APPENDIX C

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.

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.

<u>Note</u>: 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
 - 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	

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 (includeds 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.

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

^{**}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.

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.

<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 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	

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.