Bloodborne Pathogens Exposure Control Plan For Duke University Hospital and Clinics, Clinical Research Laboratories, Private Diagnostic Clinics, and Duke Primary Care

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 patient-care areas and work related to patients. If the primary work done in an area is non-clinical, please follow the ECP for Duke University Research Laboratories and Other Non-Healthcare Areas. 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” (OPIM): 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.

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.

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.

1. Puncture Precautions

   a. All 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.

b. All employees must be trained on the availability and use of approved safety devices where appropriate for their work responsibilities. The Biological Safety Division of OESO is available as a resource to review and recommend safety devices. Exemptions to approved devices are identified in Appendix C.

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) for specific procedures 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 must be approved by the Clinical Laboratories, and the mode for safe transport of these exceptions (i.e., in puncture-resistant containers) must be approved by the Biological Safety Division of OESO.

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. There may be exceptions in the OR where the sharp is placed in a hands-free zone before disposal.

g. The puncture-resistant containers must be located as close as practical to areas where disposable 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.

2. <u>Hand/Skin Washing</u>

a. Hands and other skin surfaces must be washed as soon as feasible if they become contaminated with blood, body fluids or OPIM.

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, or OPIM, or where human blood, body fluid specimens, or OPIM are handled.

   b. Food and drink shall not be stored in work areas where human blood, body fluids, or OPIM are present.

   c. Procedures involving human blood, body fluids, or OPIM 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 human 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. The processing and handling of clinical specimens 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.

   b. Facility requirements include, but are not limited to, handwashing sinks, impervious benchtops, no carpets or rugs, and a readily available eyewash station.

c. Laboratory specimens must be collected in leak-proof containers and placed in a sealable secondary container (i.e., Ziploc bag) for transport. Requisition slips should be attached to the outside of the secondary container.

d. 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 or body fluids, and after the work shift.

e. Human 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" or “mycobacteriocidal” disinfectant or a freshly-prepared diluted bleach solution (1:10 or 1:100 bleach:water). Alternatively, the Environmental Services “Virex” has been approved by Infection Control as suitable for human blood/body fluid spills (HIV- and HBV-cidal).

f. 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 OPIM.

g. Disposable, contaminated items (dressings, disposable gloves, gauze, 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.

h. Bulk human blood or body fluids contained in pleurevacs, blood bags, suction liners, materials dripping or saturated with blood, etc. (large volumes) are regulated medical waste and must be placed in "biohazard" boxes lined with plastic bags for proper disposal. Other medical waste is handled according to the Medical Waste Management policy, http://www.safety.duke.edu/sites/default/files/VII_3MedWaste.pdf

i. 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.

j. Biohazard warning signs must be affixed to containers of regulated medical waste, refrigerators and freezers containing 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 health-care workers must routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with any human blood, other 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, OPIM, mucous membranes, or non-intact skin of all patients, for handling items or surfaces soiled with human blood, body fluids, or OPIM, 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, other body fluids, or OPIM (such as during surgical procedures, irrigating wounds, changing tubing, airway manipulation, etc.).

   d. Appropriate protective gowns or aprons must be worn during procedures that are likely to generate splashes of human blood, other body fluids, or OPIM. For procedures during which it is anticipated that 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 human blood or other infectious materials, contact OESO – Biological Safety for assistance, 919-684-8822.

   e. Duke will provide, replace, clean or launder personal protective equipment (PPE). The PPE must be removed prior to leaving the work area. (Note: Scrubs or personal clothing do not constitute PPE.)

f. Surgical caps or hoods, shoe covers or boots must be worn in instances where gross contamination with human blood/body fluids or OPIM is reasonably anticipated (i.e. autopsy, surgery).

g. Resuscitation bags or other ventilation devices should be available in areas where resuscitation is predictable.

B. Compliance Monitoring

1. OESO and/or designee will conduct routine site audits and investigate reasons for non-compliance with the policy as identified through these audits, complaints or reported exposures.

2. OESO and/or designee 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, 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 Exposure Control Plan (ECP) and other relevant safety procedures.

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 unfixed primary or established human cell lines.

b. Employees with occupational exposures to blood or body fluids 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 (Duke Hospital) or to obtain the vaccine.

2. Post-exposure Evaluation and Follow-up

a. All human blood, body fluid, or OPIM exposures via needlesticks, punctures, or broken skin or mucous membrane contact must be reported immediately by calling the Exposure Hotline at 115 (Duke Hospital phone system) or 919-684-8115 (other 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.

1. Labels and Signs

a. Biohazard warning signs must be affixed to containers of regulated medical wastes, refrigerators, freezers, and incubators containing human blood, body fluids, or OPIM; and other containers or bags used to store or transport contaminated equipment, materials, needles and sharps.

i. 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 warning signs must incorporate the universal biohazard symbol and be predominantly fluorescent orange. All biohazard warning signs can only be distributed by OESO.

2. 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, for example orientation training for nurses, incoming housestaff, volunteers, and allied health / medical students.

c. On-line training includes a quiz that must be passed for compliance.

d. Area-specific training is provided upon request.

e. Physician-oriented training is provided during physician Grand Rounds upon request. On-line training modules designed for attending physicians and housestaff are also available.

f. Departments who wish to provide area-specific or departmental training may do so upon approval of training material by OESO.

g. 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.

h. 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 at least quarterly.

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.

3. 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 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 Exposure Control Plan 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 at the time were initially 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, EOHW, and Infection Prevention at Duke Hospital at least annually and submitted for approval by the Duke University HICC, 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 HICC, 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, 2/14, 2/15, 2/16, 2/17, 5/18, 9/19, 12/19, 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, other body fluids, OPIM 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 (off-site service) 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 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, other 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.

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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, other 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 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 lll 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 lll 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, other 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.

<u>Patient source is anti-HCV reactive or has diagnosis of Hepatitis C:</u>
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.

INFECTED EMPLOYEE

The purpose of these guidelines is to address health care workers (HCWs) who have active infection with Hepatitis B virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus (HIV).

HCWs infected with HBV, HCV and/or HIV shall inform EOHW of their status.

Those who come to the attention of EOHW will be assessed individually as to risk of transmission in patient care setting. A confidential occupational assessment will be conducted by a committee made up of the chairperson of the HICC, the director of EOHW, and a key informant (often a division chief, physician or clinical operations manager selected to preserve anonymity of the employee) who provides detailed information on job duties. The function of the committee is to assure that no patient is exposed to undue risk from a HCW known to have tested positive for HBV, HCV and/or HIV. The HBV and HIV-Infected HCWs will be notified of their responsibility to report to the State Health Director via State law.

Information concerning health status and work activities will be confidentially collected from appropriate resources and presented confidentially to the assessment committee. Decisions of this committee on need for a change in work activities will be based on current clinical standards of care and recent

recommendations (SHEA Guideline for Management of Healthcare Workers who are infected with HBV, HCV and/or HIV (*Infect Cont Hosp Epid.* 2010. Vol. 31, no.3. 203-232). It is the function of the assessment committee to advise EOHW regarding a change in work activities and any required periodic surveillance. Implementation of recommendations made by the committee will be administered through and according to policies of EOHW.

HCWs with HBV, HCV, and/or HIV infection will be reassessed periodically (based on health status and job risk) for their ability to safely continue their work activities.

The work status of the healthcare worker will be communicated to the hiring manager or Director. Information regarding specific cases will include recommendations for changes in the work status but will be strictly confidential. Medical records are not shared with management.

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 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 Physicans (BBP) (available on-line)**
5. **Biological Safety Lovel 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.

APPENDIX C

APPROVED SAFETY DEVICES IN USE AT DUKE UNIVERSITY

All employees must be trained on the availability and use of approved safety devices where appropriate for their work responsibilities. The Biological Safety Division of OESO is available as a resource to review and recommend safety devices. Exemptions to approved devices are identified below.

Exemptions:

Clinical areas or departments may apply to the Biological Safety Office for an exemption from use of a safety device stocked in the hospital or clinic if there is documented, clinical need for a non-safety version of the device. The exemption must be approved through the Biological Safety Office and the Duke University Safety Committee. Temporary approval can be granted by Biological Safety when deemed necessary. Approved exemptions currently include:

1) ICN:
   - Need non-safety 24ga, 0.56" IV catheters due to the bulk added and the difficulty in obtaining access to the 400-500 gram infants. (Safety piece is sometimes bigger than the infants' extremities).
   - Need non-safety 24ga and 28ga PICC catheters for the same reasons above.

2) ED:
   - Need to stock non-safety 24ga (in addition to safety) for the infants that are very ill and often dehydrated. Some nurses have experienced that the safety catheter pulls the catheter out before you can tape in place.

3) PICU, ICN, Peds Cath Lab:
   - Need non-safety butterflies because of an established practice in pediatrics when MDs use the butterfly as an introducer for A-lines by cutting off the tubing. This cannot be done with the safety butterfly.

4) Duke Primary Care - Wake Forest (DPC):
   - Need non-safety 30ga needles for physicians to use for trigger point injections and local anesthesia. No safety needles that size are available. The 27 ½ ga safety needles are ineffective.

5) Advanced Heart and Lung Clinic (2F/2G):

- Clinic staff have to change needles on the syringe after drawing up vaccines ("dry" needle technique). The 27 ½ ga safety needles cannot be changed, so the old non-safety 27 ½ ga needle is requested. (This was a special "carve out" for the clinics when the safety hypodermic needles were implemented).

6) Duke Primary Care Oxford:
   - Staff need non-safety 30ga, ½" needles (safety not available) for Candida antigen intralesional injections in the treatment of Verruca Vulgaris according to the Pfenninger protocol. Safety insulin needles were tried but fell apart during the procedure.

7) Nuclear Medicine, Nuclear Cardiology, Radiopharmacy and PET:
   - After review of all safety devices available, cannot find a safety needle/hypodermic needle combo that will accommodate the safety radiation syringe shields. Need non-safety hypodermic needle.

   - Requests the following sizes of non-safety syringes in order to accommodate the radiation shields on the syringes:
     - 16ga, 1.5in needle
     - 16 ga, 3.25 angiocath
     - 18 ga, 3.5 in spinal needle
     - 19 ga, 3.5 in spinal needle
     - 19 ga, 5 in IMI needle
     - 20 ga, 1 in needle
     - 20 ga. 1 in needle with 5ml syringe
     - 20 ga, 1.5 in needle
     - 21 ga. 1 in needle with 3ml syringe
     - 21 ga, 2 in needle
     - 23 ga, 1 in needle
     - 23 ga, 1 in needle with 3ml syringe
     - 25 ga, 5/8 in needle
     - 27 ga. 0.5 in needle
     - 27ga, 0.5 in 1ml TB syringe
     - 28 ga, 0.5 in insulin syringe

8) Duke Primary Care (DPC):
   - Non-safety 30ga, ½" needles for injection of anesthesia for the comfort of the patient (safety not available in that size yet).

9) Duke Primary Care Croasdaile:

- Non-safety 30ga, ½" needles for local anesthesia during biopsy procedures for the comfort of the patient.

10) Transfusion Services:
- The safety Mylar coated capillary tubes are too large (diameter) and too short to phenotype donor inventory to identify suitable units for patients with antibodies. They need the Chown capillary tubes which are made of glass (non-safety).

11) Duke Urgent Care:
- Needs 25 ga, 1 ½ inch non-safety needles to use during procedures such as digital blocks (i.e., fingers or toes), cortisone injections, etc.

12) ASC OR:
- Needs 25 ga, 1 ½ inch non-safety needle: length of safety device is too short for surgeons to place anesthesia into tissues, and for patient comfort.

13) Duke Primary Care Mebane:
- Needs 30 ga non-safety needle for sclerotherapy in order to inject into the small spider veins.

14) Endocrinology (Clinic 1A):
- Needs 20 ga, 1.5 inch non-safety needle for thyroid nodule aspiration. There is a 3 inch 20 ga safety available, but it is too intrusive when aspirating the neck.

15) Cardio-thoracic Surgery:
- Physicians are having trouble with the safety needles when they place into the aorta, ventricle or other cardiac structure to "de-air" the heart. The safety feature gets in the way, and can cause injury to other vessels or structures when working in such a small area.

16) IVF lab (Obstetrics and Gynecology):
- Needs non-safety needle to manipulate oocytes and embryos. The safety needles are too cumbersome for microscopic procedures.

17) Duke Eye Center:
- Needs 22ga, 1 ½ inch non-safety needle for retrobulbar injections of the eye (the safety guard gets in the way of the eye)

- Needs 27ga, ½ inch non-safety needle for intravitreal injections of the eye. (see above)
- Needs 30ga, ½ inch non-safety needle for anterior chamber paracentesis of the eye (see above)
- Needs 25 ga, 5/8 inch non-safety needle for sub-conjunctival injections and posterior subtenon's injections of the eye (see above)
- Needs 20 ga, 1 ½ inch non-safety needle to secondarily infuse the eye during cataract fragmentation (the safety guard gets in the way)
- Needs 21 and 23 ga non-safety butterfly needles in order to secondarily infuse during some eye surgeries (safety guard is cumbersome)

18) Radiology Lab:
- Needs the following sizes of non-safety needles because of the interference of the safety shield with the radiation shields used for protection from radioactive–labeled monoclonal antibodies used for brain tumor patients:
  - 27ga, ½ in,
  - 22ga, 1 ½ in
  - 20ga, 1 ½ in
  - 16ga, 1 ½ in

19) Fine Needle Aspiration Biopsy Service:
- Needs the following sizes of non-safety needles in order to properly approach discrete lesions and perform the necessary excursions:
  - 23ga, 25ga, 1 in.
  - 20ga, 23ga, 25ga, 1 ½ in

20) Duke Sports Science Institute Wallace Clinic:
- Needs 16 and 19 ga non-safety (Sports Med) and 18 ga non-safety (Orthopeds) to aspirate joints. Joint fluid is too thick to aspirate through the small gauges (no large safety needles).

21) Duke Urgent Care:
- Needs 27ga 1 ¼ ga needle to perform digital blocks. Safety sheath gets in way of visualization when manipulating needle to reach several areas of the digits of the hand or toe.

22) Duke Outpatient Clinic (Roxboro Rd):
- Needs non-safety needles in order to reach sites for the following procedures:
- 25ga,1 ½ in. - for ankle & wrist aspirations

- 21ga, 2 in. - for hip steroid injections.
- 18ga, 1 ½in. - for hip injections

23) Oral Surgery / Otolaryngology, Head and Neck Surgery (1F)::
- Requests the following non-safety needle for use in the mouth (using a recapping device, “The Protector - Needle Sheath Prop Disposable one-handed recapper", around the cap because the needle is used multiple times on the same patient): 27ga, short
- Requests non-safety for 25 Ga 1 1/2" and 27 Ga 1 1/4" for injections into the ear canal and nose. Safety cover gets in the way
- Requests non-safety for 16 Ga 1 1/2" and 19 Ga 1 1/2" needles to conduct peri-tonsillar abscess aspirations

24) Duke Aesthetic Center
- Requests non-safety for 30 Ga needles for injections around the eye, such as Botox or Kenalog injections. The safety device blocks the view of the proper injection site, preventing ideal placement of the needle tip into the tissue. Needles with a safety device are more painful for patients because they are not as sharp.

25) Duke Vascular Specialist of Raleigh
- Requests non-safety for 25 Ga 1.5” needles to conduct ultrasound guided sclerotherapy. The safety cap obstructs the ultrasound probe.

26) Duke Vascular Specialist Endovascular Center
- Requests non-safety for 25 Ga 1.5” needles to inject Lidocaine under Ultrasound Guidance. The safety cap obstructs the ultrasound probe.

Evaluation of Safety Devices:

Safety devices for the highest priority devices, such as hypodermic needles, phlebotomy needles, butterfly, and IV stylets, were implemented at Duke 1998-2002. The need for changes in engineering controls (i.e., safer sharps devices or work practices) was identified through evaluation of the employee exposure database or was requested from frontline employees. A Safety Device Steering Committee consisting of representatives from Biological Safety, Infection Control, Nursing, Procurement Services, and Material Services evaluated the needs and priorities for safety device implementation. Sub-committees with appropriate representation were then appointed to screen specific safety devices. Clinical trials were then conducted by employees in areas of high device usage. Evaluations using the standardized forms developed by the “Training for

development of innovative control technology project (TDICT)" from San Francisco General Hospital were conducted and scored. Selected devices were approved through the Duke University Product Standardization Committee.

New safety devices are implemented after performing clinical trials of proposed devices and receiving evaluations from clinical staff that use the devices. Procurement Services ensures effective implementation of the new devices. Effectiveness of the safety sharps devices is determined by evaluating associated reported employee exposures as requested.

1) In 2001, safer phlebotomy needles ("Eclipse") and the blood transfer devices were evaluated by the phlebotomy team and frontline employees in other high use areas of the hospitals (ED, clinic labs, Mother-Baby Unit, Dialysis). In addition, the "Pronto" quick-release, reusable vacutainer holder was trialed by the phlebotomy team and approved for use on phlebotomy trays or in phlebotomy work stations where the discarding of holders with every needle generates an unmanageable medical waste burden. The "Pronto" holder usage was discontinued in 2002 based on a letter of interpretation from the NC OSHA office. Employees are to use the new disposable holders and discard with every needle used.

2) A committee was established in summer, 2001, to coordinate evaluations of safer hypodermic needles for use throughout the Duke University Health System. The Committee consisted of the Safety Device Steering Committee, with additional representation from the Private Diagnostic Clinics (PDC), Duke University Affiliated Practices (DUAP), Duke Hospital Pediatrics, ED, and Anesthesiology. The Safety Hypodermic Needle Committee screened safer products and narrowed trials to 3 manufacturers: Sims Portex, BD, and Kendall. Clinical trials were conducted in the high use areas: Duke PDCs (Allergy, Infectious Disease, Travel), Pediatrics, Emergency Department, and the DUAP clinics. Evaluations were conducted by non-managerial employees responsible for direct patient care. Based on evaluations, the Duke Product Standardization Committee approved the implementation of the BD "Eclipse" in Duke Hospital and PDCs. The Sims Portex was the preferred product and was implemented at the Duke University Associated Practices (DUAPs) in December, 2002.

3) A safety syringe ("Vital Signs") that met the clinical criteria set forth by Dr. John Toffaletti, Director of the Blood Gas Lab, was evaluated by the Pulmonary Function Team. The safety syringe was accepted for procurement by the Product Standardization Committee in February, 2002, and has been implemented.

4) Based on data that indicated a slower than anticipated decline in exposures and comments from employees, a new push-button winged steel needle (butterfly) was trialed in 2003 in phlebotomy and pediatrics. Based on favorable evaluations by users, the new device was implemented in December, 2003.

5) The IV team evaluated a new adhesive system to secure IV catheters ("Statlock") in November, 2004. They tested it on PICCs but felt it did not secure the line appropriately.

6) The Atrium Chest Tube with safety access port was trialed in Duke North OR, 3100, 3200, and 3300 March 3-10, 2009. Comments from 19 employees who used the Atrium Chest Tube recommended that the Atrium Chest Tube be used at Duke University Hospital.

7) Children's Health Center, 4th floor, trialed Becton-Dickinson (BD) Eclipse SQ and ID needles and BD Eclipse Blunt needles during August 2010. Eight of nine nursing staff recommended implementation of the SQ and ID needles, and six of seven nursing staff recommended implementation of the blunt needles.

Other safety devices implemented throughout the hospital have been evaluated by employees in individual departments for devices meeting specific needs, such as the Safety hemodialysis fistula set, or the Inviromedical Retractable Needle for use in Eye Surgery.