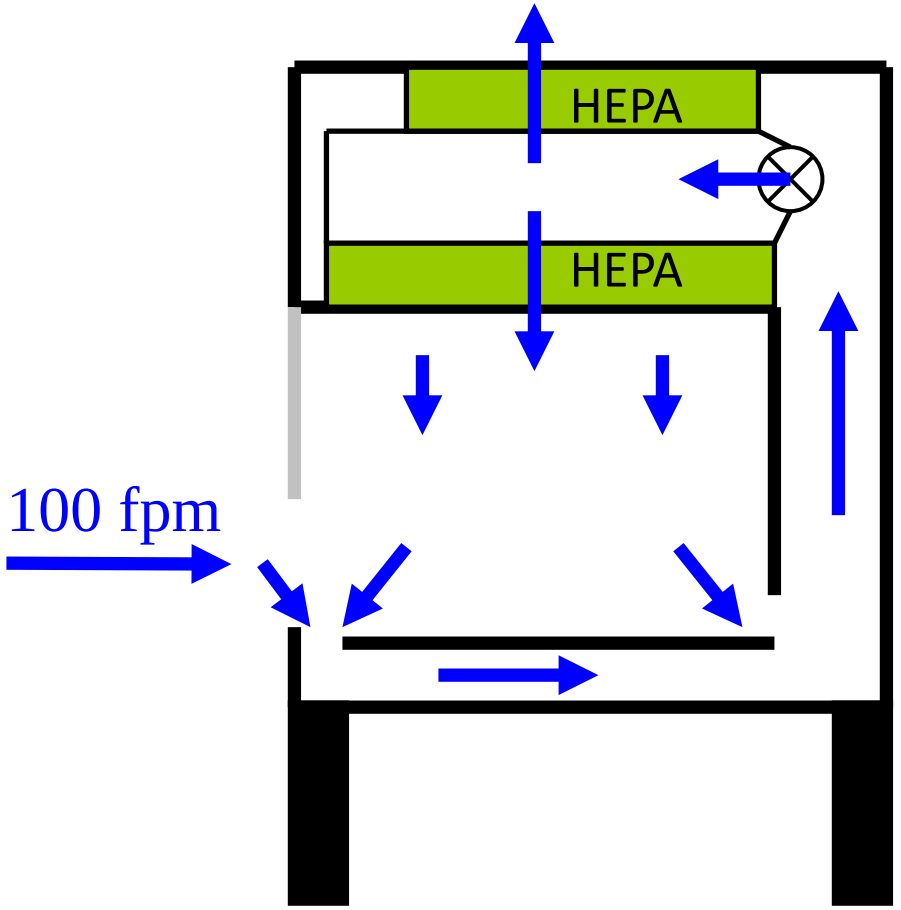
- **Proper airflow:** the airflow pattern is designed to ensure that only filtered, particulate-free air reaches the work surface.
- **Integrity of filters:** High Efficiency Particulate Air (HEPA) filters are least 99.97% efficient at filtering particles 0.3µm in size. *The filters do not remove vapors or gases – only particulates!*
- **Work practices:** Work practices are prescribed to ensure that the worker does not inadvertently defeat the engineering controls. Poor work practices introduce the potential for contamination within the BSC.



Biological Safety Cabinet (Type A2)

Click on this link to watch a brief video that demonstrates BSC operation. (Smoke is used to demonstrate proper airflow within a BSC.

Blocking grates or vents disrupts airflow.



Working in a Biological Safety Cabinet

https://youtu.be/96-aZLom340

Before Using a BSC (1)

- Check BSC positioning within room. It should be:
  - ≥3 feet from foot traffic
  - ≥6 feet from doors
- Check sticker for certification (must be within last 12 months) to ensure proper functioning.
- Turn on blower and wait 5 minutes to clear air within the unit.
- Decontaminate the sides, sash, and work surface by wiping them down with a suitable decontaminant.

Before Using a BSC (2)

- Wear appropriate PPE (lab coat and gloves - eye protection if necessary).
- Gloves should cover cuffs of lab coat.
- Create a checklist of work materials that you will need to handle within the BSC.
- Disinfect items as you load them into the BSC.

Proper Work Procedure (1)

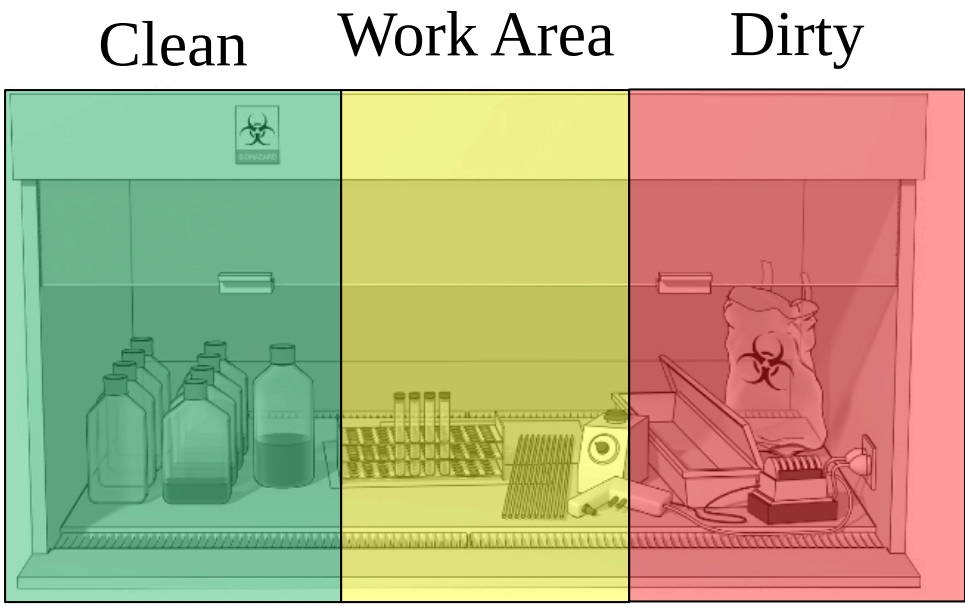
- Work at least 4 inches from front grill.
- Best work area: center 1/3 of BSC.
- For greatest personal protection work towards the back.
- ***Do not block the front grill!***

Blocking the front grill creates a channel through which contamination may be introducted or escape.

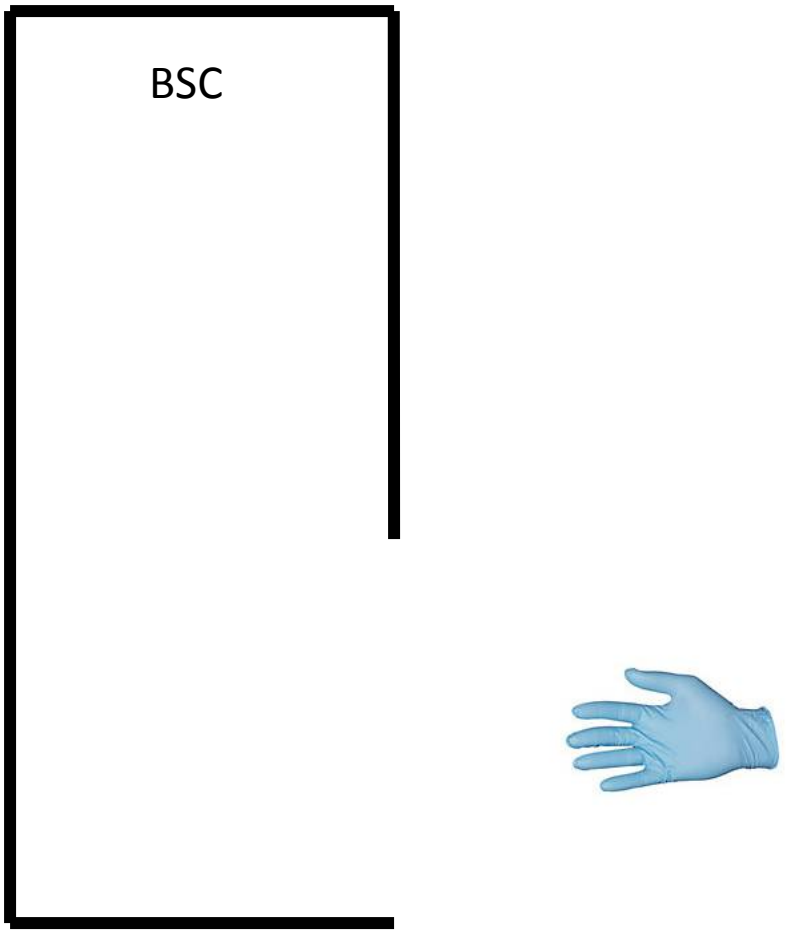
Proper Work Procedure (2)

Work from clean to contaminated:

- Set up BSC with a clean portion, a work area, and a contaminated/dirty area
- Do not move contaminated items over clean items.
- Click this link to see a demonstration of proper working procedure.



Proper Work Procedure (3)



- Hands enter and exit BSC straight on.
- Use slow, smooth movements
- Lateral motion may fan contaminants into or out of the cabinet.

Do Not Block Front Grill

Blocked Grill may provide contamination route.

Do Not Block Rear Grill

Blocked rear grill disrupts airflow within BSC.

Place Materials in Center for Optimal Performance

BSC Safety

Never Operate A BSC When it is Alarming. Alarms may indicate the sash is too high, inadequate airflow, or other operational issues.

Only use the BSC with the sash at the appropriate height

Ultraviolet Light Safety (1)

- The efficacy of the use of UV light is debated.
  - If bulbs aren't changed as required by the manufacturer (usually after about 4000 hours of use) they may not generate intensity sufficient for effective decontamination.
  - If BSC is periodically turned off and dust accumulates on UV bulb it may not be as effective as necessary.
  - UV light may not penetrate highly soiled surfaces or material.
  - May create false sense of security that area has been decontaminated.
- Proper use of chemical decontaminant may be more reliable.
- CDC, NIH, NSF, and ABSA ***recommend against its use***.

- UV light is considered a probable human carcinogen.
- Acute exposure effect: Erythema (i.e sunburn) and photokeratitis (UV damage to eyes)
- Some BSC sashes to not fully close increasing potential for exposure.
- Risk presented by the hazard may not be warranted.

Ultraviolet Light Safety (2)

Exposure to UV light must be maintained below the occupational exposure limit. The limit (ACGIH TLV) for UV light: 6 mJ/cm^2

Orientation	Time Before TLV is Reached
Sash closed	111 minutes
Center of opening at plane of the sash	50 seconds
30-45 cm from opening	24 minutes

Meechan , P, & Wilson, C. (2006) Use of Ultraviolet Lights in Biological Safety Cabinets: A Contrarian View. *Applied Biosafety, 11(4), 222-227*

Cleaning spills within BSCs

- Effective cleanup of spills within BSCs will help reduce the risk of contamination.
- Click on this link to see proper spill procedure instructions.

Hazardous Chemical Use

- ***HEPA filters in BSCs do not remove hazardous vapors or gases!***
- BSCs typically recirculate 80% of the air within the cabinet.
- May result in elevated concentrations of toxic vapors or gases in certain types of BSCs.

BSC Exhausted Outdoors

Note the ducted exhaust

Ducted BSC appropriate for limited use of hazardous chemicals at the work surface

BSC Certifications

To Ensure proper containment BSCs must be certified:

- Upon installation
- Annually
- When moved (to a different room)
- When filters are changed
- When repaired or modified

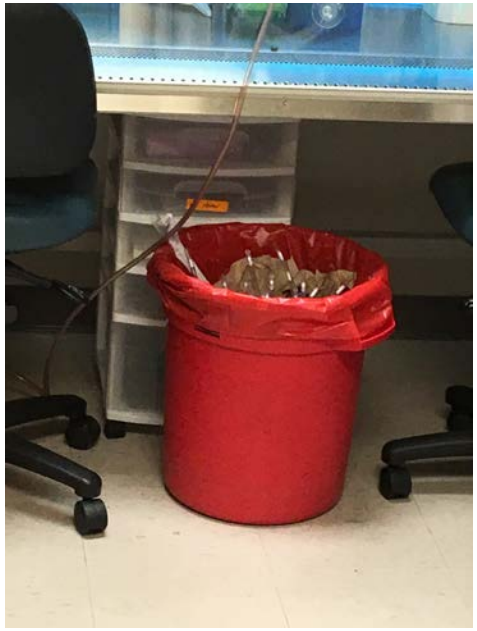
WASTE DISPOSAL

Segregating Waste

Non-hazardous

Infectious Biohazard Waste

Inappropriate lid. Container must be closed. Lid and container must be able to be decontaminated.



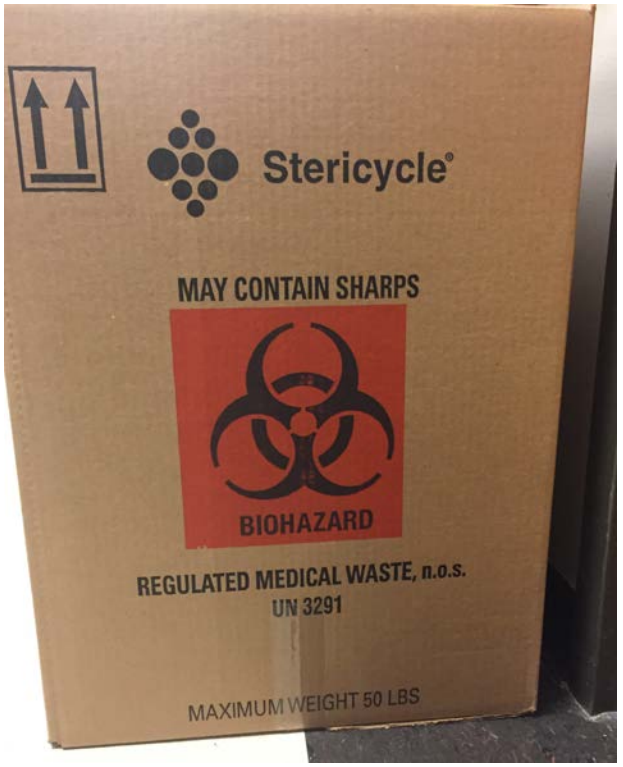
Container must be closed. Serologic pipettes must be discard in a manner not likely to penetrate the bag.

Contaminated Materials

- Red bag disposal: Potentially infectious to be disposed of by Stericycle.
- PPE used to handle BSL2 agents must be discarded as red bag waste.
- Orange bags: Not for human infectious materials. To be autoclaved on-site.
- No liquid disposal! Liquids must be decontaminated and poured down the drain, absorbed, or treated with a solidifying agent.
- Individuals packaging red bags into Stericycle boxes for shipment or signing manifests need to have completed DOT training. (Provided in Introduction to Biosafety class.)

Individuals packaging red bags into Stericycle boxes for shipment or signing manifests must have completed DOT training.

(This is provided in the Introduction to Biosafety class.)



EXPOSURE RESPONSE

Medical Surveillance

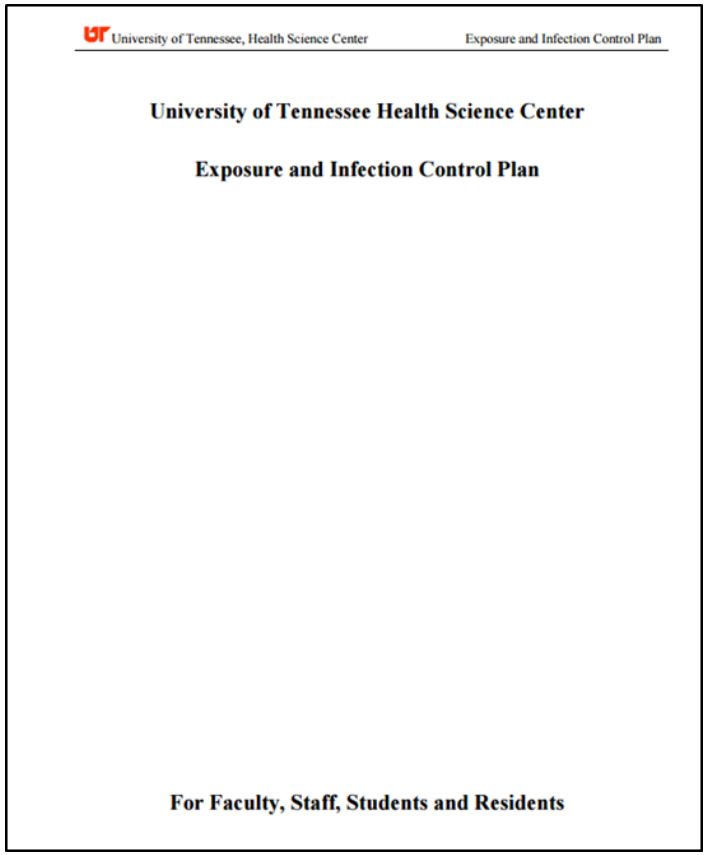
- Provided through Occupational Health.
- Report signs or symptoms of exposure to Occupational Health.
- Occ. Health located at 910 Madison Avenue, 9th floor.
- Call Corvel 1-866-245-8588 to report injuries or exposures.

Exposure Response

UTHSC Exposure and Infection Control Plan is accessible on the Safety Affairs website online.

In the event of suspected exposure:

- Wash hands
- Rinse eyes for 15 minutes
- Notify supervisor
- Call Corvel
- Report to Occupational Health


University of Tennessee, Health Science Center Exposure and Infection Control Plan

University of Tennessee Health Science Center

Exposure and Infection Control Plan

For Faculty, Staff, Students and Residents

Incident Reporting

Incidents must be reported to the appropriate authority as articulated in the Office of Research Safety policy for Incident Reporting.

The following types of incidents must additionally be reported to your Department Chair and the IBC Chair:

- Significant problems (Any spill or accident involving recombinant DNA research or that otherwise leads to personal injury or illness or to a breach of containment is considered significant and must be reported.)
- Research-related accidents,
- Illnesses and exposures involving recombinant DNA,
- Violations of the NIH Guidelines,
- The escape of a transgenic animal.

Organizations that receive NIH funding are required to provide personnel with adequate training to enable them to comply with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

NIH GUIDELINES

AND

THE INSTITUTIONAL BIOSAFETY COMMITTEE

The NIH Guidelines:

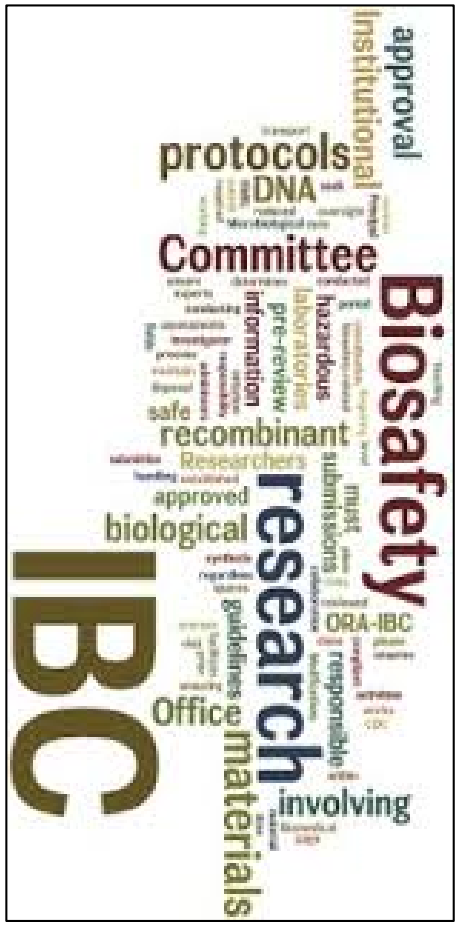
- Specify appropriate biosafety practices and procedures.
- Establish mandatory review and approval requirements for research based on the degree of risk involved.
- Work involving the greatest risk requires the most stringent review and reporting procedures.
    - E.g. “Major Actions” such as research involving the deliberate transfer of a drug resistance trait to microorganisms that may impact the ability to control disease agents in human, veterinary medicine or agriculture requires IBC approval, Recombinant DNA Adversary Committee review, and NIH Director approval prior to initiation.

NIH Guidelines Compliance

- The term “guidelines” does not mean optional. Compliance is a term and condition of NIH funding for recombinant DNA research.
- The Guidelines apply to any institution receiving NIH funding for recombinant and/or synthetic nucleic acids (rsNA) research.
- If rsNA research is not in compliance with the guidelines:
    - NIH funding can be suspended or terminated for the non-compliant project.
    - **NIH funding can be suspended or terminated for <u>ALL</u> NIH funded projects that involve recombinant and/or synthetic nucleic acids at the institution.**
    - All future projects involving recombinant and/or synthetic nucleic acids may require NIH approval prior to beginning any work.

Institutional Biosafety Committee (IBC)

- The NIH Guidelines require that research be performed under the oversight of an Institutional Biosafety Committee (IBC).
- The role of the IBC is to:
  - Promote safe and responsible biological research through the establishment of institutional biosafety policies.
  - Protect the community from the potential impacts of biological research.
  - Ensure researchers comply with requirements of the NIH Guidelines.
- UTHSC research and teaching faculty are responsible for registering with the IBC all research involving biohazardous agents.
- Research activities specifically regulated under the NIH Guidelines include those involving:
  - Recombinant and synthetic nucleic acid molecules,
  - Genetically modified microorganisms, plants and animals,
  - Artificial gene transfer,
  - Infectious agents and biologically derived toxins.



When Preparing IBC Protocol Submissions Principle Investigators shall:

- Make an initial assessment of the risk groups (RG1-4) and containment levels (BSL1-4) required to safely conduct the research in the protocol.
- Select the appropriate microbiological and lab techniques.
- Identify locations where work will take place and ensure appropriate facilities.
- Submit the completed protocol, as well as subsequent changes, to the IBC for review and approval or disapproval.
- Maintain active communication with the IBC throughout the conduct of the research.

Prior to beginning the research (after IBC approval), the PI shall:

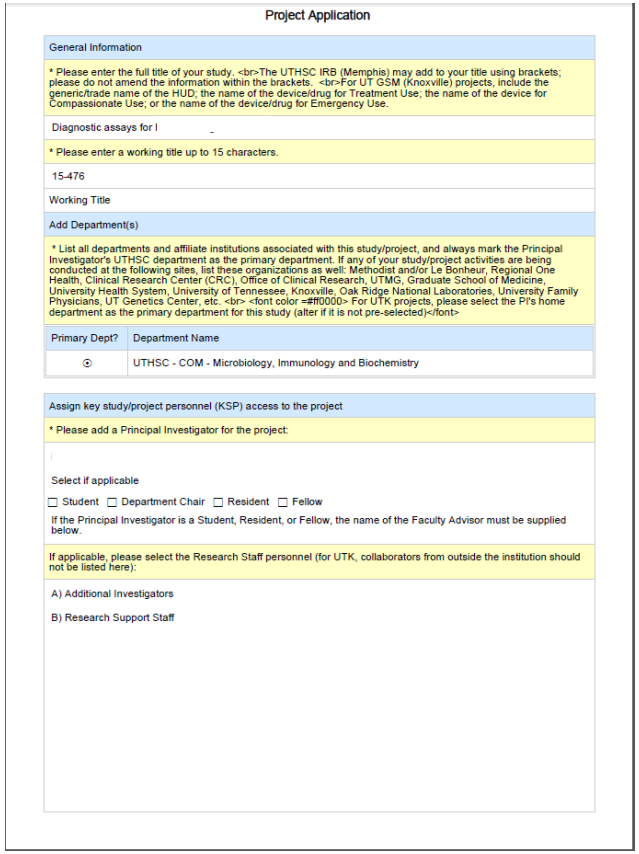
- Make all protocols and available to all personnel, describing the potential biohazards of the work, and proper working procedures. (Personnel are recommended to date and sign a copy of the protocol to document this review.)
- Instruct and train all personnel in practices and techniques required to ensure safety and how to respond accidents or exposures. (i.e. BSL2 training)
- Maintain written documentation of personnel training.
- Inform all personnel of the reasons and provisions for any precautionary medical practices that are advised or requested (e.g. vaccinations, serum collection).

During the conduct of research the PI shall:

- Supervise the safety performance of all personnel, to ensure that the required safety practices and techniques are employed.
- Investigate and report any potential exposure, accident, or incident pertaining to the operation and implementation of containment practices and procedures.
    - Accidents, injuries and exposures must be reported to Corvel. Corvel nurse will advise on how to obtain medical care, if necessary.
    - Inform the IBC Chair and Department Chair immediately.
    - The IBC Chair and Biological Safety Officer will determine if the NIH/OBA must be notified.
- Correct work errors and conditions that may result in the release of recombinant and/or synthetic nucleic acid molecules.
- Ensure the integrity of physical and biological containment in the lab(s).
- Comply with reporting requirements for human gene transfer experiments.

IBC Project Application

- IBC Project applications are submitted through the iMedris system.
- The PI uses this application to:
  - Identify staff members working on a protocol,
  - Identify the biohazardous agents being used,
  - Recommend containment levels and work practices, and p
  - Provide verification that applicable committees (e.g. IACUC, Radiation Safety, IRB) have been notified.



Project Application

General Information

* Please enter the full title of your study.
The UTHSC IRB (Memphis) may add to your title using brackets; please do not amend the information within the brackets.
For UT GSM (Knoxville) projects, include the generic/trade name of the HUD; the name of the device/drug for Treatment Use; the name of the device for Compassionate Use; or the name of the device/drug for Emergency Use.

Diagnostic assays for I

* Please enter a working title up to 15 characters.

15-476

Working Title

Add Department(s)

* List all departments and affiliate institutions associated with this study/project, and always mark the Principal Investigator's UTHSC department as the primary department. If any of your study/project activities are being conducted at the following sites, list these organizations as well: Methodist and/or Le Bonheur, Regional One Health, Clinical Research Center (CRC), Office of Clinical Research, UTMG, Graduate School of Medicine, University Health System, University of Tennessee, Knoxville, Oak Ridge National Laboratories, University Family Physicians, UT Genetics Center, etc.
  For UTK projects, please select the PI's home department as the primary department for this study (alter if it is not pre-selected)

Primary Dept?	Department Name
⊙	UTHSC - COM - Microbiology, Immunology and Biochemistry

Assign key study/project personnel (KSP) access to the project

* Please add a Principal Investigator for the project:

Select if applicable

☐ Student ☐ Department Chair ☐ Resident ☐ Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied below.

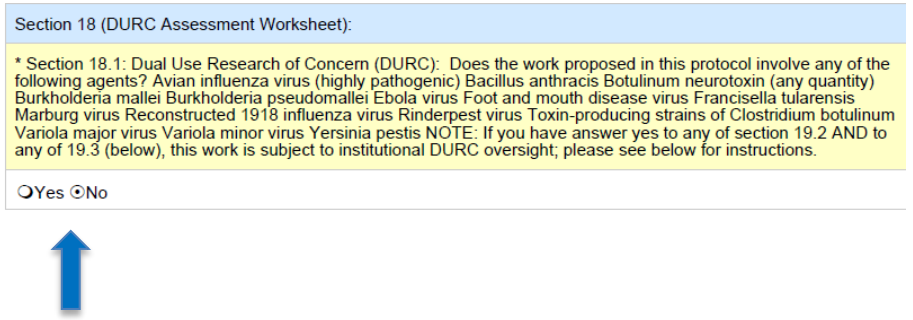
If applicable, please select the Research Staff personnel (for UTK, collaborators from outside the institution should not be listed here):

A) Additional Investigators

B) Research Support Staff

Dual Use Research of Concern

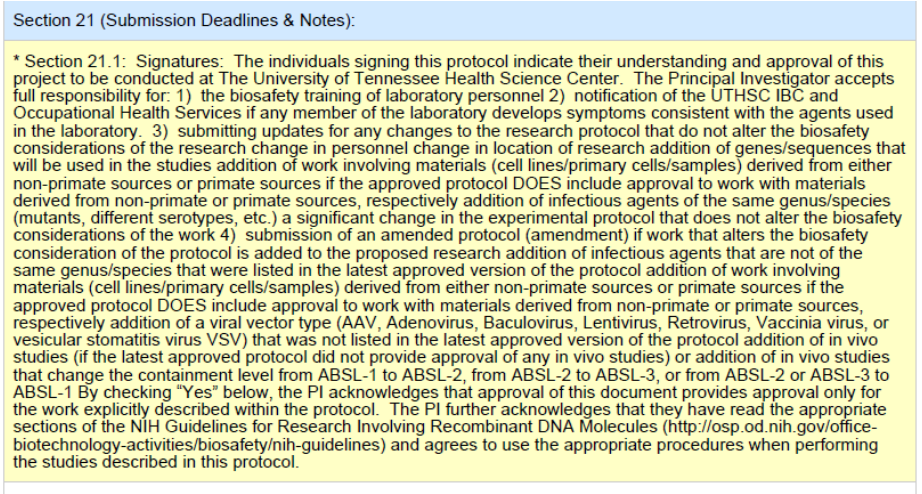
- In the IBC protocol the PI must evaluate the potential for their work to constitute **Dual Use Research of Concern** (**DURC**) and make the appropriate declaration within their IBC protocol.
- DURC is life sciences research that is intended for benefit, but which might easily be misapplied to do harm.
- The possibility that dual use research might result in misuse, either intentionally or accidentally, is a long standing concern of science.



Signing the Protocol

By signing this protocol the Principle Investigator accepts responsibility for:

1. Biosafety training of all lab personnel,
2. Notifying the IBC when necessary,
3. Submitting updates or changes as necessary,
4. Submitting amendments as necessary.



Section 21 (Submission Deadlines & Notes):

* Section 21.1: Signatures: The individuals signing this protocol indicate their understanding and approval of this project to be conducted at The University of Tennessee Health Science Center. The Principal Investigator accepts full responsibility for: 1) the biosafety training of laboratory personnel 2) notification of the UTHSC IBC and Occupational Health Services if any member of the laboratory develops symptoms consistent with the agents used in the laboratory. 3) submitting updates for any changes to the research protocol that do not alter the biosafety considerations of the research change in personnel change in location of research addition of genes/sequences that will be used in the studies addition of work involving materials (cell lines/primary cells/samples) derived from either non-primate sources or primate sources if the approved protocol DOES include approval to work with materials derived from non-primate or primate sources, respectively addition of infectious agents of the same genus/species (mutants, different serotypes, etc.) a significant change in the experimental protocol that does not alter the biosafety considerations of the work 4) submission of an amended protocol (amendment) if work that alters the biosafety consideration of the protocol is added to the proposed research addition of infectious agents that are not of the same genus/species that were listed in the latest approved version of the protocol addition of work involving materials (cell lines/primary cells/samples) derived from either non-primate sources or primate sources if the approved protocol DOES include approval to work with materials derived from non-primate or primate sources, respectively addition of a viral vector type (AAV, Adenovirus, Baculovirus, Lentivirus, Retrovirus, Vaccinia virus, or vesicular stomatitis virus VSV) that was not listed in the latest approved version of the protocol addition of in vivo studies (if the latest approved protocol did not provide approval of any in vivo studies) or addition of in vivo studies that change the containment level from ABSL-1 to ABSL-2, from ABSL-2 to ABSL-3, or from ABSL-2 or ABSL-3 to ABSL-1 By checking "Yes" below, the PI acknowledges that approval of this document provides approval only for the work explicitly described within the protocol. The PI further acknowledges that they have read the appropriate sections of the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) and agrees to use the appropriate procedures when performing the studies described in this protocol.

Reporting Problems

The following must be reported to the IBC Chair and Department Chair immediately upon becoming aware of the issue:

- Significant problems (e.g. any spill or accident involving recombinant DNA research or that otherwise leads to personal injury or illness or to a breach of containment). Research-related accidents,
- Illnesses and exposures involving recombinant DNA,
- Violations of the NIH Guidelines,
- The escape of a transgenic animal.

Incident reporting must take place in accordance with the Office of Research Safety policy for Incident Reporting.

For additional information or reference this policy is accessible through the Safety Affairs webpage.

HAZARD SPECIFIC TRAINING

Hazard-Specific Training

- Prior to working with BSL2 agents research personnel must be provided with training and information specific to the hazards that they will be handling.
- The PI is considered to be the subject matter expert for the work being performed and is therefore qualified to provide this training to their employees.
- This training must meet necessary content requirements and be documented.
- The Office of Research Safety has provided a BSL2 Hazard-Specific Training Checklist to help guide this training.
- Alternatively, the Office of Research Safety will work with researchers to provide this training.

Training provided by the PI must be hands-on and include, at a minimum, the following information:

- Identity of the hazardous agents handled in the protocol.
- Hazards associated with exposure
- Symptoms of exposure.
- Availability of vaccines or preventative treatment.
- How to respond to an exposure.
- What PPE is required and when it must be worn.
- Engineering controls (e.g. biosafety cabinets) to be used and when.
- A description of procedures and work practices to minimize the potential for exposure.
- Decontamination methods including what decontaminant to use and when to use it.
- Waste handling procedures.
- Storage procedures for biohazardous agents.

End of Self-Study
Proceed to Quiz

In-person, hazard-specific training is required to meet the NIH Guidelines and BMBL training requirements for BSL2 work.

If this training will be provided by the PI rather than the Office of Research Safety that PI or staff member must do the following:

- Complete the BSL2 Hazard Specific Training Worksheet
- The PI and any researcher being trained must sign the declaration to acknowledge that training has been provided/received.
- Email the completed "Principles of Biosafety" quiz, the worksheet and signed declaration for each employee to labsafety@uthsc.edu.

If in-person training will be provided by the Office of Research Safety you must email the following materials to labsafety@uthsc.edu:

- Completed "Principles of Biosafety" quiz
- PDFs of IBC Protocols pertinent to the training being provided.
- The Office of Research Safety will review the materials and contact you to arrange training in your work area.

Contact Safety Affairs with concerns, questions or to request assistance.

Labsafety@uthsc.edu

Phone: 448-6114