Exposure Control Plan

For Bloodborne Pathogens

In Accordance with

OSHA Standard 29 CFR 1910.1030

Revised Edition-2011-1

Preface

The enclosed document represents the Exposure Control Plan to be employed at Wright State University in all areas where employees and/or students are occupationally exposed to bloodborne pathogens.

State employees are now covered by the Ohio Public Employment Reduction Program (PERRP). The State of Ohio has simply accepted current OSHA Standards and has promulgated them as the Ohio PERRP Rules. The PERRP Rules will not require additional or new recordkeeping, etc. The program will continue to be administered as it was originally designed.

The success of the program is measured by the absence of incidents involving actual contact with blood and other potentially infectious materials. To achieve success will require the active support and involvement of all individuals covered by the Exposure Control Plan. Please work with us to provide a safe and healthy working environment for our employees and students. Thank you.

Please note: Compliance with this plan is mandatory!

Wright State University Department of Environmental Health & Safety Exposure Control Plan for Bloodborne Pathogens

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Exposure Determination

OSHA requires employers to perform an exposure determination concerning which employees may incur occupational exposure to blood or other potentially infectious materials. The exposure determination is made without regard to the use of personal protective equipment (i.e. employees are considered to be exposed even if they wear personal protective equipment). This exposure determination is required to list all job classifications in which all employees may be expected to incur such occupational exposure, regardless of frequency. At Wright State University, the following job classifications are in this category:

- Animal Handlers/LAR Personnel
- Athletic Trainers
- Athletic Coaches
- Disability Services, Personal Assistants
- Environmental Health and Safety
- Laboratory Technician*
- Laboratory Research Associate*
- Laboratory Supervisor*
- Lifeguard
- Medical Technician

- Medical Technologist
- Mortician/ Embalmer
- Nurses, Instructional
- Nurse Practitioner
- Nurses, Student Health Services
- Pathologist
- Police Officer
- Research Faculty*
- Student Athletic Trainer
- Veterinarians

In addition, OSHA requires a listing of job classifications in which some employees may have occupational exposure. Since not all the employees in these categories would be expected to incur exposure to blood or other potentially infectious materials, tasks, or procedures that would cause these employees to have occupational exposure are also required to be listed in order to clearly understand which employees in these categories are considered to have occupational exposure. The job classifications and associated tasks for these categories are as follows:

Job Classification

Tasks/Procedures

Animal Handlers/LAR Personnel	Administering injections, drawing blood, cutting with	
Veterinarian	knife or scalpel, dressing wounds, handling infectious	
	wastes, handling infected animals, necropsy of	
	infected animal carcasses, puncture wounds	

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^{*}as determined by job description (only those positions whose research/job involves working with bloodborne pathogens)

Job Classification

Tasks/Procedures

Athletic Coach Athletic Trainer Student Athletic Trainer	Dressing wounds, cleaning up human blood
Student Aunetic Trainer	
Disability Services Personal Assistant	Cleaning up human blood, assisting with personal hygiene, handling infectious wastes
Environmental Health & Safety	Cleaning up human blood, handling infectious wastes, handling infected animals, puncture wounds
Laboratory Technician* Laboratory Research Associate* Laboratory Supervisor* *as determined by job description (only those positions whose research/job involves working with bloodborne pathogens)	Administering injections, drawing blood, cutting with knife or scalpel, dressing wounds, handling infectious wastes, handling infected animals, manipulation of unfixed human tissue, manipulation of contaminated cultures/tissue, necropsy of infected animal carcasses, puncture wounds, sonication of human blood or components
Life Guard	Dressing wounds, cleaning up human blood, emergency first aid and response
Medical Technician Medical Technologist Phlebotomist	Drawing blood, handling blood specimens, handling infectious wastes, manipulation of contaminated cultures, puncture wounds
Mortician/Embalmer Pathologist	Autopsy, cleaning up human blood, cutting with knife or scalpel, embalming cadavers, handling infectious wastes, manipulation of unfixed human tissue, puncture wounds
Nurse Practitioner Nurse, Instructional Nurse, Student Health Services Physician	Administering injections, cleaning up human blood, drawing blood, cutting with knife or scalpel, dressing wounds, emergency first aid and response, handling infectious wastes, manipulation of unfixed human tissue, manipulation of contaminated cultures/tissue
Police Officer	Accident scene, cleaning up human blood, dressing wounds, emergency first aid and response, public disturbances, puncture wounds

Implementation and Methodology

OSHA requires that this plan also include a schedule and a method of implementation for the various requirements of the standard. The following complies with this requirement.

Compliance Methods

Universal precautions will be observed at Wright State University in order to prevent contact with blood or other potentially infectious materials. All blood or other potentially infectious materials will be considered infectious regardless of the perceived status of the source individual.

A Principal Investigator planning research activities involving blood or OPIM, in addition to complying with all requirements of this policy, must have an approved biosafety protocol from the Institutional Biosafety Committee prior to initiating such activity.

Engineering and work practice controls will be utilized to eliminate or minimize exposure to employees at Wright State University. Where occupational exposure remains after institution of these controls, personal equipment shall be utilized:

- Approved sharps containers
- Biological safety cabinets
- Approved disinfectants/spill kit supplies
- Training
- Needle guard systems on syringes
- Sealed rotor cups
- Shielding

- Infectious waste bags/boxes
- Biohazard signs/labels
- Standard operating procedures
- Emergency eyewash/shower stations
- Controlled access into laboratories
- Enclosed receptacles (i.e. petri dish)
- Tongs/forceps to pick up sharps

The above controls will be examined and maintained on a regular schedule. The schedule for reviewing the effectiveness of the controls is as determined by the manager, supervisor, director, or chairperson of each of the previously listed job classifications. All schedules for maintaining engineering and work practices controls must be included in the written standard operating procedure(s). The Department of Environmental Health & Safety will conduct audits at the minimum of once a year to determine if compliance methods are being met.

Responsibilities

The following have a responsibility to the implementation the university Exposure Control Plan.

Department Chairpersons and/or Directors

- Responsibilities as a Person-in-Charge.
- Provide a safe laboratory facility or work place to minimize risk of exposure to bloodborne pathogens.
- Responsible for all respective departmental laboratory and associated facilities.
- Responsible for all personnel under their direction and for those personnel to comply with the information contained within the university Exposure Control Plan.

Faculty Members, Principal Investigators or Laboratory Supervisors

- Responsibilities as a Person-in-Charge.
- Identify persons in the laboratory who are at risk of exposure to bloodborne pathogens.
- Assures identified personnel completes bloodborne pathogens training before completing job tasks that put the individual at a potential risk of exposure and within 10 days of such job assignment.
- Provide and promote a safe work environment for conducting research.
- Conduct only laboratory activities approved by the university.
- Develop and maintain a laboratory procedure manual to supplement to university Exposure Control Plan.
- Review the university Exposure Control Plan, initially and annually as long as potentially at risk of exposure.
- Review laboratory procedures for changes in potential risk or exposure, advise laboratory personnel of changes and provide for appropriate training.
- Contact the Department of Environmental Health and Safety for employee bloodborne pathogen training and review of the university Exposure Control Plan.
- Ensure laboratory specific safety training for laboratory staff has been completed, initially and annually, for all laboratory personnel at risk of potential exposure.
- Provide training to laboratory personnel for the proper clean up of spills involving bloodborne pathogens.
- Report all accidents, injuries and near accidents to the Department of Environmental Health and Safety as directed by university guidelines and policies.

Laboratory Research Associates, Graduate Students, Student Employees

- Conduct only laboratory approved activities.
- Complete appropriate training for safe work practices specific to the workplace.
- Complete initial and annual bloodborne pathogen training.
- Accept or decline offered immunizations.
- Promote safe work practices.
- Attend training courses as directed by supervisory faculty, staff, Director or Departmental Chair.
- Timely report all accidents or injuries and near accidents to the faculty member in charge and to the Department of Environmental Health and Safety.

Department Directors/Managers/Supervisors of At Risk Non-Laboratory Personnel

• Responsibilities as a Person-in-Charge.

- Provide a safe facility or work place to minimize risk of exposure to bloodborne pathogens.
- Responsible for all respective departmental facilities and equipment.
- Responsible for all personnel under their direction and for those personnel to comply with the information contained within the university Exposure Control Plan.

At Risk Non-Laboratory Personnel

- Complete appropriate safety training for the work environment.
- Complete annual and refresher bloodborne pathogen training.
- Accept or decline immunizations.
- Promote safe work practices.
- Inform supervisor or other person in charge of unsafe conditions or work practices.
- Report in a timely fashion all occupational injuries or accidents or near accidents to supervisory person.

Occupational Health Physician/Student Health Services

- Coordinate with the Department of Environmental Health and Safety to provide recommended immunizations according the university Occupational Health Program.
- Provide expert medical advice and consultation in the event of an exposure to human blood, OPIM or contaminated cultures.

Environmental Health & Safety (EH&S)

- Conduct annual laboratory assessment/audits
- Conduct assessments for potential risks of exposure.
- Provide / coordinate initial and annual training of the university Exposure Control Plan.
- Annual review of the Exposure Control Plan
- Oversee the implementation of the Exposure Control Plan.
- Manage the university Occupational Health Program for required immunizations and medical monitoring
- Perform laboratory safety audits, job hazard analysis, assisting the Institutional Biosafety Officer in evaluation of work practices associated with biological materials,
- Investigate reported accidents and injuries and those involving potential exposure to a bloodborne pathogen or OPIM
- Emergency response in the event of a spill or other potential exposure situation.

Campus Visitors

• Contact the immediate Person-in-Charge to ensure compliance with all university guidelines, policies and procedures as they apply to the work environment.

Handwashing

Handwashing facilities are also available to the employees who insure exposure to blood or other potentially infectious materials. OSHA requires that these facilities be readily accessible after

incurring exposure. At Wright State University, handwashing facilities are located in research laboratories, restrooms, patient exam rooms, procedure rooms, custodial equipment rooms, and animal research rooms. In the event that washing hands with soap and water is not immediately possible, the use of waterless hand sanitizers with paper towels or antiseptic towelettes may be substituted. Alcohol content of approved waterless hand sanitizers must contain a minimum sixty percent by volume. If waterless hand sanitizer was used, hands must be washed with soap and running water as soon as feasibly possible.

After removal of personal protective gloves, employees shall wash hands and any other potentially contaminated skin area immediately or as soon as feasibly possible with soap and water.

If employees incur exposure to their skin or mucous membranes then those areas shall be washed or flushed with water as appropriate or as soon as feasible following contact.

Needlestick Safety and Prevention Reporting of Needlesticks

Contaminated needles and other contaminated sharps will not be bent, recapped, removed, sheared, or purposely broken. OSHA allows an exception to this if the procedure would require that the contaminated needle be recapped or removed and no alternative is feasible and the action is required by the medical procedure. If such action is required then the recapping or removal of the needle must be done by the use of a mechanical device or a one-handed technique. At Wright State University recapping or removal is only permitted in the following procedures:

 Via written Standard Operating Procedures that received the Institutional Biological Safety Officer's approval prior to the use of a method allowing for the recapping or removal of needles.

In November 2000 the OSHA Bloodborne Pathogen Standard was amended to incorporate the use of safe needle devices as engineering controls. The use of safe needle devices is required where appropriate. The identification, evaluation and selection of a safer needle for use in the workplace shall involve non-management employees. An evaluation process shall be implemented and selections of preferred devices shall be documented and reviewed at least annually or as new technology is made available. Documentation of the selection of preferred devices shall be maintained in the workplace. Documentation shall be made available to inspection by regulatory agents or representatives of the university. Employees are to be trained in the proper use of the safer needles prior to implementation.

In the event of a needlestick, puncture or laceration from a contaminated sharp a *Sharps Injury Form Needlestick Report* from the State of Ohio Public Employment Risk Reduction Program (PERRP) must be completed and forwarded to the Department of Environmental Health and Safety. The two page Needlestick Report Form is available at the State of Ohio, Department of Commerce, Bureau of Occupational Health and Safety website,

https://www.ohiobwc.com/employer/forms/SHARPSInjuryReport/Default.aspx, or through the Department of Environmental Health and Safety by calling 775-2215. Submit required forms within 24 hours of incident.

Sharps reporting, SB183, and PERRAC

The Ohio 123rd General Assembly passed Senate Bill 183 which added provisions to the Public Employment Risk Reduction Act requiring the reporting of needlestick or sharps injuries. In addition, the Public Employment Risk Reduction Advisory Commission (PERRAC) is required to develop a list of safe needlestick devices.

A sharps injury log will be maintained in the Department of Environmental Health and Safety to record injuries resulting from exposure to contaminated sharps.

Work Area Restrictions

In work areas where there is a reasonable likelihood of exposure to blood or other potentially infectious materials, employees are not to eat, drink, apply cosmetics or lip balm, smoke, or handle contact lenses. Food and beverages are not to be kept in refrigerators, freezers, shelves, cabinets, or on counter tops where blood and other potentially infectious materials are present.

Mouth pipetting/suctioning of blood and other potentially infectious materials is prohibited.

All procedures will be conducted in a manner which will minimize splashing, spraying, splattering, and generation of droplets of blood or other potentially infectious materials. Methods which will be employed at Wright State University to accomplish this goal are:

- Standard Microbiological Lab practices
- absorbent bench paper
- capped or parafilmed bottles and tubes
- sealed secondary containers

- biological safety cabinets (BSC)
- sealed rotor cups
- petri dishes
- any other equipment or method identified as acceptable containment

Specimens

Specimens of blood or other potentially infectious materials will be placed in a container which prevents leakage during the collection, handling, processing, storage, transfer, or transport of the specimens.

The container used for this purpose will be labeled or color-coded (red) in accordance with the requirements of the OSHA standard. OSHA provides an exemption for specimens only when

Wright State University utilizes universal precautions in the handling of all specimens and the containers are recognizable as containing specimens (labeling with orange biohazard tape). This exemption applies only while the specimens remain in the current facility (NOT applicable i.e. when taking blood or other potentially infectious materials from Cox Institute to Wright State University's main campus).

Faculty members, principal investigators or laboratory supervisors at Wright State University are responsible to provide the adequate containment receptacles and labeling tape for all areas of use. All specimens must be placed within a second container such as Tupperware®, Rubbermaid®, Glad-Ware®, Ziploc®-type plastic bags, plastic tote-like tubs, or lidded plastic buckets to move from one area of the facility to another. Baggies must be "zipped" and containment receptacles must be sealed with a lid when transferring blood or other potentially infectious materials outside the confines of each assigned work/research area(s) and labeled with biohazard tape.

Any specimens which could puncture a primary container will be placed in a within a secondary container which is puncture resistant.

If outside contamination of the primary container occurs, the primary container shall be placed within a secondary container which prevents leakage during handling, processing, storage, the transfer or transporting of the specimen.

Contaminated Equipment

Equipment which has been become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary unless the decontamination of the equipment is not feasible. Equipment or instruments that are contaminated with blood or other potentially infectious material shall be disinfected daily or as required by the instrument manufacturer's product instructions.

Instruments and equipment shall be disinfected immediately following exposure to contaminated materials, or as soon as reasonably possible following the completion of the procedures that are being performed.

Equipment and instruments must be disinfected prior to servicing or shipping. If all components of the instrument or equipment cannot be disinfected completely, a biohazard label must be attached to the instrument or equipment indicating which parts was not disinfected and remains contaminated.

All departments shall convey this information to other employees, service personnel, transporters of the instrument or equipment, and the manufacturer, as appropriate, prior to handling, servicing, or shipping. Safety measures must be taken to minimize exposure during shipping and transporting.

Personal Protective Equipment

All personal protective equipment used at Wright State University will be provided without costs to the employees. Personal protective equipment will be chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the employees' clothing, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used. Protective clothing will be provided in the following manner:

Potential Exposure to <u>Face and Head</u>	Potential Exposure to Body <u>Extremities</u>	Potential Exposure to Body <u>Trunk</u>
• Chin-length Face Shields	• Utility Gloves	• Fluid Impervious Gowns
• Goggles	• Examination Gloves	 Fluid Impervious Lab Coats
• Masks	 Fluid Impervious Lab Coats 	Fluid Impervious Aprons
 Head Covers 	 Shoe Coverings 	 Clinic Jacket
• Respirators	 Fluid Impervious Gowns 	
 Glasses with solid side shields 	• Protective Pants	

All personal protective equipment will be cleaned, laundered, and disposed of by the employer at no cost to employees. All repairs and replacement will be made by the employer at no cost to employees.

All garments which are penetrated by blood and other potentially infectious materials shall be removed immediately or as soon as feasible. ALL personal protective equipment will be removed prior to leaving the work area. The following criteria will be followed to facilitate leaving the equipment at the work area:

- Biosafety in Microbiological and Biomedical Laboratories (BMBL). 5th edition. USDHH CDC, NIH. 2007.
- *NIH Guidelines for Research Involving Recombinant DNA* (NIH Guidelines). USDHH, NIH. 2011.
- Wright Way Policy 6000.
- Standard operating procedures established by individual departments.

Gloves shall be worn where it is reasonably anticipated that employees will have hand contact with blood, other potentially infectious materials, non-intact skin, and mucous membranes. Gloves will be available from the Person-In-Charge.

Disposable gloves used at Wright State University are not to be washed or decontaminated for re-use and are to be replaced as soon as practical when they become contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Utility gloves will be discarded if they are cracked, peeling, torn, punctured, or exhibits other signs of deterioration or when their ability to function as a barrier is compromised.

N-95 masks in combination with eye protection devices such as goggles or glasses with solid side shield, or chin length face shields, are required to be worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated. You must enroll in Wright State University's respirator program if masks are to be used. Call extension 2215 for further details.

The OSHA standard also requires appropriate protective clothing to be used, such as lab coats, gowns, aprons, clinic jackets, or similar outer garments. All work involving human or non-human primate blood, unfixed tissues, and OPIM must always wear protective clothing over street clothes. Personnel must wear long pants, crew-length socks and closed-toed shoes upon entering a laboratory area.

Facilities Maintenance

Facilities at Wright State University will be cleaned and decontaminated according to the following schedule:

• Immediately after a spill

• Daily

• Visibly soiled

• After completion of work

Decontamination will be accomplished by utilizing the following materials:

- EPA-approved disinfectant used according to instructions
- Paper towels

All contaminated work surfaces will be decontaminated after completion of procedures and immediately or soon as feasible after any spill of blood or other potentially infectious materials, as well as the end of the work shift if the surface may have become contaminated since the last cleaning. The use of plastic-backed bench paper is encouraged to minimize splash and to help contain spilled materials. Change bench paper when contaminated and discard in the infectious waste box.

All bins, pails, cans, and similar receptacles shall be inspected and decontaminated on a regularly scheduled basis:

- When visibly soiled
- Weekly

Any broken glassware which may be contaminated will not be picked up directly by hand. The following procedure will be used:

- The use of mechanical means such as forceps
- Dustpan and stiff cardboard

Regulated Waste Disposal

All contaminated sharps shall be discarded as soon as feasible in sharps containers which are located in the facility. Sharps containers must be located within the immediate work area and preferably within arm's length reach of the personnel.

Regulated waste other than sharps shall be placed in appropriate containers. Such containers are located:

• In each room identified as a work area generating infectious wastes. See EHS Compliance Specialist for list of infectious waste generators and work locations.

Laundry Procedures

Laundry contaminated with blood or other potentially infectious materials will be handled as little as possible. Such laundry will be placed in appropriately marked bags at the location where it was used. Such laundry will not be sorted or rinsed in the area of use.

All employees who handle contaminated laundry will utilize personal protective equipment to prevent contact with blood or other potentially infectious materials.

Laundry at Wright State University will be cleaned at 102 Health Sciences Building.

Hepatitis B Vaccine

All employees who have been identified as having exposure to blood or other potentially infectious materials will be offered the Hepatitis B vaccine at no cost to the employee.

Refer to- http://www.wright.edu/wrightway/6034.html for detailed information regarding the coverage of bloodborne pathogens to the community of Wright State University.

The vaccine will be offered within 10 working days of the employee's initial assignment to work involving the potential for occupational exposure to blood or other potentially infectious

materials unless the employee has previously had the vaccine or who wishes to submit to antibody testing which shows the employee to have sufficient immunity.

Employees who decline the Hepatitis B vaccine will sign a waiver which uses the wording in Appendix A of the OSHA standard.

Employees who initially decline the vaccine but who wish to have it may then have the vaccine provided at no cost. The Institutional Biological Safety Officer will offer the option of the Hepatitis B vaccine at each bloodborne pathogens training session. Prior to leaving the session for the initial training, each employee will submit a signed waiver of the declination of the vaccine at that time, consent to the vaccine series, or indicate prior completion of series. The responsibility of contacting the employee to schedule appointments, filing the waiver form, and keeping immunization records on file is the responsibility of the Health & Safety Technical Services Coordinator in the Department of Environmental Health & Safety. The physician for student health services on the main campus of Wright State University will be responsible for the administering of the Hepatitis B vaccine. At Wright State University's lake Campus location, Grand Lake Occupational Medicine at Joint Township District Memorial Hospital, 200 Saint Clair St., Saint Marys, OH 45885 is responsible for administering the Hepatitis B vaccine to employees working at this location.

Post-Exposure Evaluation and Follow-up

When the employee incurs an exposure incident, the incident must be reported to the Person-In-Charge immediately. The employee and/or the Person-In-Charge must contact the Department of Environmental Health & Safety immediately and a written accident/incident report submitted within 24 hour of incident.

All employees who incur an exposure incident will be offered post-exposure evaluation and follow-up in accordance with the OSHA standard.

The follow-up will include the following:

- Documentation of the route of exposure and the circumstances related to the incident.
- If possible, the identification of the source individual, and if possible, the status of the source individual. The blood of the source individual will be tested (after consent is obtained) for HIV/HBV infectivity.
- Results of testing of the source individual will be made to the exposed employee with the exposed employee informed about the applicable laws and regulations concerning the disclosure of the identity and infectivity of the source individual.
- The employee will be offered the option of having his/her blood collected for testing of the
 employee's HIV/HBV serological status. The blood sample will be preserved for up to
 90 days to allow the employee to decide if the blood should be tested for HIV serological

status. However, if the employee decides prior to that time that testing will or will not be conducted then the appropriate action can be taken and the blood sample discarded.

- The employee will be offered post exposure prophylaxis in accordance with the current recommendations of the U.S. Public Health Service.
- The employee will be given appropriate counseling concerning precautions to take during the period after the exposure incident. The employee will also be given information on what potential illnesses to be alert for and to report any related experiences to appropriate personnel.
- The following person(s) has been designated to assure that the policy outlined here is effectively carried out as well as to maintain records related to this policy: The Director of the Department of Environmental Health & Safety.

Interaction with Health Care Professionals

A written opinion shall be obtained from the health care professional who evaluates employees of Wright State University. Written opinions will be obtained in the following instances:

- 1) When the employee is sent to obtain the Hepatitis B vaccine.
- 2) Whenever the employee is sent to a health care physician following an exposure incident.

Health care professionals shall be instructed to limit their opinions to:

- 1) Whether the Hepatitis B vaccine is indicated and if the employee has received the vaccine. or for evaluation following an incident,
- 2) That the employee has been informed of the results of the evaluation, and
- 3) That the employee has been told about any medical conditions resulting from exposure to blood or potentially infectious materials. Written opinion to the employer is not to reference any personal medical information.

Training

Training for all employees will be conducted prior to initial assignment to tasks where occupational exposure may occur. Training will be conducted in both a lecture and on-line format. Both formats will be designed so the option of immediate access to the Institutional Biological Safety Officer for questions or comments will be available.

Training for employees will include the following as the explanation of:

- 1) The OSHA standard for Bloodborne Pathogens
- 2) Epidemiology and symptomatology of bloodborne diseases
- 3) Modes of transmission of bloodborne pathogens
- 4) This Exposure Control Plan (i.e. points of the plan, lines of responsibility, how the plan will be implemented, et cetera)
- 5) Procedures which might cause exposure to blood or other potentially infectious materials at Wright State University
- 6) Control methods which will be used at Wright State University to control exposure to blood and other potentially infectious materials
- 7) Personal protective equipment available at Wright State University and who should be contacted to obtain them
- 8) Post exposure evaluation and follow-up
- 9) Signs and labels used at Wright State University
- 10) Hepatitis B vaccine program at Wright State University

Requirements for HIV & HBV Research Laboratories and Production Facilities

This section applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues or organs. The requirements listed here apply in addition to other requirements of the OSHA Standard and of the university Exposure Control Plan.

Research laboratories engaged in the culturing or concentrating HIV or HBV are required to comply with the university Exposure Control Plan.

A Standard Operating Procedures guide specific for the facility must be prepared to address the additional requirements that follow. It is the responsibility of the facility manager to periodically review and to at least annually update and revise the standard operating procedures. Personnel working in the laboratory must read the biosafety manual and standard operating procedures and must follow the outlined practices and procedures.

Research laboratories and production facilities shall meet the following criteria:

A. Standard microbiological practices are used.

Waste generated in a research laboratory or a production facility shall be handled in accordance to the policies consistent with the Ohio EPA, the *Institutional Biosafety Manual* and the facility procedure manual.

B. Special practices include:

- 1) Laboratory doors will be kept closed when work involving HIV or HBV is in progress.
- 2) Contaminated materials that are to be transported are carried in a durable leak proof, labeled or color coded container that is closed prior to being removed from the work area.
- 3) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any special entry requirements and who comply with all entry and exit procedures will be allowed in the work areas.
- 4) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with the OSHA standard.
- 5) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets (BSC) or other physical containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.
- 6) Laboratory coats, gowns, smocks, uniforms or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.
- 7) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when hand contact with other potentially infectious materials is unavoidable.
- 8) Before disposal all waste from the work area and from affected animals shall be decontaminated by a method such as autoclaving prior to disposal by a method approved by the Ohio EPA.
- 9) Vacuum lines shall be protected with liquid disinfectant traps and HEPA filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.
- 10) Hypodermic needles and syringes shall be used only for parenteral injection and aspirations of fluids from laboratory animals and diaphragm bottles. Extreme caution shall be used when handling needles and syringes. Needles should not be bent, sheared or recapped. Needles shall be placed in an appropriate sharps container and inactivated (by steam sterilization or chemically) prior to disposal. Needle-locking syringes should be used.
- 11) All spills shall be immediately contained and cleaned up by the appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.
- 12) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director, other responsible person and to the Department of Environmental Health and Safety.
- 13) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures and shall be required to follow them.

C. Containment Equipment

- 1) Certified Biological Safety Cabinets (Class I or II) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with the other potentially infectious materials that may pose a threat of exposure to droplets, splashes, spills or aerosols.
- 2) Biological safety cabinets shall be certified when installed, serviced, whenever moved and at least annually.
- 3) Any containment device, centrifuge safety cups, centrifuge rotors or other equipment to contain droplets, splashes, spill or aerosols shall be properly disinfected prior being released for use.
- 4) Biological Safety Cabinets shall be disinfected prior to moving, service work or scraping.

HIV and HBV research laboratories shall meet the following criteria:

- 1) Each laboratory shall contain a facility for hand washing and an ANSI approved eye wash which is readily available in the work area.
- 2) An autoclave for pretreatment of regulated waste shall be available.

HIV and HBV production facilities shall meet the following criteria:

- 1) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be a basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or to other areas or activities may also be provided by a double-door, clothes-change room (showers may be included), airlock or other access facility that requires passing through two sets of doors before entering the work area.
- 2) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these areas shall be sealed or be capable of being sealed to facilitate decontamination.
- 3) Each work area shall contain a sink for washing hands and an eye wash facility. The sink shall be foot, elbow, or automatically operated and located near the exit door.
- 4) Access doors to the work area or containment module shall be self-closing.
- 5) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.
- 6) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

Training Requirements

Additional training requirements are required for employees in HIV and HBV research laboratories and production facilities are specified:

The employees shall also receive the following as part of initial training:

- 1) The employer shall ensure that the employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility prior to being allowed to work with HIV or HBV.
- 2) The employer shall ensure that employees have prior experience in the handling of human pathogens or tissue cultures prior to working with HIV or HBV.
- 3) The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall ensure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

Training shall be documented and retained for a time period of not less than three years.

Recordkeeping

All records required by the OSHA standard will be implemented by Wright State University's Department of Environmental Health & Safety.

Dates: 2/24/2011

APPENDIX A

Definitions

- **Blood** human blood, human blood components, and products made from human blood.
- **Bloodborne Pathogens** pathogenic microorganisms that are present in human blood that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).
- **Clinical Laboratory** a work place where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.
- **Contaminated** the presence, or the reasonably anticipated presence, of blood or other potentially infectious materials on an item or surface.
- **Contaminated Laundry** laundry that has been soiled with blood or other potentially infectious materials.
- **Contaminated Sharps** any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wire.
- **Decontamination** the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use or disposal.
- **Engineering Controls** controls (e.g. sharps disposal containers, self-sheathing needles) that isolate or remove bloodborne pathogen hazards from the work place.
- **Exposure Incident** eye, mouth, mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that result from the performance of an employee's duties.
- **Handwashing Facilities** facility providing an adequate supply of running potable water, soap, and single use towels or hot air drying machines.
- HBV hepatitis B virus
- **HIV** human immunodeficiency virus
- **Licensed Health Care Professional** a person whose legally permitted scope of practice allows him/her to independently perform the activities required in providing the hepatitis B vaccination and post-exposure evaluation and follow-up.
- Needleless Systems a device that does not use needles for:
 - (1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.
- **Occupational Exposure** reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.
- Other Potentially Infectious Materials (OPIM) semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; any fixed tissues or organs other than intact skin from a human (living or dead)

- and human immunodeficiency virus (HIV)-containing culture medium or other solutions as well as blood, organs, or other tissues from experimental animals infected with HIV or HBV.
- **Parenteral** piercing mucous membranes or the skin barrier through such events as needlestick, human bites, cuts, and abrasions.
- **Personal Protective Equipment** specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a bloodborne hazard are not considered to be personal protective equipment.
- **Person-In-Charge (PIC)** any person who is responsible for, and supervises, activities of other people who have the potential for an occupational exposure as defined above. This may be a Supervisor, Principal Investigator, Department Chair, etc. Additionally, said person is responsible, within the scope of their position, for carrying out and implementation of university guidelines, policies and procedures.
- **Production Facility** means a facility engaged in industrial scale, large volume or high concentration production of HIV or HBV.
- **Regulated Waste** liquid or semi-liquid blood or other potentially infectious materials; 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 materials.
- **Research Laboratory** a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the same volume found in production facilities.
- **Sharps with engineered sharps injury protection** a non-needle sharp or needle device used for withdrawing body fluids, access a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.
- **Source Individual** individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to bloodborne pathogens or other potentially infectious material(s).
- **Sterilize** the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.
- **Universal Precautions** an approach to infectious control in which all human blood and certain human body fluids are treated as if infectious for HIV, HBV, and other bloodborne pathogens.
- **Work Practice Controls** controls that reduce the likelihood of exposure to potential pathogens by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).



APPENDIX B

Hepatitis B Vaccine Accept/Decline Form

	Today's Date:
Printed Name:	Signature:
Last Four Digits of Social Security 1	No.: Month/Day of Birth
Department:Supervi	isor/Lab Supervisor (print name):
Department Phone No	Email address:
I am (check one):Faculty	StaffStudent EmployeeStudent
I decline at this time	e, to receive the Hepatitis B Vaccine Series.
If you marked "	pational exposure to blood or other potentially infectious materialitis B vaccine, I can receive the vaccination series at no charge to a decline" you may stop HERE pleted the Hepatitis B Vaccine Series.
A copy of past vaccination	ion records <u>must</u> be submitted to EHS – Rm 129 Allyn Hall.
I DO NOT have a history of all	
	Y EACH PERSON TO EACH INJECTION, AND THEN ACH INJECTION TO 129 ALLYN HALL, or faxed to 937-775-
STOP! For Office Use Only. Signature: EH&S	
Ammyouth	
Date:	
Signature: Health Care Provider; inje	iection given:
Date:	