

University of Nebraska Medical Center

Biosafety Policies and Procedures

TITLE:	Immunization Policy for Research Using Vaccinia Virus
OVERVIEW:	<p>The UNMC policy on the use of vaccinia virus in research follows national guidelines issued by the Centers for Disease Control and Prevention. Generally, standard vaccinia virus which is used to immunize humans against smallpox has the capability to replicate in human cells and thus presents a risk to humans. Therefore, immunization is recommended for personnel under these circumstances. 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. Vaccination is not recommended for individuals who handle these highly attenuated strains.</p>
APPLIES TO:	<p>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 be counseled and offered vaccinia vaccine by Employee Health prior to initiating work with vaccinia virus.</p>
PROCEDURES:	<p>Principal Investigators must complete the ‘<i>CDC Request for Vaccinia Vaccine</i>’ form (see Attachment 1), starting at the section titled ‘Head of Laboratory Doing Research with Vaccinia’.</p> <p>Return the completed form to Employee Health. They will complete the remainder of the vaccine request form and submit this along with the FDA Form 1572 (see Attachment 2) to order the vaccine from the CDC (CDC; Drug Services, National Center for Infectious Diseases; Mailstop D-09; Atlanta, GA 30333, Telephone: 404-639-3670)</p> <p>Once the vaccine has been received in Employee Health, the PI will be notified. The PI will contact each person on the vaccine request form to contact Employee Health to set up an appointment for mandatory confidential vaccine counseling, which should occur within 15 days of the vaccine request date.</p> <p>Employee Health 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 http://www.bt.cdc.gov/agent/smallpox/vaccination/. At risk employees will at this time have the opportunity to either accept or decline the vaccination.</p> <p>If an employee gets vaccinated, he/she will be required to return to</p>

University of Nebraska Medical Center

Biosafety Policies and Procedures

	<p>Employee Health at 3 days, 5 to 7 days, 14 days, and 17 days after immunization for follow up. It is the responsibility of the PI to insure that individuals attend these follow-up visits.</p> <p>Individuals who decline immunization will be asked by Employee Health to sign the Vaccinia Vaccine Waiver form (see Attachment 3). If Employee Health determines during the counseling that the vaccine is medically contraindicated for a person, they will advise the individual to avoid contact with infectious vaccinia in the workplace.</p>
RECORD KEEPING:	<p>Employee Health will document vaccinia counseling with or without immunization by notifying the PI 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 virus. No confidential medical information will be included in this notification.</p>
OTHER INFORMATION :	<p>Individuals who because of medical contraindications, or who may cause risk to their household contacts per CDC guidelines, or for other reasons, will not be vaccinated. Employee Health will contact the PI and the individual(s) to discuss additional safety precautions that should be followed when immunization is declined or is contraindicated.</p> <p>Copies of the CDC Request for Vaccinia Vaccine and the Vaccinia Virus Waiver forms are submitted to the IBC Chairman for filing with the IBC protocol prior to initiation of the research study.</p>
REFERENCES:	<p>CDC. 2001. Vaccinia (smallpox) vaccine recommendations of the advisory committee on immunization practices (ACIP), 2001. <i>MMWR, Recommendations and Reports</i>, 50 (RR10); 1-25.</p> <p>CDC. 2003. Recommendations for using smallpox vaccine in a pre-event vaccination program. <i>MMWR, Recommendations and Reports</i>, 52 (RR07); 1-16.</p>
STATUS:	<p>Drafted: June 23, 2003</p>

University of Nebraska Medical Center

Biosafety Policies and Procedures

REQUEST FOR VACCINIA (SMALLPOX) VACCINE

The Centers for Disease Control distributes Vaccinia Vaccine to physicians for immunization of laboratory personnel who are working with orthopox viruses. The vaccine must be administered by or under the supervision of a licensed physician.

To initially receive the vaccine the entire form must be completed and returned along with the FDA form 1572 (Statement of Investigator) to the address listed below. This 'Request for Vaccinia Vaccine' form must be completed and returned to CDC for each vial of vaccine required. Each vaccine must be reported on this form to the Drug Service prior to vaccination.

Physician: _____
(first) (middle) (last)

Clinic Name: _____

Number and Street: _____

City: _____ State: _____ Postal Code: _____ Country: _____

Telephone: _____ Fax: _____

Head of the Laboratory doing research with vaccinia: _____

Institute of that individual, if other than above: _____

Number and Street: _____

City: _____ State: _____ Postal Code: _____

Telephone: () _____ Fax: () _____

Virus(es) involved: _____

Used in development of/study of: _____

If this virus is part of a Food and Drug Administration (FDA) approved Investigational New Drug (IND) Protocol, what is the IND number _____. (attach copy of protocol if this is your first request)

Name, age, position (e.g., research associate, virologist, etc.) and duties which could cause exposure of this individual to the virus used in this research project: (If more space is needed attach extra sheet)

Name	Age	Position-Duties
_____	_____	_____
_____	_____	_____

PHYSICIAN SIGNATURE: _____ Date: _____

Return to: Centers for Disease Control
Drug Service (D09)
1600 Clifton Road
Atlanta, GA 30333

CDC: NCID; SRP; Drug Service
SMLPOX, FRM

University of Nebraska Medical Center
Biosafety Policies and Procedures

**University of Nebraska Medical Center
Vaccinia Vaccine Waiver Form**

I understand that due to my occupational exposure to vaccinia virus that I may be at risk of acquiring vaccinia virus infection. I have been given the opportunity to be vaccinated with the vaccinia (smallpox) vaccine at no charge to myself. However, I decline vaccinia virus vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring vaccinia infection. If in the future I continue to have occupational exposure to vaccinia virus and I want to be vaccinated with the vaccinia vaccine, I can receive the vaccination at no charge.

Signed _____ Date _____

Printed Name _____

Department _____ Ext _____

I received the vaccinia virus vaccine in the past ____ (check here)
Year _____ and sign above

Date Counseled _____

Counselors Signature _____ Date _____