

STANDARD OPERATING PROCEDURES (SOP)

Rabies Protection Program

1. SCOPE

Rabies is a virus causing an acute central nervous system infection, which is typically transmitted by introducing the rabies virus into open cuts or wounds, or via percutaneous exposure (i.e. scratches, punctures or bites). An effective rabies virus vaccination is available and is offered free of charge to employees who are determined to have exposure to rabies virus through employment with the University of Pittsburgh. This SOP was designed to establish a system of information and safeguards that should be followed at the University of Pittsburgh when using rabies virus or certain animals in the research environment.

2. PROCEDURE

2.1 AGENT

Rabies virus (prototype of the genus *Lyssavirus*, family *Rhabdoviridae*)

2.2 EMPLOYEES AT RISK

Naturally or experimentally infected laboratory animals are a potential source of infection to exposed unvaccinated laboratory personnel. Such personnel are also at risk of acquiring rabies infection when working with rabies virus, having direct contact with quarantined animals potentially infected with rabies, having exposure to potentially infected animal tissues and having responsibility for capturing or destroying wild animals. To further delineate employees at risk, categories of exposure and risk have been developed.

- 2.2.1 Continuous Risk Category- Potential exposure due to the manipulation of rabies virus in the research environment. This category includes all individuals involved in experiments using rabies virus and all animal care staff handling animals that have been infected with the rabies virus.
- 2.2.2 Frequent Risk Category- Potential exposure due to the manipulation of wild animal species known to harbor rabies virus, including but not limited to bats, dogs, cats, ferrets, and wild terrestrial carnivores. This category includes veterinarians and animal care staff and other staff who handle wild or pre-quarantined animals whose species is known to harbor rabies virus.
- 2.2.3 Infrequent Exposure- Exposure to rabies virus is typically episodic with a recognized source but exposure may be unrecognized although very rare. This category includes veterinarians and animal care staff who handle purpose-bred or post-quarantine wild animals that have not been infected with the rabies virus but their species is known to harbor rabies virus, including bats, dogs, cats, ferrets, and wild terrestrial carnivores.
- 2.2.4 Rare Exposure- Exposure is always episodic from a recognized source. This category would include employees exposed to research animals with negligible rabies rates. It should be noted that small rodents and rabbits have not been known to transmit rabies to humans.

2.3 **LABORATORY HAZARDS**

Virus-laden saliva introduced via a bite, scratch or very rarely into a fresh break in the skin or mucous membrane or body fluids from an animal in the research environment is the typical route of transmission, although very rare instances of transmission have been reported via inhalation or ingestion of very high concentrations of virus.

2.4 **PRE-EXPOSURE PROPHYLAXIS**

2.4.1 Continuous Risk Category

2.4.1.1 These individuals are required to undergo a primary course of vaccination with serologic levels of rabies antibodies monitored every six months. Vaccination shall be the human diploid cell vaccine (1.0 ml HDCV) given intramuscularly in the deltoid. Vaccine is given on days 0, 7 and 21.

2.4.1.2 Four weeks after vaccine dose 3 at day 21, persons will undergo serological testing by having a serum sample tested for rabies antibody using rapid fluorescent focus inhibition tests (RFFIT). And thereafter, persons in the continuous risk category will undergo serological testing every six months. Booster doses of vaccine are administered to maintain a serum titer corresponding to at least complete neutralization at a 1:5 serum dilution.

2.4.2 Frequent Risk Category

2.4.2.1 These individuals are required to undergo a primary course of vaccination with serologic levels of rabies antibodies monitored every two years.

2.4.2.2 Four weeks after vaccine dose 3 at day 21, persons will undergo serological testing by having a serum sample tested for rabies antibody using rapid fluorescent focus inhibition tests (RFFIT). And thereafter, persons in the continuous risk category will undergo serological testing every two years. Booster doses of vaccine are administered to maintain a serum titer corresponding to at least complete neutralization at a 1:5 serum dilution.

2.4.3 Infrequent Risk Category

2.4.3.1 Animal users as defined in the infrequent risk category are offered rabies vaccination as the primary course is listed above.

2.4.3.2 It is recommended that infrequent risk category persons who elect to be vaccinated have a serum sample tested for rabies antibody according to the frequencies and administrations outlined in 2.4.2.2.

2.4.4 Rare Risk Category- the primary course of rabies vaccination is offered but not recommended for these individuals. If the vaccination is accepted, no ongoing serological testing is required.

2.5 **POST EXPOSURE PROPHYLAXIS**

- 2.5.2 The exposed individual should immediately cleanse the wound with soap and water and a virucidal agent, such as a povidone-iodine solution. If the exposed site is the mucous membranes, an irrigation of the site with potable water for 15 minutes is conducted.
- 2.5.3 The individual should report the exposure to their supervisor and to the appropriate occupational health clinic.
 - 2.5.3.1 The occupational health clinic for the Oakland campus of the University of Pittsburgh is Employee Health Services, 3708 Fifth Ave, Medical Arts Building, Fifth floor, Suite 500.59. Monday through Friday 7:30am – 4pm. Rabies exposures occurring outside these times should proceed to the UPMC Presbyterian Emergency Department for clinical evaluation and treatment.
 - 2.5.3.2 Rabies exposures occurring on the job but outside the Oakland Campus should be treated emergently at the nearest hospital emergency room.
- 2.5.4 After wound cleansing, a previously vaccinated individual should be injected intramuscularly with 1.0 ml of HDCV. An additional 1.0 ml intramuscular injection of HDCV should be given day 3 post exposure.
- 2.5.5 After wound cleansing, an unvaccinated individual should receive a dose of human rabies immunoglobulin HRIG (20 IU per kilogram body weight). If anatomically feasible, the full dose should be infiltrated around the wound. Any remaining volume should be administered intramuscularly at an anatomical site distant from the site of subsequent vaccine administration. In addition, intramuscular injections in the deltoid area of 1.0 ml HDCV are to be administered at the time of exposure and post exposure on days 3, 7, 14 and 28.

3. **IMPLEMENTATION**

- 3.1 Completion of a vaccination series for rabies virus and documentation of current and adequate immunity to rabies virus is required for all individuals entering spaces or rooms in which rabies infected animals are present and for all individuals whose job duties include anticipated contact with wild animals known to carry rabies virus.
- 3.2 All principal investigators using rabies virus must enroll all personnel manipulating rabies virus in this Rabies Protection Program. Those individuals with potential exposure to animals which are rabies infected or which belong to species known to carry rabies virus are offered rabies protection upon enrollment in the University of Pittsburgh Animal Exposure Surveillance Program.
- 3.3 Biosafety Level 2 practices, containment equipment and facilities are required for all activities involving the use or manipulation of rabies virus or rabies infected animals (ABSL-2).

- 3.4 All laboratories utilizing rabies virus and all ABSL-2 animal housing areas utilizing rabies virus are inspected by the Department of Environmental Health and Safety to verify appropriate containment and practices. Additional primary containment, personnel precautions and personal protective equipment, such as those described for biosafety level 3, may be indicated for activities with a high potential for droplet and aerosol production and for activities involving production quantities or concentrations of rabies virus.
- 3.5 The University of Pittsburgh Rabies Protection Program is designed to reflect full compliance with the recommendations of the Advisory Committee on Immunization Practices (ACIP) in their document Human Rabies Prevention, published in Morbidity and Mortality Weekly on January 8, 1999 (volume 48 #RR-1).

Committee Chairperson

Date

Biosafety Officer

Date

University of Pittsburgh

Human Diploid-Cell Rabies Vaccine

I understand that due to my occupational exposure to potentially infectious material and/or animals, I may be at risk of getting a rabies infection. The purpose of the Human Diploid-Cell Rabies vaccine (HDCV) is to provide immunity to the rabies virus. The vaccine consists of three (3) injections. The injections are given on days 0, 7 and 28.

For persons at continuous risk of rabies exposure (i.e. persons working with rabies virus in research environment) a blood sample will be tested for rabies antibody titers every 6 months. If the serum titer is not adequate, a booster injection of HDCV vaccine will be required. For those who are frequently exposed to the rabies virus (i.e. veterinarians and staff handling wild animal species known to harbor rabies) a blood sample will be tested for rabies antibody titers every 2 years and a booster injection of HDCV vaccine will be given if necessary. Employees in these two groups are required to undergo vaccination, which is offered free of charge at Employee Health Services.

Veterinarians and staff who handle purpose-bred or post-quarantine wild animals that have not been infected with rabies virus, or staff that handle animals not known to harbor rabies virus are offered rabies vaccination. Any individual in these categories who elects to be vaccinated is then offered testing for rabies antibody level every two years.

The vaccine has the potential to produce certain side effects including but not limited to the following: injection site soreness, redness, or itching; headache, fatigue or dizziness; nausea, vomiting, abdominal pain; arthralgias (aching joints), fever and malaise. The incidence of serious side effects from the vaccine is less than one percent (1%), whereas the outcome after a rabies infection causing encephalomyelitis (swelling and inflammation of the brain and spinal cord) is often fatal.

Name: _____ SSN _____ - _____ - _____

University of Pittsburgh

Consent for Rabies Vaccination

The risks and benefits of receiving the Human Diploid-cell Rabies Vaccine (HDCV) and the risks of acquiring rabies from an occupational exposure have been explained to me. I acknowledge that no guarantees have been made to me regarding the effectiveness of the vaccine or the absence of adverse reactions to the vaccine. I voluntarily give my consent to receive the HDCV vaccine.

Signature

Date

Human Diploid-Cell Rabies Vaccine (HDCV) DECLINATION

I understand that due to my occupational exposure to potentially infectious materials and/or animals, I may be at risk of acquiring rabies infection. I have been given the opportunity to be vaccinated with HDCV vaccine at no charge to myself. However, I decline the HDCV vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring rabies. Failure to be vaccinated may result in my exclusion from those projects that involve working with rabies virus, or from tasks which are included in the Frequent Risk Category.

Signature

Date

**PRIOR Human Diploid-Cell Rabies Vaccine (HDCV)
(Complete if applicable; documentation must be provided)**

I have previously received the rabies vaccination in _____ (*indicate year received*). By _____ (*indicate doctor/clinic*).

Signature

Date

FOR CLINIC USE ONLY	
Date Administered	
Vaccine Manufacturer	
Lot Number	
Expiration Date	
Injection site	
Signature	Date