

Infection Control Policy
And
Exposure Control Plan for
Bloodborne Pathogens



Research Service
VA Medical Center, Miami, FL
March 2006

IMPORTANT SAFETY TELEPHONE NUMBERS

FIRE	Pull alarm and call	3322
MEDICAL	Employee Health Office	4282
	Emergency (non-cardiac)	4282
	Cardiac Arrest	2222
	Infection Control	3770/3779
ENVIRONMENTAL MANAGEMENT SERVICE		3324
LAUNDRY	Laundry bags/service	4356
BIOSAFETY INFORMATION	RESEARCH SAFETY	4495
	RESEARCH OFFICE	4211/3179

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SECTION A

INFECTIION CONTROL POLICY AND PROCEDURES

March 2006

RESEARCH SERVICE POLICY MEMORANDUM
NO.....151-1

INFECTIION CONTROL POLICY AND PROCEDURES FOR RESEARCH SERVICE

I. PURPOSE:

To establish policies and procedures concerning the responsibility of Research Service for infection control.

II. POLICY:

The Service infection control policy is to minimize or eliminate the risk of employee occupational exposure to any biohazards as may be present in the work area. The goals of this policy are: (1)to provide a safe working environment through employee compliance with appropriate written exposure control procedures for all research activities involving the use of potentially infectious etiologic agents or other biohazardous materials; (2) to reinforce employee knowledge and skills in the safe handling and disposal of biohazardous materials through annual employee education classes; and, (3)to assist members of the Chemical Hygiene and Biosafety Subcommittee in maintaining currency on biosafety issues, guidelines, and regulations by means of continuing education, books, and reference materials.

III. DEFINITIONS:

The term biohazards refers to any viable microbial, fungal, parasitic, or viral agent of known pathogenicity to humans. This term also applies to any recombinant DNA material which may present a human health risk on the basis of the pathogenicity of the DNA source, and/or associated host-vector systems.

IV. RESPONSIBILITY:A. CHEMICAL HYGIENE AND BIOSAFETY SUBCOMMITTEE:

1. Aid in the development and implementation of policies for infection control in Research Service. Periodically review these policies for compliance with guidelines from VACO, CDC, OSHA, and the Medical Center Infection Control Policy.
2. Review all research protocols involving the use of biohazardous etiologic agents/materials to assure that the available or proposed facilities, equipment, and personnel are sufficient to conduct the study in full safety.
3. Review reports of exposure incidents arising from contaminated or infected samples from Research laboratories and recommend appropriate remedial actions.

B. SERVICE CHIEF:

1. Assure Research Service compliance with the Medical Center PPD Skin-testing Program and the Respiratory Protection Program.
2. Assure employee attendance at mandatory Medical Center refresher training classes relevant to Infection Control, and Bloodborne Pathogens and Infectious Tuberculosis Exposure Control.

C. RESEARCH ADMINISTRATION:

1. The Administrative Officer for Research Service has the responsibility for assuring employee compliance with the provisions of this Infection Control Policy.

2. Update the Bloodborne Pathogens Determination form for Research Service as necessary.
3. Maintain list of employees who require use of a N-95 respirator.
4. Maintain documentation of employee attendance at annual In-Service refresher training classes on the safe handling and disposal of biohazardous etiologic agents/materials as may be present in the laboratory work setting.

D. PRINCIPAL INVESTIGATORS:

1. Assure that all employees under their supervision are aware of, and understand, the provisions of the Research Service Infection Control Policy and of the Bloodborne Pathogens Exposure Control Plan.
2. To monitor employee compliance with practices and procedures designed to reduce the risk of occupational exposure to bloodborne pathogens or infectious tuberculosis.
3. Assure that their employees are in compliance with the Medical Center PPD Skin-testing Program and attend scheduled Medical Center and In-service training classes.

E: ENVIRONMENTAL AND INFECTIONS CONTROL COMMITTEE:

1. Assist in preparing and presenting continuing education programs in infection control to Research Service personnel.
2. Assist in review of all infection control policies.

3. Investigate incidents of infection which may be possibly occupationally-related.

V. INFECTION CONTROL PROCEDURES:

A. Biohazard Issues of Concern

1. Personnel working in laboratories where biohazardous agents/materials are present must be fully advised of the nature of the health risks associated with such materials and be specifically trained in the appropriate procedures for safely working with the identified biohazard(s).
2. Because some diseases may be transmitted by persons who do not exhibit the symptoms of the infection, all specimens from patients such as blood, exudates, unfixed tissues or organs, or other body fluids with visible blood should be considered potentially infectious, and therefore handled with the same precautions that would be taken as if they were known to be infectious. Standard Precautions apply (refer to Research Service Bloodborne Pathogen Exposure Control Plan).
3. Some infectious agents may survive and be transported long distances in air currents or by dust. Thus, it is imperative that any spills within the laboratory be promptly disinfected with a working solution of Wexcide (one ounce/gallon of water) or other appropriate disinfectant.
4. Laboratory animals present unique problems for employee occupational health and safety, and should always be considered a potential threat for infection or injury. Although precautions are taken to assure the health status of experimental animals, it should never be assumed that there are no risks for exposure when no experimental biohazardous agents/materials are involved. Certain diseases carried by animals (zoonotic) are transmittable to humans. Thus, employees must comply with all Animal Research Facility safety

practices and procedures when working with experimental animals.

5. The animal populations in the VMU are periodically (every 3 months) monitored for the presence of zoonotic disease agents by means of the sentinel animal surveillance program. Monitoring reports, upon receipt, will be forwarded to the Associate Chief of Staff for Research. In the event serological tests of sentinel animals are positive for a potential zoonotic disease agent, the Associate Chief of Staff for Research and the Chief of Infection Control will be notified immediately so that appropriate infection control measures can be implemented.
6. All employees must be aware of the potential risk of exposure to tuberculosis (TB) because this Medical Center is designated an acute medical facility in an area with a high incidence of TB, including multidrug resistant TB. For this reason, employees having direct contact with patients should know about the practices which can minimize their exposure. (Refer to Medical Center Infectious Tuberculosis Exposure Control Plan).
7. Any employee having an illness which could present an infection risk to others will be referred to the Employee Health Office for medical evaluation. If an infection risk is determined to exist, the employee will be excluded from duties until such time as that employee provides written documentation from Employee Health, or private physician, stating that he/she no longer represents an infection risk to others.

B. Standard Practices and Procedures

The following practices and procedures are applicable to all situations where biohazardous agents or materials are present in the research laboratory.

1. All research personnel are required to comply with the Medical Center PPD Skin-testing Program.

2. The Principal Investigator in consultation with the Biosafety Officer makes all decisions regarding restrictions or requirements for access into the laboratory.
3. Personal protection equipment (gloves, masks, gowns, eye protection, face shields, footwear) is used as a barrier between employee and exposure source (Standard Precautions apply). Personal protection equipment is selected on the criterion that provides the best protection against the most expected exposure. Employees having direct contact with patients with known or suspected TB, or who enter AFB (acid-fast bacilli) isolation areas are required to wear a NIOSH-approved N-95 respirator.
4. Personal protection equipment is provided at no cost to the employee. Use of personal protection equipment as deemed necessary when performing exposure-prone tasks is mandatory.
5. Personal protection equipment, including laboratory coats, is always removed before exiting from the laboratory.
6. Face shields (full) are required during removal and thawing of samples stored in liquid nitrogen (major explosion risk).
7. Biohazardous agents/materials stored in Common Resource refrigerators, cold rooms, or freezers must be contained within a properly labeled, leakproof, durable primary container, within a sealed, non-breakable, leakproof secondary container. The secondary container must have a label which accurately identifies the contents of the primary container and include the name, room number, and contact numbers of the responsible Investigator. Storage facilities must have the proper Biohazard warning signage.

8. Thermometers (non-mercury) must be placed in all refrigerators where biohazardous agents/materials are stored, and regularly monitored to assure proper storage temperature is maintained. A log recording daily temperature must be maintained.
9. Storage of foods or beverages in laboratory refrigerators or cold rooms where biohazardous materials are present is strictly prohibited.
10. Eating, drinking, smoking, or applying of cosmetics in areas where biohazardous agents or materials are present is strictly prohibited. The use of laboratory glassware for eating or drinking, or for storage of foods, is never allowed.
11. Work area should be ample, and work surfaces kept uncluttered.
12. Whenever possible, laboratory procedures should be carried out in a manner that minimizes the creation of aerosols to reduce the risk of exposure from inhalation. Appropriate personal protection equipment is required for procedures that might result in the creation of aerosols.
13. Mouth pipetting of infectious materials is strictly prohibited. Only mechanical devices should be used.
14. The use of needles, surgical blades, or other sharp devices should be avoided whenever possible. Do not recap needles, or attempt to intentionally bend, break, or remove needles from disposable syringes. These objects, and other sharps including broken glassware or hard plastic, are to be promptly discarded in a non-reusable, puncture-proof, approved sharps container. When full, container is disposed of in accordance with Medical Center regulations.

15. Handwashing is required after handling biohazardous materials and always before leaving the laboratory.
16. Special care should be exercised in the selection of centrifuge tubes for centrifugation of biohazardous materials. They must be sealable and able to withstand the centrifugal forces imposed without cracking or breaking. The use of centrifuge safety cups is prudent practice. Centrifuge rotors should never be run above their rated speed.
17. Work surfaces, instruments, and equipment must be decontaminated with an appropriate chemical disinfectant, daily, and immediately after spills.
18. A spill kit should be present in the laboratory, and it should contain extra items of personal protection equipment, RED bags, and other items necessary for decontamination and cleanup of spills.
19. Mechanical devices, such as tongs or brush and dust pan, must be used to pick up contaminated broken glassware or hard plastic. These items are never picked up with hands, even if gloves are worn.
20. All biohazardous liquid waste materials must be collected into a properly labeled, durable, closeable container, and the container and contents autoclaved when work is completed. Contaminated reusables must be placed in a properly labeled, durable container which can be closed and autoclaved. Solid disposable biohazardous waste materials must be placed in RED disposal bags, which are closed to prevent spillage, and then disposed by on-site incineration or in accordance with current Medical Center regulations.
21. Efficacy of steam sterilization of contaminated wastes or reusable devices must be monitored.

Documentation in the autoclave logs must include: name of operator, nature of the load, highest temperature that is reached and the length of time this temperature is maintained. Use temperature sensitive tape on each container or package, and where appropriate, indicators should also be placed inside packages to verify that steam has penetrated the package. Tests for sterility are conducted weekly using a biological sterilization indicator and the results are documented in the autoclave log.

22. Biological Class I or II safety cabinets are to be tested and certified at the time of installation, whenever moved, and at least once annually.
23. All laboratory personnel should receive and document training in infection control. Policies and procedures are to be reviewed annually. All personnel should know their emergency plan for major spills.
24. Laboratory personnel handling materials known or suspected to contain bloodborne pathogens are required to strictly comply with the provisions of the Research Service Bloodborne Exposure Control Plan, and with any additional practices and procedures specific to the laboratory in which they are working. These employees are encouraged to be immunized against the Hepatitis B virus.
25. Employees having direct contact with patients who have known or suspected TB, or who may be assigned to "high-risk" areas, regardless of frequency, are expected to comply with the Medical Center Infectious Tuberculosis Exposure Control Plan, and with any additional control measures that may be designated by the Principal Investigator or Infection Control.
26. Animal-care Technicians are required to pass a pre-employment physical examination to ensure that the prospective new employee is capable of the physical demands of the position, and that pre-existing medical conditions will not place the

employee or others at risk. It is also recommended that animal-care technicians complete an annual medical follow-up questionnaire. The pre-employment health assessment and subsequent evaluations are provided through the Employee Health Office.

27. Animal-care technicians are provided the Tetanus and Rabies immunizations, and the Hepatitis B vaccination is strongly encouraged. These immunizations are also offered to research laboratory employees whose duties include substantial daily contact with animals.

VI. POST-EXPOSURE EVALUATION AND TREATMENT PROCEDURES:

Employees should report any bloodborne pathogen or TB exposure incident immediately to their supervisor (or as soon as practical), and then report to the Medical Center Employee Health Office for medical evaluation and treatment. Be prepared to provide information concerning the nature of the exposure incident and how it happened to aid Employee Health in their medical evaluation.

A. BLOODBORNE PATHOGEN EXPOSURES FOLLOW-UP:

1. Employees reporting significant bloodborne exposure are provided immediate confidential medical evaluation and follow-up treatment through the Medical Center Employee Health Office (refer to Medical Center Policy Memorandum-Accidental Exposure to Bloodborne Pathogens).
2. When a bloodborne exposure incident occurs, decisions regarding HBV or HIV prophylaxis requires obtaining certain information on the possible infectivity of the source individual and the susceptibility of the employee exposed. If HBV or HIV status is unknown, legal signed consent must be obtained from both the source and employee prior to serological testing.

3. This Medical Center provides HBV and HIV serological testing, counseling, and safe and effective post-exposure prophylaxis following current recommendations of the U.S. Public Health Service.
4. Strict confidentiality is maintained between the Employee Health Office and employee concerning any medical information pertaining to the evaluation and treatment relevant to the exposure incident.

B. INFECTIOUS TUBERCULOSIS FOLLOW-UP:

1. All PPD skin-test conversions will be considered occupationally-related. Converters will have chest x-rays taken and may be referred to Pulmonary Section through the Employee Health Office.
2. PPD-negative employees who have been exposed will be offered the PPD skin-test at once, and again at 10-12 weeks post-exposure.
3. PPD-positive employees who have been exposed will be counseled as to the signs and symptoms of the disease by Employee Health. If signs or symptoms appear, the employee must report to the Employee Health Office.
4. All employees found to be converters, or to have TB, will be offered treatment by Employee Health with appropriate consultation with Pulmonary Section at no cost. Compliance with prescribed treatment is expected.

C. REPORTING REQUIREMENTS:

1. The employee must submit VA Form CA-1 (Federal Employee Notice of Traumatic Injury) by means of the Automated Safety Incident Surveillance Tracking System, ASISTS (electronic processing). Paper submissions of this Form will no longer be

accepted. For assistance in submitting the information, call extension 3009 or 4495.

2. The Principal Investigator for whom the employee works must complete VA Form-2162 (Report of Accident, Injury, Occupational Illness or Fire) by means of the Automated Safety Incident Surveillance Tracking System, ASISTS (electronic processing). Paper submissions of this Form will no longer be accepted.
3. Employees may be requested by the Employee Health Office to complete additional forms or questionnaires. Employees are expected to comply with any such requests.

VII. REFERENCES:

1. Centers for Disease Control. Recommendations for Prevention of HIV Transmission in Health-care Settings. MMWR. Vol. 36, No. 2S, 1987.
2. Centers for Disease Control. Agent Summary Statement for Human Immunodeficiency Virus and Report on Laboratory-acquired Infection with Human Immunodeficiency Virus. MMWR Vol. 37, No. S4, 1988.
3. Centers for Disease Control and Prevention. Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis. MMWR. Vol. 47, No. RR-7, 1998.
4. Centers for Disease Control and Prevention and National Institute of Health. Biosafety in Microbiological and Biomedical Laboratories. 4th Edition.
5. Department of Veterans Affairs, Veterans Health Administration. Occupational Health and Safety for Research with Animal Contact. VHA Handbook 1200.7, Appendix C., June 2005.

6. Medical Center Policy Memorandum. No. 11-10-04. Infection Control Policy/Program Plan. June 21, 2004.
7. Medical Center Policy Memorandum. No.11-10-04, attachment B. Medical Center Infectious Tuberculosis Exposure Control Plan. June 21, 2004.
8. Medical Center Policy Memorandum. No.001 SEM-27-04. Respiratory Protection Program. July 12, 2004.
9. Medical Center Policy Memorandum. No. 11-06-05. Accidental Exposure to Bloodborne Pathogens. Nov. 14, 2005.
10. U.S. Department of Labor Occupational Safety and Health Administration. 29 CFR Part 1910. Occupational Exposure to Bloodborne Pathogens, Needle sticks and Other Sharps Injuries. Final Rule. Federal Register, 66(12): 5318-5325. 2001.
11. U.S. Department of Labor Occupational Safety and Health Administration. 29 CFR Part 1910, 1030. Occupational Exposure to Bloodborne Pathogens. Final Rule. Federal Register, 56(235): 64175-64182, 1991.

VIII. RECISSIONS:

Previous Service Policy Memorandum Infection Control Policy and Procedures in Research Service Manual. This policy remains in effect until August 31, 2008 unless rescinded earlier.

Robert M. Jackson, M.D.
Associate Chief of Staff for Research

SECTION B

RESEARCH SERVICE BLOODBORNE PATHOGENS

EXPOSURE CONTROL PLAN

RESEARCH SERVICE BLOODBORNE PATHOGENS EXPOSURE CONTROL PLANI. PURPOSES:

To protect all Research employees, including part-time temporary, work without compensation (WOC's) basis, consultants, student trainees, and contract personnel from occupational exposure to HIV, HBV, and other bloodborne pathogens by identifying ACTUAL and POTENTIAL sources of employee exposure to blood and other body fluids.

To protect employees against bloodborne pathogens through identification, evaluation, and documentation of specific task exposure levels for each employee based on work related duties.

To match task exposure levels with the concept of Standard Precautions and additional anti-bloodborne exposure control measures.

To assist Principal Investigators in interpreting and simplifying OSHA's final bloodborne pathogens standard in order to facilitate implementation through a written Exposure Control Plan for Research Service.

To provide appropriate counseling and treatment for employees post-exposure.

II. DEFINITIONS:A. EXPOSURE CONTROL PLAN:

A performance oriented program developed to identify Research personnel at risk of exposure to bloodborne pathogens.

B. OCCUPATIONAL EXPOSURE:

The 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.

C. OTHER POTENTIALLY INFECTIOUS MATERIALS (OPIMS):

1. Any unfixed tissue or organ (other than intact skin) from a human (living or deceased).
2. Body fluids including: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood.
3. All body fluids in situations where it is difficult or impossible to differentiate between body fluids.
4. HIV-containing cell or tissue cultures, organ cultures, and HIV-or HBV-containing culture medium or other solutions.
5. Blood, organs or tissues from experimental animals infected with HIV, HBV, or other bloodborne pathogens.

D. EXPOSURE-PRONE PROCEDURE:

Any procedure which results in the simultaneous presence of an employee's finger or hand with a needle or other sharp device.

E. TASK LEVELS OF POTENTIAL EXPOSURE:

1. Level I - Tasks that involve routine exposure, or have the potential for exposure, to blood, body fluids, tissues, organs, or manipulations of concentrates of bloodborne pathogens regardless of

frequency, and which exists on the basis of position description or statement of function.

2. Level II (no exposure) - Tasks that do not involve routine or potential exposure to blood, body fluids, tissues, organs, or handling preparations of bloodborne pathogens, and Level I tasks are not a condition of employment on the basis of position description or statement of function.

F. EXPOSURE INCIDENT:

A specific eye, mouth, other mucous membrane, non-intact skin or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

G. ENGINEERING CONTROLS:

Any device or control that removes the hazard, or isolates the employee from the hazard.

H. WORK PRACTICE CONTROLS:

Specific practices, procedures, or operations that employees are expected to follow when performing tasks where exposure can be reasonably anticipated.

I. PERSONAL PROTECTION EQUIPMENT:

Specialized clothing or equipment worn by an employee for protection against a biohazard. General work clothing (eg., uniforms, pants, shirts, or blouses) are not intended to function as protection.

J. BIOHAZARDOUS WASTE:

Liquid or semi-liquid blood, or other potentially infectious materials or contaminated items that could

release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; pathological wastes containing blood or potentially infectious materials; and laboratory and animal wastes which are known to contain human disease-causing pathogens.

K. SOURCE INDIVIDUAL:

Any individual, living or deceased, whose blood or other potentially infectious materials may represent a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinical patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

L. PARENTERAL:

Piercing of mucous membranes or skin barrier through such events as needle sticks, human or animal bites, cuts or abrasions.

III. RESPONSIBILITY:

A. SERVICE CHIEF:

1. Identify all laboratories within Research Service where employees encounter actual exposure or can reasonably anticipate contact with blood, body fluids, or other potentially infectious agents or materials.
2. Evaluate exposure incidents with Principal Investigator to identify and correct sources of exposure.

3. Review Principal Investigator initiated requests and justifications for deviation from VAMC Infection Control Policy on handling contaminated sharps. Approved requests are then submitted to the Medical Center Environmental and Infections Control Committee for review and recommendations prior to notifying Principal Investigator that the requested deviation can be implemented.
4. Develop a Research Service Exposure Control Plan, and include this Plan in the Service Level Infection Control Policy. A final draft of the Research Service Infection Control Policy and Exposure Control Plan is to be reviewed by the Medical Center Environmental and Infections Control Committee prior to implementation.
5. Provide that the Service Exposure Control Plan is included in the Service Orientation Program for new employees.
6. Assure that copies of the Service Exposure Control Plan are made visible and accessible to employees and OSHA.
7. Notify Principal Investigators and Research personnel of mandated Infection Control training classes on bloodborne pathogens exposure control.
8. Obtain documentation from Principal Investigators that the Exposure Control Plan is reviewed annually with employees under the Principal Investigator's supervision.
9. Review Research Service Exposure Control Plan annually and update Plan as necessary based on changes in guidelines from CDC, VAHQ, and OSHA.

B. PRINCIPAL INVESTIGATOR:

1. Will make appropriate exposure determination for each employee if not in concurrence with exposure determination made by Research Administration.
2. For each employee required to perform Level I tasks or procedures, establish the appropriate personal protection equipment necessary to protect the employee from the anticipated occupational exposure risk associated with the specific task or procedure.
3. Determine restrictions or requirements for access into the laboratory or infected animal room, and post such requirements at entrances to the laboratory and/or infected animal room as applicable.
4. Submit request and justification for any deviations from Medical Center Infection Control Policy on handling contaminated sharps to Service Chief for review. Any requests must be approved by the Service Chief and by the Medical Center Environmental and Infections Control Committee before requested deviation can be implemented.
5. When appropriate, develop and implement a written laboratory-specific Exposure Control Plan for a specific biohazard (human disease-causing agent or potentially infectious material) which defines the nature of the health risks associated with the identified biohazard, and the work practice controls and procedures that must be followed for the safe use and disposal of the identified biohazard.
6. Explain the Service and/or Laboratory-specific Exposure Control Plan to new employees, and provide information where a copy of the Plan will be available for reference.
7. Review the Exposure Control Plan with all laboratory personnel annually, and whenever new or modified tasks or procedures affecting occupational exposure are implemented.

8. Update Exposure Control Plan when necessary to reflect new or modified tasks or procedures which affect occupational exposure, or when an employee assumes new responsibilities which may result in a new exposure.
9. Assure and document laboratory personnel attendance at mandated Medical Center (Infection Control) training courses on bloodborne pathogens exposure control, and In-Service training courses on laboratory biosafety.
10. Monitor employee compliance with safety practices and requirements of the Service or Laboratory-specific Exposure Control Plan.

C. EMPLOYEES:

1. Know the tasks they perform that have occupational exposure risks.
2. Plan and execute tasks and procedures in accordance with established work practice controls.
3. Use appropriate engineering controls and personal protection equipment to protect themselves against bloodborne pathogens exposure in the work setting.
4. Know that failure to comply with the provisions and requirements of the written Exposure Control Plan may result in appropriate disciplinary action.

D. ENVIRONMENTAL AND INFECTIONS CONTROL COMMITTEE:

1. Work with administrators and other employees to develop and administer any additional bloodborne pathogen related policies and practices needed to

support the effective implementation of the Service Plan.

2. Review and recommend revision in Service level policies based on changes in guidelines from OSHA, CDC, and VACO.
3. Compile copies of Exposure Control Plans submitted by each Service and include them in the Service Policy Reference Manual.
4. Provide training courses to review mandated topics, at least yearly.
5. Maintain appropriate training documentation such as "Sign-in Sheets and/or Quizzes". (Principal Investigators can refer to this documentation for verification of employee attendance).
6. Review and request suitable references to maintain a reference library on the OSHA Bloodborne Pathogens Standard.

IV. EXPOSURE DETERMINATION - PROCEDURES:

The purpose of the exposure determination is to identify employees by position, who perform anticipated exposure Level I tasks. This determination is made without regard to the use of personal protection equipment or clothing. Employees not included in Level I are identified as having no anticipated exposure (Level II).

A. EXPOSURE DETERMINATION FORM:

1. The anticipated occupational exposure risk for each position (job classification and code) in Research Service has been determined by Research Administration (see Bloodborne Exposure Determination Form in Appendix). All positions are listed regardless of anticipated exposure risk.

2. In determining the anticipated exposure level, the following factors were considered:
 - a. All procedures or work-related tasks involving direct contact or exposure, regardless of frequency, to frank blood, body fluids containing blood, tissue, cerebrospinal fluid, pleural fluid, peritoneal fluid, pericardial fluid, semen, or vaginal secretions are at Level I anticipated exposure.
 - b. Tasks and procedures involving the potential for exposure as described in a above, are considered as Level I anticipated exposure.
 - c. Tasks or procedures involving infected animals are considered as Level I anticipated exposure.
 - d. Manipulations involving blood specimens or concentrates of bloodborne pathogens are considered as Level I anticipated exposure.
 - e. Tasks and procedures that do not involve the routine or potential for exposure to bloodborne pathogens on the basis of position description or performance of expected duties are considered as having no anticipated exposure and are identified as Level II.

B. OTHER REQUIREMENTS:

1. The Exposure Determination for an employee must be revised and updated whenever:
 - a. New or modified tasks and procedures are implemented in the laboratory that may affect an employee's occupational exposure.

- b. An employee's occupational exposure is affected by a significant change in job responsibilities.
2. The Principal Investigator must submit an amendment for any new or significant modification in laboratory procedures, together with a revised copy of the Exposure Determination form to the Chemical Hygiene and Biosafety Subcommittee for review and approval.

V. EXPOSURE CONTROL PLAN - METHODS OF COMPLIANCE

A. STANDARD PRECAUTIONS:

1. OSHA's Bloodborne Pathogens Standard mandates Standard Precautions be observed throughout the Medical Center to prevent exposure to HIV, HBV, and other bloodborne pathogens.
2. The Standard Precautions concept of infection control assumes that all blood, and other potentially infectious materials (refer to Definitions, Section II) are infectious for HIV, HBV, and other bloodborne pathogens irrespective of the perceived "low-risk" of the patient source.
3. Gloves are to be worn to prevent potential or actual contact with patient secretions, blood, blood components or products derived from blood.
4. Face and eye protection is required to protect against potential or actual splash contact with patient blood, secretions, or other potentially infectious materials when occurrence may be reasonably anticipated.
5. Standard Precautions also apply to procedures involving handling of blood or tissues from infected experimental animal sources.

6. All research laboratory personnel are expected to observe Standard Precautions, including the appropriate use of frequent hand washing (more detailed information on Standard Precautions can be found in Section 3 of the Medical Center Infection Control Manual).

B. ENGINEERING CONTROLS:

Engineering controls include physical equipment devices and technological advances which can be used in order to reduce employee occupational exposure by either removing or isolating the biohazard, or isolating the employee from exposure. Examples of engineering controls include splash shields on instruments, self-sheathing needle/syringe units, and biosafety cabinets. Engineering controls must be inspected on a regularly scheduled basis and maintained, or replaced, to ensure their functional efficacy. Engineering Controls having applicability in the Research Laboratory include the following:

1. WASHING FACILITIES:

- a. Each laboratory in Research Service should have hand and eye wash facilities available.
- b. Accessibility to these facilities shall remain unblocked at all times.
- c. The eye wash facility should be tested weekly to check for water clarity and proper function (3 minute continuous flow is required). (This should be done by a designated person and documented).

2. SHARPS:

- a. Only single-use sharps (needles, blades, etc.) and sharps containers should be used.

- b. Laboratory personnel shall not attempt to decontaminate and reuse sharps or sharps containers.
- c. Contaminated sharps are to be discarded immediately after use into closeable, puncture resistant, leak proof (from side and bottom), color-coded containers bearing a biohazard warning.
- d. Sharps containers must be easily accessible to the employee, and located in close proximity to the work area. Sharps containers must also be located in areas where sharps are not normally used but may be reasonably anticipated to be found.
- e. Sharps containers must be maintained in an upright position at all times.
- f. Contaminated broken glass or hard plastic is to be considered a sharp. Such items must be picked up with a mechanical device, such as tongs, forceps, or brush and dust pan, and promptly discarded into a sharps container.
- g. Sharps containers are to be promptly replaced when the full line on the container is reached.

3. SPECIMENS:

- a. Blood or other potentially infectious materials are to be placed in non-spill, airtight, and puncture resistant containers during collection, handling, processing, transport, storage, or shipment.
- b. The primary container must bear a biohazard warning label, and must also have a label which lists the nature of the contents, and name and telephone number of the Principal Investigator.

- c. If the primary container becomes contaminated, or the possibility exists, it must be placed in a secondary container which is leak proof, properly labeled, and red in color.
- d. If transporting a specimen(s) from the Medical Center, it must be placed in a secondary container which is leak proof, properly labeled, and red in color.
- e. Specimens and etiologic agents must be packaged and shipped in accordance with current Federal regulations (refer to Research Biosafety Manual).

4. BIOSAFETY CABINETS:

- a. Biosafety cabinets (Class I or II) must be used when performing procedures having a high potential for generation of aerosols, or for manipulations involving concentrates of bloodborne pathogens.
- b. Personnel must be trained or have experience in proper use of biosafety cabinets.
- c. Biosafety cabinets (Class I or II) are required to be tested and certified at the time of installation, whenever moved, and at least once yearly. The required tests must be performed by trained personnel. A current certification decal (or tag) must be affixed to the cabinet. A certification report may be used for documentation, but must be signed and dated by the person performing the required tests.

5. CENTRIFUGES:

- a. Centrifuge safety cups are recommended when tubes containing specimens or cultures are centrifuged. They must be regularly inspected for cracks, chipping, or deterioration of the seals.
- b. Special consideration should be given to the selection of centrifuge tubes. They must be sealable and able to withstand the centrifugal forces imposed without breakage. Tubes should be inspected regularly for cracking or chipping.
- c. Centrifuge rotors should not be run above their rated speed. Rotors must be inspected regularly for signs of pitting or other deterioration, and replaced as necessary.

6. OTHER:

Each laboratory should develop an inspection schedule for engineering controls used in that laboratory.

C. WORK PRACTICE CONTROLS:

Work practice controls in conjunction with Engineering controls represent the primary methods used for prevention of occupational transmission of HBV, HIV, or other bloodborne pathogens. Appropriate work practice controls include, but are not limited to, the following:

1. HAND WASHING:

- a. Hand washing is required after handling biohazardous materials, after removal of personal protection equipment, and before leaving the laboratory.

- b. When hand washing is not immediately feasible, the use of moist toweletts followed by antiseptic hand rub is an acceptable interim measure. Hand washing should be done as soon as practical thereafter.
- c. Immediately following contact with blood or other potentially infectious material, employees must wash hands and/or any other exposed body areas with soap and water.
- d. Immediately flush mucous membranes coming into contact with blood, body fluids, or infectious materials with copious amounts of water.

2. SHARPS:

- a. Needles, surgical blades, or other sharps should be used only when absolutely necessary. Self-sheathing needle-syringe units should be used.
- b. No attempt should be made to recap needles, or to intentionally bend, break, or remove needles from syringes.
- c. Never place hands or fingers through the opening of sharps containers for any reason, and do not attempt to remove lid.
- d. Contaminated sharps, broken glass, or hard plastic are promptly discarded in approved sharp containers (see Subsection B-2, above). Mechanical devices used for picking up broken glass or hard plastic must be disinfected or discarded.
- e. Filled sharps containers (do not fill above designated line) are to be closed and the lid

sealed with tape. However, tape is not to serve as a substitute for a lid.

- f. Before removal from the laboratory, all surfaces of closed sharps containers should be disinfected with an appropriate chemical disinfectant. Containers are to be picked up by Environmental Management Service for proper disposal.

3. SPECIMENS:

- a. All laboratory personnel who will have contact with clinical specimens must be trained to handle all specimens in accordance with Standard Precautions.
- b. Specimen containers must not be transported through the use of the pneumatic tube. Safety transport carriers should be used. Carriers are to be chemically disinfected and then cleaned after use.
- c. Mouth pipetting of specimens is strictly prohibited. Mechanical devices must be used. Pipette tips are to be discarded as a sharp.
- d. Specimens are placed only in designated containers (see Subsection B-3, above).
- e. Storage of specimens in Common Resource cold rooms, refrigerators or freezers must be in a properly labeled primary container (see Section V-B-3, above), and enclosed in a non-breakable leak proof secondary container. The secondary container must have a biohazard label which clearly identifies the contents, and bears the name, room number, and contact number of the responsible Investigator. These requirements also apply to the storage of any other biohazardous agents or materials.

- f. It is prudent practice to remove rubber stoppers from specimen blood tubes by covering the stopper with gauze, or opening tube behind a protective splash shield.

4. WORK AREA:

- a. Work space should be ample, and kept free of unnecessary materials and equipment.
- b. Work surfaces should be covered with plastic-backed absorbent paper. This protective covering should be replaced immediately if overtly contaminated during use, and must be replaced at the end of the procedure.
- c. Eating, drinking, smoking, or applying of cosmetics in laboratories is not permitted at any time.
- d. Storage of foods or beverages in refrigerators, cold rooms or other areas where biohazardous materials may be present is not permitted.
- e. Thermometers must be placed in refrigerators which are used for storage of biohazardous materials, and regularly monitored to assure the appropriate temperature is maintained.
- f. Laboratory procedures should be carried out in a manner which minimizes the potential for generation of infectious aerosols. When this is not feasible, such procedures must be performed in a biosafety cabinet (Class I or II).
- g. Mouth pipetting of cultures of biohazardous etiologic agents is strictly prohibited. Mechanical devices must be used. Pipette tips are to be discarded as a sharp.

- h. Laboratory personnel are responsible for decontaminating work surfaces. This task is not a responsibility of Environmental Management Service.

5. CONTAMINATED EQUIPMENT:

Equipment which may become contaminated with blood or other potentially infectious materials must be examined prior to servicing or shipment, and must be decontaminated.

- a. Where complete decontamination can not be accomplished, those parts of the equipment remaining contaminated must be labeled with a biohazard warning which specifically identifies each contaminated part. More than one label may be needed. In order to properly identify the part, write on the label(s) if necessary.
- b. If complete decontamination is not possible, and the area of contamination poses a health risk to others, request assistance from Infection Control, equipment service representative, or the manufacturer.
- c. Verbally communicate area(s) of contamination to all personnel who use the equipment, and to equipment representatives (sales and service), and other persons servicing the equipment.

D. PERSONAL PROTECTION EQUIPMENT:

In addition to implementation of engineering and work practice controls, personal protection equipment may be needed to prevent occupational exposure to infectious materials. Such equipment includes, but is not limited to, gloves, gowns, aprons, laboratory coats, face shields, masks, and eye protection devices. Personal protection equipment is intended to provide a barrier

against contact of infectious materials with an employee's street clothing, skin, eyes, mouth and other mucous membranes.

1. GENERAL:

- a. The type and amount of personal protection equipment is determined by the Principal Investigator, and is selected on the basis that provides the best protection against the most expected exposure.
- b. Personal protection equipment that is determined to be needed is provided at no employee cost, in appropriate sizes, and is made readily accessible.
- c. An employee who wishes to choose, wear, and maintain a personally owned laboratory coat is required to use laboratory provided gowns as an outer covering when performing tasks where exposure can be reasonably anticipated.
- d. The use of personal protection equipment is mandatory when determined to be needed by the Principal Investigator.
- e. Reusable personal protection equipment such as face shields and goggles must be inspected periodically and repaired or replaced as necessary.
- f. Contaminated disposable gowns, gloves, or masks are to be discarded into red biohazard disposal bags as soon as feasible, but immediately if overtly contaminated, torn, or punctured.
- g. Personal protection equipment must be removed before exiting the laboratory.

- h. Laboratory provided reusable garments will be laundered on-site. Personally owned contaminated laboratory coats will also be laundered on-site. Laundering of contaminated garments at home is not permitted as this may result in migration of infectious agents into the home.

2. GLOVES:

- a. Hypoallergenic gloves will be provided for laboratory personnel who are allergic to gloves normally provided. Employees must be referred to Employee Health for evaluation.
- b. Disposable (single-use) gloves must be worn whenever biohazardous materials are to be handled, including cultures of etiologic agents. In some situations double-gloving may be necessary to permit frequent changing of the contaminated outer pair.
- c. General utility gloves such as rubber household gloves should be worn for housekeeping tasks. Such gloves can be decontaminated and washed for re-use, but must be replaced if cracked, peeling, torn, or punctured.
- d. Disposable (single-use) gloves must be discarded. They are not to be washed or reused under any circumstance.
- e. Gloves of the type recommended by the Animal Research Facility Supervisor must be worn when handling infected experimental animals.

3. CLOTHING:

- a. Protective clothing (gowns, aprons) with minimum ability to resist penetration by

liquids should be used when minimal contact with blood or other potentially infectious materials is expected.

- b. Impervious (plastic or plastic-backed) gowns with long sleeves should be worn when body exposure to blood or other potentially infectious materials is anticipated. In such situations the clothing must be replaced as soon as feasible if overt contamination occurs.
- c. If gross contamination can be reasonably anticipated, protective head and shoe covers may be necessary in conjunction with other clothing.

4. MASK, FACE, EYE PROTECTION:

- a. Laboratory personnel must use fluid resistant masks (molded) and eye protection (with side shields) or full-face shields when carrying out procedures where there is a potential for splashing or splattering of infectious materials.
- b. Fluid resistant masks (molded) and full face protection are required when performing procedures where the potential for aerosol generation exists. All such procedures should be carried out in a biosafety cabinet (Class I or II). Masks, however, do not provide sufficient protection from infectious respirable particles. In situations where there is a risk of inhalation of infectious respirable particles which can not be contained within a biosafety cabinet, or other physical containment device, the use of an approved respirator and enrollment in the Medical Center Respiratory Protection Program may be necessary.
- c. Full-face shields are required during removal and thawing of biohazardous materials stored

in liquid nitrogen to protect against the risk of explosion of the container.

E. HOUSEKEEPING:

A clean and sanitary laboratory provides a safer working environment. Laboratory personnel must assume the responsibility for keeping the laboratory safe by cleaning up after themselves, and not leave this important task to others. The OSHA Bloodborne Pathogens Standard stipulates that a written cleaning schedule be implemented and which lists what is to be cleaned, the frequency of cleaning, appropriate methods of disinfection, and the cleaning procedures which are to be followed. Consequently, each laboratory must develop and implement a regular cleaning schedule (see form in Appendix). A copy of the cleaning schedule is to be posted in the laboratory for easy reference.

1. WORK SURFACES:

- a. To facilitate decontamination and cleanup, working surfaces of benches and biosafety cabinets should be covered with plastic-backed absorbent paper. If overt contamination occurs, the protective covering is removed as soon as feasible, and the affected area flooded with a working solution (one ounce/gallon of water) of Wexcide (or other appropriate liquid disinfectant). Wait 10 minutes, clean affected area using a soap and water wash, and then treat with the disinfectant. The disinfectant used in the laboratory must be shown to be effective against the types of biohazardous materials present in the laboratory as documented on the product label, or based on current accepted practice.
- b. Minor contamination from droplets etc. should be contained by the protective covering, but the protective covering should be replaced as soon as feasible after contamination occurs.

- c. Routine decontamination of work surfaces, including interior sides of biosafety cabinets, should be done at the completion of the procedure. The area should be first disinfected using a working solution (one ounce/gallon of water) of Wexcide (or other appropriate liquid disinfectant) cleaned by means of a soap and water wash, and again treated with the disinfectant. Routine decontamination of working surfaces must be done at least at the end of the workday.

2. BINS AND TRASH CONTAINERS:

- a. Bins or other containers used for collection and transport of autoclavable solid or liquid wastes should be autoclaved with the waste materials following completion of the procedure. Further cleaning can be accomplished using a soap and water wash.
- b. Trash containers for red biohazard disposal bags must be examined daily for signs of contamination.
 - (1) Minor contamination can be removed by first disinfecting with a working solution (one ounce/gallon of water) of Wexcide, followed by a soap and water wash, and then again treated with disinfectant.
 - (2) Overtly contaminated containers must be promptly disinfected by flooding with a working solution (one ounce/gallon of water) of Wexcide (or other appropriate disinfectant). Wait 10 minutes, and then clean with a soap and water wash, followed by treatment with disinfectant.

3. FLOORS AND WALLS:

- a. Spills on floors or splashes on walls should be immediately disinfected with a working solution (one ounce/gallon of water) of Wexcide (or other appropriate disinfectant). Wait 10 minutes, then clean the area with a soap and water wash, followed by treatment with disinfectant.
- b. A spill kit should be available in the laboratory. It should contain extra items of personal protection equipment, red biohazard disposal bags, absorbent materials, and other necessary items for decontamination and clean up of a major spill.

4. EQUIPMENT:

- a. Protective coverings on equipment (plastic wrap, aluminum foil, etc.) should be replaced when visibly contaminated, and after each use of the equipment.
- b. Contaminated equipment must be disinfected and cleaned following use. Procedures for disinfection and cleaning must be in accordance with manufacturer instructions or recommendations, or in accordance with written instructions provided by the Principal Investigator (see also, Section V-C-5, above).
- c. Freezers, refrigerators, and cold rooms used for storage of biohazardous materials should be inspected periodically for the presence of broken containers by laboratory personnel. Any broken containers must be removed by mechanical means, disinfected, and discarded into a sharps container. The equipment must be disinfected and then cleaned.
- d. Incubators may become contaminated over time. The interior surfaces should be cleaned with a suitable disinfectant. Shelving should be disinfected and then autoclaved.

5. LAUNDRY:

- a. Standard Precautions must be observed when handling all contaminated reusable protective clothing.
- b. Laundry bags used at this Medical Center are color-coded white and are impervious to prevent leaking.
- c. Contaminated reusable protective clothing must be bagged where it is generated, ie, the laboratory.
- d. Principal Investigators should contact the Medical Center Laundry Service (x4356) to obtain laundry bags and service. If garments are seriously contaminated the Laundry Manager should be notified (x4070).

F. LABELS:

1. Biohazard warning signs or labels must be predominately fluorescent orange or orange-red with the international biohazard symbol and the word BIOHAZARD in a contrasting color.
2. Biohazard warning signs are required at the entrance to research laboratories and infected animal rooms where HIV, HBV, other bloodborne pathogens, or other human disease-causing etiologic agents or biohazardous materials are present.
3. The following items must be labeled:
 - a. Waste containers for liquid or solid biohazardous wastes.

- b. Sharps disposal containers.
- c. Containers that are used for collection, transport, storage, or shipment of blood or other potentially infectious materials, or etiologic agents.
- d. Refrigerators, cold rooms, freezers and incubators where blood, other potentially infectious materials, or etiologic agents are stored, held, or incubated.
- e. Contaminated equipment (see Section V-C-5, above).
- f. All used laundry is treated as contaminated.

G. BIOHAZARDOUS WASTE:

Biohazardous waste is defined as any waste which may represent a threat of infection to humans. Laboratory personnel must know what is regarded as biohazardous waste (see definition, Section II) and how to handle and dispose of it properly.

1. SEGREGATION OF WASTES:

- a. Discarded sharps must be kept separate from all other wastes. Intact or broken glass and hard plastic are to be considered as sharps.
- b. Keep liquid and solid biohazardous wastes generated during laboratory procedures separate.

2. PROCEDURES FOR DISPOSAL OF SHARPS:

- a. Contaminated sharps (including pipette tips from mechanical devices or broken glass or hard plastic) must be discarded immediately into an approved sharps container (see Section V-B-2, above).

- b. It is prudent practice to chemically disinfect surfaces of sharps containers when work is finished.
- c. When full (fill only to designated line), close and seal lid, and have picked up by Environmental Management Service for proper disposal.

3. PROCEDURES FOR DISPOSAL OF LIQUID WASTES:

- a. Liquid wastes generated during laboratory procedures should be collected in a suitable color-coded or labeled, closeable, leak proof, autoclavable, durable container.
- b. When work is completed, close container to prevent leakage or splashing, and chemically disinfect all surfaces.
- c. Transport in a safe manner to autoclave room, and before autoclaving loosen container cover. Decontaminate by autoclaving for a minimum of 30 minutes at 121°C, and 15 psi. Treated, and only treated, liquid wastes can be disposed through the sanitary sewer system.

4. PROCEDURES FOR DISPOSAL OF SOLID WASTE:

- a. Contaminated labware and other reusables should be placed in a color-coded, leak proof, autoclavable, durable transport container which can be covered. Solid wastes capable of releasing liquids should be placed in autoclavable biohazard bags in the same container.
- b. When work is completed, close autoclavable biohazard bags (tape loosely), cover

container, and chemically disinfect surfaces of container.

- c. Safely transport container to autoclave room, and decontaminate container and contents by autoclaving for a minimum of 60 minutes at 121°C, and 15 psi, followed by a 10 to 15 minute dry cycle. Sterilized solid waste is not considered biohazardous waste.
- d. All disposable solid laboratory wastes should be placed in trash containers lined with red biohazard disposal bags (preferably use double-bagging). These bags are always available through Environmental Management Service.
- e. When filled, laboratory personnel should securely close bags (use twist ties), and chemically disinfect all surfaces before bags are removed from the laboratory.
- f. Red biohazard disposal bags should be picked up by Environmental Management Service for proper disposal (Transport must be effected in such a manner that no release of the contents occurs).

5. AUTOCLAVE PROCEDURES:

- a. Monitoring records must be maintained to document proper sterilization of biohazardous wastes and contaminated reusables.
- b. The autoclave log should identify the name of the operator, nature of the load, the highest temperature that is reached during the sterilization process and the length of time this temperature is maintained.
- c. An autoclave temperature-sensitive indicator tape (changes color or displays the word

autoclaved when exposed for 15 min at 121°C and 15 psi) should be placed on each package or container. Where appropriate, indicator strips which change color should also be placed inside packages to assure steam penetration into the package. Results of the indicator changes should be documented in the autoclave log.

- d. Sterility tests are performed weekly to assure that autoclaves are operating properly. A biological sterilization indicator is used, and the results of the weekly tests are documented in the autoclave log book.
- e. Do not attempt to use an autoclave if a sign has been posted indicating it is not functioning properly. The sign will indicate the location of another autoclave that can be used.

VI. HIV AND HBV RESEARCH LABORATORIES:

Research laboratories engaged in the culture, production, concentration, experimentation, or manipulation of HIV or HBV must follow additional safety procedures. A minimum of a Biosafety Level 2/3 facility is recommended (see the specific laboratory guidelines in the Research Service Biosafety Manual). The following practices apply to HIV and HBV Research laboratories.

A. WORK PRACTICES:

1. All engineering and work practice controls described in this Exposure Control Plan must be strictly followed.
2. Biohazard warning signs are mandatory on all laboratory entrance doors.

3. The biohazard signs must list all infectious agents used in that area, the name and telephone number of the Principal Investigator, and any special requirements for entering the laboratory, including the personal protection equipment needed. In general, access is limited only to essential personnel. Persons at increased risk of acquiring infection, or for whom infection may be particularly hazardous, will not be allowed entrance into the laboratory (eg., children, pregnant women, patients undergoing immunosuppressive therapy). Visitors must be accompanied by a staff member.
4. When work is in progress, all doors are kept closed, and entry by others is not permitted.
5. Mandatory personal protection equipment includes solid front disposable gowns, fluid resistant masks (molded), disposable gloves (double-gloved), and eye protection.
6. Electrical outlet boxes should be protected to prevent leakage of aerosols through electrical conduits.
7. Vacuum lines must be protected with high-efficiency particulate air (HEPA) filters and liquid disinfectant traps.
8. All activities involving manipulations of viral preparations must be conducted in a biosafety cabinet (Class I or II). No work in open vessels or on open benches is permitted. Containers for deposit of contaminated wastes or reusable items are placed in the cabinet before work begins.
9. The use of glassware should be avoided whenever possible. Disposable labware should be used in preference.
10. The use of needle/syringe units or other sharp devices should be avoided. If absolutely

necessary, sharps must be handled with extreme caution to prevent auto-inoculation. Sharps should be disinfected with 10% bleach, and syringes partially filled with this disinfectant before depositing in a puncture-proof autoclavable sharps container.

11. Containers for liquid wastes should contain 20% bleach solution, and be filled only to a capacity equal in volume to the original volume of the disinfectant.
12. Any centrifugation of viral preparations must be done using sealed centrifuge tubes contained within centrifuge safety cups. In the event of tube breakage, safety cups must be opened only in the biosafety cabinet.
13. When work is finished, the outer pair of gloves are to be discarded in the solid waste biohazard bag located in the biosafety cabinet. Eye protection devices should be cleaned with a germicidal soap and water wash.
14. Before exiting from the laboratory disposable protective equipment (first) and the second pair of gloves are to be discarded in a red biohazard disposal bag located near the exit. Hands must be washed before leaving the facility.

B. DECONTAMINATION AND CLEANING PROCEDURES:

1. All laboratory areas must be kept clean and orderly.
2. Small items of reusable equipment must be decontaminated with 10% bleach or 70% ethanol.
3. Work surfaces and interior sides of biosafety cabinets should be decontaminated with 10% bleach, followed by a 70% ethanol wash.

4. All notes taken in the laboratory must be disinfected with 10% bleach before removing them from the work area.
5. Floors should be washed with a disinfectant solution (Wexcide) daily, and promptly after any spills of infectious materials.
6. Laboratory personnel must assume the responsibility for decontamination and cleaning tasks.

C. DISPOSAL OF WASTES:

1. All waste containers in the biosafety cabinet must be closed (bags loosely taped), and surfaces chemically disinfected before they are removed.
2. Biohazard bags should be placed in a second bag (also taped loosely), and then placed in a closeable transport container. Water is added, after which the lid is placed on the container, and the ends sealed with an indicator autoclave tape.
3. Minimum autoclaving time is 60 minutes at 121°C, and 15 psi for non-contaminated laboratory wastes. Contaminated liquid waste and sharps containers should be autoclaved for 90 minutes at 121°C, and 15 psi. Solid contaminated wastes should be autoclaved 90 minutes at 121°C, and 15 psi, followed by a 10 to 15 minute dry cycle.
4. Laboratory personnel have the responsibility to autoclave all wastes generated in the laboratory.
5. Tests on the autoclave for temperature and sterility must be performed weekly.

D. SPECIAL TRAINING REQUIREMENTS:

1. Employees must demonstrate proficiency in standard microbiological procedures and practices and have prior experience in the handling of human pathogens or tissue cultures, and receive training in the practices and operations specific to the laboratory before being allowed to work in HIV or HBV research laboratories.
2. Employees having no prior experience in handling human pathogens are restricted to initial work activities which do not involve handling of infectious agents. A training program must be implemented for these employees wherein a progression of work activities are assigned as techniques are learned and proficiency is established. Once proficiency has been established through the training program, employees can work with infectious agents or materials. Training must be documented.
3. Additional training is to be provided whenever an employee's current tasks or procedures have been modified, or when new responsibilities are assigned that may affect their occupational exposure.
4. Once a year, all personnel working in the laboratory will receive training on the safety procedures specific to the laboratory. Attendance at this session is mandatory.

VII. HEPATITIS B VACCINATION AND POST-EXPOSURE EVALUATION AND FOLLOW-UP

A. VACCINATION PROGRAM:

1. The Hepatitis B vaccine is offered at no cost to Research laboratory personnel with occupational exposure to blood and other potentially infectious materials.

2. Hepatitis pre-screen testing is offered to determine whether the employee has already developed immunity to Hepatitis B from a prior-exposure or illness. Positive results on either HBSAg or anti-HBS eliminates the need to be vaccinated.
3. The Hepatitis B vaccination program is offered within 10 days after initial employment. The vaccination consists of a series of three inoculations over a six month interval. Following completion of the vaccination regimen, serology testing is done to confirm immunity.
4. The employee may decline the Hepatitis B vaccination program. A vaccine declination form must be signed. Declination does not preclude the employee from requesting and receiving the vaccine at a later time.

B. POST-EXPOSURE EVALUATION AND FOLLOW-UP TREATMENT:

The program offers post-exposure evaluation and follow-up treatment should an exposure incident to blood or other potentially infectious materials occur.

1. Potential occupational bloodborne exposure incidents include, but are not limited to: needlesticks by potentially contaminated needles, cuts, punctures, mucous membrane splashes, or ingestion of blood or body fluids or infectious etiologic agents or other biohazardous materials.
2. When a bloodborne exposure incident occurs, decisions regarding HBV and HIV prophylaxis requires obtaining certain information on the possible infectivity of the source individual (patient) and the susceptibility of the person exposed. The source individual of the exposure, if known, should be tested for HBsAg and HIV serostatus as soon as possible.

- a. Testing is not required if either the source individual or person exposed is known to be HIV and/or HBV positive.
 - b. The exposed person should be tested for anti-HBs unless they have had prior active immunization with the Hepatitis B vaccine.
3. Medical post-exposure and follow-up treatment for HIV or HBV will be done in accordance with protocol.

C. EVALUATION AND TREATMENT PROCEDURES:

1. Employees reporting significant occupational bloodborne exposures are provided immediate confidential medical evaluation and follow-up treatment through the Medical Center Employee Health Office.
2. During off-hours, the exposed person will be evaluated through the Admitting and Discharge Office, and referred to the Employee Health Office on the next scheduled working day.
3. Documentation of an occupational bloodborne exposure incident is required:
 - a. The employee must complete VA Form CA-1 "Federal Employee Notice of Traumatic Injury" using the Automated Safety Incident Surveillance Tracking System, ASISTS (electronic processing). Call extension 3009 if need assistance. The report must be completed within 2 (two) working days of the incident.
 - b. Principal Investigators must separately complete VA Form-2162 "Report of Accident, Injury, Occupational Illness, or Fire" using the Automated Safety Incident Surveillance Tracking System, ASISTS (electronic processing). Paper submissions of

Form 2162 will not be accepted. The report must be filed within 6 (six) working days of the incident.

- c. The Employee Health Office will complete the "Potential Exposure to Bloodborne Pathogen Sheet", and may request the employee's assistance in completing this or other forms. Research employees are expected to promptly comply with any such requests.
4. The source individual of the exposure will be identified (if possible) and documented on the appropriate forms by the Employee Health Office.
5. In order for anyone to obtain a copy of the Employee Health Medical Evaluation, a release of Medical Records form must be completed.

VIII. EMPLOYEE TRAINING:

A. SERVICE TRAINING:

1. All Research Service employees are required to attend the Medical Center (Infection Control) annual refresher training program on Bloodborne Pathogens Exposure Control as mandated in the OSHA Standard. Sessions are held monthly in the Medical Center Auditorium. Topics covered in this training program include, but are not limited to:
 - a. Information on how to obtain a copy of the OSHA Occupational Exposure to Bloodborne Pathogens Standard, and an explanation of its contents.
 - b. Epidemiology and symptoms of bloodborne diseases.
 - c. Mode of transmission of bloodborne pathogens.

- d. The Hepatitis B vaccination program.
 - e. Procedures for reporting an occupational exposure incident, and how to obtain post-exposure medical evaluation and follow-up treatment.
2. Research Service employees are also required to attend the In-Service annual refresher training program on laboratory biosafety. Advance notification is given as to date, time, and location. Topics covered in this training program include:
- a. A review of the Research Service Infection Control Policy, and the Service Bloodborne Pathogens Exposure Control Plan.
 - b. A review of work practice controls, engineering controls, types and use of personal protection equipment, biohazardous waste disposal procedures, and signage and labeling requirements as may apply when working with biohazardous agents/materials present in the laboratory setting.
 - c. Updating employees on changes in biosafety guidelines as may be recommended from OSHA, CDC, or VAHQ.

B. LABORATORY INVESTIGATOR:

- 1. The Principal Investigator has the direct responsibility to provide new employees, upon initial assignment, with copies of the Service Infection Control Policy and Procedures, the Service Level Exposure Control Plan, and the Laboratory-specific Exposure Control Plan (if applicable).

2. The Principal Investigator also will have the responsibility to discuss these documents with the new employee, and to specifically describe laboratory procedures in effect to prevent or avoid exposure to blood or body fluids, or other biohazardous agents/materials.
3. Each Principal Investigator must provide annual refresher training for laboratory personnel on operating and safety practices specific to the laboratory.

C. OTHER TRAINING:

1. Employees who may perform procedures that may result in splashing or spraying of blood or other potentially infectious materials must be specifically trained in procedures which are designed to reduce the risk of exposure. This training is to be provided by the Principal Investigator.
2. The Principal Investigator must provide additional training whenever current tasks or procedures have been modified, or when new responsibilities are assigned that may affect an employee's occupational exposure.

IX. COMPLIANCE MONITORING:

1. The Principal Investigator has the direct responsibility to assure that all employees in the laboratory are in compliance with the operating practices and procedures designed to eliminate or reduce occupational exposure to bloodborne pathogens.
2. Incidents of non-compliance should be documented and discussed with the employee. This discussion should include corrective action(s) to be taken by the employee.

3. The Principal Investigator should maintain a log for documentation of employee non-compliance with laboratory safety practices.
4. Compliance monitoring can aid in identifying procedures or practices which may need to be changed. This might involve revision of existing procedures, or development of new procedures.
5. Repeated non-compliance by an employee is cause for appropriate disciplinary action. The Principal Investigator should carefully document incidents of non-compliance and corrective action(s) recommended. The Principal Investigator should consult with Research Administration regarding appropriate disciplinary action which may be warranted.

X. GENERAL PROGRAM MANAGEMENT

1. Name of Service

Research

2. Name of person or persons responsible for maintaining the list of employees who have specific responsibilities in your service.

Gustavo Godoy
Ana Valls
Principal Investigators

3. Person or persons appointed to be the Exposure Control Officer in your service.

Richard A. Cowman, Ph.D.
Gustavo Godoy

4. Locations where copies of your Exposure Control Plan are accessible to employees.

Laboratory
Research Administration Office

5. Name of the person or persons responsible for maintaining and updating the list of job classifications, and task/procedures where exposure to bloodborne pathogens might occur.

Gustavo Godoy
Ana Valls
Principal Investigator

6. Name of the person or persons responsible for monitoring engineering controls and work practice controls.

Principal Investigator

7. The frequency of reviewing your service's engineering controls: 12 months.
8. Name of the person or persons responsible for monitoring the availability of personal protection equipment in predetermined, appropriate locations.

Principal Investigator

9. Name of the person or persons who monitors exposure incidents in your service.

Gustavo Godoy
Richard A. Cowman, Ph.D.

XI. REFERENCES:

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2. Centers for Disease Control and Prevention. Agent Summary Statement for Human Immunodeficiency Virus and Report on Laboratory-Acquired Infection with Human Immunodeficiency Virus. MMRW 37: S4, 1988.
3. Medical Center Policy Memorandum No 11-10-99. Infection Control Policy and Program Plan. Jan. 12, 1999.
4. Rowe, T. Laboratory Biosafety Manual. Retrovirus Diseases Branch. Centers for Disease Control and Prevention, Atlanta, GA, 1990.
5. State of Florida Department of Health and Rehabilitative Services. Chapter 10D-104 - Florida Administrative Code - Biohazardous Waste. April 3, 1997.
6. U.S. Department of Labor Occupational Safety and Health Administration. 29 CFR Part 1910, Occupational Exposure to Bloodborne Pathogens; Needlesticks and Other Sharps Injuries, Final Rule, Federal Register 66(12): 5318-5325, 2001.
7. US Department of Labor Occupational Safety and Health Administration. 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens; Final Rule. Federal Register 56(235): 64175-64182, 1991.
8. US Department of Labor Occupational Safety and Health Administration. Occupational Exposure to Bloodborne Pathogens. OSHA Publication No. 3127. 1992.
9. World Health Organization. Biosafety Guidelines for Diagnostic and Research Laboratories Working with HIV (Booklet), 1991.

XII. APPENDIX

1. Service Bloodborne Exposure Determination Form
2. Cleaning Schedule Example
3. OSHA Bloodborne Pathogens Exposure Control Standards:
 - a.) 29 CFR Part 1910
 - b.) 29 CFR-Part 1910.1030

BLOODBORNE EXPOSURE DETERMINATION

Research Service

<u>Position Title</u>	<u>Occ. Code.</u>	<u>Anticipated Exposure</u>	
		I	II
1 Microbiologist	403		X
2 Microbiologist	403	X	
1 Research Physiologist	413	X	
1 Research Physiologist	413		X
2 Medical Data Clerk	303		X
1 Computer Specialist/ Programmer	334		X
1 Computer Specialist/ Systems Analyst	334		X
1 Computer Specialist	334		X
1 Statistician/Medicine	1530		X
1 Statistical Assistant	1531		X
1 Administrative Officer	341		X
1 Staff Assistant	301		X
1 Administrative Support Assistant	303		X
1 Physicians/Med. Invest. Med. Invest.	602	X	
14 Nurses/Researchers	610	X	
4 Nurses/Researchers	610		
4 BLT	404		X
1 BLT	404	X	
1 BLT/Animal	404	X	
2 BLT/Animal	404		X
6 BLT/Biochem.	404		X
3 BLT/Micro.	404	X	
2 BLT/Micro.	404		X
1 Biological Science Aid	404		X
2 Laboratory Worker	3511	X	
1 Health Technician	640	X	
6 Research Chemist	1320		X
1 Research Chemist	1320	X	
1 Program Support Asst.	303		X
1 Program Support Clerk/ Office Automation	303		
1 Program Support Clerk/ Typing	303		X
3 Secretary/Typing	318		X
1 Secretary/Office Auto.	318		X

Bloodborne Exposure Determination (cont.)

Research Service

University of Miami Research Personnel

Position Title	Anticipated Exposure	
	I	II
51 UM Research Associates	X	
10 UM Research Assistants	X	
6 UM Staff Assistants		X

TOTAL: 67

South Florida VA Foundation Research Employees

Position Title	Anticipated Exposure	
	I	II
14 Foundation Research Assistants	X	
17 Foundation Staff Assistants		X

TOTAL: 31

CLEANING SCHEDULE

EXAMPLE

1. Lab bench surfaces: Clean daily or after each use; disinfect with working solution of Wexcide and after 10 min clean with soap/water solution.
2. Biosafety cabinets: Clean after each use; disinfect with Wexcide or approved disinfectant and after 30 min wipe down with 70% ethanol.
3. Trash containers: Inspect daily; if minor contamination, disinfect with Wexcide, clean with soap/water solution, then disinfect with Wexcide. If heavy contamination, flood with Wexcide, followed by soap/water wash after 10 minutes, then disinfect with Wexcide.
4. Floors: For minor spills, disinfect area with Wexcide, clean with soap/water wash after 10 min., followed by disinfection with Wexcide. For major spills, follow procedures outlined in Research Service Biosafety Manual (Section III-D).
5. Equipment: Inspect daily; Disinfect and clean in accordance with manufacturer recommendations.
6. Freezers/Refrigerators: Inspect monthly; disinfect with 0.4% Wexcide, followed by soap/water solution after 30 min.
7. Centrifuge rotors: Check daily; disinfect and clean in accordance with manufacturer or Principal Investigator instructions.