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STANDARD OPERATING PROCEDURES (SOP) VACCINIA VIRUS USAGE

1. SCOPE

Cases of laboratory- associated infections with pox viruses (e.g. smallpox, vaccinia, yaba, tanapox) have been reported. Human poxvirus infection ranges from severe systemic febrile disease to less severe rarely fatal vesicular diseases. This SOP was designed to establish a system of information and safeguards that should be followed at the University of Pittsburgh when using vaccinia virus.

2. PROCEDURE

- 2.1 Agent- Vaccinia virus, human host poxvirus, smallpox vaccine
- 2.2 **Employees at risk-** Naturally or experimentally infected laboratory animals are a potential source of infection to exposed, unvaccinated laboratory personnel. Genetically engineered recombinant vaccinia viruses pose an additional potential risk to laboratory personnel, through direct contact or contact with clinical materials from infected volunteers or animals.

2.3 **Laboratory hazards**

- 2.3.1 Ingestion, parenteral inoculation, and droplet or aerosol exposure of mucous membranes or broken skin with infectious fluids or tissues, are the primary hazards to laboratory and animal personnel. The agents may be present in lesion fluids or crusts, respiratory secretions, or tissues of infected hosts. Some poxviruses are stable at ambient temperature when dried and may be transmitted by fomites.
- 2.3.2 The different strains of vaccinia virus used in the laboratory present different levels of risk to humans. Replication competent vaccinia strains, such as WR, NYCBOH, Copenhagen or Lister, present a greater risk to humans based on an ability to replicate in human cells. Replication deficient strains, such as MVA, NYVAC, ALVAC, and TROVAC do not initiate productive infection in humans. The recommendations for vaccinia immunization differ depending upon the strain of experimental virus and setting in which it will be used in the individual laboratory.

2.4 Required Procedures

- 2.4.1 All Principal Investigators (PI's) using vaccinia virus, recombinant vaccinia virus or any orthopox virus must be registered with the Biosafety Officer/EH&S. A registration document may be obtained from the web site www.ehs.pitt.edu or by calling the Biosafety Officer at 412-624-8919.
- 2.4.2 Biosafety Level 2 practices, containment equipment and facilities are required for all activities involving the use or manipulation of vaccinia virus.

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- 2.4.3 Laboratories are inspected by EHS to verify appropriate BSL-2 containment and practices.
- 2.4.4 All individuals who directly handle a) cultures or b) animals contaminated or infected with replication competent vaccinia virus strains or other Orthopoxviruses that infect humans must undergo initial medical screening by Employee Health Services for contraindications to vaccinia exposure and will be counseled on the risks and benefits of vaccinia vaccination. During normal business hours (7 AM – 3:30PM) contact Employee Health Services (MyHealth@Work), Suite 500.59, Medical Arts Building, 3708 Fifth Avenue, Pittsburgh, PA 15213, 412-647-4949. These individuals will be offered vaccinia vaccination at no cost (provided no contraindications exist). Following this counsel, all individuals, as previously described, must sign a Vaccinia Vaccination Immunization Acceptance/Declination Form prior to work with vaccinia at the University of Pittsburgh. The original form will be maintained by Employee Health Services. Individuals who continue to work with replication competent vaccinia virus or other Orthopoxviruses will be required to be re-screened by Employee Health Services every three years for contraindications to vaccinia exposure. Revaccination shall be offered every 10 years for personnel working with replication competent vaccinia virus and every 3 years for personnel working with more virulent nonvariola orthopoxviruses. In addition individuals should notify Employee Health Services if there are any significant changes to their health status.
- 2.4.5 Vaccination is NOT recommended for individuals working only with replication deficient vaccinia strains, such as MVA, NYVAC, ALVAC, and TROVAC. However, these individuals must be medically screened by Employee Health Services prior to initiating work with replication deficient strains and every three years thereafter while work continues.
- 2.4.6 It shall be the responsibility of the Principal Investigator to assure that individuals with potential vaccinia virus exposure as described in section 2.4.4 and 2.4.5 are enrolled in the medical screening component of this Procedure prior to initial exposure to vaccinia virus.
- 2.4.7 Individuals having a medical contraindication to vaccinia exposure as determined by the Employee Health Services will be prohibited from performing tasks with potential vaccinia exposure. The determination of prohibited tasks will be made by the employee's supervisor in consultation with the Department of Environmental Health and Safety, and if necessary, the Office of General Counsel, Office of the Provost (faculty and students), Human Resources (staff), and the University Biohazards Committee.
- 2.4.8 Laboratory personnel not directly handling or manipulating cultures of vaccinia virus or animals exposed to vaccinia virus, but working in the same lab where replication competent vaccinia virus strains are utilized shall be offered initial and continuing medical screening for potential contraindications to vaccinia exposure as described above. It shall be the responsibility of the Principal Investigator to assure that individuals in labs where vaccinia virus is utilized as described in section 2.4.8 are offered medical screening through Employee Health Services.

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- 2.4.9 Non-lab personnel, such as janitors or trades workers, who may enter labs where vaccinia is used, are exempted from the vaccination and medical screening requirements. All work areas must be disinfected prior to their entry. Agents must not be in active use when non-lab personnel are in the lab.
- 2.4.10 Laboratory personnel must wear personal protective equipment when handling these agents to include at a minimum a lab coat and liquid barrier gloves. Refer to the University of Pittsburgh Safety Manual Section V, Policy 05-003 for more details on Biosafety level 2 requirements.

3. REFERENCES

- 3.1. Rotz, LD, Dotson, DA, Damon, IK, Becher, JA. Advisory Committee on Immunization Practices. Vaccinia (smallpox) vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001. MMWR Recomm Rep 2001; 50(No. RR-10): 1-25.
- 3.2. Hsu, CH, Farland, J, Winters, T, Gunn, J, Caron, D, Evans, J, Osadebe, L, Bethune, L, McCollum, AM, Patel, N, Wilkins, K, Davidson, W, Petersen, B, Barry, MA. Laboratory-acquired Vaccinia virus infection in a recently immunized person Massachusetts, 2013. MMWR 2015; 64(16): 435-438.

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VACCINIA VACCINE DECLINATON FORM

Vaccination of individuals who are potentially exposed to vaccinia in the laboratory has been shown to reduce the risk of laboratory acquired vaccinia infection among lab workers and to prevent secondary spread of vaccinia to close contacts.

I understand that vaccinia immunization is highly recommended for laboratory workers who may be exposed to vaccinia, and I have been offered the vaccinia vaccination at no cost to myself through Employee Health Services. I have been informed of the risk to myself, my close contacts and family if I do not accept immunization. I also certify that I have carefully reviewed the University's Vaccinia Virus Usage Guidelines and I am aware of the risks and benefits of immunization.

University's Vaccinia Virus Usage Guidelines and I am aware of the risks and benefits of immunization.

However, I chose to decline immunization at this time for one of the following reasons:

| I have medical contraindication(s) to vaccinia immunization.
| I have close contacts or family members with contraindication(s) to vaccinia immunization.
| I have carefully evaluated risks/benefits and choose to decline vaccinia immunization.

If I decline now and change my mind in the future, I can receive a free vaccinia vaccination at Employee Health Service as long as the vaccination is available and I continue to have potential exposure to vaccinia in the laboratory.

Print Name Date of Birth

Signature Date

Date