PROTOCOL SUMMARY

In the event of an accidental exposure or injury, the protocol is as follows:

1. Modes of Exposure:
   a. Skin puncture or injection
   b. Contact with mucous membranes (eyes, nose, mouth)
   c. Contact with non-intact skin

   (Per CDC: “Feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomitus are not considered infectious unless visibly bloody”)

2. First Aid:
   Intact Skin Exposure, immediately go to the sink and thoroughly wash the skin with soap and water. Antiseptic scrub solutions should not be used.
   a. Open Skin Wound, immediately go to the sink and thoroughly wash the wound with soap and water and pat dry.
   b. Splash to Eye(s), Nose or Mouth, immediately flush the area with running water for at least 15 minutes.
   c. Splash Affecting Garments, remove garments that may have become soiled or contaminated and place them in a double red plastic bag.

3. Treatment:
   a. In the event of an acute injury which requires immediate medical care, the injured individual should report to the Emergency Department for acute medical treatment. The injured individual must take a copy of this entire protocol document to the Emergency Department, including information regarding the specific HIV strains associated with exposure.
   b. In the event of an exposure, with or without an injury, call the Needlestick Exposure Hotline in order to get access to medical care for the exposure.

4. Follow-up is needed in the event of any Laboratory Exposure:
   a. After first-aid is complete, immediately inform your supervisor of the exposure.
   b. In the event of a large spill in a secure area, leave the area, secure the lab to prevent entry of other personnel and possible secondary exposures and contact the emergency response team (9-911) for clean-up.
   c. Contact Occupational Health Services for follow-up care after first aid/emergency department treatment.
ROLES & RESPONSIBILITIES
AFTER ACCIDENTAL EXPOSURE TO HIV/SIV

1. WORKER’S RESPONSIBILITIES (Worker’s Initial Self-Care)
   a. **First Aid:** Perform recommended first aid and decontamination according to the posted instructions. Wash exposed skin surfaces with soap and water.
   b. **Treatment:**
      i. In the event of an acute injury resulting from a laboratory incident which requires immediate medical care, the injured individual should report to the Emergency Department for acute medical treatment.
      ii. In the event of an exposure, with or without an injury, call the Needlestick Exposure Hotline in order to get access to medical care for the exposure.
   c. **Access to Needlestick Hotline:** Call the Needlestick Exposure Hotline in order to get access to medical care for the exposure. Dial 415 /353-STIC (7842). If there is no call back in 15 minutes, call again. If there is no call back the second time, proceed to the nearest Emergency Department with a copy of this protocol.
   d. **Reporting:** Immediately inform your laboratory supervisor/principal investigator of the exposure.
   e. **Secure the laboratory:** Identify the equipment involved in the exposure and the mechanism of exposure. Make sure that the laboratory area has been secured and that notification of contamination has been posted to prevent other individuals from entering the area.
   f. Remove any garments that may have become soiled/contaminated and place them in a double red biohazard bag.
   g. **Follow-up:** Contact Occupational Health Services (OHS) at 415/885-7580 for any needed follow-up care.

2. SUPERVISOR’S RESPONSIBILITIES
   a. **First Aid and Decontamination:** Verify that the worker has washed and decontaminated himself/herself. Ensure that appropriate first aid has been received.
   b. **Secure the laboratory:** Confirm that the laboratory area has been secured and that notification of contamination has been posted to prevent other individuals from entering the area.
   c. **Laboratory clean-up (as needed):** Contact the Office of Environmental Health & Safety (OEH&S) through the UC Police Department Emergency Dispatch (from a campus telephone 9-911, from a non-campus phone 415/476-1414).
   d. **Report the exposure:** The exposure must be immediately reported to the Biosafety Officer and to the EH&S Public Health Officer during regular business hours. A report summarizing any suspected HIV exposure needs to be submitted to the Biosafety Committee by the Principal Investigator (PI).

   The report must include the following:
   - A brief description of the exposure event, a description of the area involved, and the extent of
employee exposure.

- If applicable, specification of the amount of HIV released, time involved, and explanation of procedures used to determine the amount involved.
- Corrective action taken to prevent the re-occurrence of the incident.
- Decontamination procedures.

e. **Follow-Up:** Confirm that the worker has called for an appointment at the UCSF Occupational Health Services clinic.

f. **Report the Injury:** Within 24 hours, report the injury to the UCSF Human Resources Disability Management Services (HR DMS) Office on the Supervisor’s Report of Injury (SRI) form, available here:

   [http://ucsfhr.ucsf.edu/files/SIR.pdf](http://ucsfhr.ucsf.edu/files/SIR.pdf)

3. **PRINCIPAL INVESTIGATOR RESPONSIBILITIES**

   a. The PI will ensure that all lab personnel are trained in the use of safe laboratory procedures to prevent accidental exposure before assignment to any laboratory where HIV is used.

   b. The PI may request assistance from UCSF OEH&S in providing information about safe laboratory procedures. For assistance, the PI should call the UCSF Public Health Officer or Biosafety Officer.

   c. The PI must ensure that all researchers who will be working with HIV have read the entire protocol.

   d. The PI shall ensure that any known or suspected HIV exposure is reported to the UCSF Biosafety officer and Public Health Officer.

   e. Provide consultation on as needed basis to the Needlestick Exposure and/or Emergency Department regarding information regarding the potential risk of transmission given the specific events of the exposure.
MATERIAL SAFETY DATA SHEET - INFECTIOUS SUBSTANCES

SECTION I - INFECTIOUS AGENT
Organism: Human Immunodeficiency Virus
Synonym or Cross Reference: HIV, AIDS, Acquired Immune Deficiency Syndrome, HTLV III LAV
Characteristics: Retroviridae (Lentivirus); ss RNA, enveloped icosahedral nucleocapsid, glycoprotein envelope, reverse transcriptase.

SECTION II RECOMMENDED PRECAUTIONS
Containment Requirements: Biosafety level 2 practice, containment, and facilities are for replication incompetent HIV and activities involving clinical specimens and non-cultured procedures. Biosafety level 2* or BSL3 practice, containment, and facilities are for replication competent HIV, for activities involving any animals experimentally infected or inoculated with HIV and for all work with concentrated HIV or SIV.
Protective Clothing: Gloves should be worn when handling potentially infectious specimens, cultures or tissues; laboratory coats, gowns or suitable protective clothing should be worn. When working with animals infected with HIV, only tongs, thick or double gloves should be used to manipulate animals. Avoid using sharps.
Other precautions: Keep hands away from the eyes, nose and mouth in order to avoid potential exposure of the mucous membranes; eye goggles or face shields may assist in accomplishing this objective.

SECTION III - HANDLING INFORMATION
Spills: Allow aerosols to settle; wearing protective clothing, gently cover spill with paper towels and apply 0.5% sodium hypochlorite, starting at perimeter and working towards the centre; allow sufficient contact time (30 min) before clean up.
Disposal: Dispose all waste as biohazardous waste. Decontaminate before disposal - steam sterilization, incineration, and chemical disinfection.
Storage: In sealed containers that are appropriately labeled.

SECTION IV - HEALTH HAZARD
Pathogenicity: Insidious onset with non-specific symptoms such as lymphadenopathy, anorexia, chronic diarrhea, weight loss, fever, and fatigue; opportunistic infections and malignant diseases without a known cause for immune deficiency.
Epidemiology: First reported in 1981; cases recorded in Americas, Europe, Africa and many other areas; patient categories - homosexually or bisexually active men, drug abusers, Haitian/African emigrants, hemophiliacs, sexual partners of men and women in these categories, infants born to parents in this category.
Host Range: Humans.
Infectious Dose: Unknown.
Mode of Transmission: Through direct exposure to infected body fluids (blood, semen), skin puncture or injection, ingestion, contact with mucous membranes (eyes, nose, mouth), and contact with non-intact skin.

Incubation Period: Epidemiologic evidence suggests that duration from exposure to onset of symptoms has a minimum range from 6 months to more than 7 years.

Communicability: Period of communicability extends from asymptomatic period through appearance of opportunistic diseases.

Reservoir: Humans.

Zoonosis: None.

Vectors: None.

FOR THE USE OF THE NEEDLESTICK EXPOSURE HOTLINE

SECTION V - VIABILITY

Drug Susceptibility: Several reverse transcriptase and protease inhibitors now licensed.

Susceptibility to disinfectants: Susceptible to many disinfectants - 1% sodium hypochlorite, 2% glutaraldehyde, formaldehyde, ethanol.

Physical Inactivation: Effectiveness of 56·C - 60·C heat in destroying HIV in serum not certain, however, heating small volumes of serum for 30 min at 56·C before serologic testing reduces residual infectivity to below detectable levels.

Survival Outside the Host: Drying in environment causes rapid (within several hours) 90-99% reduction in HIV concentration.

SECTION VI - MEDICAL

Surveillance: Serological monitoring for evidence of HIV infection.

First Aid / Treatment: Washing and decontamination of the exposed area. Multidrug treatment is available for HIV positive individuals.

Immunization: None available.

Prophylaxis: Prophylaxis with AZT/3TC (Combivir) or other appropriate drug is available for exposures that are assessed to be high risk for transmission.

SECTION VII - LABORATORY HAZARDS

Laboratory Acquired Infections: Although there have been many reported cases of HIV infection through occupational transmission, the numbers of laboratory acquired infections are low. As of 2011, there have been a total of 57 cases of documented occupationally acquired HIV among U.S. health care workers.

Source Specimens: Blood, semen, vaginal secretions, CSF, other specimens containing visible blood, unscreened or inadequately treated blood products.

Primary Hazards: Direct contact with skin and mucous membranes of the eye, nose and mouth; accidental parenteral inoculation; ingestion; hazard of aerosols exposure unknown.

Special Hazards: Extreme care must be taken to avoid spilling and splashing infected materials - virus should be presumed in/on all equipment and devices coming in direct contact with infected materials.

FOR THE USE OF THE EMERGENCY DEPARTMENT

SECTION VIII – Emergency Medical Treatment

Treatment Indications: Emergency department treatment will be required for immediate treatment. The treatment needs to consist of the following: 1) decontamination and debridement 2) wound repair 3) evaluation for post exposure prophylaxis and 4) follow up with OHS.

Exposure Indications: In the event of an exposure, with or without an injury, the Exposure Hotline must be called.
Decontamination: Ensure that the wound has been adequately decontaminated.

Replication Competency: Must indicate if exposure involved virus that is replication competent or incompetent.

Review the “Viral Vector Exposure Risk Assessment Part 1”: Each PI must develop an emergency response plan in case of exposure to HIV viral vectors. It is the responsibility of the PI to provide risk assessment information if emergency department providers have any questions regarding health hazards related to HIV recombinant DNA research. The exposed worker should have a copy of the “Viral Vector Exposure Risk Assessment Part 1” for your review, which provides potential hazards of the vector and an analysis of the hazards of each expressed gene included in the construct. If you have any questions, please have the on-call infectious disease consultant assist in the evaluation of the injured worker.


**FOR SIV EXPOSURES:**

Specimen Collection to CDC for Testing
1. Collect 10-20 ml of EDTA-treated blood in EDTA tubes using standard clinical venipuncture techniques. For samples collected Mondays through Thursdays, please follow shipment information below. For samples collected on Fridays and weekends, please contact William Switzer at the CDC (404-639-0219, email: bis3@cdc.gov) to make other shipping arrangements.

2. All specimens and paperwork should be coded without any personal identifiers.

3. Place the sample in a shipping container following the instructions found at the CDC or IATA websites: ([http://www.cdc.gov/od/ohs/biosfty/shipdir.htm](http://www.cdc.gov/od/ohs/biosfty/shipdir.htm); [http://www.iata.org/whatwedo/cargo/dgr/Pages/infectious_substances.aspx](http://www.iata.org/whatwedo/cargo/dgr/Pages/infectious_substances.aspx)) and ship at room temperature to the CDC Serum Bank using an overnight, next morning delivery service.

4. Unless other arrangements are made, all shipments are to be sent to:
   CDC Serum Bank (STAT)
   Centers for Disease Control and Prevention
   1600 Clifton Road NE
   Atlanta, GA 3033
   “Attention: Project 139”

5. Provide advance notice of the shipment by faxing a copy of the shipment manifest to both William Switzer (404-639-1174) and the CDC Serum Bank (770-339-5915) the day the samples are collected. Alternatively, email notification to William Switzer will suffice.

6. UCSF Occupational Health Services and Public Health Officer must provide details of the specific exposure in an email to William Switzer, including when, where, how the exposure occurred, the strain of SIV or SHIV involved, animal species, occupational and antiretroviral treatment.

**Prophylaxis:** Truvada alone for 28 days can be considered for SIV exposures after risk assessment. If SHIV or HIV exposure, use Truvada and Kaletra consistent with PEP for clinical exposure.

**Surveillance:** Serial testing for HIV and SHIV exposures should occur according to the following schedule: Baseline, 3 weeks, 6 weeks, 12 weeks and 26 weeks.
**Risks in Laboratory Workers/Clinical Summary**

**Overview**

This protocol had been developed for laboratories where HIV is present. Clinicians who treat clinical exposures to HIV have known for many years that the risk of seroconversion following exposure is directly related to the quantity of HIV to which exposed individuals are exposed. Clinical research laboratories where high titer HIV is present are individual and unique challenges for biosafety professionals. Any activities that increase the chance of aerosols or droplets must be minimized. Furthermore, it is essential that any potential exposures must be immediately evaluated since they are inherently more dangerous than clinical exposures, and infection may occur rapidly. In general, HIV post exposure prophylaxis should be started within 72 hours. This is even more important in the case of high risk exposure. Typical clinical titers range from 0 to 10 million copies HIV RNA per ml of plasma. Experimental titers may be many folds higher, and may approach $1.4 \times 10^{10}$ infectious units per ml of cell culture fluid.

If a laboratory is working with drug resistant strains of HIV, each researcher should be aware of the antiviral resistance pattern of the strain being used, and the PI shall determine, before working with a strain, which antiviral medications would be effective for treatment. This information shall be given to the treating needlestick hotline provider. Laboratory staff must be aware that HIV is a risk group 2 organism. Any high risk procedures shall be performed in a BSL 3 lab, or with guidance from biosafety, may be performed in a BSL 2 facility, using BSL3 practices (BSL2*).

The following section has been taken directly from the BMBL:


**Retroviruses, including Human and Simian Immunodeficiency Viruses (HIV and SIV)**

The family Retroviridae is divided into two subfamilies, the Orthoretrovirinae with six genera including the Lentivirus genus, which includes HIV-1 and HIV-2. Other important human pathogens are human T-lymphotropic viruses 1 and 2 (HTLV-1 and HTLV-2), members of the Deltaretrovirus genus. The Spumaretrovirinae, with one genus, Spumavirus, contains a variety of NHP viruses (foamy viruses) that can occasionally infect humans in close contact with NHPs.

**Occupational Infections**

Data on occupational HIV transmission in laboratory workers are collected through two CDC-supported national surveillance systems: surveillance for 1) AIDS, and 2) HIV-infected persons who may have acquired their infection through occupational exposures. For surveillance purposes, laboratory workers are defined as those persons, including students and trainees, who have worked in a clinical or HIV laboratory setting anytime since 1978. Cases reported in these two systems are classified as either documented or possible occupational transmission. Those classified as documented occupational transmission had evidence of HIV seroconversion (a negative HIV-antibody test at the time of the
exposure which converted to positive) following a discrete percutaneous or mucocutaneous occupational exposure to blood, body fluids, or other clinical or laboratory specimens. As of June 1998, CDC had reports of 16 laboratory workers (all clinical) in the United States with documented occupational transmission.

Workers have been reported to develop antibodies to simian immunodeficiency virus (SIV) following exposures. One case was associated with a needle-stick that occurred while the worker was manipulating a blood-contaminated needle after bleeding an SIV-infected macaque monkey. Another case involved a laboratory worker who handled macaque SIV-infected blood specimens without gloves. Though no specific incident was recalled, this worker had dermatitis on the forearms and hands while working with the infected blood specimens. A third worker was exposed to SIV-infected primate blood through a needle-stick and subsequently developed antibodies to SIV. To date there is no evidence of illness or immunological incompetence in any of these workers.

Natural Modes of Infection

Retroviruses are widely distributed as infectious agents of vertebrates. Within the human population, spread is by close sexual contact or parenteral exposure through blood or blood products.

Laboratory Safety and Containment Recommendations

HIV has been isolated from blood, semen, saliva, tears, urine, CSF, amniotic fluid, breast milk, cervical secretion, and tissues of infected persons and experimentally infected nonhuman primates.

Although the risk of occupationally-acquired HIV is primarily through exposure to infected blood, it is also prudent to wear gloves and goggles when manipulating other body fluids such as feces, saliva, urine, tears, sweat, vomitus, and human breast milk. This also reduces the potential for exposure to other microorganisms that may cause other types of infections.

In the laboratory, virus should be presumed to be present in all blood or clinical specimens contaminated with blood, in any unfixed tissue or organ (other Agent Summary Statements: Viral Agents 223 than intact skin) from a human (living or dead), in HIV cultures, in all materials derived from HIV cultures, and in/on all equipment and devices coming into direct contact with any of these materials.

SIV has been isolated from blood, CSF, and a variety of tissues of infected nonhuman primates. Limited data exist on the concentration of virus in semen, saliva, cervical secretions, urine, breast milk, and amniotic fluid. Virus should be presumed to be present in all SIV cultures, in animals experimentally infected or inoculated with SIV, in all materials derived from SIV cultures, and in/on all equipment and devices coming into direct contact with any of these materials.

The skin (especially when scratches, cuts, abrasions, dermatitis, or other lesions are present) and mucous membranes of the eye, nose, and mouth should be considered as potential pathways for entry of these retroviruses during laboratory activities. It is unknown whether infection can occur via the respiratory tract. The need for using sharps in the laboratory should be evaluated and sharps with engineered safety devices should be used when possible. Needles, sharp instruments, broken glass, and other sharp objects must be carefully handled and properly discarded. Care must be taken to avoid spilling and splashing infected cell-culture liquid and other potentially infected materials.

BSL-2 practices, containment equipment, and facilities are recommended for activities involving blood-contaminated clinical specimens, body fluids and tissues. HTLV-1 and HTLV-2 should also be handled at this level. Activities such as producing research-laboratory-scale quantities of HIV or SIV, manipulating concentrated virus preparations, and conducting procedures that may produce droplets or aerosols, are performed in a BSL-2 facility, using BSL-3 practices. Activities involving large-scale volumes or preparation of concentrated HIV or SIV are conducted at BSL-3. ABSL-2 is appropriate for NHP and
other animals infected with HIV or SIV. Human serum from any source that is used as a control or reagent in a test procedure should be handled at BSL-2.

In addition to the aforementioned recommendations, persons working with HIV, SIV, or other bloodborne pathogens should consult the Cal/OSHA Bloodborne Pathogen Standard. Questions related to interpretation of this Standard should be directed to federal, regional or state Cal/OSHA offices.

Special Issues

It is recommended that all institutions establish written policies regarding the management of laboratory exposure to HIV and SIV, including treatment and prophylaxis protocols.

The risk associated with retroviral vector systems can vary significantly, especially lentiviral vectors. Because the risk associated with each gene transfer system can vary, no specific guideline can be offered other than to have all gene transfer protocols reviewed by an IBC.

Transfer of Agent

Importation of this agent may require CDC and/or USDA importation permits. Domestic transport of this agent may require a permit from USDA/APHIS/VS. A DoC permit may be required for the export of this agent to another country.
DESCRIPTION AND IMPLICATIONS OF RISK:

INADVERTENT AEROSOLS
Emphasis must be placed on evaluating and modifying experimental procedures to eliminate the possibility of inadvertent generation of HIV aerosols. Pressurized tubes or other containers holding high titer HIV must be opened in a biosafety cabinet (BSC). Operations that expose HIV solutions to vacuum or pressure must always be handled in this manner, and the operator should also use appropriate respiratory protection. Centrifugation of cultures or materials potentially containing HIV should only be performed using sealed, thick-walled tubes in safety centrifuge cups or sealed rotors. The outside surfaces of containers and rotors must be routinely cleaned before each use to prevent contamination that may generate an aerosol. After centrifugation, the entire rotor assembly must be taken from the centrifuge to a BSC to open it and remove its tubes. Face shield must be worn while thawing tubes containing HIV to prevent potential exposures.

MECHANICAL INJURIES
Accidental needle-sticks or mechanical injury from “sharps” such as glass or metal implements pose a well-known risk to laboratory workers, and the consequences may be catastrophic for operations involving high titer HIV. Laboratory should avoid using sharps or replace all sharps with safe sharps. Discarded needles/syringes and other sharps should be placed directly into properly labeled, puncture-resistant sharps containers. Glassware must be replaced with plastic for handling HIV solutions wherever practical to minimize the risk of cuts or abrasions from contaminated surfaces. Thin-walled glass equipment must be completely avoided. Glass Pasteur pipettes are particularly dangerous for transferring HIV-infected solutions and must be replaced with disposable plastic pipettes. Glass chromatography columns under pressure must be enclosed within a plastic water jacket or other secondary container.


ADDITIONAL RESOURCES

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition:

Pathogen Safety Data Sheet:

UCSF Supervisor Incident Protocol and Report Form:
http://ucsfhr.ucsf.edu/index.php/workcomp/cat/site/For%20Supervisors

UCSF Employee Incident Protocol and Report Form:
http://ucsfhr.ucsf.edu/index.php/workcomp/cat/site/For%20Employees