

Bloodborne Pathogens Exposure Control Plan Duke University Research Laboratories and Other Non- Healthcare Areas

July, 2021 (first approved: May, 1992)

The following Exposure Control Plan (ECP) has been developed to eliminate or minimize employee exposure to bloodborne pathogens. This **plan** addresses all of the provisions of the Occupational Safety and Health Administration's (OSHA) Occupational Exposure to Bloodborne Pathogens Standard (29CFR 1910.1030), and is implemented by the Occupational and Environmental Safety Office (OESO).

I. UNIVERSAL BLOOD AND BODY FLUID PRECAUTIONS (STANDARD PRECAUTIONS)

A. Scope

Blood and body fluid precautions must be used by all employees who come in contact with any human blood, body fluid, or other potentially infectious materials (OPIM).

The following ECP has been developed with a focus on research and non-clinical areas. If the primary work done in an area includes patients or patient-care related activities, please follow the ECP for Duke University Hospital and Clinics, Clinical Research Laboratories, Private Diagnostic Clinics, and Duke Primary Care. Both ECPs address 29CFR 1910.1030.

B. Rationale

- 1. According to OSHA, Universal Precautions are defined as the infection control practices in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. The Universal Precaution approach is based on the premise that a medical history and examination cannot reliably identify all people infected with bloodborne pathogens.*
- 2. OSHA mandates that Universal Precautions shall be observed to prevent contact with blood or other potentially infectious materials.*
3. Duke employees should consider **all** human blood and body fluids as potentially infectious and must employ appropriate protective measures to prevent possible exposures. All body fluids are included, not just those that appear bloody. Blood is not always visible in body fluids or is not recognized until an exposure has occurred.

4. Duke University also includes the following under “other potentially infectious materials”: Any unfixed human tissues or organs, HIV-, HBV-, or HCV-containing cell lines, any animals or animal tissues infected with these pathogens, and all human cell lines. All human cell lines (including established lines) are included in the definition of “other potentially infectious materials” because it is not practical to test cell lines for all bloodborne pathogens and ensure that they are never contaminated with pathogens during research. In addition, human cell cultures purchased from vendors are typically not certified to be free of bloodborne pathogens.

I. EXPOSURE RISK DETERMINATION

- A. Exposure risk is determined by reviewing employee positions for reasonably anticipated risk of occupational exposure to human blood, body fluids, or other potentially infectious materials (OPIMs) as defined by the Bloodborne Pathogens Standard and OSHA interpretations as follows:
 1. **Occupational Exposure Risk** is “reasonably anticipated skin, eye, mucous membrane, non-intact skin, or parenteral contact with blood and other potentially infectious materials that may result from the performance of an employee’s duties.”
 2. **Other Potentially Infectious Materials** are any unfixed tissue or organ (other than intact skin) from a human (living or dead); **including primary and established human cell lines** and HIV-containing cell or tissue cultures, organ culture medium or other solutions, and blood, organs, or other tissues from experimental animals infected with HIV, HBV, or HCV. (A description of the requirements for laboratories handling cultures of HIV, HBV, or HCV, or animals infected with these agents is found in the specific laboratory’s SOP. A list of these laboratories is found in Appendix C, with the SOPs available upon request.)
- B. All employees will be assessed using the following criteria to determine occupational exposure risk:
 1. Direct patient care activities likely to result in direct or indirect exposure to a patient’s blood or body fluids.
 2. Processing or handling human blood, body fluids, tissues or organs.
 3. Processing or handling of equipment, materials or waste that may have been contaminated with human blood, body fluids or other potentially infectious material (OPIM) as defined above.

4. Routine administration of first aid.
 5. Processing or handling unfixed primary or established human cell lines.
- C. This exposure risk determination will be conducted by the direct supervisor in collaboration with OESO. OESO may also add this exposure risk based on research protocols that require compliance with the Duke Bloodborne Pathogens ECP.
1. Each assessment should be made without regard to the use of personal protective equipment.
 2. Exposure determinations are to be made at the time a position is created and each time there is a change in work duties which may result in a change in occupational exposure risk.
 3. Exposure risk determinations are attached to the employee's position code or to the employee's Duke Unique ID number. A status report identifying positions that require an exposure risk determination assessment is available on-line to supervisors and managers at www.safety.duke.edu > Training & Reports > Safety Training Reports. Safety compliance reports are also available at this site.
 4. An exposure risk determination must be recorded for each active employee.
- Note:** More than one category of exposure prone tasks may apply to an employee and all must be recorded.
5. All employees identified as having occupational exposure potential must comply with all provisions of the ECP.
- D. OESO maintains a complete database of the exposure risk determinations.
- E. Contact OESO Biological Safety at 919-684-8822 or the Training Coordinator at 919-684-2794 for further information.

II. SCHEDULE AND METHOD OF IMPLEMENTATION

A. Engineering and Work Practice Controls

Where possible, engineering and work practice controls shall be used to eliminate or minimize employee exposures.

a. Puncture Precautions

- a. The use of sharps in laboratories must be minimized. If sharps are necessary to use with human blood, body fluids, or OPIM, employees must take precautions to prevent injuries when using needles, scalpels, scissors, pipettes, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles and sharps; and when handling sharp instruments after procedures. The need for sharps and specific precautions to be used must be clarified in the laboratory Standard Operating Procedure for BSL2.
- b. All employees must be trained on the availability and use of approved safety devices where appropriate for their work responsibilities.
- c. Needles must not be recapped, purposely bent or broken, removed from disposable syringes, or otherwise manipulated by hand. Exceptions (such as when needles must be recapped for sterility, i.e., re-use of needle on the same patient) may include recapping procedures that must be done either by using a recapping device or a one-handed scoop method for recapping.
- d. Specimens with attached needles must not be transported to the laboratories. Exceptions for the need to process such specimens and the mode for safe transport of these exceptions (i.e., in puncture-resistant containers) must be included in the laboratory Standard Operating Procedure for BSL2.
- e. Broken, contaminated glassware must not be handled directly with hands, but must be cleaned up by mechanical devices such as brush and dustpan or forceps.
- f. After use, disposable syringes and needles, scalpel blades, scissors, slides, any activated or inactivated safety devices, and other sharp items must immediately, or as soon as feasible, be placed in puncture-resistant containers for disposal by the sharps user.
- g. The puncture-resistant containers for disposal or transport must be located as close as practical to areas where needles or sharps are used. The needle disposal containers are to be replaced before they become full.

- h. Leak proof, puncture-resistant containers must be used to transport reusable sharps to the reprocessing area.

b. Hand/Skin Washing

- a. Hands and other skin surfaces must be washed as soon as feasible if they become contaminated with human blood, body fluids, or other PIMs.
- b. Hands must be washed as soon as feasible after gloves are removed, and when leaving the work area.

3. Standard Safe Work Practices

- a. Eating, drinking, smoking, applying cosmetics, and handling contact lenses are prohibited in work areas where there is reasonable likelihood of occupational exposure to human blood, body fluids, OPIMs, or where these specimens are handled.
- b. Food and drink shall not be stored in work areas where human blood, body fluids, or OPIMs are present.
- c. Procedures involving human blood, body fluids, or OPIMs are to be performed in a manner to minimize splashing, spraying, spattering, and droplet generation.
- d. Mouth pipetting is prohibited.

4. Laundry

- a. Soiled linen or reusable protective clothing must be handled as little as possible.
- b. All used laundry should be considered potentially infectious and should be placed in fluid resistant laundry bags.
- c. If linen is soaked with blood or body fluids and is likely to leak through a single bag, "double-bags" are to be used.
- d. Laundry to be processed via an outside contractor must be placed in a labeled laundry bag for transport.

5. Environmental Controls

- a. Laboratory Containment:

- i. The processing and handling of human blood, body fluids, or OPIMs shall be done in accordance with biosafety level-2 (BSL-2) containment guidelines

<http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>

BSL-2 work practices are consistent with the concept of Universal/Standard Precautions. Standard Operating Procedures for BSL2 containment must be developed for each laboratory handling these materials.

- ii. Facility requirements include, but are not limited to, handwashing sinks, impervious benchtops, no carpets or rugs, and a readily available eyewash station.
 - iii. Laboratory specimens must be collected in leak-proof containers and placed in a sealable secondary container (i.e., Ziploc bag, cooler) for transport.
- b. Work areas must be maintained in a clean and sanitary condition. Work surfaces must be decontaminated with an appropriate disinfectant after completion of procedures or as soon as feasible when contaminated with human blood, body fluids, or OPIMs and after the work shift.
 - c. Blood or body fluid spills must be decontaminated as soon as feasible. Spills should be soaked up with absorbent material (i.e., paper towels), and disinfected with an EPA-approved "hospital tuberculocidal", "mycobacteriocidal", or HIV-and HBV-cidal disinfectant or a freshly-prepared diluted bleach solution (1:10 or 1:100 bleach:water).
 - d. Protective coverings, such as an impervious-surface-backed absorbent paper, used to cover surfaces must be removed as soon as feasible when overtly contaminated with human blood, body fluids, or OPIMs.
 - e. Disposable, contaminated items (disposable gloves, lab diapers, etc.) should be placed in a sturdy, leak-proof plastic bag and tightly closed for transport. Double bagging may be necessary if hard edges might perforate a single bag.
 - f. Bulk human blood, body fluids, or OPIMs (large volumes) are regulated medical waste and should be placed in "biohazard" boxes lined with plastic bags for incineration. Large volumes of human blood or cells (i.e., liquid aspirants from cell culture) must also be

treated with an appropriate chemical disinfectant (e.g. 1:10 bleach:water), or autoclaved, and then carefully poured down the sanitary sewer with copious amounts of water, wearing eye and face protection, gloves, and other appropriate PPE. Other medical waste is handled according to the Medical Waste Management policy,
http://www.safety.duke.edu/sites/default/files/VII_3MedWaste.pdf

- g. Contaminated, reusable equipment must be either decontaminated on-site or covered (i.e., placed in a plastic bag) and labeled with a biohazard warning sign to prevent exposures during transport.
- h. Biohazard warning signs must be affixed to containers of regulated medical waste, refrigerators and freezers containing human blood or OPIM; and other containers or bags used to store or transport contaminated materials, needles and sharps. Sharps containers and biohazard bins made of red plastic do not need an additional biohazard label, as the red color indicates the hazard.

6. Barrier Precautions (Personal Protective Equipment)

- a. All employees must routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with any human blood, body fluids, or OPIM is anticipated. Each department must assess the exposure potential from procedures performed by their employees and identify all procedures which necessitate routine use of personal protective equipment because of a probability of exposure. In addition, each employee should critically review their work responsibilities to make informed decisions regarding the appropriate use of personal protective equipment.
- b. Gloves must be worn for touching human blood, body fluids, or OPIM, or handling items or surfaces soiled with these materials, and for performing venipuncture and other vascular access procedures.
- c. Masks and protective eyewear or face shields must be worn to prevent exposure of mucous membranes of the mouth, nose, and eyes during procedures that are likely to generate splashes or splatters of human blood, body fluids, or OPIM.
- d. Appropriate protective gowns or aprons must be worn during procedures that are likely to generate splashes of human blood, body fluids, or OPIM. For procedures during which it is anticipated

clothing will be soaked, fluid resistant aprons or gowns must be worn. PPE should never be taken home for laundering. Note: If personal clothing is visibly contaminated with blood or other infectious materials, contact OESO – Biological Safety for assistance, 919-684-8822.

- e. Surgical caps or hoods, shoe covers or boots must be worn in instances where gross contamination with human blood/body fluids is reasonably anticipated (i.e. autopsy, surgery).
- f. Resuscitation bags or other ventilation devices should be available in areas where resuscitation is predictable.

B. Compliance Monitoring

1. OESO will conduct routine or purpose driven site audits and investigate reasons for non-compliance with the policy as identified through these audits, complaints or reported exposures.
2. OESO will make suggestions to modify procedures based on an investigation of the problem, and will provide additional education and training as needed.
3. OESO will provide supervisors and department heads with on-line access to reports on employee compliance to safety training requirements and to compliance with the Hepatitis B provisions of the Standard.
4. Department heads, managers, principle investigators, and supervisors are responsible for ensuring compliance and monitoring adherence to this safety policy. Specifically, they must ensure that all personnel working under their supervision:
 - a. Understand and comply with practices/procedures identified in the ECP and other relevant safety procedures such as the laboratory Standard Operating Procedure for BSL2.
 - b. Have access to appropriate and necessary personal protective equipment.
 - c. Receive training, as required by this ECP. Training provided for compliance with this ECP is described in Appendix B.
5. Failure to comply with this policy will be managed as a work rule violation through the University policy on disciplinary actions.

C. Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up

1. Hepatitis B Vaccination

- a. Supervisors must ensure that new employees meeting the following criteria for occupational exposure risk receive the required training and meet with Employee and Occupational Health and Wellness (EOHW) for a health review and Hepatitis B evaluation within 10 working days of initial assignment:
 - i. Direct patient care activities likely to result in direct or indirect exposure to a patient's blood or body fluids.
 - ii. Processing or handling human blood, body fluids, tissues or organs.
 - iii. Processing or handling of equipment, materials or waste that may have been contaminated with human blood, body fluids or other potentially infectious material (OPIM) as defined above.
 - iv. Routine administration of first aid.
 - v. Processing or handling of unfixed primary or established human cell lines.
- b. Employees with occupational exposures to human blood, body fluids, or OPIM must be offered and should be encouraged to participate in the free Hepatitis B vaccination program. Employees are to contact Employee Occupational Health and Wellness (EOHW) at 919-684-3136 to obtain the vaccine.

2. Post-exposure Evaluation and Follow-up

- a. All human blood, body fluid, or other PIM exposures via needlesticks, punctures, or broken skin or mucous membrane contact must be reported immediately by calling the Exposure Hotline at 115 (Duke phone system) or 919-684-8115 (off-site service) for appropriate post-exposure follow-up and reporting on-line to the Safety Reporting System. Employee Occupational Health will respond promptly.
- b. Follow first aid procedures for potential exposures: clean the wound with soap and water for 1 minute or flush eyes or mucous membranes with water.

- c. The EOHW healthcare professional completing the post exposure evaluation will inform the employee of the test results and any potential medical conditions resulting from exposure. If further testing is required for the employee, EOHW will provide written instructions for follow-up evaluation and testing.

- 3. Hepatitis B vaccination procedures and post-exposure evaluation and follow-up procedures are described in Appendix A.

D. Communication of Hazards to Employees.

I. Labels and Signs

- A. Biohazard warning signs must be affixed to containers of regulated medical wastes, refrigerators, freezers, and incubators containing blood, body fluids, or OPIM; and other containers or bags used to store or transport contaminated equipment, materials, needles and sharps.
 - 1. Sharps containers and biohazard bins made of red plastic do not need an additional biohazard label, as the red color indicates the hazard.
- B. Biohazard signs must be posted on all doors when blood, body fluids, OPIM, or infected animals are present in the laboratory.
- C. Biohazard warning and door signs must incorporate the universal biohazard symbol and be predominantly fluorescent orange. Biohazard door signs must include the name of the infectious agent, requirements for entering the area, and the name and telephone number of the responsible person. All biohazard warning and door signs can only be distributed by OESO.

II. Information and Training

- a. The requirements of the bloodborne pathogens training program are detailed in Appendix B.
- b. Employee training is provided by OESO as an on-line training module and “in-person” upon request.
- c. On-line training includes a quiz that must be passed for compliance. A 24-hour pager number is provided for any questions.

- d. Area-specific training is provided upon request.
- e. Departments who wish to provide area-specific or departmental training may do so upon approval of training material by OESO.
- f. Training is required for all employees with exposure risk determinations of 1-5 (under I. "Exposure Risk Determination", B. 1-5) as follows:
 - i. Within 10 working days of initial assignment to work area involving exposure prone tasks.
 - ii. At least annually thereafter.
 - iii. When changes in tasks and procedures result in a change in the employee's occupational exposure potential.
- g. OESO is available for consultation on questions relating to the standard.

E. Recordkeeping

1. Exposure risk determination records will be maintained by OESO in an electronic safety management database.
2. Training Records
 - a. Institutional training records will be maintained by OESO in an electronic safety management database.
 - i. Supervisors, training coordinators and other persons responsible for providing training should submit copies of updated training records to OESO.
 - ii. Records will be maintained for 3 years from the date of training.
 - iii. Training records will contain the following:
 - Dates of training sessions.
 - Contents or a summary of the training session.
 - Name and qualifications of the trainer.

- Name and Duke Unique ID of all persons attending the session.
 - b. Documentation of employee participation in appropriate training will be maintained by the employee's administrative office.
- III. Hepatitis B vaccine and post-exposure follow-up records will be maintained by EOHW. Employee compliance with Hepatitis B vaccine provisions are downloaded from EOHW and maintained in the OESO electronic safety management database.

III. EMPLOYEE ACCESS TO ECP

- A. A copy of the ECP is available on the safety web-site, www.safety.duke.edu through the "Policies/Manuals" tab, under "University Safety Manual" link.
- B. Copies of the ECP are available in many work areas. Ask your supervisor about the location of the ECP in your work area.
- C. A copy of the ECP will be provided to any employee upon request to OESO.

IV. ASSISTANCE

Additional information regarding Universal Precautions and the Bloodborne Pathogens may be found at the biological safety website at <http://www.safety.duke.edu/biological-safety/bloodborne-pathogens>. The Biological Safety Division of OESO should also be contacted at 919-684-8822 for assistance in implementing procedures or to provide training for employees in Universal Precautions and the Bloodborne Pathogens Exposure Control Plan.

V. APPROVAL

The ECP and all appendices were approved by the Hospital Infection Control Committee (HICC) on May 20, 1992. This material is reviewed and updated when indicated, but at least annually.

VI. REVIEW AND UPDATE OF ECP

- A. The ECP will be reviewed by OESO at least annually and submitted for approval by the DUSC, and the Executive Committee of the Medical Staff.

B. The ECP will be updated whenever tasks or procedures affecting occupational exposure are modified. The DUSC, and the Executive Committee of the Medical Staff will approve all such modifications.

C. Affected employees will be trained regarding these modifications following approval either through the annual update training or through department-specific training.

Date Revised: 6/97, 8/98, 8/99, 2/10/03, 12/09/04, 02/15/05, 02/06, 03/07, 03/08, 2/09, 2/10, 2/11, 2/12, 3/12, 2/13, 2/14, 2/15, 2/16, 2/17, 5/18, 9/19, 10/20, 07/21

APPENDIX A

Post-exposure Evaluation and Follow-Up Procedures

HEPATITIS B VACCINATION

Employees who fall under this standard are required by the institution to have a placement health review at Employee Occupational Health and Wellness (EOHW). At the time of the health review, the employee will be provided with pertinent information about the Hepatitis B vaccine and it will be determined whether or not the employee falls under the exemptions for offering the vaccine.

If the employee is not exempt, the vaccine will be offered. If the employee does not want to start the series at that time, he/she will be asked to read and sign the declination form and be given instructions that the vaccine will be available should he/she change his/her mind. The Hepatitis B vaccine is administered according to the Centers for Disease Control and Prevention (CDC) Guidelines (MMWR, vol 50, no. RR-11, June 29, 2001; available via internet at <http://www.cdc.gov/mmwr/PDF/RR/RR5011.pdf>). Recent CDC publication pertaining to Hepatitis B vaccine status and post-exposure management in healthcare workers was issued in 2013 (MMWR vol 62, no RR-10, December 20, 2013); available via internet at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm>.

It is the employee's department that is responsible for making certain the employee goes through this process within 10 working days of initial assignment.

POST BLOOD/BODY FLUID EXPOSURE EVALUATION AND FOLLOW-UP

Exposure Definition

Significant exposure includes contamination by human blood, body fluids, OPIMs or high titers of cell-associated or free virus via 1) percutaneous, e.g., needlestick; 2) mucosal, e.g., splash in eye or mouth; or 3) cutaneous exposure, e.g., non-intact skin, or involving large amounts of blood or prolonged contact with blood, especially when exposed skin is chapped, abraded, or afflicted with dermatitis.

Employee Exposure

A 24-hour hotline number is available at 115 (Duke phone system) or 919-684-8115 (from a non-Duke number) for immediate evaluation of exposures by EOHW staff. The exposure will be reviewed. Hepatitis B virus (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV) infection status of the source patient/sample will be specifically investigated but the presence of other

bloodborne diseases will be evaluated and appropriate protocols instituted, as needed. Examples of these disease include malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob disease, HTLV-1, and viral hemorrhagic fever.

Information regarding all human blood or body fluid exposures is entered into the OESO blood/body fluid exposure surveillance database (Exposure Prevention Information Network, otherwise known as EPINet). Information includes the type, brand, and purpose of device involved in the incident (if known), the location where the incident occurred, the occupation of the injured employee, an explanation of how the injury occurred, and the source material's infectious status. This data forms the basis for the Duke University Medical Center Sharps Injury Log.

Duke University Employee Occupational Health & Wellness
BBF PROTOCOL: HEPATITIS B EXPOSURE PROTOCOL

EXPOSURE DEFINITION

Significant exposure includes human blood, body fluid, or OPIM contamination via percutaneous route, e.g., needlestick; mucosal contact, e.g., splashed in eye or mouth; or open skin area.

EMPLOYEE EXPOSURE

EOHW staff will review the exposure. Other blood or body fluid exposure protocols will be instituted, as indicated.

Check HBsAg status of source patient.

I. Unvaccinated employee

- A. Source known HBsAg (+) or High Risk that Unknown Source is HBsAg (+), e.g., patients with high risk of HBV carriage or patients with acute or chronic liver disease (serologically undiagnosed)
 - 1. Draw HBsAb, HBsAg, liver panel baseline.
 - 2. Administer single dose of HBIG (0.06 ml/kg body weight) as soon as possible but within 7 days.
 - 3. Start Hepatitis B Vaccine series.
Note: If exposure is >7 days, effectiveness of HBIG is unknown; start Hepatitis B vaccine series if within reasonable proximity of exposure.

4. Post exposure follow-up- for infection - HBsAb, HbsAg in at least 6 months for HBIG administration.

Note: If HBsAb status is non immune, initiate revaccination and perform post vaccination serologic testing (HBsAb) 6 weeks after booster or last dose.

B. Source known, HBsAg (-)

1. Start Hepatitis B vaccine series.

C. Source is Unknown or Source not tested, and low risk that source HBsAg (+)

1. Draw HBsAb, HBsAg, liver panel baseline
2. Start Hepatitis B vaccine series;
3. Post exposure follow-up- HbsAb, HbsAg in 6 months. Note: If HbsAb status is non immune, initiate revaccination and perform post vaccination serologic testing (HbsAb) 6 weeks after third dose.

II. Vaccinated employee

A. Source known, HbsAg (+) or High Risk that source is HbsAg (+), e.g., patients with high risk of HBV carriage or patients with acute or chronic liver disease (serologically undiagnosed).

1. Employee completed all 3 doses.
 - a. If known responder, no treatment.
 - b. If antibody response unknown, test employee and if adequate, no treatment.
 - c. If employee completed a three dose series of HB vaccine and post exposure antibodies inadequate on testing or employee has previously not responded after 3 doses of the vaccine.
 - i. Draw HBsAb, HBsAg, liver panel baseline.
 - ii. Administer single dose of HBIG immediately; (no later than 7 days post exposure) and begin revaccination

series.

- iii. Initiate revaccination
- iv. Post exposure follow-up- HBsAb, HBsAg in 6 months.
Note: If HbsAb status is non immune and second vaccination series completed then classify as nonresponder.

2. Employee completed 1 or 2 dose HB vaccine.

- a. Draw HBsAb, HBsAg, liver panel baseline
- b. Administer single dose of HBIG immediately and continue on schedule with vaccine series.
- c. Continue on schedule with HBV vaccine series.
- d. Post exposure follow-up HBsAb, HBsAg in 6 months
Note: If HBsAb status is non immune, initiate second vaccination series and perform post vaccination serologic testing (HbsAb) 6 weeks after last dose. If HBsAb status remains non immune, classify as a non-responder.

3. If employee is a non-responder status determined after a total 4+ doses.

- a. Draw HBsAb, HBsAg, liver panel baseline.
- b. Administer HBIG x 2 (1 month apart) Administer first HBIG no later than 7 days post-exposure.
- c. If employee previously received less than 6 doses, complete a full second series.
- d. Post exposure follow-up- HBsAb, HBsAg in 6 months Note:
If HBsAb status remains non immune, classify as a non-responder.

B. Source known, HBsAg (-)

- 1. No testing or treatment.

C. Source unknown, or source not tested and low risk.for HBsAg(+).

1. If employee has completed series (3 doses), perform post exposure testing for HBsAb; if adequate response- no further testing or treatment,
2. If antibody response inadequate-
 - a. Draw HBsAb, HBsAg, liver panel baseline
 - b. Initiate re-vaccination to complete series of 3 doses.
 - c. Perform post vaccination serologic testing (HBsAb) 6 weeks after vaccination series completed.

Note: If HBsAb status remains non-immune, classify as a non-responder.
 - d. Post exposure follow-up HBsAb, HBsAg in 6 months.

Duke University Employee Occupational Health & Wellness
BBF PROTOCOL: HUMAN IMMUNODEFICIENCY VIRUS (HIV)

EXPOSURE DEFINITION

Significant occupational exposure includes contamination by human blood, body fluids, OPIM or high titers of cell-associated or free virus via 1) percutaneous route, e.g., needlestick; 2) mucosal contact, e.g., splash in eye or mouth; or 3) cutaneous exposure, e.g., non-intact skin, or involving large amount of blood or prolonged contact with blood, especially when exposed skin is chapped, abraded, or afflicted with dermatitis. For percutaneous injuries, increased risk for HIV infection has been associated with exposure to a large quantity of blood from the source patient via (1) an instrument visibly contaminated with the patient's blood, (2) a procedure that involved a needle being placed directly in a vein or artery, or (3) a deep tissue injury. Feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomitus are not considered potentially infectious unless visibly bloody for the purposes of this exposure protocol.

EMPLOYEE EXPOSURE

Employee must inform EOHW of exposure. Other BBF exposure protocols will be instituted, as indicated. EOHW staff will review the type of exposure, employee status, patient source requesting HIV ab testing as necessary, make a decision on risk, and counsel the exposed employee offering the appropriate post exposure prophylaxis (PEP) based on CDC guidelines*. Source patient will be

informed of HIV AB testing by on site health care provider. This includes research lab personnel who have exposures to high titers of cell-associated or free virus. Other blood and body fluid (B/BF) exposure protocols will be instituted, as indicated.

I. Patient Source is HIV infected, HIV Ab negative but risk behaviors present**, or source is unknown

A. Baseline encounter

1. Evaluate type of exposure, employee status, patient source
2. Counsel employee: risk of exposure, patient source information, offer PAS/EAP
3. Offer/recommend PEP as appropriate. Potential for resistance will be considered and EOHW will consult with ID as needed.
4. Labs
 - a. Stat pregnancy test for women of child-bearing age
 - b. OHS III Panel (includes LFTs, renal function, lipids, glucose, CBC with diff)
 - c. HIV Ab (even in those who decline PEP)

B. 4 week post-exposure

- a. OHS III Panel
- b. HIV Ab

C. 3 months post exposure HIV Ab

D. 6 month post exposure HIV Ab

E. 1 year post exposure for high risk exposure and/or co-infection with HCV: HIV Ab

Note: The 3 month follow-up activity is terminal for compliance purposes.

II. Patient Source HIV Ab negative with no known risk behaviors

- Baseline encounter
- No testing is advised but if the exposed employee requests testing, then HIV Ab is offered
- * Prophylactic medications may be altered based on source patient status.
- ** Some risk behaviors include: any STD (presumptive or documented) now or within recent years (including HBV); IVDU: multiple sexual partners, bisexual, or sexual partners who have the previous risk factors; males who have sex with males; sexual abuse/possibility of sexual abuse; TB.

The employee is counseled privately by EOHW staff on the results of all HIV testing.

Duke University Employee Occupational Health & Wellness
BBF PROTOCOL: HEPATITIS C

EXPOSURE DEFINITION

Significant occupational exposure includes human blood, body fluid or OPIM contamination via percutaneous route, e.g., needlestick; mucosal contact, e.g., splash in eye or mouth; or cutaneous exposure, e.g., non-intact skin.

EMPLOYEE EXPOSURE

EOHW staff will review the exposure. Other blood or body fluid exposure protocols will be instituted, as indicated.

Check HCV status of patient source.

Patient source is anti-HCV reactive or has diagnosis of Hepatitis C:
Baseline Hep C-Ab drawn on all source patients. Request PCR from source patient if Hep C-Ab is positive and exposure indicates or source is newly diagnosed with HCV

- I. If Hep C-PCR is negative then:
 - A. Baseline Hep C-Ab and liver enzymes
 - B. 3 month Hep C-Ab and liver enzymes
 - C. 6 month Hep C-Ab - optional
- II. If Hep C-PCR is positive or not available then:
 - A. Baseline Hep C-Ab and liver enzymes
 - B. 1 month Hep C-PCR and liver enzymes
 - C. 3 month Hep C-PCR
 - D. 6 month Hep C-Ab - optional
- III. Unknown source exposure:
 - A. Baseline Hep C-Ab, HIV ab, and liver enzymes
 - B. 2 month liver enzymes
 - C. 3 month Hep C-Ab, HIV ab
 - D. 6 month Hep C-Ab, HIV ab- optional

Note: For Hepatitis C the 3 month follow-up activity is terminal for compliance purposes.

HBV-, HIV-, or HCV-INFECTED EMPLOYEE*

- A. Employee infected from occupational exposure at Duke University.
 - 1. Evaluation by EOHV and referral for specialty medical treatment.

APPENDIX B

Training Program Contents

BLOODBORNE PATHOGENS TRAINING PROGRAM

Course Title: OSHA Bloodborne Pathogens Standard

Target Population: All employees with routine, anticipated exposure to blood, body fluids, and other potentially infectious materials (OPIM), meeting the following criteria for occupational exposure risk:

1. Direct patient care activities likely to result in direct or indirect exposure to a patient's blood or body fluids.
2. Processing or handling human blood, body fluids, tissues or organs.
3. Processing or handling of equipment, materials or waste that may have been contaminated with human blood, body fluids or other potentially infectious material (OPIM) as defined above.
4. Routine administration of first aid.
5. Processing or handling of unfixed primary or established human cell lines

Course Medium: A variety of courses are available to accomplish this training, including:

1. Medical Center Orientation
2. Allied Health Student Orientation
3. Biological Safety for Housestaff (available on-line)
4. Biological Safety for Physicians (BBP) (available on-line)
5. Biological Safety Level 2 and BBP for Lab Workers (available on-line)
6. Bloodborne Pathogens Training (available on-line)
7. Grand Rounds for Physicians
8. Hospital Administration training

OBJECTIVES:

1. Understand the modes of transmission of bloodborne pathogens, and the philosophy behind "Universal Precautions";

2. Have a general understanding of the epidemiology and symptoms of bloodborne diseases;
3. Be familiar with the Duke University Exposure Control Plan and the means by which the employee can obtain a copy of the written plan;
4. Know the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and OPIM;
5. Be familiar with the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;
6. Know the types, and proper use of personal protective equipment;
7. Know the basis for selection of personal protective equipment;
8. Be informed about Hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;
9. Be informed of the appropriate actions to take and persons to contact in an emergency involving blood or OPIM;
10. Know the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;
11. Be informed on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;
12. Know the signs and labels and/or color-coding required by the standard;
13. Be familiar with waste management, laundry, and housekeeping practices specific for Duke University;
14. Understand his/her role and the University's role in the standard.

HIV, HBV and HCV Research Laboratories Policy

Research laboratories engaged in the culturing or concentration of human immunodeficiency virus (HIV), hepatitis B virus (HBV) and/or hepatitis C virus (HCV) must comply with all requirements outlined in the Duke University Bloodborne Pathogens Exposure Control Plan (ECP) and Biosafety Manual. Standard Operating Procedures (SOPs) are available for the following HIV, HBV, HCV research laboratories. Please contact OESO for copies of these SOPs:

1. HIV RESEARCH LABORATORIES – SORF Building

Director: Kent Weinhold

Location: Surgical Oncology Research Facility (SORF) Building

2. DUKE HUMAN VACCINE INSTITUTE (DHVI)

Director: Barton Haynes

HIV RESEARCH LABORATORIES

Location: Medical Sciences Research Building II (3rd and 4th floors)

HIV RESEARCH LABORATORIES at production scale - DHVI

Location: Global Health Research Building

3. HCV RESEARCH LABORATORY

Principal Investigator: Stacy Horner

Location: CARL 0047, 0062