

UNIVERSITY of PENNSYLVANIA

Office of Environmental Health and Radiation Safety
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PROTOCOL FOR APPROVAL TO USE VACCINIA VIRUS IN RESEARCH
(revised February, 2003)

Effective Date: April, 2003, modified June 2005

Responsible Persons:

Dr. Neal Nathanson, Vice Provost for Research _____

Dr. Charles E. Benson, IBC Chair _____

Matthew D. Finucane, EHRS Director _____

The Penn policy on the use of vaccinia virus in research follows national guidelines issued by the [Centers for Disease Control and Prevention \(CDC\)](#)*. The policy has been approved by University Institutional Biosafety Committee (IBC) and is administered by the Office of Environmental Health and Radiation Safety (EHRS). Principal Investigators (PI's) must obtain written EHRS approval to use vaccinia virus.

There are different strains of vaccinia virus with different levels of risk for humans. **“Standard” vaccinia virus** was used historically to immunize humans against smallpox, and it is this virus that is still used to immunize humans. This virus can replicate in human cells and thus presents a risk to humans. Recombinant variants of this virus created for experimental purposes present a similar risk to laboratory personnel. **Highly attenuated poxvirus strains** (MVA, NYVAC, ALVAC, and TROVAC) are unable to replicate or replicate poorly in human cells and do not initiate productive infection in humans. These viruses, often in recombinant form, can also be used for experimental purposes. The recommendations for vaccinia immunization differ depending upon the experimental virus that will be used in the individual laboratory.

Standard vaccinia virus or recombinant viruses derived from standard vaccinia virus

If the laboratory uses standard vaccinia virus or recombinant viruses derived from standard vaccinia virus:

1. All laboratory personnel who **directly** handle a) cultures or b) animals contaminated or infected with *standard vaccinia virus, recombinant vaccinia viruses or other similar orthopoxviruses that infect humans*, must receive mandatory confidential counseling and (if it is medically appropriate) be offered Vaccinia (Smallpox) vaccine by Occupational Medicine prior to initiating work with vaccinia virus.

The current Vaccinia (Smallpox) vaccine, Dryvax[®], is a freeze-dried preparation of live vaccinia virus mixed with a new diluent. Its use was recently approved by the FDA.

2. CDC recommends (but does NOT require) that all persons working with vaccinia virus or other similar Orthopoxviruses that infect humans be immunized, if medically eligible, before beginning work with virus.

However, there is no universal agreement among experts as to whether immunization should be routinely recommended for workers who work with vaccinia virus. Penn’s policy is to offer mandatory confidential counseling and provide information so that individuals can make their own decision regarding immunization. While immunization is not a

* Vaccinia (Smallpox Vaccine): Recommendations of the Immunization Practices Advisory Committee (ACIP), MMWR, June 22, 2001/Vol. 50/No. RR-10.

prerequisite for working with vaccinia virus at the University, counseling about vaccination is mandatory prior to working with vaccinia virus.

3. Other healthcare workers (e.g., physicians and nurses) whose contact is limited to contaminated materials (e.g., dressings) but who adhere to appropriate infection control procedures, are at a lower risk for inadvertent infection, and are not advised to be vaccinated. However, confidential counseling and vaccination is available to these individuals on request.

4. An employee who would be put at serious risk by performing a job because of exposure to vaccinia will be prohibited from doing so.

Highly attenuated poxvirus strains

Because highly attenuated poxvirus strains (MVA, NYVAC, ALVAC, and TROVAC) are unable to replicate or replicate poorly in mammalian host cells they do not create productive infections. Therefore, vaccination is NOT recommended for workers who handle these highly attenuated virus cultures or materials or who work with animals contaminated or infected with these viruses. (The Occupational Safety and Health Board of NIH no longer recommends Vaccinia (Smallpox) vaccination for personnel manipulating MVA or NYVAC strains in a laboratory where no other vaccinia viruses are being manipulated.)

A. Counseling and Vaccination Procedure

1. Principal Investigators (PI's) must complete the CDC "[Request For Vaccinia \(Smallpox\) Vaccine](#)" form, starting at the section titled "Head of Laboratory Doing Research with Vaccinia". Even if you know that you or others working in your lab are not interested in receiving the vaccine, this form must be completed to record who is working with vaccinia virus and who needs mandatory confidential counseling. Please note that everyone in your lab should not be listed on this form, only people who directly work with and handle vaccinia virus. This form is available by calling EHRS (215-898-4453) or at the [EHRS web site](#).

2. PI's must return the completed form and a brief abstract of the research project that also notes the PI's prior experience, if any, in working with poxviruses, by mail, FAX or email to:

Occupational Medicine
HUP/4283
FAX: 215-614-0666
Email: Dorothy Dragoni, Surveillance Coordinator, dragonid@uphs.upenn.edu

3. Occupational Medicine will complete the remainder of the Vaccinia (Smallpox) vaccine request form and order the vaccine from CDC.

4. After the vaccine request form is sent to Occupational Medicine, **each person listed on the form is responsible** to call Occupational Medicine (215-349-5514) to set up an appointment for mandatory confidential vaccine counseling, which should occur within 15 days of the vaccine request date.

5. Occupational Medicine will counsel personnel in conjunction with a review of CDC documents, [Smallpox Vaccine: What You Need to Know](#) and [Smallpox Vaccine and Heart Problems](#). Copies of these documents are available at the [EHRS website](#) or by calling EHRS (215-898-4453) or Occupational Medicine (215-349-5514). If the worker opts to get vaccinated and the vaccine is not available at the time of counseling, Occupational Medicine will notify personnel when the vaccine is available.

6. If the worker gets vaccinated, he/she will be required to return to Occupational Medicine on the following days after immunization: 3 days, 5-7 days, 14 days and 17 days. **It is the responsibility of the PI to insure that individuals attend these follow-up visits.**

7. Individuals who decline immunization will be asked by Occupational Medicine to sign the vaccinia declination form. If Occupational Medicine determines during counseling that the vaccine is medically contraindicated for a person, they will advise the individual to avoid contact with infectious vaccinia viruses in the workplace.

8. Occupational Medicine will document vaccinia counseling or immunization by notifying EHRS and the PI/supervisor in writing as to whether each person who signed up: (1) was or was not immunized or (2) is or is not restricted regarding working directly with vaccinia. No confidential medical information will be included in this notification.

9. Individuals who cannot be vaccinated because of medical contra-indications, or who decline vaccination because of risk to their household contacts per CDC guidelines, or for other reasons will not be vaccinated. EHRS will contact the PI and the individual(s) to discuss additional safety precautions that should be followed when immunization is declined or is contra-indicated.

B. Procedure to Receive EHRS Approval to Use Vaccinia Virus

Requests for EHRS approval to use vaccinia virus must be submitted by FAX, mail or email to:

EHRS, 3160 Chestnut Street, Suite 400 / 6287
FAX: 215-898-0140
Email:ehrs@ehrs.upenn.edu

Submit the following:

1. A brief abstract of the research project and a brief description of the PI's experience overseeing research with vaccinia virus.
2. A [recombinant DNA registration document](#) for experiments involving the generation of recombinant vaccinia virus. Approval of the Penn IBC is required. A registration form is available at the EHRS web site.
3. A copy of the completed CDC "[Request For Vaccinia \(Smallpox\) Vaccine](#)" form, available at the EHRS web site listing all workers who will need mandatory counseling by Occupational Medicine. Please note that everyone in your lab should not be listed on this form, only people who directly work with and handle vaccinia virus.

EHRS approval will be contingent on verification that the PI and all lab staff have been counseled by Occupational Medicine.

C. Procedures for laboratory use of vaccinia viruses

1. **Biosafety Level 2 practices and procedures must be followed for work with standard strains of vaccinia virus, recombinant vaccinia virus or other similar Orthopoxviruses that infect humans.** Lab personnel must wear appropriate personal protective equipment: lab coat, disposable gloves and eye protection.
2. **Biosafety Level 1 practices and procedures may be followed for work with highly attenuated vaccinia strains (NYVAC, ALVAC and TROVAC).** However, CDC recommends **Biosafety Level 2 practices and procedures when manipulating MVA.**

For complete descriptions of Biosafety Level 1 and 2 guidelines consult the University's Biological Safety Manual at the EHRS website, http://www.ehrs.upenn.edu/programs/bio/bio_manual.html.

NOTE: Hepatitis B Vaccine

If work with vaccinia virus involves human source material, free Hepatitis B immunization must be offered to all University employees who are at risk of occupational exposure to human blood, body fluids and/or tissues. The [University's Exposure Control Plan](#), available by calling EHRS or at the EHRS web site, must be completed by the Principal Investigator/Area Supervisor, reviewed with laboratory personnel and available in the laboratory as a reference.