
HARVARD MEDICAL SCHOOL
COMMITTEE ON MICROBIOLOGICAL SAFETY
Max L. Nibert, MD, PhD
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Chair
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Jeff Lichtman, MD, PhD
Harvard Faculty of Arts & Sciences
MCB

Dear Dr. Lichtman,

The Committee on Microbiological Safety (COMS) has reviewed your registration #21-009-A01, “*Harvard Center for Biological Imaging and Optical Imaging Core*” which does not contain the use of recombinant or synthetic nucleic acid molecules and has found it to be in compliance with the CDC BMBL and COMS policies.

This registration will expire on April 30, 2026

The work is approved with the following containment and work practices:

- Biosafety Level 2 (BSL2) for use of discarded human patient tendons

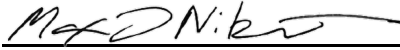
The following stipulations apply:

- Please see attached for standard BL1 & BL2 stipulations.
- BL2 materials used in procedures with a potential for creating infectious aerosols or splashes, used in high concentrations or large volumes, must be used in an annually certified biosafety cabinet.
- Aerosol-proof rotors or centrifuge buckets with safety caps should be used during centrifugation of BL2 materials.
- Follow sharps precautions when there are no alternatives to the use of sharps. Contaminated sharps must be discarded into sharps containers immediately after use.
- Liquid potentially infectious cultures and recombinant waste must be treated with an appropriate disinfectant, such as bleach, prior to sink disposal.
- Lab personnel must be trained on the health hazards associated with the agents handled in the laboratory.
- Personnel exposure related to the project must be reported to COMS through Harvard Biosafety as soon as possible.

The Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens standard (29 CFR 1910.1030) requires maintenance of a laboratory specific Exposure Control Plan (ECP) for work with human materials, annual training on blood borne pathogens, and documentation of hepatitis B vaccination offer for potentially exposed personnel. For more information, please visit <https://www.ehs.harvard.edu/programs/bloodborne-pathogens>.

Harvard EH&S will arrange to visit your laboratory to ensure compliance with local, state, and federal requirements. Please notify Harvard Biosafety at biosafety@harvard.edu if there is a change in the personnel, scope or location of your work, or if you have any questions.

Sincerely,



Dr. Max L. Nibert, COMS Chair

1/27/2023

Date

Minimum Biosafety Level 1 Laboratory Requirements for COMS-Approved Projects

Additional stipulations may be listed in your approval letter.

Work Practices

- Laboratory access is restricted at the discretion of the Principal Investigator (PI).
- Work may be performed on open bench tops using standard microbiological practices.
- Minimize use of sharps such as needles, scalpels, glass pipettes, and broken glassware. Use safe-sharp products whenever possible. Substitute plasticware for glassware whenever possible. If sharps cannot be eliminated, they must be disposed immediately after use into a solid sharps waste container. Needles must never be recapped or bent without approval from the Biosafety Officer (BSO).
- Minimize the creation of splashes and/or aerosols.
- Decontaminate work surfaces with appropriate disinfectant after completion of work and after any spill or splash of biological material. .
- Decontaminate all liquid cultures, stocks, and other biological materials using an effective method (e.g. 10% household bleach for 20 minutes).before disposal into the sink
- Dispose of solid biohazardous waste directly into biowaste containers.
- Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption is not permitted in laboratory areas.
- Researchers must wash hands with soap and water after handling research materials and before leaving the laboratory.
- It is the PI's responsibility to ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly persons of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to institutional occupational health services for appropriate counseling and guidance.
- Chairs and other laboratory furniture must be covered in non-porous material that is easily cleaned and decontaminated. Carpets and rugs are not permitted in laboratories.

Personal Protective Equipment (PPE)

- Researcher must wear proper street clothing into the laboratory before donning PPE. This includes long pants or other garment that covers one's legs and shoes that cover the entire foot.¹

¹ Local institutional policies may supersede this requirement

Minimum Biosafety Level 1 Laboratory Requirements for COMS-Approved Projects

Additional stipulations may be listed in your approval letter.

- Laboratory coats or gowns are recommended to prevent contamination of personal clothing.
- Protective eyewear must be worn when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Persons who wear contact lenses in laboratories should also wear eye protection.
- Disposable gloves must be worn. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary. Do not wash or reuse disposable gloves. Wash hands after removal of gloves.

References

NIH guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).
<https://osp.od.nih.gov/biotechnology/nih-guidelines/>

Biosafety in Microbiological and Biomedical Laboratories, 5th ed.
<https://www.cdc.gov/biosafety/publications/bmbl5/index.htm>

Minimum Biosafety Level 2 Laboratory Requirements for COMS-Approved Projects

Additional stipulations may be listed in your approval letter.

Biosafety Level 2 (BL2) builds upon Biosafety Level 1 (BL1). All requirements of BL1 are also required for BL2, with the addition of the following:

Work Practices

- The Principal Investigator (PI) limits access to the laboratory and has final responsibility for determining who may enter or work in the laboratory.
- The PI must ensure that the laboratory members demonstrate proficiency in procedures performed.
- A sign incorporating the universal biohazard symbol must be posted at all entrances to the laboratory.
- All persons entering the laboratory must be advised of the potential hazards and meet established entry/exit requirements.
- This COMS approval letter must be available and accessible to all working in the laboratory.
- Laboratory equipment should be routinely decontaminated (in addition to after spills and at the completion of work). Equipment must be decontaminated before repair or maintenance.
- Animals not associated with the work being performed are not permitted in the laboratory.
- Infectious material used in procedures with a potential for creating aerosols or splashes, or used in high concentrations or large volumes, must be handled in an annually certified biosafety cabinet.
- Laboratory doors must be self-closing and remain unblocked.

Personal Protective Equipment (PPE)

- Laboratory coats or gowns must be worn while working in the laboratory.

References

NIH guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). <https://osp.od.nih.gov/biotechnology/nih-guidelines/>

Biosafety in Microbiological and Biomedical Laboratories, 5th ed.
<https://www.cdc.gov/biosafety/publications/bmb15/index.htm>