EXPOSURE CONTROL PLAN

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EXPOSURE CONTROL PLAN

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Exposure Control Plan for μM.D. - ERL

Adapted directly from Mississippi State University's Office of Regulatory Compliance Template

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PURPOSE
Research projects in the Medical micro-Device Engineering Research Laboratory (μM.D. - ERL) focus on developing dielectrophoretic microdevices for human blood, human mesenchymal stem cells (hMSCs), tears, and particles for medical applications. While not all projects in the lab involve blood, plasma, or hMSCs, all researchers must be proficient with safety precautions and actively police the lab for any unsafe conduct. Unless hMSC samples have been tested and are free of pathogens, they are included in the OSHA bloodborne pathogen rule. In the remainder of this document, the term "bloodborne pathogen" will refer to pathogens in human biofluids (including blood, plasma, mesenchymal stem cells, tears, etc.). Human blood (blood cells plus plasma) and hMSCs are very dangerous to work with todue of the potential for bloodborne pathogens. Every sample should be treated as if it is contaminated; safety precautions must always be followed. The purpose of this Exposure Control Plan is to describe procedures and techniques utilized by μM.D. - ERL personnel to eliminate or minimize the danger of exposure to human biofluids. This is in compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), the MIOSHA Bloodborne Infectious Diseases Standard (OH Part 554), and Michigan Technological University (MTU) biosafety policies and procedures [0].

SCOPE
This document is always available to μM.D. - ERL researchers and is made available to any visitors prior to entering the lab. Copies of this document are in the safety folder (on the shelf to the right of the door of the lab) and on μM.D. – ERL's biosafety training Canvas course page. All current Institutional Biosafety Committee (IBC) applications are also filed in the safety folder in the lab.

This plan is reviewed annually by Dr. Minerick (also referred to as the Principal Investigator (PI) and lab director) and all researchers in the lab to address any concerns. After review/revisions, the plan is forwarded to the **Chair of the Department of Chemical Engineering and the Dean of the College of Engineering for review and support.** The original approval was conducted on 4 August 2005 while the lab was located at Mississippi State University. Written comments were solicited from all μM.D. - ERL researchers on 17 August 2006, 12 September, 2006, 31 May 2007, 14 September 2007, 17 January 2008, 27 May 2008, 1 September 2008, 13January 2009 (adapted to MTU guidelines), 21 May 2009, 1 June 2009, 4 February 2010, 10 August 2010, 11 May 2011, 11 September 2011, 5 January 2012, 7 May 2012, 7 September 2012, 17 January 2013, 5 June 2013, 10 September 2013, 16 January 2014, 12 May 2014, 1 August 2014, 16 January 2015, 5 May 2015, 8 September 2015, 20 January 2017, 16 May 2017, 22 September 2017, 26 January 2018, 30 May 2018, 11 September 2018, 21 January 2019, May 2022, **and are compiled in this updated document 1 February 2026**.

POLICY STATEMENT
Michigan Technological University is committed to providing a safe and healthy work environment for all staff. In pursuit of this goal, the following **Exposure Control Plan (ECP)** is provided to minimize or eliminate occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR Part 1910.1030, ***"Occupational Exposure to Bloodborne Pathogens"***.

The ECP is a key document to assist **Michigan Technological University** in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes the following:

- Determination of employee exposure
- Implementation of various methods of exposure control, including:
  - Universal precautions
  - Engineering and work practice controls
  - Personal protective equipment (PPE)
  - Housekeeping

- Hepatitis B vaccination (twinRX is a vaccine for both HBV and HAV, there is no FDA-approved vaccine

to prevent hepatitis C)
- Post-exposure evaluation and follow-up
- Training
- Recordkeeping
- Procedures for evaluating circumstances surrounding exposure incidents

Implementation of these elements of the standard are discussed in subsequent sections of this ECP.

DEFINITIONS

• **Biofluids** – Any liquids containing biological organisms or components. This could include bacteria (cells) down to viruses (functional units).

• **Human Biofluids** – Human biofluids include blood and its components (red blood cells, plasma, etc.), stem cells, tears, etc. All samples containing any biofluid are treated as infectious materials.

• **Bloodborne Pathogens (BBP)** *(additional information with the OSHA Fact Sheet on Bloodborne Pathogens)* – disease-causing microorganisms present in human cell tissue, blood, blood components, and blood products that can cause disease in humans [3].

• **Universal Precautions** – a method of infection control in which all human blood is treated as if known to be infectious for bloodborne pathogens or other potentially infectious material (OPIM).

• **IBC (Institutional Biosafety Committee) and IBC Officer, David Dixon** –The purpose of the Institutional Biosafety Committee (IBC) and IBC Officer within **Research Integrity and Compliance** is to facilitate compliance with federal regulations to better protect workers who generate, process, and dispose of potentially hazardous biological materials at Michigan Technological University, as well as others who may become exposed to biological hazards within the university environment [1].

• **HBV (Hepatitis B Virus), HCV (Hepatitis C Virus), HAV (Hepatitis A Virus) and HIV (Human Immunodeficiency Virus) -** Hepatitis is an inflammation of the liver, and it can be caused by a viral infection transported via human blood. Although there are several forms of hepatitis, the condition is usually caused by one of three viruses: hepatitis A, hepatitis B, or hepatitis C. The hepatitis A virus is transmitted through the feces of infected individuals and rarely leads to permanent liver damage. Hepatitis B and C are serious infections that may lead to a condition called **cirrhosis** (permanent scarring of the liver) or liver cancer, both of which cause severe illness and even death. Hepatitis B and C are transmitted from person to person through blood or other body fluids [4]. Individuals can carry Hepatitis C without symptoms. Human Immunodeficiency Virus (HIV) destroys an immune system cell called a CD4 helper lymphocyte. This causes infected persons to become immune deficient and thus susceptible to deadly diseases. HIV can be transmitted from an infected person to another person through blood or sharing of some body fluids [5].

• **Occupational Exposure Event** – any reasonably anticipated specific eye, mouth, non-intact skin, inoculation, or injection contact with blood or other potentially infectious material or inhalation contact with material potentially infected with pathogenic material such as bloodborne pathogens as a result of the performance of job duties [6].

• **Regulated Medical Waste** – any potentially infectious material requiring disposal following decontamination; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious material – including liquid, semi-liquid, or solid material.

• **Sharps –** any tool or object with the potential to puncture skin. These include all slides, coverslips, polystyrene pipettes, pipette tips (μM.D. - ERL lab procedure), capillary tubes, needles, syringes, etc.

• **Engineering Controls –** controls that isolate or remove the bloodborne pathogens or OPIM hazard from the workplace (e.g., sharps disposal containers, safer medical devices, and needleless systems).

• **Work Practice Controls –** controls that reduce the likelihood of exposure by altering the manner in which a task is performed.

• **Needleless Systems** – devices that do not use needles for obtaining or transferring fluid to the body. These minimize occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

• **Work Area –** region of the lab where biosafety level 2 work is conducted and contact with a bloodborne pathogen is possible (across orange tape line).

• **Safe Zone –**region near the door marked off with orange tape for donning proper PPE or for washing hands before exiting the lab.

• **Aerosols –** particles or droplets of liquid that can remain suspended in air. They range in size from a few nanometers up to about 500 nanometers with the larger particles falling out of the air faster.

- **Parenteral** - the piercing of mucous membranes or the skin barrier through such events as needle sticks, bites, cuts, and abrasions.

- **Percutaneous** - through the skin.

EXPOSURE DETERMINATION (partially copied from MSU's ORC Exposure Control Plan)
The Principal Investigator, in consultation with all research personnel, identifies positions and procedures in the laboratory, which present the possibility of occupational exposure to human blood or other potentially infectious material. This determination is based on the risk of performing each procedure **without** the use of personal protective equipment (PPE). The required PPE provides an additional layer of protection for lab personnel.

The materials used in this laboratory that may be associated with potential exposure to human bloodborne pathogens are: *Human blood, serum, plasma, blood products, blood components, blood cells, or human mesenchymal stem cells.*

The job classifications in which employees may have occupational exposure to human pathogens in this work setting include:

Professor [x]
Lecturer [x]
Postdoctoral Researcher [x]
Laboratory Assistant [x]
Graduate Student [x]
Visiting graduate students from Dr. Caryn Heldt's lab [x]
Undergraduate Student [x]
Building Maintenance Personnel [ ]

The tasks and procedures used in this work setting that may pose risk of exposure to human bloodborne pathogens may include:

- pipetting human blood or OPIM
- mixing human blood or OPIM
- loading blood samples or OPIM into microdevice ports
- centrifuging human blood or OPIM
- handling tubes or other containers of human blood or OPIM
- handling contaminated sharps (no needles in μM.D. - ERL, only glass slides) or other contaminated waste
- cleaning up spills of human blood or OPIM

Grounds, Maintenance, or Environmental Services Personnel are at risk of exposure to bloodborne pathogens while performing their duties. If one of these individuals enters the lab unescorted, blood or blood-contaminated containers may be encountered. For this reason, building maintenance personnel may not enter **Room 403** without express written (email is acceptable) permission from Dr. Minerick (sign also posted on the door). Via the 407 entrance, students also have access to Room 405 and the associated microscope room.

The laboratory door to Room 407 is kept locked and closed at all times to protect limited access to the

lab. All biohazard trash is either autoclaved before exiting the lab or autoclaved in the basement and is placed in the designated can with a black trash bag once treated. Autoclaving is a cleaning method that uses high temperatures and pressures to sterilize material. All surfaces and equipment are disinfected with 10% bleach solution (or 70% ethanol) immediately after an experiment is completed and according to a daily schedule. Both methods are effective at killing bloodborne and hMSC pathogens. However, diluted bleach solutions lose efficacy and may only be stored for 1 week before a new bleach solution must be made. New solutions are made in μM.D. - ERL every 7 days or more frequently.

Occupational risks for exposure to HIV, HBV, and HCV are well documented and specifically are associated with injection, inoculation (including contamination of broken skin) or mucous membrane exposure to blood and other potentially infectious body fluids. As a precaution, University employees must treat all human body substances as if contaminated in a manner consistent with the concept of universal precautions.

RESPONSIBILITIES (partially copied from MSU's ORC template Exposure Control Plan)
I, Dr. Adrienne Minerick, as the Principal Investigator / Laboratory Director, recognize my responsibility to implement and monitor this Exposure Control Plan.

Dr. Minerick ensures that lab personnel receive information and specific training on the laboratory procedures and techniques to be followed as well as information included in this document as required by the Bloodborne Infectious Diseases Standard. Documented training must occur within ten days of starting work with human specimens or OPIM, and on a semesterly basis thereafter with records maintained by Dr. Minerick for at least the last 3 years, per standard OSHA guidelines. If an individual becomes exposed and is then referred to a physician, then the record of the exposure is kept on file for the life of the patient.

REQUIREMENTS

1. Dr. Minerick, with the input of personnel of μM.D. - ERL, a laboratory where human blood or OPIM is used, must maintain this Exposure Control Plan. This document is submitted for annual review to the IBC.
2. All projects including human/primate blood or OPIM must be approved by the IBC after evaluation of a completed IBC application and Exposure Control Plan forms.
3. Universal precautions and Biosafety Level 2 practices, procedures, equipment, and facilities will be followed to minimize exposure to bloodborne pathogens.
4. Laboratory staff will keep documentation for equipment requiring regular examination or maintenance.
5. The worksite is maintained in a clean and sanitary condition. At a minimum, benches and biosafety cabinets are cleaned – by researchers - at the end of the day and after any spill using disinfectant(s).
6. Protective gloves are worn on the lab side of the orange line and are mandatory if exposure to blood or OPIM is possible. They must be replaced frequently and immediately if they become contaminated or damaged in any way. Hand creams and lotions may affect the protective properties of gloves and their use in conjunction (i.e., applied immediately before) with protective gloves is prohibited. [NOTE: Some compounds used in lotions may degrade gloves or increase the permeability of the polymer.]
7. Nonlatex gloves without powders are used in μM.D. - ERL to avoid the issue of latex / other sensitivity.
8. **Computers, keyboards/mouse, microscope controls, or anything in the safe zone entranceway are not to be touched while wearing gloves.**
9. Hands are washed after removing gloves, before removing safety glasses and exiting the lab, and before eating, drinking, smoking, handling contact lenses or other activities that may result in hand contact to a mucous membrane. You cannot touch your face with gloves on or touch anything with ungloved hands that you had previously touched with gloved hands prior to disinfecting.
10. Some items may be used inside the lab and then moved outside the lab including laptop computers and the lab notebook. The surface of these items must be wiped down with a towel soaked with 70% ethanol before transfer.
11. Only approved sharps containers are to be used for sharps disposal. In μM.D. - ERL, small plastic micropipetter tips are used during sample preparation. These are disposed of in the sharps container, which is then autoclaved before disposal in the regular medical trash. Only sharps should be disposed of in the sharps container. Larger macropipettes with the vacuum pipettor that do not fit in the sharps containers are autoclaved and also given to sharps disposal in a dedicated bag within a cardboard box.
12. Although μM.D. – ERL procedures have been designed to avoid the use of needles while handling blood, very small silica tubing coated with polyimide or PEEK tubing and luer locks, as well as precision tips, are

used with the LabSmith microfluidics platform. Needles shall not be recapped, removed from disposable syringes, purposefully bent, or otherwise manipulated.

13. Engineering controls are evaluated and used whenever possible, in an effort to reduce the potential for sharps injury (and thus exposure to bloodborne pathogens or OPIM hazards) to the user as well as those working downstream (i.e., waste handlers, environmental services, and laundry personnel).
14. Disposal containers (bags, sharps containers, red trash cans, etc.) are required to be closed during transport. Sharps containers should be autoclaved once they are two thirds (2/3) full or have been in service for 3 months. An autoclaved 2/3 full sharps container can be stored for the next sharps collection date. Bags of biohazard waste must not sit more than 1 day prior to autoclaving. A new sharps container should be dated immediately after it is put in use. If there is a chance of leakage, an additional labeled container will be used and must be autoclaved after use. All autoclaved biohazard waste is now treated medical waste and must be double bagged into a black trash bag before placing in the designated trash can.
15. Personal protective equipment (PPE) and clothing is used in this laboratory to minimize or eliminate exposure to human bloodborne pathogens. Dr. Minerick or the department is responsible for supplying personal protective equipment and clothing and making arrangements for replacement or cleaning as needed.
16. Laboratories using high volumes or concentrations of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV) will follow additional safety practices and procedures according to their laboratory specific safety manual. [NOTE: µM.D. - ERL is not considered a high-volume laboratory]
17. Regulated medical waste is handled in accordance with the policies of the Michigan OSHA [11].

PROGRAM ADMINISTRATION

Dr. Adrienne Minerick is responsible for the implementation of the ECP. She may be contacted at 259 H-STEM, 906-487-2796, minerick@mtu.edu, or 906-231-2012. Dr. Minerick maintains, reviews, and updates the ECP at least annually, and whenever necessary to include new or modified tasks and procedures. Those employees who are determined to have occupational exposure to blood or OPIM must comply with the procedures and work practices outlined in this ECP. Further, Dr. Minerick is responsible for training, documentation of training, and making the written ECP available to employees.

Purity Angwenyi, as µM.D. – ERL's biosafety student liaison provides and maintains all necessary personal protective equipment (PPE), organizes the surface decontamination schedule, autoclave schedule, disinfects safety glasses monthly, oversees lab coat disinfection/laundering at the beginning of each semester, replaces engineering controls (e.g., sharps containers), labels, and red bags as required by the standard. She ensures, via coordination with Dr. Minerick, that adequate supplies of the above-mentioned equipment are available in the appropriate sizes.

Portage Health at (906) 483-1860, will be responsible for ensuring that all medical actions required by the standard are performed and that appropriate employee health and OSHA records are maintained. Michigan Tech's Chemical Safety Officer in EHS also maintains records of any incidents.

POST EXPOSURE PLAN [6,7]

Purpose - To establish a protocol for the protection of Michigan Tech employees exposed to bloodborne pathogens in the course of performing their work.

Policy: We use the latest updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. (currently 9/25/2013, updated 5/23/2018) https://stacks.cdc.gov/view/cdc/20711

Procedure: Please consult the Biosafety Contract, which outlines µM.D. - ERL's policies regarding the handling of human blood and hMSCs in the safest manner possible. In addition, µM.D. - ERL documents all samples handled within the lab. All student researchers in µM.D. - ERL, regardless of whether they work on a blood-related project or not, have the option to receive or decline (must document via Appendix A) the Hepatitis B vaccination (paid for by Michigan Tech) at any time. Documentation of adequate vaccine response at the end of the primary vaccination series is currently not mandatory but advised. If an adequate vaccine response (anti-HBs >10mlu/ml) is not achieved with the primary series, then it should be repeated. If the employee does not develop an adequate response after the second series, they should receive Hepatitis B Immune Globulin within 24 hours of exposure to known positive HBsAg (hepatitis B surface antigen) human blood.

Management of Occupational Bloodborne Viral Exposures:

A. Provide immediate care to the exposure site (done by exposed researcher, with assistance of any other researcher in the lab).

1. Wash wounds and skin thoroughly with soft antibacterial soap and water.
2. Flush mucous membranes with water. For any splashes to the nose, mouth, or skin, flood with water for 15 minutes or greater.
3. If applicable, irrigate eyes with clean water (eye wash near the door) for 15 minutes. Alternatives are saline, or sterile irrigates.
4. Immediately seek medical treatment at Portage Health (906) 483-1860. If you cannot transport yourself to the clinic, call 911.
5. Report the incident to Dr. Minerick (minerick@mtu.edu, (906) 487-2796, 231-2012) and to the Occupational Safety and Health Services department at 906-487-2118.
6. Document incident on safety log sheet (see Appendix B) unless it involves a sharps injury. All such injuries must be reported to Dr. Minerick, who keeps a confidential log of sharps injuries and reports it to Michigan Tech's Environmental Health and Safety https://www.mtu.edu/ehs/report/injury-form/

B. Determine risk associated with exposure by (done by exposed researcher in consultation with Dr. Minerick)

1. Type of fluid
2. Type of exposure
3. Time & duration of exposure

C. Evaluate exposure source. (done by exposed researcher in consultation with Dr. Minerick, David Dixon in MTU RIC, and the Portage Health Medical Group).

1. Assess the risk of infection using available information.
2. Test known sources for HBsAg, Anti HCV, and HIV antibody.
3. For unknown sources, assess risk of exposure to HBV, HCV, or HIV infection.
4. Do not test discarded tips, sharps, other for virus contamination.

D. Evaluate the exposed person (Portage Health Medical Group).

1. Assess immune status for HBV infection.

E. Give Post Exposure Prophylaxis (PEP) for exposures posing risk of infection / transmission (Portage Health Medical Group).

1. Initiate PEP as soon as possible, preferably within hours of exposure. This is a short-term antiretroviral treatment that reduces the risk of infection. It varies by suspected BBP, and medical advice should be sought when determining course of treatment.
2. Offer pregnancy testing to all women of childbearing age not known to be pregnant should they be concerned about this risk.
3. Seek expert consultation if viral resistance is suspected.
4. Administer PEP for 4 weeks if tolerated.

F. Perform virus (HBV, HCV, HIV) specific follow-up testing and provide counseling (Portage Health).

1. Advise exposed persons to seek medical evaluation for any acute illness occurring during the follow-up

PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

At the time of exposure an exposure report should be filled out and a copy filed with Dr. Minerick, a copy sent to the **MTU Occupational Safety and Health Services office,** and a copy should go with the researcher to their clinician. The incident will be kept confidential between the involved parties and these university/medical officials. An incident report form can be found on the MTU safety website here: https://www.mtu.edu/ehs/report/injury-form/ It includes:

- Date, time, and duration of exposure
- Details of the procedure being performed, including where and how the exposure occurred; if related to a sharp device, the type and brand of device as well as how and when while handling the device the exposure occurred.
- Details of the exposure, including the type and amount of fluid or material and the severity of the exposure (e.g., for a percutaneous exposure, depth of injury, and whether fluid was injected; for a skin or mucous membrane exposure, the estimated volume of material and the condition of the skin {e.g., chapped, abraded, intact}).

- Details about the exposure source (e.g., whether the source material contained HBV, HCV, or HIV; if the source is HIV-infected, the stage of the disease, history of antiretroviral therapy, viral load and antiretroviral resistance information, if known); NOTE: This can only be done via Portage Health who may test the original sample if it remains or request the original blood and/or stem cell donor consider the tests.
- Details about the exposed person (e.g., hepatitis B vaccination and vaccine-response status), and
- Details about counseling, post-exposure management and follow-up. Based on the nature of the exposure, the type and amount of virus to which exposure occurred, the employee's vaccine status, the employee's clinician will make recommendations in compliance with the US Public Health Service Guidelines in the Management of Occupational Exposures to HBV, HCV, and HIV. https://stacks.cdc.gov/view/cdc/20711 and https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a3.htm

METHODS OF IMPLEMENTATION AND CONTROL

Universal Precautions are observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids are considered potentially infectious materials. All employees will utilize universal precautions.

Exposure Control Plan (ECP): Employees covered by the BBP standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their semesterly refresher training. All employees can view this plan at any time during their work shifts by looking in the lab's biosafety manual, consulting the webpage, www.mderl.org, consulting the biosafety training canvas course, or contacting Dr. Minerick. She is responsible for reviewing and updating the ECP annually or more frequently if necessary to reflect any new or modified tasks and procedures that affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

OSHA Bloodborne Pathogen Training: OSHA Blood borne pathogen training must be completed annually by completing the modules at https://www.usg.edu/facilities/training/pathogens/ or equivalent. Once done, employees are encouraged to discuss with Dr. Minerick or other researchers in the group. Suggestions for improvements or changes should be brought to the attention of the most senior graduate student and Dr. Minerick. Once ready, the employees must contact Dr. Minerick to take the quiz. This training, discussion and quiz must be completed annually.

ENGINEERING & WORK PRACTICE CONTROLS

Engineering and work practice controls are used to prevent or minimize exposure to bloodborne pathogens (see definitions). All blood sample preparation must be conducted in the biological safety cabinet. There is a sharps container next to and in the biosafety cabinet for pipette tips. Hypodermic needles and syringes are not used for blood preparation in μM.D. - ERL. However, syringes, precision tips, and small glass/silica tubing are sometimes used to interface the syringe pumps with microdevices.

Human Blood Dielectrophoresis Experiments

Whole blood is obtained from donors via a clinician in the Portage Health Group. The blood samples are drawn in vacutainers (Becton Dickinson) containing 1.8 mg K_2 EDTA per mL of blood. They are stored at 4°C in the certified BioSafety Level 2 Medical micro-Device Engineering Research Laboratory. Many sample preparations, such as the separation of red blood cells from plasma and cell washing, include centrifugation. A facemask is available, and a respirator would provide additional protection during centrifugation and may be requested (contact EHS). A facemask will protect against splashes, but aerosols can get around or through the pores. A respirator is sealed to the face and the pore sizes prevent transport of aerosols. Aerosols are particles that can remain suspended in air. They range in size from a few nanometers up to about 500 nanometers with the larger particles falling out of the air faster. Most BBPs are 100s of nm and typically are not able to aerosolize. The centrifuge has sealed safety cups within which the sample vial is placed; when done, this entire cup is removed and opened only in the Biosafety Cabinet using the absorbent pads. The pads absorb any blood drops on the lid or any that may spill when removing the cap. Students have been trained to properly use the BSC such that aerosols escaping the vial would not be transported out of the BSC. When a researcher is using the BSCs, no one is to walk up to or around the BSC because this may interfere with air flow in the hood. Aliquots of blood cells are then diluted with dextrose/phosphate buffer saline for testing. Additional treatments of the cells include the use of β-galactosidase to remove ABO antigens on the cells surface. Cells are transferred to the incubator in sealed vials. The student loads the diluted blood cell samples into ports using a micropipettor to fill the microdevice then mount the microdevice on the stage of the microscope. Syringe pumps with luer locks and

fused silica capillaries, PEEK tubing, or precision tips are interfaced to the fluidic microdevice via the LabSmith interface. The applicable function generator is connected to the electrodes in the microdevice. The microscope video camera is used to record high-resolution video of the red blood cell motion within the microdevice before and after the power is switched on. Data of blood cell velocities and cell aggregate size can then be obtained.

~~*Human Mesenchymal Stem Cells Dielectrophoresis Experiments (not currently ongoing in uMD-ERL)*~~
~~hMSC samples were previously grown in Dr. Caryn Heldt's laboratory in Chemical Sciences and Engineering Room 405A or Dr. Feng Zhao's laboratory in Minerals and Materials Room 414 . αMEMc, PBS, and trypsin are warmed to 37°C while the biosafety hood is cleaned with 70% ethanol. The old medium is removed and the cells are washed with 10 mL of PBS. Four mL of trypsin is added the cells and the mixture is allowed to incubate for 1-3 minutes before adding 5 mL of αMEMc to cells. The cell layer is gently washed by pipetting αMEMc over bottom of flask before removing cells, trypsin and αMEMc from the flask and transferring them into a 15 mL conical centrifuge tube. The flask is washed with 5mL of αMEMc and then added to centrifuge tube. The cells are centrifuged for 10 min at 500 xg at room temperature (20°C). While waiting 15 mL of fresh αMEMc is added to a new flask. The supernatant is removed and 1 mL of αMEMc is added to the cell pellet. The cells are re-suspended using a 5 mL pipette (slowly drawing cells up and down in pipette to disperse clumps). Cells are diluted to a seeding density of 4500 cells/mL (about 60 cells/cm^2) and the proper volume of cells/cell culture medium suspension is added and 4500 cells/mL are placed in a new flask. The cells are incubated in a flask until the cells are 80% confluent, changing medium every 2 days. This procedure is repeated until the desired passage number is reached. The hMSC pellet is then mixed with a dextrose solution and the pellet is mixed using a 5 mL pipette. The cells are transported across the hall to the laboratory for the dielectrophoresis experiments. A microdevice is loaded with the hMSC sample using the inlet port. The microdevice is filled and mounted on the microscope stage. An AC function generator is connected to the electrodes in the microdevice. The microscope video camera is used to record high-resolution videos of the hMSC motion inside the microdevice before and after the AC function generator is turned on. Data of hMSC dielectrophoretic responses and cell size are obtained.~~ Research is not being conducted at this time.~~

~~Microcentrifuge use: This entire instrument must be moved into the Biosafety Cabinet for use with any biological samples. The lid must remain down until the rotor has stopped spinning. The chance for a tube failure is remote for speeds at or below 1500 RPM. The BSC may not provide additional protection against aerosols in the event of a tube failure, since the air currents generated by the microcentrifuge will likely compromise the airflow in the biosafety cabinet.~~ Broken and hasn't been replaced.

A small vortexer does exist in the lab. This may only be used with closed microcentrifuge tubes, or it must be moved inside the Biosafety Cabinet for use with any open vial. Closed microcentrifuge tubes with any biofluids or OPIM must be opened in the Biosafety Cabinet.

Sharps disposal containers are inspected and maintained, or replaced when necessary, to prevent overfilling (containers should be discarded when 2/3 full). Contaminated and small non-contaminated sharps may all be added to the sharps disposal containers. This laboratory identifies the need for changes in engineering controls and work practices during semesterly discussions of their Biosafety Contract. We evaluate new procedures and new products regularly (at least each year) via consultation with MTU's Institution Biosafety Committee and Office of Health and Safety. All personnel are involved in this review. Dr. Minerick is responsible for ensuring these recommendations are implemented.

PERSONAL PROTECTIVE EQUIPMENT (PPE)
PPE is provided to employees at no cost to them. Training in the use of the appropriate required PPE for specific tasks or procedures is provided by Dr. Minerick and augmented by senior lab personnel. The types of PPE available to employees are gloves, a lab coat, safety glasses, and surgical masks (respirator available upon request). PPE is located in the file cabinet to the left when entering the lab. Additional or replacement equipment may be obtained by talking to Dr. Minerick. The most senior graduate student is responsible for inventory, communicating purchase needs, and storage of PPE. All employees using PPE must observe the following precautions:

- Wash hands immediately or as soon as possible after removing gloves or other PPE.
- Remove PPE after it becomes contaminated and before leaving the work area.
- Used PPE must be disposed of properly.

Lab coats are to be kept on the hooks beside the door and disinfected if soiled in any way. Disposables such as gloves and surgical masks are discarded in the biohazard bin. Contaminated safety glasses and face shields are also placed in a biohazard labeled bin until the time they are decontaminated.

- Wear the appropriate gloves provided when it is reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated items or surfaces; replace gloves if torn, punctured, or contaminated, or if their ability to function as a barrier is compromised.
- Never wash or decontaminate disposable gloves for reuse.
- Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing or deterioration.
- Wear appropriate face and eye protection when splashes, sprays, splatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.
- Remove immediately, or as soon as possible, any garments contaminated by blood or OPIM in a manner that avoids contact with the outer surface.
- Blue lab coats are provided for transporting any materials outside of the lab for any reason. White lab coats are utilized inside the lab. Both are cleaned on a semester basis.

Face shields and safety glasses are decontaminated by wiping down with 10% bleach or 70% ethanol then rinsed with distilled water. This should occur as needed; in addition, disinfection of all safety glasses will occur once per month for redundancy and will be coordinated by the senior graduate student. Please refer to the following sections on Housekeeping and Laundry for additional disinfection procedures.

HOUSEKEEPING

Regulated waste is placed in containers which are constructed to contain all contents (they may not be allowed to overflow) and prevent leakage, can be appropriately labeled or color-coded (See "**Labels**" section), and the bag closed prior to removal to prevent spillage or protrusion of contents during handling. Disposal of all regulated waste is in accordance with the State of Michigan Department of Environmental Quality policies detailed in "Part 138, Medical Waste Regulatory Act, of the Michigan Public Health Code, 1978 PA 368, As Amended" https://www.michigan.gov/egle/about/organization/materials-management/medical-waste-regulatory-program.

All sharps (slides, coverslips, glass pipettes, pipette tips, capillary tubes, needles (not present in μM.D. - ERL), syringes, etc.) are placed in the sharps container. Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled or color-coded. Extra sharps containers are located in the cabinet labeled, "Sharps Containers". Broken glassware that may be contaminated is only picked up using mechanical means such as with a dustpan and brush.

When the sharps containers are 2/3 full, they are collected, autoclaved, and disposed as medical waste. These sharps containers, any biofluids, solutions of biofluids, or materials that have come in contact with a biofluid, and all material in the biohazard disposal bag must be decontaminated (autoclaved / chemically treated with 10% bleach solution for > 20 minutes) before disposal (refer to procedure on bulletin board and sign log). Bins and pails are cleaned and decontaminated as soon as possible after visible contamination.

The bleach is stored in the cabinet underneath the dishwashing sink. The ethanol is in the flammables cabinet. Double check to refill disinfecting bottle with the lower-grade ethanol – not the 200-proof bottle. Solutions are mixed into the designated containers either for spraying or squirting onto surfaces. The bleach solution must be remade weekly, and a date is added when a new solution is mixed to ensure it is still effective. New solutions of ethanol must be prepared each month or more frequently as needed.

Additional housekeeping items:

- Each time the Millipore E-pure water system is utilized, check the water level in the tank and refill.
- Each time the pH or conductivity meters are used, double-check and refill the storage beakers. Do not allow the salt to precipitate out on the wand or excessively around the storage beaker.
- Refill the pipette tips if the box is less than 25% left.
- To ensure the timely disposal of biological samples, the refrigerator and freezer will be cleaned out at the beginning of each semester.
- Use the lower-grade ethanol for disinfection. Do not use the highest purity, 200 proof ethanol, which is

reserved for analytical experiments.

EQUIPMENT

All equipment in the lab is to be properly disinfected according to the guidelines outline above. In the rare occurrence that a piece of equipment must be removed from the lab and transported either to another lab or off site for repairs the equipment must first be disinfected according to the guidelines. The equipment can then be safely transported out of the lab.

Whenever a new piece of equipment is delivered to the lab, students using the equipment must read the protocols provided first. Training will be scheduled, and students must attend prior to utilizing the equipment. Some equipment requires observation first, followed by supervised trials, followed by checkout. This is handled on an equipment basis.

LAUNDRY

All personnel will use the lab coats provided. Do not exit the lab wearing any PPE. Lab coats and other fabric items are to be treated with 10% bleach solution overnight or for at least 20 minutes using the designated trashcan in the lab. Once the trashcan is drained, the coats can be double bagged in trash bags and washed at the local Laundromat. Laundry is to be completed in a cooperative employee effort led by the senior graduate student at the beginning of each semester. The following laundering requirements must be met:

- Handle contaminated laundry as little as possible, with minimal agitation.
- Place wet, contaminated laundry in leak-proof, labeled or color-coded containers before transport.
- Wear PPE such as gloves, mask, eye protection, face shield, Tyvek or lab coat when handling and /or sorting laundry before it has been washed.

LABELS & SIGNS

A warning label that includes the universal biohazard symbol, followed by the term "biohazard," must be included on bags/containers of regulated waste, on bags/containers of contaminated laundry, on refrigerators and freezers that are used to store blood or OPIM, and on bags/containers used to store, dispose of, transport, or ship blood or OPIM (e.g., specimen containers). In addition, contaminated equipment which is to be serviced or shipped must have a readily observable label attached which contains the biohazard symbol and the word "biohazard" along with a statement relating which portions of the equipment remain contaminated. Some examples of the universal biohazard symbol are on Wikipedia https://en.wikipedia.org/wiki/Biological_hazard. The background must be **fluorescent orange** or **orange-red** or predominantly so, with symbols and lettering in a contrasting color. The label must be either an integral part of the container or affixed as close as feasible to the container by a string, wire, adhesive, or other method to prevent its loss or unintentional removal. Red bags or red containers may be substituted for the biohazard labels. The supervisor or PI is to be notified if items are not appropriately labeled.

All vials located in the lab that are not empty must be labeled with the contents, responsible party's name, and the date. Any vials with biofluids or OPIM should also have the appropriate biosafety warnings. The label should be legible so that if the vial is left on the counter another lab member should be able to properly dispose of the contents. If the contents are an acid or base, the pH should also be included on the label.

HEPATITIS B VACCINATION

MTU makes available the Hepatitis B Vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident. Please contact Dr. Minerick and EHS at 906-487-2131. All medical evaluations and procedures, including the Hepatitis B vaccine and vaccination series, post-exposure evaluation and follow-up, including prophylaxis, are made available at no cost to the employee.

Hepatitis B vaccination is made available to employees after their attendance at a bloodborne pathogen training and information session conducted by the Office of Research Integrity. The vaccine is made available to all employees with occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons, or the individual declines. The vaccine can be provided by the Portage Health Group. It is recommended that the series begin within **10 days** of initial assignment to all employees identified in the exposure determination section of this ECP.

All employees who decline to accept hepatitis B vaccination offered by MTU will be required to sign a Hepatitis B Vaccine Declination form available in Appendix A on a yearly basis. If an employee decides to accept the vaccination at a later date, MTU will make available hepatitis B vaccination at that time. To receive the hepatitis B vaccine and vaccination series, contact Dr. Minerick, who will initiate the process, then the Portage Health Group at (906) 483-1000 or (800) 573-5001. Information about hepatitis B can be obtained at: https://www.cdc.gov/hepatitis-b/about/index.html

EMPLOYEE TRAINING

All employees with occupational exposure to BBP receive initial and annual training from the Environmental Health and Safety Office, in coordination with the Institutional Biosafety Committee. All students are provided with the following training:

1. Review the NIH learning module on Biosafety Levels and laboratory precautions (initial training).
2. Biosafety training. All researchers will renew Biosafety training on a semester-by-semester basis; Refer to the Biosafety Contract.
3. Exposure Control Plan: All researchers review this document each semester and provide feedback and comments to improve it.
4. OSHA guided Bloodborne Pathogen training on a yearly basis using the University of Georgia's Online Training Module https://www.usg.edu/facilities/training/pathogens/. A quiz developed by μM.D. - ERL checks trainees' knowledge from the online courses. This procedure meets the MIOSHA requirements that "(d) The person or persons who conduct training shall be knowledgeable in all of the following areas: (i) The information presented in the training session. (ii) The employer's exposure control plan. (iii) Conditions of the work environment that affect the implementation of the exposure control plan."
5. General laboratory safety and hazardous waste training through the departmental safety course (start of lab experience) and through yearly review of the department's safety manual. Hazardous waste training is provided by the university and should be refreshed yearly.
6. Human Subjects training through the Online Training - CITI Program Biomedical Research modules must occur immediately at the start of the lab experience. These are 2-year certifications and must be repeated as necessary.

NOTE: All researchers in μM.D. - ERL, regardless of whether they are working on the blood microfluidics research project, are required to complete training in 1 through 6.

Further, it is μM.D. - ERL policy that all undergrads may not work in the lab unsupervised during at least their first semester in μM.D. - ERL. Official approval will be granted in writing to any undergraduate having accrued enough experience to conduct experiments independently of their graduate student mentor.

RECORDKEEPING

Training Records

Training records are completed for each employee upon completion of training. These documents are kept for at least 3 years by the PI: Dr. Adrienne R. Minerick. The training record includes the following information:

- Dates of training session
- Contents or summary of the training sessions
- Name and qualification of trainer
- Name/job title of all attendees

Medical Records

Medical records are maintained for each employee with occupational exposure at the Portage Health Group. These confidential records are kept for at least the duration of employment plus 30 years. Employee medical records are provided upon request of the employee or to anyone with written consent of the employee.

OSHA Records

All percutaneous injuries from contaminated sharps are recorded in a **Sharps Injury Log** and reported to Michigan Tech's Occupational Safety and Health Services Department (https://www.mtu.edu/ehs/report/injury-form/). All incidences must include at the minimum:

- Date of the injury
- Type and brand of device involved
- Department where incident occurred
- Explanation of how the incident occurred

This log is reviewed as part of the annual program evaluation and maintained for at least 5 years following the end of the calendar year covered. If a copy is requested by anyone, it must have any personal identifiers removed from the report. See Appendix B for this lab's sharps injury log. The log is kept by Dr. Adrienne Minerick.

Miscellaneous

*All regulated waste in this lab is autoclaved on a regular basis (e.g. tips in sharps container, spilled materials, decontamination towels, etc.). Liquid regulated waste should be chemically treated with bleach prior to disposal. Bleach treated waste should not be autoclaved to avoid corrosion of the autoclave. Any bags with biohazard markings must be placed inside a secondary black trash bag after treatment and prior to placement in the hallway for pickup.

*Laboratory doors are kept closed when work is in progress. Access to the work area is limited to authorized personnel. Written policies and procedures are established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements and who comply with all entry and exit procedures are allowed to enter the work areas. Procedures are specified in the lab's biosafety manual and in the Biosafety Contract reviewed each semester.

*All access doors to the lab or contained work area are posted with a hazard warning sign that includes the Universal Biohazard symbol.

*No work involving potentially infectious materials will be conducted on the open bench. All activities involving blood or other potentially infectious materials are conducted in a biological safety cabinet or other physical-containment device within the containment module.

*Lab coats, gowns, uniforms, or other appropriate protective clothing are worn in the work area. Protective clothing is not to be worn outside of the work area and will be decontaminated before being laundered.

*Syringes with attached hypodermic needles are not used at all with biofluids in μM.D. - ERL. However, syringes and 360 μm outside diameter fused silica capillaries, precision tips, or PEEK tubing 1/16" OD are used to interface the syringe pumps with microdevices, and care should be taken when handling. Biofluids are not present during the set up and configuration of the syringe pump.

*All spills are immediately contained and cleaned up by properly trained personnel equipped to work with potentially infectious materials. A spill or accident that results in an exposure incident is immediately reported to the laboratory director or other responsible person.

*Biological safety cabinets are certified when installed, whenever they are moved, and at least annually. μM.D. – ERL's biosafety cabinet in ChemSci 403 was purchased and installed in January 2010, then inspected and recertified each spring semester since. Certificates of inspection can be requested from the PI. Ventilation in this cabinet is to be turned on at the start of use and turned off after disinfecting the cabinet.

Please consult M.D.-ERLs biosafety manual for this facility.

*The hand washing sink is closest to the lab door. Make sure this sink is kept clean and turned off tightly. The eye wash and shower are located adjacent to the lab door. Push the large handle or pull the large triangle handle to active each, respectively.

*Chemical hood has an airflow alarm. If the sash is too high, an alarm will sound. If airflow stops, an alarm will sound. If correcting the sash height does not mute the alarm, immediately leave the lab.

RESOURCES

[0] Michigan Government: LEO (Labor and Economic Opportunity): MIOSHA General Industry and Health Standards https://www.michigan.gov/leo/bureaus-agencies/miosha/standards/standards-and-interpretations/general-industry-safety-and-health-standards

[1] Initial resources outlined in this document were primarily developed through help from the Mississippi State University Office of Regulatory Compliance: Biosafety https://www.orc.msstate.edu, Revisions and adaptation to Michigan Technological University occurred in January and February 2010 with the help of Allen Niemi, Director, Occupational Safety and Health Services (new name is Environmental Health and Safety, https://www.mtu.edu/ehs/.

[2] Centers for Disease Control and Prevention. General information on *Vibrio parahaemolyticus* *https://www.cdc.gov/vibrio/about/index.html*

[3] Occupational Exposure to Blood, Center for Disease Control. https://www.cdc.gov/dental-infection-control/hcp/dental-ipc-faqs/occupational-exposure.html

[4] Teens Health: Hepatitis https://kidshealth.org/en/teens/hepatitis.html

[5] Teens Health: HIV / AIDS https://kidshealth.org/en/teens/std-hiv.html

[6] 2001 Report U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. https://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf

[7] Kuhar, David T.; Henderson, David K.; Struble, Kimberly A.; Heneine, Walid; Thomas, Vasavi; Cheever, Laura W.; Gomaa, Ahmed; Panlilio, Adelisa L.; "Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis." USPHS Working Group on Occupational Postexposure Prophylaxis.; National Center for Emerging and Zoonotic Infectious Diseases (U.S.). Division of Healthcare Quality Promotion.; 9/25/2013 Update (May 23, 2018) https://stacks.cdc.gov/view/cdc/20711

[8] Centers for Disease Control and Prevention. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

[9] McCunney, Robert J. ed. *Medical Center Occupational Health and Safety*,. Philadelphia, PA: Lippencott Williams & Wilkins, 1999.

[10] Risk and Management of Bloodborne Infections in Health Care Workers. Clin. Micro. Rev. July 2000.

[11] Michigan OSHA regulation of medical waste: https://www.michigan.gov/statelicensesearch/0,4671,7-180-24786-245023--,00.html

[12] US Department of Labor/Occupational Safety and Health Administration (OSHA). 1991. Occupational exposure to bloodborne pathogens; final rule. 29CFR part 1910.1030. *Federal Register*, 56:64175-64182. https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030

[13] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Institutes for Health. Biosafety in Microbiological and Biomedical Laboratories (6th ed.), 2020 https://www.cdc.gov/labs/bmbl/index.html

For more information about the Bloodborne Pathogen Standards, this written Exposure Control Plan, or for assistance in compliance, please contact

Dr. Adrienne Minerick (906-487-2796, minerick@mtu.edu, or 906-231-2012)

or the Environmental Health and Safety Office at ***906-487-2118 or https://www.mtu.edu/ehs/***

Appendix A

Hepatitis B Vaccine Declination

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccine at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. This statement of declination must be resubmitted each year so that any researcher feels comfortable to obtain the vaccine at any time. If in the future I continue to have occupational exposure to blood or other potentially infectious materials, and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Name: _____

Signed: _____ Date: _____

Appendix B

Safety and Sharps Injury Log (to be completed by student or researcher)

The following information, if known, is documented within 14 working days of the date on which each exposure incident was reported. In addition, the form at https://www.mtu.edu/ehs/report/injury-form/ must be completed by Dr. Minerick and filed with Michigan Tech's office of Occupational Safety and Health Services.

Date and time of the exposure incident:_____

Date of exposure incident report:_____

Employee involved:_____

Report written by:_____

Type of sharp involved:_____

Description of exposure incident:

Job classification of exposed employee:_____
Department/room where incident occurred:_____

Procedure being performed by the exposed employee at the time of the incident:

How did the incident occur?

Body part involved:_____

Does the exposed employee believe that any controls (engineering, work practice or administrative) could have prevented the injury?

Comments on the exposure incident (e.g. additional relevant factors):

Written by:_____Date:_____