

## ASU FACT SHEET

### Working Safely with Vaccinia Virus

#### PURPOSE

In the interest of providing a safe workplace and to comply with federal regulations, ASU [Health Services](#) and Biosafety & Biosecurity have developed these procedures regarding work with and immunization of personnel in laboratories using vaccinia virus. Recommendations for vaccination are dependent on the strain used in the research project. These procedures follow federal guidelines set forth by the CDC/NIH [Biosafety in Microbiological and Biomedical Laboratories](#) (BMBL), 5<sup>th</sup> edition and the vaccinia virus vaccination recommendations of the CDC [Advisory Committee on Immunization Practices](#) (ACIP).

#### OVERVIEW

These requirements apply to all personnel with direct or indirect exposure to vaccinia virus. Direct exposure is defined as working with viral cultures, materials exposed to viral cultures, body fluids or tissues from infected animals or patients, and any other potentially vaccinia-infected material. Indirect exposure includes that of personnel who not directly work with cultures of vaccinia virus, infected tissues, or animals infected with vaccinia virus as described above, but work in the same lab where vaccinia virus is used. All proposed work with vaccinia virus must be approved in advance by the ASU Institutional Biosafety Committee (IBC).

All laboratory personnel who work in a laboratory with vaccinia virus and have direct or indirect exposure to vaccinia will receive **confidential medical counseling** at an individual's request through ASU Health Services before beginning work with the virus. These individuals will be counseled on the risks and benefits of the vaccine and medically screened for contraindications to vaccinia virus exposure or vaccination. If work duties change from indirect exposure to include direct exposure to vaccinia virus, unvaccinated employees should receive counseling from ASU Health Services. After medical counseling, the vaccine will be offered to individuals that ASU Health Services has determined meet acceptable criteria to receive the vaccine. Vaccinations are provided at ASU Health Services.

ASU Health Services will make recommendations to the individual regarding suitability of working with vaccinia virus. Based on the risk assessment and medical review, some staff may be excluded from working with vaccinia virus.

In addition to annual OSHA Biosafety and Bloodborne Pathogen training offered by Biosafety & Biosecurity, the Principal Investigator (PI) will be responsible to ensure that staff members are trained annually in various aspects of safely working with vaccinia virus. Records of this training shall be kept and reviewed by the Biological Safety Officer (BSO) during regular lab inspections.

#### HAZARDS OF EXPOSURE

Vaccinia virus may enter the body through mucous membranes, broken skin, or by ingestion, parenteral inoculation, or droplet or fine-particle aerosol inhalation. **Ocular exposure is of particular concern.** Vaccinia virus is stable in a wide range of environmental temperatures and humidity and may be transmitted by fomites. Sources of laboratory-acquired infection include exposure to aerosols, environmental samples, naturally or experimentally infected animals, infectious cultures, or clinical samples, including vesiculopustular rash lesion fluid or crusted scabs, various tissue specimens, excretions and respiratory secretions.

The different strains of vaccinia virus used in research, teaching, and clinical settings present different levels of risk. Vaccinia virus strains such as Western Reserve (WR), New York City Board of Health (NYCBH), Copenhagen or Lister, present a greater risk to humans based on an increased ability to replicate in human cells. Attenuated strains such as MVA (Modified Vaccinia Ankara), NYVAC, ALVAC and TROVAC are unable to replicate or replicate poorly in human cells and do not initiate infection in healthy humans. The recommendations

for vaccinia vaccination differ depending upon the strain of virus, characteristics of vaccinia viral vectors, and the setting in which they will be used.

## **MEDICAL SURVEILLANCE**

### ***Immunization***

In general, all persons working in or entering laboratory or animal care areas where activities with vaccinia virus are being conducted should have evidence of satisfactory vaccination (e.g., DRYVAX, ACAM 2000). Vaccinations are provided at ASU [Health Services](#). Vaccination is recommended at baseline and then every 10 years for lab personnel who work with vaccinia virus. Ultimately, the best protection is afforded by training laboratory personnel in appropriate biosafety practices and procedures and by workers following these procedures.

### ***Symptoms of Exposure***

Mild to moderate illness in healthy humans can occur after infection with vaccinia virus. Common symptoms include rash, fever, headache, and body aches. Localized skin lesions such as pustules can occur at sites of inoculation. More severe, disseminated reactions can occur, including post-vaccinial encephalitis and progressive (spreading) vaccinia. The latter usually occurs only in the immunosuppressed or those with multiple skin lesions or severe eczema.

### ***First Aid/Treatment***

Any wounds should be washed immediately with soap and water. Mucous membranes should be flushed with copious amounts of water. Any exposed person should notify his/her supervisor of the incident and immediately report to ASU Health Services. Contact ASU [Health Services](#) for more information. **If after hours, the on-call Health Services Physician should be contacted at 800.293.5775.**

### ***Post-Exposure***

If the exposed person is unvaccinated, he/she should receive the vaccinia virus vaccination within 4 days of the exposure. Previous vaccinia virus vaccination may lessen the severity of the infection. The use of the antiviral medicine cidofovir or vaccinia immunoglobulin may be considered under certain circumstances. Treatment may also include use of agent ST-246. The use of this medication would need approval of all appropriate agencies.

## **SCREENING PROCESS**

PIs that plan to work with vaccinia virus in a research laboratory must complete an IBC [disclosure](#) and submit it to the IBC for review prior to beginning any work with vaccinia virus. The IBC must approve the disclosure and containment level prior to initiation of work.

Laboratory personnel and animal care staff with indirect exposure (those who do not directly work with cultures of vaccinia virus or animals infected with vaccinia virus, but work in the same lab where vaccinia virus is being used) will also be offered the same medical screening and counseling.

ASU Health Services will review the following with each employee:

- Medical history, allergies, and contraindications to vaccination.
- Discussion of risks and benefits of vaccination.

Based on this review a determination will be made regarding vaccination.

Contraindications to vaccinia virus vaccination include:

- 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.
- Allergy to polymyxin B, streptomycin, tetracycline, neomycin.
- Pregnancy or planning to become pregnant within 1 month following vaccination.
- Anyone with a physician diagnosed heart condition, with or without symptoms should not get the vaccinia virus vaccination at this time. These include conditions such as:
  - Known coronary disease including: previous myocardial infarction, angina.
  - Congestive heart failure.
  - Cardiomyopathy.
  - Stroke or transient ischemic attack.
  - Chest pain or shortness of breath with activity.
  - Other heart conditions under the care of a doctor.

**In addition, anyone with 3 or more of the following risk factors should NOT get the vaccinia virus vaccination:**

- Anyone who has been told by a doctor that he/she has high blood pressure.
- Anyone who has been told by a doctor that he/she has high blood cholesterol.
- Anyone who has been told by a doctor that he/she has diabetes or high blood sugar.
- Anyone who has a first degree relative (e.g., mother, father, brother, or sister) who had a heart condition before the age of 50.
- Anyone who smokes cigarettes.

**Note: These may be temporary exclusions and may change as more information is gathered.**

## **VACCINATIONS**

If an employee consents to vaccination, ASU Health Services will provide this service, including appropriate instructions for dressing and care of the vaccination site, and all appropriate follow up. ASU Health Services staff will monitor personnel for development of rare complications to vaccination. Complications following vaccination may include vaccinia necrosum, eczema vaccinatum, and generalized vaccinia. Whether they receive the vaccine or not, all employees with direct contact with vaccinia virus must complete and sign the Vaccinia Vaccination Acceptance/Declination statement from ASU Health Services. Health Services will keep this record. Revaccination every 10 years is recommended for people working with vaccinia virus strains. Research staff who experience a change in medical condition may return to ASU Health Services for follow up confidential medical counseling which may change whether they have clearance to work with vaccinia virus or not.

### ***Restrictions***

Following medical consultation the individual will either:

- Sign a vaccinia vaccination consent form and receive the vaccine (which requires follow-up visits to monitor the vaccination site), OR
- Sign a declination form.

**Note:** If ASU Health Services determines that vaccination is contraindicated, ASU Health Services may recommend restrictions on the employee's work in order to protect the health and safety of the employee and others.

In cases where ASU Health Services recommends work restrictions, the PI will make the determination of duties and take appropriate precautions to minimize employee exposure to vaccinia virus.

All work with vaccinia virus in laboratories will typically be conducted using Biological Safety Level 2 (BSL-2) practices and those outlined in the laboratory-specific biosafety manual. Biosafety & Biosecurity, in consultation with the IBC and the PI, may require additional work practices and exposure controls on a case-by-case basis dependent on the particular strain of vaccinia virus, the work to be performed, and the immunization status of laboratory personnel who have direct contact with the virus.

### **TRAINING**

Per IBC requirements, all staff working with vaccinia virus must complete the ASU Biosafety Training on an annual basis. All biosafety classes are available online through MyASU/Blackboard.

In addition to the ASU Biosafety Training, the PI is responsible to ensure that lab personnel are trained in the proper techniques for safely handling vaccinia virus. This training shall include laboratory-specific information on what tasks, procedures and equipment in the lab involve the use of vaccinia virus; information on how to recognize signs and symptoms of exposure; the steps to take in case of accidental exposure; and medical conditions that would warrant caution when working with vaccinia virus. A record of this training must be retained by the PI and made available for review by the IBC or BSO.

### **PERSONAL PROTECTIVE EQUIPMENT**

Working with vaccinia virus requires the use of the following Personal Protective Equipment (PPE) **in addition to working in a Biological Safety Cabinet (BSC)**.

Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with vaccinia virus. Remove protective clothing before leaving for non-laboratory areas. Dispose of protective clothing appropriately, or deposit it for laundering by the institution. Laboratory clothing must not be taken home.

Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of vaccinia virus. ASU policy requires the use of eye protection in all laboratories. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories should also wear eye protection.

Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, laboratory personnel should:

- Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
- Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
- Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

### **RESPONSIBILITIES**

PIs are responsible for the following:

- Obtaining prior approval from the IBC before beginning research with vaccinia virus.
- Making arrangements with ASU Health Services for new employees to receive screening/counseling for vaccinations.

- Reporting any lab accidents or exposures to Biosafety & Biosecurity.
- Following ASU Health Services recommendations when assigning duties to research staff
- Providing documented, lab-specific training for all researchers in their laboratory.

Researchers are responsible for the following:

- Adhering to work practice controls outlined in the latest edition of the BMBL and the laboratory-specific biosafety manual and any other requirements imposed by the IBC or PI for working with vaccinia virus.
- Reporting any exposure or potential exposure to the PI or lab supervisor and Biosafety & Biosecurity.

Biosafety & Biosecurity is responsible for the following:

- Inspecting laboratories on an annual basis to verify that researchers are following appropriate practices and procedures and to review training records.
- Reviewing research involving vaccinia virus.
- Providing recommendations on additional work practice controls that may be warranted.

IBC is responsible for the following:

- Reviewing all research with vaccinia virus.
- Reviewing and approving biosafety levels and additional work practice controls if deemed necessary.

ASU Health Services is responsible for the following:

- Performing medical surveillance for all individuals working with vaccinia at ASU.
- Administering vaccines.