

VACCINIA VIRUS RESEARCH SAFETY POLICY

POLICY SCOPE

This policy is for the health and safety of individuals working with vaccinia viruses, including recombinant and wild-type strains, at the University of Washington (UW). The Occupational Health requirements of this policy apply to **non-highly attenuated virus**. Examples of non-highly attenuated and highly attenuated strains are shown in Tables 1 and 2 below. This policy provides background information about vaccinia virus in Appendix I, who is affected, requirements for research approval, medical counseling, and vaccination.

The practices and procedures outlined in this document are in accordance with those described in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL), the NIH Guidelines for Recombinant and Synthetic Nucleic Acid Molecules, and University Policy Statement 12.3, with input from Environmental Health and Safety (EH&S) Research and Occupational Safety (ROS), EH&S Campus Preventive Health, EH&S Employee Health Center (EHC), the Institutional Biosafety Committee (IBC), Office of Risk Management, and Human Resources.

This policy is predicated on shared responsibility among principal investigators (PIs), research staff, research support staff, department chairs and directors, EH&S, and the IBC. This policy is the minimum requirement at the University; there may be specific departmental policies or requirements in addition to this policy.

Table 1. Non-Highly Attenuated Vaccinia Strains

Strain	Biosafety Level
WR (Western Reserve)	2
NYCBH (New York City Board of Health)	2
Copenhagen	2
Temple of Heaven	2
Lister	2
Derivatives of any of the above	2

Table 2. Highly Attenuated Vaccinia Strains

Strain	Biosafety Level
MVA	2
NYVAC	1
TROVAC	1

Please note that these tables do not include all strains of Vaccinia virus. If you are unsure what biosafety level is required for a particular strain, contact EH&S at ehsbio@uw.edu.

POLICY SUMMARY

All research involving vaccinia virus (both highly attenuated and non-highly attenuated) must be reviewed and approved by the IBC.

Principal Investigators or lab/facility managers must provide and document vaccinia specific hazard training. They must also ensure personnel receive medical counseling, follow safety protocols, and any workplace restrictions outlined by the Employee Health Center.

Personnel with **direct contact** to non-highly attenuated vaccinia virus are required to receive in-person medical counseling and screening from the UW Employee Health Center (EHC) prior to initiation of work

with vaccinia virus. Personnel must fill out the Vaccinia Vaccine Form and either accept or decline the vaccine following medical counseling. Hazard awareness training for these individuals is provided by the Principal Investigator/lab or facility manager.

Personnel with **indirect contact** to non-highly attenuated vaccinia virus may choose to receive medical counseling and screening from the UW Employee Health Center prior to initiation work with vaccinia virus. Personnel will then fill out the Vaccinia Vaccine Form and either accept or decline the vaccine following medical counseling. Hazard awareness training for these individuals is provided by the Principal Investigator or lab/facility manager.

Other personnel with very minimal likelihood of exposure to vaccinia are not required to receive medical counseling and screening but are encouraged to contact EHC if they have health or medical questions.

Table 3. Vaccinia Occupational Health Requirements

Potential for exposure	Work activities	Medical counseling	Vaccination
Direct contact	<ul style="list-style-type: none"> • Work directly with vaccinia viral cultures, infected material, or any items that have come into contact with vaccinia • Animal husbandry and care of infected animals, including handling bedding of infected animals • Work in rooms or facilities where animals and procedures are not in primary containment devices (e.g., NHP rooms) 	Required prior to work	Required to be offered
Indirect contact	<ul style="list-style-type: none"> • Do not directly handle vaccinia virus, infected animals, or any materials contaminated with the virus as described above • Are present in the same laboratory or animal room where work with vaccinia occurs. Animals and work is in containment devices (e.g., ABSL-2 rodent rooms). 	Available (voluntary)	Not generally recommended
Very minimal likelihood of exposure	<ul style="list-style-type: none"> • May enter the workspace where vaccinia work occurs after agents secured and space decontaminated • Includes custodians, facilities services, and other non-research personnel 	Available (voluntary)	Not recommended

WHO IS AFFECTED

This policy is for UW personnel whose work involves direct or indirect contact with vaccinia virus and for personnel with peripheral responsibilities that support facilities or research spaces where work with vaccinia occurs. Personnel are categorized by potential for exposure to vaccinia virus based on work activities. This policy is also for principal investigators with research involving vaccinia virus and for facility/lab managers with personnel who may have contact with vaccinia.

Personnel with direct contact includes those who work directly with vaccinia virus, including inoculating and growing virus in cell culture, harvesting virus, sonicating and centrifuging virus, inoculating animals with vaccinia, handling infected animals, or handling any other potentially vaccinia-infected material. Direct contact includes animal husbandry and care of vaccinia-infected animals. It also includes working in animal rooms where primary containment devices are not used (e.g., non-human primate rooms). Personnel with direct contact are required to receive in-person medical counseling and screening from the UW Employee Health Center (EHC) at Hall Health prior to initiating work with vaccinia virus. Recommendations for vaccination will be made after medical counseling and screening.

Personnel with indirect contact includes those who do not directly handle vaccinia virus, infected animals, or materials contaminated with vaccinia virus but may work in the same laboratory or animal room where work with vaccinia occurs. This may include laboratory research staff, students, and support staff. Personnel with indirect contact are required to receive hazard and safety information in this policy. Medical counseling and screening is available from UW EHC (206-685-1026) but not required.

Personnel with very minimal likelihood of exposure includes those who may have to enter the workspace where work with vaccinia occurs but are not anticipated to have exposure to potentially infectious materials. This may include custodians, facilities services, and other non-research personnel that support research spaces. These personnel may enter the room only after vaccinia has been secured and the space has been decontaminated. Medical counseling and screening is not required; however, if personnel in this category have health or medical questions, they are encouraged to contact UW EHC at 206.685.1026.

Vaccinia virions are extraordinarily environmentally stable but are quite susceptible to decontamination with oxidizers (bleach) and alcohols. Thus, lab surfaces and animal cages that have come into contact with vaccinia or vaccinia-infected animals with open skin lesions should be considered potentially infectious until thoroughly decontaminated. For immunocompetent animals infected with vaccinia by dermal scarification (e.g., non-human primates), once all visible lesions have healed, the animals, their bedding, and excreta are no longer considered potentially infectious. Thus, handling, care, and necropsy of previously infected non-human primates is generally considered indirect contact as long as all skin lesions are long-healed and the bedding and cages have been cleaned in the interim. In contrast, some immunocompetent rodents harbor long-term persistent infection of vaccinia in the ovaries. Therefore, dissection of rodents with a past history of vaccinia infection, even by routes that never led to skin lesions such as intramuscular or intravenous, is considered direct contact.

OCCUPATIONAL HEALTH REQUIREMENTS

Medical Counseling

All laboratory, husbandry and associated personnel who work in a lab with vaccinia and have direct exposure to vaccinia are required to receive confidential medical counseling through UW EHC before beginning work with the virus. Those with indirect contact may also contact UW EHC to receive medical counseling if they desire but it is not required.

- Individuals will be counseled on the risks of working with the virus, consequences of exposure, the risks and benefits of the vaccine, and medically screened for contraindications to vaccinia exposure or vaccination.
- After medical counseling, the vaccine will be offered to individuals who UW EHC has determined meet acceptable criteria to receive the vaccine. These individuals will review and sign a Vaccinia Vaccination Consent or Declination form. Whether they receive the vaccine or not, all personnel with direct or indirect contact with vaccinia must complete the form. EHC will keep this record.
- Personnel have the option to decline the vaccine unless it is a condition of employment specified in the job description. If personnel opt to decline, personnel will sign a declination (form) attesting that they are aware of the risks of working with the virus and have made an informed, personal decision.

Clearance for Work

- Based on the risk assessment and medical review, some staff may be excluded from working with vaccinia.
- A Vaccinia Clearance form will be completed by UW EHC for each employee and returned to the PI indicating whether or not an individual is cleared to work with vaccinia. Any restrictions will also be communicated to the PI with this Clearance form. The PI must receive this form prior to assigning any duties that may involve exposure to vaccinia. The PI will be responsible to follow recommendations on the form when assigning duties to research staff. (More on PI responsibilities below.)
- Research staff who experience a change in medical condition may, at the request of the employee, return to UW EHC for follow up confidential medical counseling. If a change in clearance to work with vaccinia is needed, an updated Vaccinia Clearance Form will be completed and sent to the PI. (More on Employee responsibilities below.)

ROLES AND RESPONSIBILITIES

Principal Investigators (PIs) or Lab/Facility Manager Responsibilities:

- Receive IBC and EH&S approval before beginning research with vaccinia. PIs should submit a [Biological Use Authorization Application \(BUA\)](#) with a list of personnel with potential exposure to vaccinia to initiate the approval process.
- Notify EH&S of current and new employees who may need the vaccine and make arrangements with the EHC for personnel to receive medical counseling at least 4-6 weeks prior to starting work with vaccinia.
- Assign duties that involve potential exposure to vaccinia **only after** personnel have completed medical screening/counseling and clearance.
- Ensure workplace medical restrictions for personnel are adhered to.
- In some cases, the PI may not be willing or able to modify the duties of the employee. The PI will consult with Human Resources prior to making that decision.
- Provide and document annual lab-specific training for research staff. In addition to EH&S biosafety training, the PI will be responsible to ensure that staff are trained annually in various aspects of safely working with vaccinia. Records of this training shall be kept and reviewed by the BSO during regular lab inspections. (Use Appendix I)
- Ensure staff read and follow this policy.

- Ensure staff follow BSL-2 lab practices including use of personal protective equipment (PPE) to include eye and mucous membrane protection, and implement a lab-specific vaccinia standard operating procedure (SOP) for any procedures outside of standard BSL-2 lab practices.
- Follow the vaccinia SOP for first aid and reporting of possible exposure to the agent or biohazardous materials. Report any lab accidents to UW EHC immediately (PH: 206-685-1026).
- Restrict access to required personnel when work with vaccinia is in process.
- Ensure proper decontamination procedures are followed.
- Ensure activities with vaccinia are suspended and laboratory spaces are properly decontaminated before non-lab personnel enter.

Research personnel responsibilities:

- Complete the Vaccinia Vaccination or Declination form after medical consultation with UW EHC.
- Adhere to any other restrictions imposed by the EHC, PI, IBC, or EH&S for work with vaccinia.
- Follow this policy, BSL-2 lab practices (including appropriate PPE), and lab-specific vaccinia SOP (if required).
- Decontaminate laboratory spaces and equipment appropriately after work with vaccinia.
- Report any exposure, potential exposure, or spill to the PI or lab supervisor and EH&S immediately after completing first aid (Appendix II).
- If personal health conditions or job duties change during the year, personnel must contact UW EHC.

EH&S responsibilities:

- Provide medical counseling, screening, vaccine administration, and maintenance of confidential employee health records. (EHC)
- Complete Vaccinia Clearance Form and return to the PI/supervisor. (EHC)
- Provide hazard communication to PI in Occupational Health Recommendations (OHR). (ROS)
- Review research involving work with vaccinia and determine if lab-specific vaccinia SOP is needed; provide recommendations to the IBC if additional practices and controls are necessary. (ROS)
- Inspect labs regularly to verify that researchers follow appropriate practices and procedures and have received appropriate training. (ROS)
- Report lab accidents to NIH, OSHA, and other agencies as appropriate. (ROS)

IBC responsibilities:

- Review and vote to approve all research proposals with vaccinia.
- Review and approve any additional work practice controls and SOPs if necessary.

APPENDIX I

Vaccinia Hazard Information

What is Vaccinia?

Vaccinia is a complex, enveloped virus belonging to the poxvirus family. Vaccinia virus (VACV) is the live viral component of smallpox vaccine. Inadvertent exposure to VACV can result in infection, and severe complications can occur in persons with underlying risk factors (e.g., pregnancy, immunodeficiency, or certain dermatologic conditions).

Vaccinia virus is well-known for its role as a vaccine that eradicated the smallpox disease. Scientists study vaccinia virus to use as a tool for delivering genes into biological tissues and cells to explore gene therapy and genetic engineering, immunology, and other areas of study.

Is Vaccinia infection still a disease seen in the United States?

In 2004 a CDC Emerging Infectious Diseases dispatch article described an ocular infection in a laboratory worker in Philadelphia. See the following web link, page 2, for review of practices that provided opportunity for infection - <http://wwwnc.cdc.gov/eid/article/12/1/pdfs/05-1126.pdf>.

During 2005-2007, five cases of laboratory-acquired VACV infection were reported to CDC. No known contact transmission of VACV was reported from these laboratory-acquired infections; however, instances of contact transmission of VACV from smallpox vaccines to close contacts, including children and partners, has occurred. In 2008, CDC was notified of a suspected case of inadvertent autoinoculation and VACV infection in an unvaccinated laboratory worker.

In 2010, the Centers for Disease Control and Prevention (CDC) reported that a woman in Washington had contracted vaccinia virus infection after physical contact with a military member who had recently been vaccinated for smallpox. The CDC indicated that it was aware of four similar cases in the preceding 12 months of vaccinia infection after contact with a recent military vaccine.

How is Vaccinia virus spread?

Accidental exposure to vaccinia may occur through ingestion, parenteral inoculation, and droplet or aerosol exposure of mucous membranes or broken skin with infectious particles. Ocular exposure is of particular concern. Protective eyewear or other shielding must be used when working with vaccinia virus outside of a biological safety cabinet.

The different strains of vaccinia virus used in research and clinical settings present different levels of risk. The recommendations for vaccinia vaccination differ depending upon the strain of virus, characteristics of vaccinia vectors, and the setting in which they will be used. The following medical conditions may increase risk of infection or risk of complications following exposure to vaccinia:

- Diagnosis and/or history of eczema even if condition is mild and not presently active.
- Household contacts with diagnosis and/or history of eczema.
- Other acute or chronic skin conditions including atopic dermatitis, burns, impetigo, etc.
- Any diseases or conditions that cause immunodeficiency including leukemia, lymphoma, other malignancies, HIV infection, therapy with alkylating agents, antimetabolites, radiation, high dose steroids.
- Household contacts with immunodeficiency disease or therapy listed above.
- Pregnancy or planning to become pregnant within 1 month following vaccination or accidental exposure.

What are the symptoms?

A vaccinia virus infection is very mild and is typically asymptomatic in healthy individuals, but it may cause a mild rash and fever. Symptoms seen rarely and usually in immunocompromised individuals may include a severe rash, which can leave scars when healed, a high fever, tiredness, severe headaches and backache, blindness, or even death.

What is the treatment for exposure?

Treatment for vaccinia includes antivirals and pain medication. Treatment for vaccinia infection depending on severity may include: antivirals, vaccinia immune globulin and/or local care of lesions and symptomatic treatment.

How soon do symptoms appear?

Normally symptoms occur in 6 to 15 days after exposure.

Is there a vaccine?

Vaccinia virus is still being used as a live-virus vaccine against smallpox. Unlike vaccines that use weakened forms of the virus being vaccinated against, the vaccinia virus vaccine cannot cause a smallpox infection because it does not contain the smallpox virus. The immune response generated from the vaccinia virus protects the person against a lethal smallpox infection. Complications and/or vaccine adverse effects occasionally arise primarily in people who are immunocompromised.

If I am only using the vaccine grade strain, why should I be vaccinated?

During 2005-2007, five cases of laboratory-acquired VACV infection were reported to CDC. Although no national surveillance system exists to track laboratory-related VACV exposures, the five cases were reported to CDC informally in the course of seeking consultation on treatment and prevention. All five cases involved the Western Reserve vaccinia strain. Cases 1 - 4 involved recombinant VACVs with an insertion at the thymidine kinase (TK) locus. Case 5 also involved a recombinant VACV, but details of the virus are not known.

I was vaccinated for small pox as a child do I need to be vaccinated?

The Advisory Committee on Immunization Practices (ACIP) recommends smallpox vaccination at least every 10 years for personnel who handle non-highly attenuated VACV strains or other orthopoxviruses (e.g., monkey pox, cowpox, or variola).

APPENDIX II

What to do if Exposed to Vaccinia Virus at Work

1. Provide First Aid

- a. Sharps injury (*needle stick and subcutaneous biological exposure*)
 - Scrub exposed area thoroughly for 15 minutes using warm water and lathering soap.
- b. Skin Exposure (*non-intact skin*)
 - Immediately go to the sink and thoroughly wash the skin wound with soap and water.
- c. Splash to Eye(s), Nose or Mouth
 - Immediately flush the area with running water for at least 15 minutes.
 - For eyes, use the eye wash for 15 minutes while holding eyelids open.
- d. Inhalation
 - Move out of contaminated area. Get medical help.
- e. Splash Affecting Garments
 - Remove garments that may have become soiled or contaminated and place them in a double red plastic bag.

2. Get Help

Be ready to share details of exposure (agent, dose, route, time of exposure, MSDS/SDS).

- a. For immediate medical emergencies, call 911 or go to emergency room.
- b. For all other injuries and exposures, do the following:
 - During Business hours:
Call the UW Employee Health Center at 206-685-1026.
 - At Harborview sites call 206-744-3081.
 - Outside of Business hours or if Employee Health Center is closed:
Biological exposures: go to the nearest emergency room or call 911.
- c. In all cases, notify your supervisor as soon as possible. Secure the area before leaving.

3. Complete UW Online Accident Report *within 24 hours at*

<http://www.EH&S.washington.edu/ohsoars/index.shtm>.

- a. For serious or fatal accident or hospitalization, notify EH&S immediately at 206-543-7262 (within 8 hours).
- b. After hours contact the UW Police Department (911).

APPENDIX III

References

- [CDC Biosafety in Microbiological and Biomedical Laboratories](#) (BMBL) 5th Edition
- [Centers for Disease Control Small Pox Vaccine information website](#)
- [Laboratory-Acquired Vaccinia Exposures and Infections --- United States, 2005—2007. MMWR 57 \(15\)](#); April 18, 2008; pp 401-404.
- [Ocular Vaccinia Infection in Laboratory Worker, Philadelphia, 2004](#); Emerging Infectious Diseases, vol.12, No.1, Jan.2006; www.cdc.gov/eid.
- [UW Biosafety Manual](#)
- [Vaccinia \(Smallpox\) Vaccination Recommendations of the Advisory Committee on Immunization Practice](#). MMWR 50 (RR 10); June 22, 2001; pp 1-25.
- [Vaccinia Virus Infection After Sexual Contact with a Military Smallpox Vaccine --- Washington, 2010](#). MMWR Vol. 59 / No. 25; July 2, 2010; pp 773-775.

APPENDIX IV

Documentation of Training and Offering of Vaccinia Vaccine (retained by Principal Investigator)

Training is required for personnel who have both direct and indirect contact.

By signing below, I indicate that I have read and understand the UW Vaccinia Policy. I have been given a chance to ask questions. I will adhere to the policy, hazards, medical requirements, safe work practices, and accident reporting outlined in the policy.

Employee Name	Hazard Awareness Training Date	Date Vaccine Offered	Employee Signature	PI Signature