

Exposure Control Plan for M.D. ERL

Adapted directly from MSU Office of Regulatory Compliance Template

<http://www.msstate.edu/dept/compliance/biosafety/bioforms.htm>

last updated: 19 June 2008

PURPOSE

Research projects in the Medical micro-Device Engineering Research Laboratory (M.D. ERL) focus on developing dielectrophoretic microdevices for human blood. While other projects in the lab do not involve blood, all researchers must be proficient with safety precautions and actively police the lab for any unsafe conduct. Human blood is a very dangerous fluid to work with because of the potential bloodborne pathogens it may carry. Every sample should be treated as if it is contaminated and so safety precautions must be followed at all times. The purpose of this Exposure Control Plan is to describe procedures and techniques utilized by M.D. ERL personnel to eliminate or minimize the danger of exposure to human blood. This is in compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) in conjunction with MSU biosafety polices and procedures.

SCOPE

This document is made available to M.D. ERL researchers every semester and any visitors prior to entering the lab. Copies of this document are also located in the safety folder (on shelf upon entering lab) at all times. All current Institutional Biosafety Committee (IBC) applications are also filed in this folder. This plan was reviewed for compliance with the MSU guidelines by the IBC on 26 July 2005, and re-approved during the lab's annual review on 28 June 2006.

This plan will be reviewed on an annual basis by Dr. Minerick, (also referred to as the Principal Investigator (PI) and lab director) and all researchers in the lab to address new concerns. The plan will then be forwarded to the Director of the Swalm School of Chemical Engineering and the Dean of the Bagley College of Engineering for review and support. This approval was conducted on 4 August 2005. Written comments were solicited from all M.D.-ERL researchers on 17 August 2006, 12 September, 2006, 31 May 2007, and are compiled in this updated document 14 September 2007.

DEFINITIONS (partially copied from MSU's ORC template Exposure Control Plan)

- **Bloodborne Pathogens** (*additional information attached with the OSHA Fact Sheet on Bloodborne Pathogens*) – disease-causing microorganisms present in the 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).
- **OPIM (Other Potentially Infectious Material)** – In M.D. ERL, the other infectious material is cultures of *Vibrio parahaemolyticus*, a bacterium known to cause food poisoning. It can even cause death in immuno-compromised individuals. All cultures are contained within the

incubator in the lab and all biosafety precautions must be followed at all times [2].

- **IBC (Institutional Biosafety Committee) and BSO (BioSafety Officer)** –The purpose of the Institutional Biosafety Committee (IBC) and Biosafety Officer (BSO) is to facilitate compliance with federal regulations in order to better protect workers who generate, process, and dispose of potentially hazardous biological materials at Mississippi State 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), 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 virus. 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] 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* 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, glass pipettes, pipette tips, 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).

- **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.

EXPOSURE DETERMINATION (partially copied from MSU's ORC Exposure Control Plan)

The Principal Investigator, in consultation with all research personnel, will identify positions

MEDICAL MICRODEVICE ENGINEERING RESEARCH LAB

DAVE C. SWALM SCHOOL OF CHEMICAL ENGINEERING AT MISSISSIPPI STATE UNIVERSITY

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 will then provide an additional layer of protection for lab personnel.

The material used in this laboratory that may be associated with potential exposure to human bloodborne pathogens is:

Human blood, serum, plasma, blood products, components or cells.

The material used in this laboratory that may be associated with potential exposure to pathogenic bacterium is:

Vibrio parahaemolyticus cultures.

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

Professor

Postdoctoral Researcher

Laboratory Assistant

Graduate Student

Undergraduate Student

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 M.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 during the performance of 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 Swalm 175 without express written permission from Dr. Minerick (sign also posted on the door). All biohazard trash is autoclaved before exiting the lab and is discarded directly into the dumpster behind the building. All surfaces and equipment is disinfected with bleach immediately after an experiment is completed.

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)

MEDICAL MICRODEVICE ENGINEERING RESEARCH LAB

DAVE C. SWALM SCHOOL OF CHEMICAL ENGINEERING AT MISSISSIPPI STATE UNIVERSITY

I, Dr. Adrienne Minerick, as the Principal Investigator / Laboratory Director, recognize my responsibility to implement and monitor this Exposure Control Plan.

Dr. Minerick will ensure 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 Pathogens 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 records of the exposure is kept on file for the life of the patient.

REQUIREMENTS

- 1). Dr. Minerick with the input of personnel of M.D. ERL, a laboratory where human blood or OPIM is used, must maintain this Exposure Control Plan. This document will be 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 work-site is maintained in a clean and sanitary condition. At a minimum, benches and biosafety cabinets are cleaned at the end of the day and after any spill using disinfectant(s).
- 6). Protective gloves are worn on the lab side of the yellow and black 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 with protective gloves is prohibited.
- 7). Nonlatex gloves are used in M.D. ERL to avoid the issue of latex sensitivity.
- 8). Hands are washed after removing gloves, before exiting the lab, and before eating, drinking, smoking, handling contact lenses or other activities that may result in hand contact to a mucous membrane. Computers and the microscope are not to be touched while wearing gloves.
- 9). Only approved sharps containers are to be used for sharps disposal.
- 10). Needles shall not be recapped, removed from disposable syringes, purposefully bent or otherwise manipulated. M.D. ERL procedures have been designed to avoid the use of needles.
- 11). Engineering controls will be evaluated and used whenever possible, in an effort to reduce the potential for sharps injury (and thus exposure to blood borne pathogens or OPIM hazards) to the user as well as those working downstream (i.e., waste handlers, environmental services, and laundry personnel).
- 12). Disposal containers (bags, sharps containers, red barrels, etc.) are required to be closed during transport. If there is a chance of leakage, an additional labeled container will be used and must be autoclaved after use.
- 13). Personal protective equipment (PPE) and clothing is used in this laboratory to minimize

MEDICAL MICRODEVICE ENGINEERING RESEARCH LAB

DAVE C. SWALM SCHOOL OF CHEMICAL ENGINEERING AT MISSISSIPPI STATE UNIVERSITY

or eliminate exposure to human blood borne pathogens. Dr. Minerick or the department is responsible for supplying personal protective equipment and clothing and making arrangements for replacement or cleaning as needed.

- 14). 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.
- 15). Regulated medical waste will be handled in accordance with the policies of the State of Mississippi Department of Health [11].

OCCUPATIONAL MEDICINE PROGRAM

Dr. Minerick has arranged for occupational medical services with the Longest Student Health Center and is familiar with their Post-Exposure Plan **before** initiating research wherein an exposure event could occur [6,7].

POST EXPOSURE PLAN [6,7]

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

Policy: We will use the latest US Public Health Service Guidelines in the Management of Occupational Exposures to HBV, HCV and HIV (currently MMWR Recommendations and Reports 06/29/2001 Vol. 50, No. RR-11)

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm>

Procedure: Please consult the Biosafety Contract, which outlines M.D. ERL's policies regarding the handling of human blood in the safest manner possible. In addition, M.D. ERL will document all samples handled within the lab. All student researchers in M.D. ERL, regardless of whether they work on a blood related project or not, will have Hepatitis B vaccination (paid for by M.D. – ERL). Documentation of adequate vaccine response at the end of the primary vaccination series is currently not mandatory (i.e. not paid for by M.D.-ERL), but is strongly advised. If 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:

- 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 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. Irrigate eyes with clean water, saline, or sterile irrigants (eye wash near the door).
 4. Document incident on safety log sheet unless it involves a sharps injury. All such injuries must be reported to Dr. Minerick, who will keep a confidential log of sharps injuries.
 5. Report the incident to Dr. Minerick.
 6. Immediately seek medical treatment at Longest Student Health Center.

MEDICAL MICRODEVICE ENGINEERING RESEARCH LAB

DAVE C. SWALM SCHOOL OF CHEMICAL ENGINEERING AT MISSISSIPPI STATE UNIVERSITY

- 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
- Evaluate exposure source. (done by exposed researcher in consultation with Dr. Minerick, the BSO, and the Longest Student Health Center)
 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 needles or syringes for virus contamination.
- Evaluate the exposed person (Longest Student Health Center).
 1. Assess immune status for HBV infection.
- Give **Post Exposure Prophylaxis** for exposures posing risk of infection / transmission (Longest Student Health Center).
 1. Initiate PEP as soon as possible, preferably within hours of exposure.
 2. Offer pregnancy testing to all women of childbearing age not known to be pregnant.
 3. Seek expert consultation if viral resistance is suspected.
 4. Administer PEP for 4 weeks if tolerated.
- Perform virus (HBV, HCV, HIV) specific follow-up testing and provide counseling (Longest Student Health Center).
 1. Advise exposed persons to seek medical evaluation for any acute illness occurring during the follow-up

At the time of exposure an exposure report should be filled out and a copy filed with Dr. Minerick, a copy sent to the MSU Office of Sponsored Programs and a copy should go with the researcher to their clinician. It should include:

- 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 and how and when in the course of 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);
- 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. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm> and

MINERICK@CHE.MSSTATE.EDU

[HTTP://WWW.CHE.MSSTATE.EDU/RESEARCH/MDERL/](http://WWW.CHE.MSSTATE.EDU/RESEARCH/MDERL/)

MEDICAL MICRODEVICE ENGINEERING RESEARCH LAB

DAVE C. SWALM SCHOOL OF CHEMICAL ENGINEERING AT MISSISSIPPI STATE UNIVERSITY

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a3.htm>

RESOURCES

- [1] Mississippi State University Office of Regulatory Compliance: Biosafety
<http://www.msstate.edu/dept/compliance/biosafety/index.html>
- [2] Centers for Disease Control and Prevention. General information on *Vibrio parahaemolyticus*
http://www.cdc.gov/ncidod/dbmd/diseaseinfo/vibrioparahaemolyticus_g.htm
- [3] Exposure to Blood: What Healthcare Personnel Need to Know. Department of Health & Human Services, Center for Disease Control.
http://www.cdc.gov/ncidod/hip/Blood/Exp_to_Blood.pdf
- [4] Teens Health: Hepatitis <http://kidshealth.org/teen/infections/stds/hepatitis.html>
- [5] Teens Health: HIV / AIDS http://kidshealth.org/teen/infections/stds/std_hiv.html
- [6] Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis.
<http://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf>
- [7] US Public Health Service Guidelines in the Management of Occupational Exposures to HBV, HCV and HIV (currently MMWR Recommendations and Reports 06/29/2001 Vol. 50, No. RR-11) <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm>
- [8] Centers for Disease Control and Prevention. Recommendations for prevention of HIV transmission in health-care settings. *MMWR* 1987; 369 (suppl no 2S).
- [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] Mississippi State Department of Health. 1994. Adopted standards for the regulation of medical waste.
- [12] US Department of Labor/Occupational Safety and Health Administration. 1991. Occupational exposure to bloodborne pathogens; final rule. 29CFR part 1910.1030. *Federal Register*, 56:64175-64182.
- [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* (4th ed.), 1999.

For more information about the Bloodborne Pathogen Standards, this written Exposure Control Plan, or for assistance in compliance, please contact Dr. Adrienne Minerick (662-325-7323, minerick@che.msstate.edu, or 662-722-1243) or call the Office of Regulatory Compliance at 662-325-3294. Copies of the standards and guidelines are available on the ORC Biosafety website (<http://www.orc.msstate.edu/biosafety/>).