UNIVERSITY OF CALIFORNIA SAN FRANCISCO ENVIRONMENTAL HEALTH AND SAFETY/BIOSAFETY

VACCINIA (SMALLPOX) IMMUNIZATION POLICY FOR THE RESEARCH LABORATORY SETTING

The University of California San Francisco policy on the use of vaccinia virus in research follows national guidelines issued by the Centers for Disease Control and Prevention. This policy has been approved by the Institutional Biosafety Committee (IBC) and is administered by the Office of Environmental Health and Safety (EH&S).

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.

A. Standard Vaccinia

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

- All laboratory personnel who directly a) handle cultures or b) inoculate animals
 with standard vaccinia virus, recombinant vaccinia viruses or other similar
 orthopoxviruses that infect humans, MUST be vaccinated for Vaccinia (Smallpox)
 or provide proof of smallpox immunization within the past ten years. In addition,
 lab personnel must attend a mandatory counseling session with Occupational
 Health Services prior to receiving the vaccinia vaccine.
- 2. Cultures, or animals contaminated or infected with vaccinia will not be directly handled by other laboratory workers listed on the protocol or LARC or IACUC personnel. Such personnel may be required to handle cages or move animals using tongs in an emergency situation. These individuals have a lower risk of inadvertent infection and must receive mandatory confidential counseling and (if it is medically appropriate) be offered Vaccinia (Smallpox) vaccine by Occupational Health Services (OHS). Such individuals may receive the vaccination or complete a signed declination form.

Other laboratory workers sharing the same animal housing and procedural space are at a very low risk for inadvertent infection, and are NOT advised to be

vaccinated. However, confidential counseling is available to these individuals upon request.

Any employee who would be put at a serious health risk by exposure to vaccinia will be prohibited from working in a laboratory area where vaccinia is studied.

3. CDC has begun distribution of a new-generation smallpox vaccine, ACAM2000[™] (Acambis, Inc., Cambridge, Massachusetts), to civilian laboratory personnel, the military, and state public health preparedness programs. ACAM2000 is a live, vaccinia virus smallpox vaccine that was licensed for use in the United States by the Food and Drug Administration in August 2007. ACAM2000 will be replacing Dryvax[®] smallpox vaccine (Wyeth Pharmaceuticals, Inc., Marietta, Pennsylvania) because of withdrawal of the Dryvax license. ACAM2000 is a live vaccinia virus derived from plaque purification cloning from Dryvax.

B. 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 recommend Vaccinia (Smallpox) vaccination for personnel manipulating MVA or NYVAC strains in a laboratory where no other vaccinia viruses are being manipulated.)

c. Counseling and Vaccination Procedure

- Principal Investigators (PI's) must complete the CDC Request for Vaccinia (Smallpox) Vaccine form, for section 2 titled "Laboratory Details" and section 3 titled "Recipient Details" and "Head of Laboratory Doing Research with Vaccinia." This form must be completed to record who is working with vaccinia virus and who requires mandatory vaccination or counseling. This list must include all individuals who have been counseled about vaccination and plan to receive the vaccinia vaccine.
- If only one person in the lab directly handles the vaccinia virus, the PI must identify one additional laboratory workers to participate in the vaccinia counseling and vaccination procedures. This allows for work in the laboratory to continue safely in the event that the primary person responsible for working with vaccinia is absent.

3. 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:

Public Health Office
Office of Environmental Health and Safety
50 Medical Center Way
San Francisco, CA 94143
Campus Mail: Box 0942
Phone: (415) 514 – 3531

Fax: (415) 476 - 0581 lusha.wang@ucsf.edu

- 4. Occupational Health Services will coordinate all appointments for mandatory counseling for those exposed to vaccinia.
- 5. Occupational Health Services will counsel personnel in conjunction with a review of CDC documents, Important Information About Vaccinia (Smallpox) Vaccine For Laboratory Workers and Medication Guide ACAM2000[™]. If the worker opts to get vaccinated and the vaccine is not available at the time of counseling, Occupational Health Services will notify personnel when the vaccine is available.
- 6. If the worker gets vaccinated, he/she will be required to return to Occupational Health Services on the following days after immunization: 3 days, 5-7 days, 14 days, and 17 days. It is the responsibility of the PI or supervisor to ensure that individuals attend these follow-up visits.
- Individuals who decline immunization will be asked by Occupational Health Services to sign the vaccinia declination form. Lab workers directly handling cultures or inoculating animals with vaccinia virus cannot decline vaccina immunization.

D. Safe Work Practices

Personnel working in laboratory spaces or animal rooms where vaccinia virus is used must wear a face shield and double gloves in addition to the standard Personal Protective Equipment (PPE) required for entry into that specified laboratory area.

Only personnel who have been vaccinated for vaccinia will be permitted into the area when laboratory workers are performing procedures with cultures or inoculating animals with vaccinia virus. It is the laboratory workers' responsibility to ensure that other staff members are <u>not</u> permitted into the area when this work is occurring. A sign should be placed on the outside of the door, informing staff

that work with vaccinia is in progress and should indicate an estimate time of completion.

Once the work with vaccinia cultures or animals inoculated with vaccinia is complete, the room must be thoroughly decontaminated. It is the laboratory workers responsibility to thoroughly decontaminate any equipment and or surfaces immediately following any procedures involving vaccinia virus.

E. Vaccinations

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.

Vaccinia Vaccination

CDC is the only source of vaccinia vaccine. CDC will provide vaccinia vaccine to protect laboratory and other health-care personnel whose occupations place them at risk for exposure to vaccinia and other closely related Orthopoxviruses, including vaccinia recombinants. Vaccine should be administered under the supervision of a physician selected by the institution. Vaccine will be shipped to the responsible physician. Please contact the Public Health Office at (415) 514 – 3531 or email lusha.wang@ucsf.edu for a copy of the CDC Request Form for Vaccinia Vaccination.

References

Centers for Disease Control and Prevention Smallpox Immunization Policy. http://emergency.cdc.gov/agent/smallpox/vaccination/infopacket.asp. Accessed May 24 2012.

Notice to Readers: Newly Licensed Smallpox Vaccine to Replace Old Smallpox Vaccine, MMWR, Feb 22, 2008/Vol. 57/No. 207-208.

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

UNIVERSITY OF CALIFORNIA SAN FRANCISCO

Office of Environmental Health and Safety

VACCINIA EXPOSURE PROTOCOL FOR THE RESEARCH LABORATORY SETTING

VACCINIA VACCINE DECLINATION FORM

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

I understand that vaccinia immunization is highly recommended for all laboratory workers who may be exposed to vaccinia, and I have been offered the vaccination at no cost to myself by the Occupational 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 UCSF Biosafety Poxvirus Exposure Control Protocol, 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 contraindications to immunization.
- I have family members with contraindications to immunization.
- I have carefully evaluated risks/benefits and choose to decline immunization.

If I decline for personal reasons and change my mind, I can receive a free vaccination at Occupational Health Service as long as the vaccination is available.

| Print Name | Date of Birth | Lab | |
|------------|---------------|-----|--|
| Signature | Date | | |