

SECTION	VI	Biological Safety
Chapter	1	Bloodborne Pathogens
Revision Date		03/2009

Duke University Bloodborne Pathogens Exposure Control Plan
March, 2009 (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](#), and is implemented by the Occupational and Environmental Safety Office (OESO). The ECP represents an expansion of the procedures detailed in the Duke University Blood and Body Fluid Precautions Policy (Appendix A). The major provisions of this plan are as follows:

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 (PIMs) 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 (see Appendix A)**; 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.

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 (PIM) as defined above.
- 4. Routine administration of first aid.
- 5. Processing or handling 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 under "Management Reports". Safety compliance reports are also available at this site. Employees who do their training on-line are asked to complete bloodborne pathogens exposure determinations at the time they log in if this information is not available.
 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 will maintain a complete database of the exposure risk determinations.
- E. Contact OESO Biological Safety at 684-8822 or the Training Coordinator at 684-2794 for further information.

II. SCHEDULE AND METHOD OF IMPLEMENTATION

- A. The ECP and all appendices were approved by the Hospital Infection Control Committee (HICC) on May 20, 1992. This material will be reviewed and updated when indicated, but at least annually. The revised ECP will be approved by the HICC, the Duke University Safety Committee (DUSC), and the Executive Committee of the Medical Staff.
- B. Methods of Compliance
1. Methods of compliance are defined in the Duke University Blood and Body Fluid Precautions Policy (Appendix A).

2. Implementation will be accomplished through training, the [Duke University Safety Manual](#), the [Infection Control Manual](#), and site audits.

C. Compliance Monitoring

1. OESO will conduct site audits and investigate reasons for non-compliance with the policy as identified through 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, 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.
 - b. Have access to appropriate and necessary personal protective equipment.
 - c. Receive training, as required by this ECP.
5. Failure to comply with this policy will be managed as a work rule violation through the University policy on disciplinary actions.

D. HIV and HCV Research Laboratories

1. The HIV and HCV Research Laboratories and Production Facilities Policy are defined in Appendix B.
2. Implementation will be accomplished through site audits and on-site training.

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

1. 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:

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

2. Hepatitis B vaccination procedures and post-exposure evaluation and follow-up procedures are presented in Appendix C.

F. Communication of Hazards to Employees.

1. Labels and Signs

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

2. Information and Training

- a. The requirements of the bloodborne pathogens training program are detailed in Appendix D.
- 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. A 24-hour pager number is provided for any questions.
- d. Area-specific training is provided upon request.

- e. Physician oriented training is provided during physician Grand Rounds.
- 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 1-4 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 a 24-hr basis on questions relating to the standard.

G. Recordkeeping

- 1. Exposure risk determination records will be maintained by OESO in a safety management computer database.
- 2. Training Records
 - a. Institutional training records will be maintained by OESO in a safety management computer 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 computer 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 "Safety Manuals" link, under "University Safety Manual".
- B. A link to the ECP is also included in the Duke University Laboratory Safety Manual.
- C. Copies of the ECP are available in many work areas. Ask your supervisor about the location of the ECP in your work area.
- D. A copy of the ECP will be provided to any employee upon request to OESO.

IV. REVIEW AND UPDATE OF ECP

- The ECP will be reviewed by OESO at least annually and submitted for approval by the HICC, the DUSC, and the Executive Committee of the Medical Staff.
- 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.
- Affected employees will be trained regarding these modifications following approval either through the annual update training or through department-specific training.

APPENDIX A

DUKE UNIVERSITY BLOOD AND BODY FLUID PRECAUTIONS POLICY

A. UNIVERSAL BLOOD AND BODY FLUID PRECAUTIONS

1. 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.

2. Rationale

- *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.*
- *OSHA mandates that Universal Precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.*
- The “Duke University Blood and Body Fluid Precautions Policy” requires that 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.
- 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, all primary human cell lines, and any established 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.

3. Authority

OSHA mandates that universal blood and body fluid precautions be implemented as part of an exposure control plan (29CFR 1910.1030). The N.C.

Communicable Disease Law mandates compliance with Universal Precautions in the healthcare setting as of February 1, 1988 (10NCAC 7A.0209 d 9). At Duke University, the Hospital Infection Control Committee (HICC), the Duke University Safety Committee (DUSC) and the Executive Committee of the Medical Staff have approved the implementation of Universal Precautions.

B. SPECIFIC IMPLEMENTATION

1. Engineering and Work Practice Controls

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

a. Puncture Precautions

- i. 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.
- ii. All employees must be trained on the availability and use of approved safety devices where appropriate for their work responsibilities. The specific safer sharps in use at Duke University and dates of implementation include:

Retractable safety lancets - 1989
Blunt suture needles - 1994
The "Interlink" needleless IV heplock system - 1996
The "safety-lok" shielded winged steel needle - 1999
Safety "Autogard" IV catheter needles - 1999
Mylar-coated capillary tubes – 1999
The "Eclipse" safety phlebotomy needle – 2001;
The "Pronto" push-button release vacutainer holder – 2001(discontinued 2002)
The Blood Transfer Device – 2001
"Vital Signs" safety blood gas syringe – 2002
The "Eclipse" safety hypodermic needle (DH, RCH, PDCs)-2002
The Sims Portex safety hypodermic needle (DRH, DUAPs)-2002
Safety "PICC" catheter – 2002
"Safety Glide" insulin and TB needle - 2002
Blood Transfer Device #2 (Kendall) – 2003
Push-button winged steel needle – 2003
Arrow Introducer Kits (Safety scalpel) – 2003

Safety Huber needle – 2004
Sims (Futura Medical) safety disposable scalpels – 2004
“Safeset” closed A-line blood collection system - 2004
Safety hemodialysis fistula set (Medisystems Corp) – 2004
Integra retracting needle/syringe – 2004
Crile-Wood needle driver – 2005
Vantex double lumen kit (Edwards’) – 2005
Accudrain CSF drainage system (needleless sample aspiration) – 2005
Foley bags (BARD) (needleless sample aspiration) – 2005
Arrow Triple Lumen kits, CDC version, 100k lives campaign (all safety products except for finder needle: not available) – 2005
InviroMedical Retractable Safety Syringe-Eye Center - 2007

- iii. The need for changes in engineering controls (i.e., safer sharps devices or work practices) is identified through evaluation of the employee exposure database or as requested from frontline employees. A Safety Device Steering Committee consisting of representatives from Biological Safety, Infection Control, Nursing, Procurement Services, and Material Services evaluates the needs and priorities for safety device evaluation. Sub-committees with appropriate representation are then appointed to screen specific safety devices. Clinical trials are 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 are conducted and scored. Selected devices are approved through the Duke University Product Standardization Committee. Procurement Services ensures effective implementation of the new devices. Effectiveness of the safety sharps devices is determined by evaluating associated reported employee exposures on a quarterly basis and is part of the Performance Improvement Plan of the hospital.
- iv. 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. 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 feel 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) Nuclear Medicine, Nuclear Cardiology, PET, and Radiopharmacy:
 - 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.
 - 5) Wake Forest Family Physicians (DUAP):
 - 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.
 - 6) Allergy 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).
 - 7) Oxford Family Physicians:
 - Dr. Joanne Fruth needs 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.

- 8) Radiopharmacy and PET:
- Diane Walker 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, 1.5 in needle
 - 21 ga, 2 in needle
 - 23 ga, 1 in needle
 - 23 ga, 1 in needle with 3cc syringe
 - 25 ga, 5/8 in needle
 - 27ga, 0.5 in 1cc TB syringe
 - 28 ga, 0.5 in insulin syringe
- 9) DUAP:
- Non-safety 30ga, ½” needles for injection of anesthesia for the comfort of the patient (safety not available in that size yet).
- 10) Family Medical Associates:
- Non-safety 30ga, ½” needles for local anesthesia during biopsy procedures for the comfort of the patient.
- 11) 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).
- 12) 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.
- 13) 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.
- 14) Brookhollow Family Practice:

- Needs 30 ga non-safety needle for sclerotherapy in order to inject into the small spider veins.
- 15) Endocrinology (Dr. Warner Burch):
- 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.
- 16) 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.
- 17) IVF lab:
- Needs non-safety needle to manipulate oocytes and embryos...the safety needles are too cumbersome for microscopic procedures.
- 18) 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).
- 19) Dr. Xiao-Guang Zhao’s 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

- 20) 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
- 21) PDC Sports Medicine and Orthopedics Clinic:
- Needs 16 and 19 ga non-safety (Sports Med) and 18 ga non-safety (Orthopedics) to aspirate joints. Joint fluid is too thick to aspirate through the small gauges (no large safety needles).
- 22) 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.
- 23) 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
- 24) Oral Surgery:
- 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
- 25) Otolaryngology, Head and Neck Surgery:
- 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

v. Evaluations:

- 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), Durham Regional Hospital, Raleigh Community Hospital, 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, Durham Regional Hospital, Duke Raleigh Hospital, 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 “Eclipse” was also the preferred product at Duke Raleigh Hospital. The Sims Portex was the preferred product and was implemented at Durham Regional Hospital and 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. Therefore, the hospital will continue with the Arrow stapling

device to secure catheters, except in areas where patients complain about the pain of removal of the staple (Cardio-Thoracic and SICU). In those situations, the suture needle is used to suture in the catheter.

- 6) 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.
- vi. 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 approved by the Biological Safety Division. Any approved recapping procedures must be done either by using a recapping device or a one-handed scoop method for recapping.
 - vii. 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.
 - viii. 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.
 - ix. After use, disposable syringes and needles, scalpel blades, scissors, slides, any activated or unactivated safety devices, and other sharp items must be placed in puncture-resistant containers for disposal.
 - x. 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.
 - xi. Leak proof, puncture-resistant containers must be used to transport reusable sharps to the reprocessing area.
- b. Hand/Skin Washing
- i. Hands and other skin surfaces must be washed as soon as feasible if they become contaminated with blood or body fluids.

- ii. Hands must be washed as soon as feasible after gloves are removed, and when leaving the work area.

c. Standard Safe Work Practices

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

d. Laundry

- i. Soiled linen or reusable protective clothing must be handled as little as possible.
- ii. All used laundry should be considered potentially infectious and should be placed in the standard laundry bags which have been chemically treated to minimize fluid leakage.
- iii. If linen is soaked with blood or body fluids and is likely to leak through a single bag, "double-bags" are to be used.
- iv. Laundry to be processed via an outside contractor must be placed in a labeled laundry bag for transport.

e. Environmental Controls

c. Clinical Laboratory Containment:

- i. The processing and handling of clinical specimens shall be done in accordance with biosafety level-2 (BSL-2) containment guidelines [<http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s3.htm>]. BSL-2 work practices are consistent with the concept of Universal/Standard Precautions.

- ii. Facility requirements include, but are not limited to, handwashing sinks, impervious benchtops, no carpets or rugs, and a readily available eyewash station.
- ii. 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.
- iii. 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 blood or body fluids, and after the work shift.
- iv. 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).
- v. Protective coverings, such as imperviously-backed absorbent paper, used to cover surfaces must be removed as soon as feasible when overtly contaminated with blood or body fluids.
- vi. 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.
- vii. Bulk 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 Center Medical Waste Policy.
- viii. 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.
- ix. Biohazard warning signs must be affixed to containers of regulated medical waste, refrigerators and freezers containing blood or other PIM; and other containers or bags used to store or transport contaminated materials, needles and sharps.

2. **Barrier Precautions (Personal Protective Equipment)**

All health-care workers must routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with any blood or other body fluids 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.

- a. Gloves must be worn for touching blood or body fluids, mucous membranes, or non-intact skin of all patients, for handling items or surfaces soiled with blood and body fluids, and for performing venipuncture and other vascular access procedures.
- b. 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 blood or other body fluids.
- c. Appropriate protective gowns or aprons must be worn during procedures that are likely to generate splashes of blood or other body fluids. For procedures during which you anticipate your clothing will be soaked, fluid resistant aprons or gowns must be worn.
- d. Surgical caps or hoods, shoe covers or boots must be worn in instances where gross contamination with blood/body fluids is reasonably anticipated (i.e. autopsy, surgery).
- e. Resuscitation bags or other ventilation devices should be available in areas where resuscitation is predictable, in order to minimize the need for emergency mouth-to-mouth resuscitation.

3. **Hepatitis B Vaccination**

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 684-3136 to obtain the vaccine.

C. **EXPOSURES**

All blood or body fluid 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 684-8115 (off-site service) for appropriate post-exposure follow-up and reporting on-line to the Safety Reporting System or calling Employee Occupational Health and Wellness (684 3136)

D. ASSISTANCE

Additional information regarding Universal Precautions and the Duke University Bloodborne Pathogens Exposure Control Plan may be found in the [Infection Control Manual](#) and the [Medical Center Safety Manual](#). The Biological Safety Division of OESO should also be contacted at 684-8822 for assistance in implementing procedures or to provide training for employees in Universal Precautions and the Bloodborne Pathogens Exposure Control Plan.

Date Revised: 6/97, 8/98, 8/99, 2/10/03, 12/09/04, 02/15/05, 02/06, 03/07, 03/08

HIV, HBV and HCV Research Laboratories Policy

1. HIV RESEARCH LABORATORIES – SORF Building

- A. 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).
- B. A biosafety manual and Standard Operating Procedures (SOP) must be prepared to address the additional requirements that follow. This manual must be periodically reviewed and updated at least annually. Personnel working in the laboratory must read the biosafety manual and SOPs and must follow the outlined practices and procedures.

1. Standard Microbiological Practices

- a. Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the work area.
- b. Mouth pipetting is prohibited.
- c. Persons must wash their hands after handling infectious materials and animals and when they leave the laboratory.
- d. All procedures must be performed in a biological safety cabinet to minimize the exposure to aerosols.
- e. Work surfaces must be decontaminated at least once a day and after any spill of infectious material.
- f. All infectious liquid or solid wastes must be decontaminated before disposal.

2. Special Practices

- a. Access to the work area must be limited to authorized persons. Procedures for authorizing admittance to the work area must be described in a written document, and only persons who meet the following criteria shall be allowed to enter the work areas or animal rooms:

- i. Individuals must be advised of the potential biohazard,
 - ii. Individuals must meet specific entry requirements, i.e. immunization, or alternatively they must sign a waiver indicating that they have been informed of the potential hazards.
 - iii. Individuals must comply with all entry and exit procedures.
- b. Signs incorporating the universal biohazard sign must be posted on all access doors and must contain the following information:
 - i. Name of the infectious agent
 - ii. Special requirements for entering the area
 - iii. Name, telephone number of the laboratory director or other responsible person.
- c. Laboratory doors must be kept closed when experiments involving HIV, HBV, or HCV potentially infected materials are in progress.
- d. Laboratory coats, gowns, or other appropriate protective clothing must be used in the work area and animal rooms. Protective clothing must not be worn outside of the work area and must be decontaminated before laundering or disposal.
- e. Gloves must be worn when working with infectious materials and when handling infected animals.
- f. All activities involving infectious materials that pose a threat of exposure to droplet, spills, or aerosols must be conducted in biological safety cabinets or other physical-containment devices, such as centrifuge safety cups and sealed centrifuge rotors.
- g. The following shall apply to hypodermic needles, syringes, and other sharps:
 - i. glass pipettes are not permitted in the laboratory and use of other sharps and glassware should be avoided whenever possible,
 - ii. extreme caution must be used when handling needles and syringes,

- iii. needles shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles,
 - iv. only needle-locking syringes or disposable syringe-needle units shall be used for the injection or aspiration of potentially infectious materials,
 - v. needles must not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use,
 - vi. the needle and syringe must be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.
- h. Vacuum lines must be protected with high efficiency particulate air (HEPA) filters or filters of equal or superior efficiency and with traps containing liquid disinfectant traps. Filters must be checked routinely and maintained or replaced as necessary.
 - i. All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with concentrated infectious materials.
 - j. All spills or accidents that result in an exposure to personnel must be immediately reported to the laboratory director and Employee Occupational Health Services by calling the Exposure Hotline at 115 (Duke phone system) or 684-8115 (off-site) for appropriate follow-up.
 - k. Equipment which may become contaminated with blood or other potentially infectious material must be examined prior to servicing or shipping and must be decontaminated as necessary.
 - l. Contaminated materials that are to be decontaminated at a site away from the laboratory must be placed in a durable, leak-proof, labeled or color-coded container which is closed and disinfected on the outside surface before being removed from the work area.
 - m. All waste from work areas and animal rooms must be either incinerated or autoclaved before disposal.
3. Containment Equipment

Biological safety cabinets shall be certified when installed, whenever they are moved, and at least annually.

4. Laboratory Facilities

- a. The work areas must be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the work area from access corridors or other contiguous areas.
- b. Access doors to the work area or containment module must be self-closing.
- c. Each laboratory shall contain a facility for hand washing and an eye wash unit which is readily available within the work area. The sink at the work area exit shall be foot, elbow, or automatically operated.
- d. An autoclave for decontamination of regulated waste must be available within or as near as possible to the work area.
- e. The surfaces of doors, walls, floors and ceilings in the work area must be water resistant so that they can be easily cleaned. Penetrations in these surfaces must be sealed or capable of being sealed to facilitate decontamination.
- f. A ducted exhaust-air ventilation system must be provided. This system must create directional airflow that draws air into the work area through the door (i.e., negative pressure). The exhaust air must not be recirculated to any other area of the building, must be discharged to the outside, and must be dispersed away from occupied areas and air intakes. The proper direction of the airflow must be verified.

C. Training Requirements

1. Employees in HIV, HBV, and HCV Research Laboratories shall participate in the training program outlined in Appendix F of the ECP (or equivalent).
2. In addition, employees in HIV, HBV, and HCV Research Laboratories shall meet the following requirements:
 - a. Demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV, HBV, or HCV.
 - b. Possess experience in the handling of human pathogens or tissue cultures before working with HIV, HBV, or HCV.

OR

- c. The supervisor must provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities must not include the handling of infectious agents. The supervisor must assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

D. Medical Surveillance

All research personnel that actively handle HIV and SIV cultures or human specimens in the HIV Research Lab must complete the following through Employee Occupational Health and Wellness (EOHW):

- EOHW health screening for laboratory worker
- Must be offered the hepatitis B vaccination/serology as indicated
- HIV baseline serology, initial and exit

Accidental exposures, such as splash to the face or a sharps injury shall be reported immediately to EOHW by dialing **684-8115**. The EOHW representative will help categorize the risk of developing occupationally-acquired infection and provide advice on an appropriate post-exposure treatment.

2. HIV RESEARCH LABORATORIES - DHVI

A. Introduction

A significant portion of the DHVI's research activities are focused on better understanding the mechanism of human immunodeficiency virus (HIV) infection, and the roadblocks of protective immunity. The research will involve the manipulation and culturing of live HIV and simian immunodeficiency virus (SIV).

B. Purpose

The purpose of this procedure is to outline the DHVI's approach to laboratory containment of all laboratory-scale HIV and SIV work. The term "containment" includes a combination of laboratory work practices, safety equipment and facility design.

C. Routes of Exposure

Prior to assigning containment requirements, it is imperative to understand the routes of transmission.

Sharps exposures: This is the **most important exposure route** for HIV and other bloodborne pathogens. Virtually all cases of laboratory-acquired HIV infection have resulted from injury by a contaminated sharp object, such as a needlestick. This is the most important focus of this procedure. No glassware or needles will be used for work with HIV. Staff will attempt to eliminate the use of all other sharps, and adhere to strict precautions when they must be used. The absolute risk for HIV infection in laboratory workers is low. Without treatment, the rate of HIV infection after a needlestick with infected blood is around 0.3%. This rate may be lowered further by treatment after exposure.

Splash exposures: Splashes are **less likely** than sharps exposures to transmit HIV and other bloodborne pathogens. HIV and hepatitis C virus (HCV) have been transmitted in the laboratory environment by a splash to the eye. It is theoretically possible to acquire HIV infection by exposure of the nose and mouth. Our goal is to eliminate splash risk by using eye, nose, and mouth protection (full-face protection) at all times in an HIV Research Lab.

Non-intact skin exposures: The risk of transmission of HIV by skin contact is **very low**. Non-intact skin refers to the presence of cuts, scrapes, or a significant rash. HIV was transmitted to a health care worker after exposure of non-intact skin to a large volume of HIV-infected blood. Staff shall wear

gloves and seamless-front gowns, a practice that will minimize the risk of skin contact.

Other exposures: HIV and other blood borne pathogens are **not transmitted** by food and drink, or by inanimate objects such as clothing, books, and paper. Staff shall still take precautions to avoid contamination of these objects with hazardous materials.

D. Medical Surveillance and Screening

All research personnel that actively handle HIV and SIV cultures or human specimens in the HIV Research Lab must complete the following through Employee Occupational Health and Wellness (EOHW):

- EOHW health screening for laboratory worker
- Must be offered the hepatitis B vaccination/serology as indicated
- HIV baseline serology, initial and exit.

Accidental exposures, such as splash to the face or a sharps injury shall be reported immediately to EOHW by dialing **684-8115**. The EOHW representative will help categorize the risk of developing occupationally-acquired infection and provide advice on an appropriate post-exposure treatment.

E. Safety Procedures

Universal Precautions All specimens manipulated in the HIV Research Lab shall be handled as if known to be infectious for HIV, hepatitis B virus, or other bloodborne pathogens.

Biosafety Level. All laboratory work within the DHVI shall fully comply with biosafety level -2 (BSL-2) containment as described in the current edition of the CDC/NIH's *Biosafety in the Microbiological and Biomedical Laboratories*. Additionally, several BSL-3 containment practices and facility design will be required including:

- Strict sharps precautions including no glassware or needles in the laboratory.
- Open container work is conducted in a class II biological safety cabinet (BSC).
- Operating procedures for any open container work outside a BSC are reviewed and approved in advance by the DHVI Safety Committee. Examples may include specialized equipment that will not fit in a BSC.
- A hands-free sink is available and dedicated for handwashing only.
- The lab is separated from the main corridor by two self-closing doors.
- Directional airflow to the lab is required.

- Airflow monitors are installed at each doorway.
- Exhaust air is not circulated to any other part of the building.

Required Personal Protective Equipment (PPE)

- Blue, seamless-front gown with cuffs
- Full-face protection
- Double gloves
- Close-toed shoes

Laboratory Entry Requirements. Required PPE must be donned while in the anteroom prior to entering the laboratory.

Aerosol Containment. Work should be carefully planned to minimize the risk of aerosols being generated. All procedures that are likely to create an aerosol must be confined to a primary containment device. Biological safety cabinets are one example of such devices.

Centrifugation of samples can create aerosols. All samples, including microtitre plates, must be enclosed in proper aerosol-tight buckets when spun on the open benchtop. After centrifugation, the enclosed bucket with sample is removed and placed inside a biological safety cabinet prior to opening.

Waste Handling. All solid waste shall be collected in orange biohazard bags and autoclaved for 90 minutes at 121°C prior to disposal.

Sharps shall be placed in puncture-proof containers. Serologic pipettes shall NOT be placed directly into biohazard bags as there is a risk of puncture. After use, serologic pipettes will be collected in a cardboard box which is located inside the BSC. Once filled, the box will be closed and placed in a biohazard bag and processed for autoclaving.

Liquid waste will be chemically treated with a disinfectant that is known to be effective against HIV and HBV. An example is a freshly-prepared bleach solution. After an appropriate exposure time, the decontaminated waste may be poured down the laboratory sink.

Disinfectants and Environmental Decontamination. Disinfectants used must be known to be effective against HIV and hepatitis B virus (HBV). A list of EPA-registered products is found at the following website:

<http://www.epa.gov/oppad001/chemregindex.htm>. Solutions of sodium hypochlorite (bleach) are known to be effective against HIV and HBV.

Freshly-prepared 1:10 bleach solutions will be used for spill clean-up. 70% ethanol may be used for routine surface decontamination.

Work surfaces shall be wiped-down with disinfectant after completion of work procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of any potentially infectious material. Work surfaces shall also be wiped at the end of each work shift before leaving the work area.

Training. Workers conducting research under this procedure must comply with the following training requirements:

- Completion of the Bloodborne Pathogens Training, provided by Duke's Occupational and Environmental Safety Office. This training is required annually and is documented by OESO.
- Read, understand and agree to comply with this procedure. This is documented by worker's signature on Attachment 1 of this procedure.
- Demonstration of proficiency in standard microbiological practices and techniques and in site-specific practices and operations.
- Workers must also have prior experience working with human pathogens or tissue culture before being allowed to work in the HIV lab.

Warning Signage. A universal biohazard warning sign shall be posted at the doorway to the laboratory. The sign will indicate the biosafety level, the types of hazards in the lab (e.g., HIV cultures) and a contact name and phone number.

An "HIV Research Lab" (see Attachment 2) shall be posted to communicate entry and exit requirements for the laboratory when active HIV work is being conducted.

When there is no active work with HIV, a "Biomedical Research Lab Status" sign (see Attachment 3) shall be posted. Prior to removing the HIV Laboratory Status sign, the following must be completed: (1) HIV work is suspended, (2) all hazardous materials are secured by putting away appropriately, (3) all potentially contaminated surfaces are decontaminated.

Specimen Transport. All transfers that require entering a common corridor shall require the following packaging and labeling:

- At a minimum, materials are double-packaged prior to transport. At least one layer of packaging must be leak-proof if the material is a liquid. Example: placement of a leak-proof Vacutainer blood tube in a tube rack, and then placing the rack in closeable carrier (e.g., Igloo cooler)

- For packages containing liquids, absorbent material must be included in sufficient quantity to absorb the entire contents of the primary containers should a spill occur.
- The outer sides of the carrier must be sprayed with a disinfectant that is effective against HIV and HBV. Hard plastic exteriors are best for cleanability. Once this step is complete, the outer surfaces of the carrier are considered safe for handling with bare hands. Gloves should not be worn to transport carriers outside the laboratory.
- A biohazard warning label shall be applied when applicable to the carrier to communicate the potential hazard of its contents. Any potentially infectious material (e.g., human blood, unfixed human tissue, bacterial culture) would require the biohazard label.

Housekeeping or Maintenance Services in the Laboratory. Prior to entry, laboratory work is suspended, all hazardous materials are secured, all potentially-contaminated surfaces are decontaminated, and signage is placed on the door to indicate that the room is Biomedical Research Lab Status (see Attachment 3).

Laboratory Exit Requirements

- Remove outer pair of gloves in the laboratory before entering the anteroom.
- Remove other PPE in the anteroom. Gloves must be placed in the biohazard trash. The gown and face protection may be stored in the anteroom for reuse. Visible contamination of PPE should be addressed before storing the item. A blood spot on a face shield may be wiped off with an appropriate disinfectant. Gowns with visible contamination should be placed in the biohazard trash.
- Wash hands with soap and water.

Removal of Materials from the Laboratory

- All biohazardous waste materials are decontaminated in the laboratory or are autoclaved.
- Radiological and chemical wastes are contained, labeled and processed according to institutional policy (OESO-Hazardous Waste Policies). The outer surface of storage containers shall be wiped down with an effective disinfectant if biological contamination is likely.
- Laboratory equipment is decontaminated prior to removal.

- Laboratory notebooks without visible contamination may be used outside the lab area.

6. References

- OSHA. *Occupational Exposure to Bloodborne Pathogens*. 29 CFR 1910.1030
- CDC/NIH. *Biosafety in Microbiological and Biomedical Laboratories*. 5th Edition. 2007
- Duke University. *Bloodborne Pathogens Exposure Control Plan*. Current version.
http://www.safety.duke.edu/SafetyManuals/University/VI_1BloodBornePathogens.pdf

3. STANDARD OPERATING PROCEDURE FOR THE HCV RESEARCH LABORATORY

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December 1, 2006

Scope of work: Isolation of Hepatitis C virus in the form of whole virions or genetic material (RNA) from human specimens (blood, serum, tissues, etc.)

A. Governing SOPs:

1. Research laboratories involved in the culturing or concentration of hepatitis C virus (HCV) must comply with all requirements outlined in the Duke University Bloodborne Pathogens Exposure Control Plan (ECP).

2. A biosafety manual and/or Standard Operating Procedures is prepared to address the additional requirements that follow. This manual must be periodically reviewed and updated at least annually. Personnel working in the laboratory must read the biosafety manual/SOP and must follow the outlined practices and procedures.

3. Other applicable SOPs include the Duke Human Vaccine Institute (DHVI) human specimen SOP and the DHVI general lab SOP. Personnel working in the laboratory must also read and comply with these standards as long as they are working in a DHVI laboratory.

B. Precautions for HCV work:

1. Facility:

- a. The majority of the work will take place in GSRB1, room 1064 which is a tissue culture room dedicated for virus work (adenovirus previously), and is classified as **BSL2**. Standard (Universal) Precautions will be followed in the clinical specimen lab (GSRB1). The HCV gradient experiments (concentrated virus) will occur in Feng Gao's laboratory in the **BSL3** suite of RP3.
- b. Both labs have a secure corridor, and secure laboratory access. The viral concentration work will be done in the BSL3 suite, which requires passage through 2 closed doors.
- c. Each laboratory contains a facility for hand washing and an eye wash unit which is readily available within the work area.
- d. An autoclave for decontamination of regulated waste is available within or as near as possible to the work area.
- e. The surfaces of doors, walls, and floors in the work area are water resistant so that they can be easily cleaned.
- f. An exhaust-air ventilation system is provided that creates directional airflow that draws air into the work area through the entry area. The exhaust air is not recirculated to any other area of the building, is

discharged to the outside, and dispersed away from occupied areas and air intakes. The proper direction of the airflow is verified in the BSL3 lab.

2. Practices:

- a. Access to the work area is limited to authorized persons.
 - i. Individuals who enter the laboratory must be advised of the potential biohazard,
 - ii. Entry requirements for the RP3 **BSL3** lab include:
 - a. Seamless front gown, gloves at entry
 - Eye, nose, mouth protection at entry
 - Hepatitis B immunization is required for entry
 - Respirator NOT required
 - iii. Individuals leaving the lab will remove all personal protective equipment (PPE) and wash their hands.
- b. Signs incorporating the universal biohazard sign are posted on all access doors and must contain the following information:
 - i. The Biosafety Level (BSL2 for GSRB lab, BSL3 for the RP3 lab)
 - ii. Name of the infectious agent (HCV)
 - iii. Special requirements for entering the area (see (a)(ii) above)
 - iv. Name, telephone number of the laboratory director or other responsible person.
- c. Laboratory doors must be kept closed when experiments involving HCV or potentially infected materials are in progress.
- d. Laboratory coats, gowns, or other appropriate protective clothing are worn in the work area. Protective clothing is not worn outside of the work area and must be decontaminated before laundering or disposal in the BSL3 suite.
- e. Gloves are worn when working with infectious materials.
- f. All activities involving infectious materials that pose a threat of exposure to droplet, spills, or aerosols are conducted in certified biological safety cabinets or other physical-containment devices, such as centrifuge safety cups and sealed centrifuge rotors. Any open container work in the BSL3 suite is reviewed with the Biological Safety Office for a risk assessment and appropriate precautions are determined; as an example, when the equipment is too large to contain in the BSC.

g. The following shall apply to hypodermic needles, syringes, and other sharps in both the BSL2 and BSL3 labs:

- i. glass pipettes are not permitted in the laboratory and use of other sharps and glassware should be avoided whenever possible,
- ii. extreme caution is used when handling needles and syringes,
- iii. needles are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles,
- iv. only needle-locking syringes or disposable syringe-needle units shall be used for the injection or aspiration of potentially infectious materials. Safer needle devices such as the shielded hypodermic needle are evaluated and used when possible.
- v. needles must not be bent, sheared, recapped, or removed from the syringe following use,
- vi. the needle and syringe must be promptly placed in a puncture-resistant container located in the immediate work area and autoclaved before disposal.

h. Vacuum lines in the BSL3 lab must be protected with high efficiency particulate air (HEPA) filters or filters of equal or superior efficiency and with traps containing liquid disinfectant. Filters must be checked routinely and maintained or replaced as necessary.

3. Decontamination, Spills, and Waste Disposal:

- a. The Biosafety cabinet will be decontaminated with 70% ethanol routinely after every use.
- b. All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with concentrated infectious materials. Spills of human blood or body fluids may be cleaned up with soap and water, then 10% bleach; spills of concentrated virus material will be decontaminated following the BSL3 spill procedure located in the Emergency Response Guide in the laboratory (soaking first with bleach), cleaned, then final decontamination with fresh bleach solution. In BSCs, the final step will involve a wipe down with 70% ethanol to prevent corrosion of the cabinet surface.
- c. Equipment which may become contaminated with blood or other potentially infectious material must be examined prior to servicing or shipping and is decontaminated prior to removal using 70% ethanol spray and wiped down if there is no contamination. If contaminated, the

equipment is disinfected with 10% bleach initially, followed by 70% ethanol, or per manufacturer's instructions.

d. Contaminated materials that are to be decontaminated at a site away from the laboratory, must be placed in a durable, leak-proof, labeled or color-coded container which is closed and disinfected on the outside surface before being removed from the work area.

e. All contaminated waste from work areas must be placed in double layer biohazard bags and autoclaved before disposal.

f. Non-contaminated materials may enter and leave (books, manuals, etc.),

g. In the BSL3 lab, housekeeping access is only permitted when the lab has been decontaminated AND all activities are stopped. As an example, this will occur prior to floor-stripping.

4. Transport:

All hazardous materials are secured for transport from lab to lab in a leakproof, breakproof container. The outside of the transport container is sprayed with an effective germicide prior to transport.

5. Exposure Follow-up:

In the event of a needlestick or splash exposure to a mucous membrane surface, the employee should immediately cease working, contain the exposure to others by following the spill protocols listed above and immediately notify their supervisor **and** EOHW by calling the Exposure Hotline (115). The EOHW HCV exposure protocol will be followed which includes baseline HCV serologies, liver enzyme testing, and follow-up testing and PCR, based on HCV PCR results of the source material.

6. Training:

- a. All employees in the HCV laboratory will participate in the annual Duke University Bloodborne Pathogens and the Duke University Laboratory Safety Training Program.
- b. In addition, all employees in the BSL3 HCV laboratory will demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV by:

1). Possess experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

OR

2). The supervisor must provide a training program to employees who have no prior experience in handling human pathogens. Initial work

activities must not include the handling of infectious agents. The supervisor must assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

7. Specific Precautions for HCV gradient centrifugation experiments:

All HCV serum samples will be centrifuged in sealed, leakproof centrifuge plastic tubes. All open handling will take place only in the Biosafety cabinet. After the HCV serum samples are fractionated using the gradient, each fraction will be extracted from the tube and aliquoted to fresh sealed, leakproof cryovials. The fractions will be isolated using needle puncture of the centrifuge tube. (please see discussion of sharps handling). This step will be performed using a metal hard backed surface to protect the investigator. All of the fractionation will take place in the Biosafety cabinet within the BSL3 lab and the samples will be transported to the BSL2 lab (in compliance with the transport precautions) where they will be stored in a separate locked plastic container at -80 C until they are ready to be picked up by our collaborators within the Duke Liver Center.
No open specimen handling will take place in the BSL2 lab.

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 change his 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>). 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 blood or other body fluids or high titers of cell-associated or free virus via 1) percutaneous, e.g., needlestick; 2) permucosal, e.g., splash in eye or mouth; or 3) cutaneous exposure, e.g., nonintact 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 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, Creutzfeld-Jakob disease, HTLV-1, and viral hemorrhagic fever.

Information regarding all human blood or body fluid exposures is entered into the EOHW blood/body fluid exposure surveillance database (National Surveillance System for Hospital Healthcare Workers, otherwise known as NaSH).

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 blood or other body fluid 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 patient source.

I. Unvaccinated employee

A. Source known HBsAg (+)

1. Administer single dose of HBIG (0.06 ml/kg body weight within 24 hours, if possible).
2. Start Hepatitis B Vaccine series.

Note: If exposure is >7 days, do not give HBIG; start Hepatitis B vaccine series if within reasonable proximity of exposure. HBIG's value >7 days post exposure is unclear.

B. Source known, HBsAg (-)

1. Start Hepatitis B vaccine series.

C. Source known, HBsAg status undetermined

1. 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).
 - a. Administer single dose of HBIG.
 - b. Start Hepatitis B vaccine series.
2. Low risk that source HBsAg (+)
 - a. Start Hepatitis B vaccine series; categorized as "unknown source".

D. Source unknown

1. Start Hepatitis B vaccine series; Categorized as "unknown source".

II. Vaccinated employee

A. Source known, HbsAg (+)

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 antibodies inadequate on testing or employee has previously not responded to vaccine, administer single dose of HBIG immediately; (no later than 7 days post exposure) and a booster dose of Hepatitis B Vaccine or HBIG x2 1 month apart if employee has failed to respond to at least 4 doses of HBV.¹
2. Employee completed 1 or 2 doses
- a. Administer single dose of HBIG immediately and continue on schedule with vaccine series. HBsAb can be tested after 2 doses of HBV.

B. Source known, HBsAg (-)

- 1. No testing or treatment.

C. Source known, HBsAg status undetermined

1. High risk that source is HBsAg(+)

- a. Employee has completed all 3 doses
 - 1) If known responder, no treatment.
 - 2) If antibody response unknown, test employee and if adequate, no treatment
 - 3) If antibodies inadequate on testing or employee has previously not responded to vaccine, administer single dose of HBIG immediately; (no later than 7 days post exposure) and a booster dose of Hepatitis B vaccine or HBIG x2 if employee has failed to respond to at least 4 doses of HBV.¹
- b. Employee has received 1 or 2 doses of vaccine
 - 1) Administer single dose of HBIG immediately and continue on schedule with vaccine series. HBsAb can be tested after 2 doses of HBV.

2. Low risk that source is HBsAg (+).

- a. If employee has completed series (3 doses), may request testing for HBsAb; otherwise no further testing or treatment; categorized as “unknown source”.

D. Source unknown

- 1. If employee has completed series (3 doses), may request testing for HBsAb; otherwise no further testing or treatment; categorized as “unknown source”.

¹The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for non-responders who have not completed a second 3 dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, 2 doses of HBIG are preferred.

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) (see HIV and HCV Protocols).

HCWs infected with HBV 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 member of the clinical faculty to be designated by the chief of the medical staff. 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. 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. It is the function of the assessment committee to advise EOHW regarding a change in work activities. Implementation of recommendations made by the committee will be administered through and according to policies of EOHW.

HCWs with HBV 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 physician and non-physician HCWs will be communicated to the Chancellor for Health Affairs by the director of EOHW. 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.

George Jackson, MD
EOHW Director

Reviewed 02/09

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

EXPOSURE DEFINITION

Significant occupational exposure includes contamination by blood or other body fluids 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., nonintact skin, or involving large amount of blood or prolonged contact with blood, especially when exposed skin is chapped, abraded, or afflicted with dermatitis.

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.

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

1. Baseline encounter

- a. Evaluate type of exposure, employee status, patient source
- b. Counsel employee: risk of exposure, patient source information, offer PAS/EAP
- c. Offer/recommend PEP as appropriate.
 - 1) Brief medical history
 - 2) Stat pregnancy test for fertile females
 - 3) OHS III Panel (includes LFTs, renal fn, lipids, glc, CBC with diff)
 - 4) Consent form for HIV PEP
- d. HIV Ab

2. 4-6 wks. OHS III Panel

3. 3 months post exposure HIV Ab

4. 6 month post exposure HIV Ab

5. 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.

B. Pt Source HIV Ab negative with no known risk behaviors

1. Baseline encounter

- a. 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.

INFECTED EMPLOYEE

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

HCW's infected with 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 member of the clinical faculty to be designated by the chief of the medical staff. 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 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. It is the function of the assessment committee to advise EOHW regarding a change in work activities. Implementation of recommendations made by the committee will be administered through and according to policies of EOHW.

HCW's with 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 physician and non-physician HCW's will be communicated to the Chancellor for Health Affairs by the director of EOHW. 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.

George Jackson, MD
EOHW Director

Reviewed 02/09

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

EXPOSURE DEFINITION

Significant occupational exposure includes blood or other body fluid contamination via percutaneous route, e.g., needlestick; mucosal contact, e.g., splash in eye or mouth; or cutaneous exposure, e.g., nonintact 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 if Hep C-AB is positive.

- a. if HEP C-PCR is negative then:
 1. Baseline Hep C-Ab and liver enzymes
 2. 3 month Hep C-Ab and liver enzymes
 3. 6 month Hep C-Ab
- b. if Hep C-PCR is positive or not available then:
 1. Baseline Hep C-Ab and liver enzymes
 2. 2 month liver enzymes
 3. 3 month Hep C-PCR
 4. 6 month Hep C-Ab
- a. Unknown source exposure:
 1. Baseline Hep C-Ab and liver enzymes
 2. 2 month liver enzymes
 3. 3 month Hep C-Ab
 4. 6 month Hep C-Ab

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

INFECTED EMPLOYEE*

- A. Employee infected from occupational exposure at Duke University.
 1. Evaluation by EOHW and referral for specialty medical treatment.
- B. Employee infected outside of Duke University
 1. Employees infected with HCV shall inform EOHW of their status.
 2. Periodic follow-up by EOHW based on risk of communicability.

*A and B:

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 EOHW, and a member of the clinical faculty to be designated by the chief of the medical staff. The function of the committee is to assure that no patient is exposed to undue risk from a HCW known to be HCV infected.

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 any need for a change in work activities will be based on current clinical standards of care. It is the function of the assessment committee to advise EOHW regarding a change in work activities. Implementation of recommendations made by the committee will be administered through and according to policies of EOHW.

The work status of physician and non-physician HCWs will be communicated to the Chancellor for Health Affairs by the director of EOHW. 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.

George Jackson, MD
EOHW Director
Reviewed 02/09

Healthcare Professional's Written Opinion

The employee will be provided within 15 days of the completion of the evaluation a memo reflecting the EOHW recommendations for follow-up based on the testing of the source and risk of exposure.

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 (PIM), 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 (PIM) as defined above.
4. Routine administration of first aid.
5. Processing or handling primary or established human cell lines.

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

1. **Nursing and Patient Care Services Orientation**
2. **Medical Center Orientation**
3. **Allied Health Student Orientation**
4. **Biological Safety for Housestaff**
5. **Biological Safety via on-line training. OESO personnel are available via pager for questions during on-line training.**
6. **Laboratory Safety**
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 other PIM;
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 other PIM;
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.