INTRODUCTION

Vaccinia virus is used in research laboratories because of its ability to incorporate and express large amounts of foreign genetic material and to replicate in many cell types. Vaccinia and other members of the Orthopox family of viruses are human pathogens. Although the statistical risk of acquiring infection with vaccinia virus during laboratory work is unknown, those working with non-attenuated vaccinia virus [includes all strains, except modified vaccinia Ankara (MVA), NYVAC, TROVAC, and ALVAC], are at risk for infection and potentially serious complications. Reported complications of laboratory-acquired vaccinia infections include localized vaccinia (skin lesions at the exposed site) and autoinoculation (spread to additional sites), including ocular vaccinia (infection of the eye, which can lead to blindness). In addition, an infected laboratory worker could transmit the infection to household or personal contacts. If such individuals were immunocompromised or had a history of eczema or other atopic skin diseases, they would be at risk of serious complications (generalized vaccinia, progressive vaccinia, or eczema vaccinatum). Because of these risks, the Centers for Disease Control and Prevention (CDC) recommends that all persons working with vaccinia virus be immunized, if medically eligible, before beginning work with the virus or its recombinant strains and be revaccinated every ten years [MMWR June 22, 2001/ 50(RR10); 1-25]. However, the relative risks and benefits of vaccinia vaccination for the prevention of laboratory-acquired orthopox infection are uncertain. During 2003, over 38,000 such vaccinations were administered nationwide as part of bioterrorism preparedness program; the overall incidence of serious adverse events was 2.6 per 1000 vaccinations and the incidence of life-threatening illness, permanent disability or death was 0.4 per 1000 vaccinations. Nearly one-third of these adverse events were cases of inflammation of the heart muscle or outer lining (myocarditis or pericarditis) or lack of blood flow to the heart (myocardial ischemia). (Casey et al, 2003, JAMA v294:2734). The CDC did not revise their recommendations in light of this experience.

Six cases of laboratory-acquired infection with vaccinia viruses were reported between 2005 to 2008. The affected individuals had either not been vaccinated, had unsuccessful vaccination, or were vaccinated 10 years previously. One patient was hospitalized, and all recovered uneventfully. In 2009 the CDC initiated an educational campaign highlighting its continued recommendation for vaccination in researchers manipulating non-highly attenuated vaccinia virus.

Treatment for accidental infection with vaccinia virus is limited. Recently, treatment of an immunocompromised person with progressive vaccinia with a nucleotide drug, CMX001, was reported (MMWR, June, 2009: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm58e0519a1.htm). Reversal of disease progression was temporally associated with administration of this unlicensed, investigational drug1.

The UCSD Institutional Biosafety Committee (IBC) recommends that all individuals with potential exposure to non-attenuated vaccinia virus in the laboratory or vivarium be counseled by the EH&S Occupational Health Nurse or Center for Occupational and Environmental Medicine (COEM) regarding the risks and benefits of vaccination with vaccinia virus, as well as the risks of lab-acquired infection. The individual may then decide whether or not to receive vaccination. If vaccination is accepted, the individual

must sign the consent/declination form, which acknowledges the risks associated with the vaccination. The form must also be signed if the vaccination is declined. Importantly, vaccination is not indicated for individuals working with attenuated vaccinia strains [modified vaccinia Ankara (MVA), NYVAC, TROVAC, and ALVAC].

**BACKGROUND ON VACCINIA VACCINE**

Vaccinia virus, which was introduced into clinical use as a live virus for the prevention of smallpox, led to the global eradication of smallpox in 1977. Due to the eradication of smallpox from the United States much earlier than 1977 and the potentially severe complications from the vaccine, routine vaccination of the general public for smallpox was discontinued in the United States in 1971. However, during 2003 over 38,000 vaccinations were administered as part of a bioterrorism preparedness program. The incidence of serious adverse events in this recent experience was 2.6 per 1000 vaccinations, as noted above.

**VACCINIA MEDICAL CONSULT**

It is the policy of University of California, San Diego that a medical consult be completed prior to potential vaccinia exposure for any of the following individuals:

- All individuals working with vaccinia virus in a research or clinical trial setting
- All individuals handling animals infected with vaccinia
- All individuals using or handling equipment or items potentially contaminated with vaccinia (shared equipment, equipment repair, animal bedding, open animal cage).
- All individuals entering a room at the time vaccinia virus manipulation is in process.
- All individuals sharing lab space where vaccinia virus is manipulated
- All housekeeping and maintenance personnel in lab space where vaccinia virus is manipulated

The medical consult consists of the following:

1. Offer vaccinia vaccination at no cost to the individual.

2. Health history screening for medical conditions or personal situations that would contraindicate vaccination and, therefore, also place the individual at higher risk in the event of accidental vaccinia exposure and possibly contraindicate work with vaccinia (some examples given below):
   - Eczema and other dermatitis disorders
   - Altered immunocompetence
   - HIV infection
   - Pregnancy
   - Close contacts having any of the above conditions
   - Known coronary disease
   - Documented allergy to media in vaccine preparation

3. Discussion of the need for vaccination in the particular research setting and the relative risks and benefits of vaccination.

4. Medical review of personal health risks, including close contacts, to determine if work restrictions and/or vaccination are applicable.

5. Sign a declination form if vaccination is declined.
6. Sign a consent form if vaccination is accepted

7. Complete and sign a counseling checklist.

**Procedure to be followed:**

1. The Principle Investigator must obtain written approval by the IBC to conduct research involving vaccinia virus.

   The PI must assure that all individuals working with Vaccinia or entering a lab/vivarium room where vaccinia activity is conducted read, understand, and follow the requirements in the "Vaccinia Information Packet" which can be obtained at [http://www.ehs.ucsd.edu/bio/Vaccinia_POLICY.pdf](http://www.ehs.ucsd.edu/bio/Vaccinia_POLICY.pdf), and contains the following:
   - **This "UCSD Policy on Vaccinia Virus Vaccination" on the EH&S Biosafety website.** It contains the COEM Physician Checklist and the UCSD Vaccina Vaccine Consent and Declination Form.
   - **Article: "Vaccinia (Smallpox) Vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001"**
   - **Article: "Adverse events associated with smallpox vaccination on the United States, January – October 2003" from the Journal of the American Medical Association, volume 294, page 2734.**
     [http://jama.ama-assn.org/cgi/content/abstract/294/21/2734](http://jama.ama-assn.org/cgi/content/abstract/294/21/2734)
   - **Article: "Progressive Vaccinia in a Military Smallpox Vaccinee – United States, 2009"**
     [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm58e0519a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm58e0519a1.htm)
   - **Article: "Laboratory Acquired Infection with Recombinant Vaccinia Virus Containing an Immunomodulating Construct" from the Journal of Investigative Dermatology, Mempel et al, 120:356-358, 2003.**
     [http://www.nature.com/jid/journal/v120/n3/full/5603375a.html](http://www.nature.com/jid/journal/v120/n3/full/5603375a.html)
   - **Article: "Accidental Infection of Laboratory Worker with Vaccinia Virus" from Emerging Infectious Diseases, Vol 9, No. 6, June 2003.**
     [http://www.cdc.gov/ncidod/EID/vol9no6/02-0732.htm](http://www.cdc.gov/ncidod/EID/vol9no6/02-0732.htm)
   - **Article: "Laboratory-Acquired Vaccinia Exposures and Infections --- United States, 2005—2007"**
     [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5715a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5715a3.htm)
   - **Article: "Laboratory-Acquired Vaccinia Virus Infection – Virginia, 2008."**
     [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5829a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5829a1.htm)
   - **Article: "Risks Associated With Vaccinia Virus in the Laboratory", from Virology, MacNeil et al, Vol. 385, Issue 1, March 2009.**
     [http://www.sciencedirect.com/science?ob=ArticleURL&udi=B6WXR-4V8FF9X-1&user=44298_rdoc=1&_orig=search&sort=d&docanchor=&view=c&searchStrId=10060245618&rerunOrigin=google&acct=C0000596022&version=1&urlVersion=08&userid=44298md5=b640ec86f4554c5c8facedeb44436b8f4](http://www.sciencedirect.com/science?ob=ArticleURL&udi=B6WXR-4V8FF9X-1&user=44298_rdoc=1&_orig=search&sort=d&docanchor=&view=c&searchStrId=10060245618&rerunOrigin=google&acct=C0000596022&version=1&urlVersion=08&userid=44298md5=b640ec86f4554c5c8facedeb44436b8f4)
   - **Accidental Vaccinia Virus Exposure: Information Sheet for Laboratory Workers and Information Sheet for Healthcare Personnel (Appendix D).**

2. An appointment must be made to meet with the EH&S Occupational Health Nurse at (858) 534-8225 or with the COEM Occupational Health Physician or Nurse Practitioner, at (858) 657-1600 or (619) 471-9210. The above named personnel will first determine whether there are any conditions that contraindicate work with vaccinia virus. If not, they will discuss the relative risks and benefits of vaccination. A checklist is to be completed to insure that all key points have been discussed. Both must sign this checklist after it has been completed (See Attachment "A"). Refer to Appendices E & F for medical consult and
work restriction process. Written work status recommendation must be provided to the employee, the PI/Supervisor, and the EH&S Biosafety officer.

3. The consent or declination form must be signed (See Attachment "B"). Note: All of the above steps (1 - 3) must be taken before either the consent form or the declination form is signed. If vaccination is chosen, an appointment must be set up with COEM for discussion and administration of the vaccine 619-471-9210.

4. A copy of the signed consent/declination form is to be forwarded to the EH&S Occupational Health Nurse.

Reviewed and Approved by the UCSD Institutional Biosafety Committee on June 14, 2013.

Chair, UCSD Institutional Biosafety Committee

ATTACHMENT A – Vaccinia Medical Consult Counseling Checklist

ATTACHMENT B – Vaccinia Vaccine Consent and Declination Form

ATTACHMENT C – Smallpox Vaccine Vaccine Information Statement (VIS)


ATTACHMENT D – Accidental Vaccinia Virus Exposure: Information Sheet for Laboratory Workers and Healthcare Personnel

ATTACHMENT E – Vaccinia Virus Medical Consult and Work Restriction Process

ATTACHMENT F – Vaccinia Work Status and Vaccination Guidelines

ATTACHMENT G – Smallpox (Vaccinia) Vaccine Contraindications
Attachment A

UCSD CENTER FOR OCCUPATIONAL AND ENVIRONMENTAL MEDICINE
VACCINIA MEDICAL CONSULT COUNSELING CHECKLIST

Employee Name: ________________________________

Department: __________________________________

☐ Orthopox viruses
☐ Transmission
☐ Symptoms/Complications
☐ Preventive Measures
☐ Vaccinia Vaccine use in past and present
☐ Method of Inoculation
☐ Recommended care of the Inoculation site
☐ Contraindications
☐ Potential Side Effects:
  - Autoinoculation
  - Lymph node enlargement
  - Arm swelling/tenderness
  - Residual scarring at vaccination site
  - Encephalitis
  - Vaccinia necrosum (progressive vaccinia)
  - Eczema vaccinatum (progressive localized or disseminated disease in persons with a history of eczema or atopic dermatitis)
  - Myocarditis and Pericarditis
  - Myocardial ischemia
☐ Potential consequences of vaccinia vaccine and vaccinia virus to household/personal contacts
☐ Procedure to follow in event of laboratory exposure
☐ Special concerns of the employee: ________________________________

I understand that working with vaccinia virus/viral vector poses a risk of accidental exposure. In addition, I understand the medical conditions that may place me or my personal contacts at increased risk of serious complications from vaccinia infection or smallpox vaccination.

____ I plan to proceed with work involving vaccinia virus/viral vector.

____ I plan to request not to work with projects involving vaccinia virus/viral vector.

Health Care Provider
Name (printed) __________________ Signature __________________ Date __________

Participant/Employee
Name (printed) __________________ Signature __________________ Date __________
Attachment B

UCSD VACCINIA VACCINE CONSENT AND DECLINATION FORM

Name: ____________________________ Date: ________________

Job Title: ____________________________ Phone: ________________

Principal Investigator: ________________ Dept.: ________________

I have read the information package concerning biosafety considerations for working with vaccinia virus and related orthopoxviruses and I have had an opportunity to ask questions about this information of both a subject expert and a health care professional. I understand that I may obtain a vaccinia vaccination administered by the Center for Occupational and Environmental Medicine.

My decision to either receive or decline the vaccinia vaccine is based upon my independent evaluation of the risks versus the benefits of receiving the vaccination and is not based upon any recommendations or suggestions by UCSD or any of its agents or representatives. I have either sought the advice of my personal physician or have declined to do so at my own election and risk. I understand that a copy of this signed consent/declination form will be forwarded to Environment, Health and Safety, 0920.

Please indicate type of vaccinia or vector (strain) that you intend to work with:

1. CONSENT TO VACCINATION:
I authorize and request the Center for Occupational and Environmental Medicine and its designated employees to administer the vaccinia vaccine to me. I understand that the vaccinia vaccine does not guarantee protection from the vaccinia virus. Accordingly, I hereby release the University of California, San Diego, its employees, and agents, including any physicians or other health care providers from any liability related to the administration of the vaccinia vaccine.

Employee Signature ________________ Date Given ________________

Printed Name ____________________________ Lot Number ________________

Administered by: ____________________________ Expiration Date ________________

☐ Left arm ☐ Right arm

RN Printed Name ____________________________ RN Signature ________________

VACCINATION SITE INSPECTION

Site Reaction ____________________________ Date Examined ________________

RN Signature ____________________________
2. UCSD VACCINIA VACCINE DECLINATION

UCSD is offering the vaccinia vaccine to laboratory workers in keeping with the recommendation by the Centers for Disease Control and Prevention (CDC) to vaccinate laboratory workers to protect against possible infection while working with nonvariola orthopoxviruses (MMWR 2001-06-22 / Vol. 50 / No. RR-10). The program consists of a review of your work and personal health history. The medical history, vaccination series and laboratory tests will be at no cost to you.

If there have been changes in your job that impact your degree of occupational exposure, we need your assistance in updating our records. Please call Environment, Health and Safety (EH&S) at (858) 534-5366.

If you choose to DECLINE PARTICIPATION in the Vaccinia vaccine program, you must sign below and return the original copy to EH&S, and a copy to your department office. Please keep a copy for your records.

*******************************************************************************
I understand that due to my occupational exposure to vaccinia virus, recombinant vaccinia viruses and other orthopoxviruses, I may be at risk of acquiring vaccinia. I certify that I have been given the opportunity to participate in the UCSD Vaccinia Vaccine Program.
If you are declining because of prior smallpox vaccination within 10 years, please indicate month and year of prior vaccination: ____________________________

Type or strain of Vaccinia or vector you plan to work with

I acknowledge that I am aware of the following facts:
1. The Advisory Committee for Immunization Practices (ACIP) recommends smallpox vaccination as preventive measure against inadvertent infection and adverse events for researchers who manipulate non-highly attenuated vaccinia virus.
2. The benefits of vaccination as well as the potential risks.
3. Inadvertent vaccinia virus infections constitute a public health concern due to the possibility that the virus can be transmitted to an individual's personal contacts, and to health care workers.
4. Screening for contraindications to smallpox vaccine is important because severe complications can occur in persons with underlying risk factors (e.g., pregnancy, immunodeficiencies, or dermatologic conditions such as eczema). Those with contraindications to smallpox vaccine may wish to seek counseling about the pros and cons of working with live vaccinia virus.

I understand that due to my occupational exposure to aerosol transmissible diseases, including vaccinia, I may be at risk of acquiring infection with vaccinia. I have been given the opportunity to be vaccinated against this disease or pathogen at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring vaccinia infection, a serious disease. If in the future I continue to have occupational exposure to aerosol transmissible diseases, including vaccinia and want to be vaccinated, I can receive the vaccination at no charge to me.

Employee Signature

UCSD Emp. ID #

Printed Name

Date
APPENDIX C

Smallpox Vaccine Information Statement (VIS)
SMALLPOX VACCINE

WHAT YOU NEED TO KNOW

1 WHAT IS SMALLPOX?

Smallpox is a serious disease that can kill up to 3 out of 10 people who get it.

Smallpox can also cause—
- a severe rash, which can leave scars when healed.
- high fever.
- tiredness.
- severe headaches and backache.
- blindness.

Smallpox is caused by a virus called "variola," which spreads from person to person. Usually, face-to-face contact lasting 3 or more hours is needed to spread smallpox from one person to another. Smallpox can also be spread through direct contact with infected body fluids or objects such as bedding or clothing that have smallpox virus on them.

Smallpox killed millions of people over the centuries. Smallpox vaccination was developed in 1796. As a result, the last outbreak of smallpox in the United States was in 1949. The world's last case of naturally occurring smallpox was in 1977. Routine vaccination of the American public against smallpox ended in 1972.

2 WHAT IS THE SMALLPOX VACCINE?

Smallpox vaccine is made from a living virus called "vaccinia." Vaccinia virus is like smallpox virus, but less harmful.

The smallpox vaccine can NOT give you smallpox.

The vaccine is not a shot like other vaccines. The needle is pricked into the skin a number of times in a few seconds (usually in the upper arm). The pricking is not deep, but will cause one or two small drops of blood to form. The place on the skin where the vaccine is given is called the "vaccination site."

Getting the vaccine
- before exposure will protect most people from smallpox (the vaccine is about 95% effective).
- up to 3 days after exposure can prevent the disease or at least make it less severe.
- 4-7 days after exposure can still make the disease less severe and decrease the chance of death.

Smallpox vaccine protects people from getting smallpox for 3 to 5 years. Protection from severe illness and death can last 10 years or more.

3 WHY GET VACCINATED NOW?

Smallpox vaccine protects people from smallpox.

Some people should get the vaccine because they work with smallpox or related viruses in laboratories.

Others are being offered the vaccine so they can assist in responding to a smallpox outbreak.

Smallpox virus is kept in two approved laboratories in the United States and Russia. There is concern that terrorists may have obtained the smallpox virus and could use it as a weapon. If this happened, many people could become ill and many could die.

The U.S. needs teams of health care providers and others to be vaccinated so they can respond quickly if a smallpox attack happens. These teams will do many things to help control a smallpox outbreak, including quickly vaccinating people who have been exposed to the disease.
4 WHO SHOULD GET SMALLPOX VACCINE AND WHEN?

When There is NO Smallpox Outbreak—
You should get the smallpox vaccine if you—

✦ Are a lab worker who works with smallpox or viruses like it.
✦ Are a member of a smallpox response team.

When There IS a Smallpox Outbreak—
You should get the smallpox vaccine if you—

✦ Are directly exposed to smallpox virus.

If there is a smallpox outbreak, public health experts will say who else should get the vaccine.

Vaccinated persons may need to get the vaccine again at least every 3–10 years, depending on their risk of exposure to smallpox or related viruses.

5 WHO SHOULD NOT GET THE SMALLPOX VACCINE, OR SHOULD WAIT?

When There is NO Smallpox Outbreak—
You should NOT get the smallpox vaccine if you—

✦ Have Skin Problems
  People with skin problems are at risk of developing rashes which can be severe if they get the smallpox vaccine.
  
  ▪ Anyone who has atopic dermatitis (often called eczema) or had it in the past, should not get the smallpox vaccine.
  
  ▪ Anyone who has Darier’s disease (a skin disease that usually begins in childhood) should not get the smallpox vaccine.
  
  ▪ Anyone who has a skin problem that has made many breaks in the skin (such as an allergic rash, bad burn, impetigo, psoriasis, pityriasis rosea, poison oak, poison ivy, chickenpox, shingles, herpes, or very bad acne) should not get the vaccine now. They should wait until the skin heals before getting the smallpox vaccine.

✦ Have Immune System Problems
  Rarely, when a person with a weakened immune system gets the smallpox vaccine, their vaccination site does not heal. Instead, it spreads to other parts of the body. This reaction can be life-threatening. Anyone with a weakened immune system should NOT get the smallpox vaccine, including anyone who:
  
  ▪ Has HIV/AIDS, primary immune deficiency disorders, humoral (antibody) immunity problems (such as agammaglobulinemia or lack of normal antibodies), or other diseases that affect the immune system.
  
  ▪ Has lupus or another severe autoimmune disease that weakens the immune system.
  
  ▪ Has leukemia, lymphoma, or most other cancers.
  
  ▪ Is taking cancer treatment with radiation or drugs, or has taken such treatment in the past 3 months.
  
  ▪ Is taking, or has recently taken, drugs that affect the immune system. These include high-dose steroids (for 2 weeks or longer within the past month), some drugs for autoimmune disease, or drugs taken for an organ or bone marrow transplant.

✦ Have Heart Problems
  Smallpox vaccination may cause heart inflammation that can be mild to life-threatening. It is not known who is at risk for this problem. As a precaution, anyone who has been told by a doctor that they have a heart condition should NOT get the smallpox vaccine, even if they feel well. This includes anyone who has:
  
  ▪ Known heart disease, such as past heart attack or angina (chest pain caused by lack of blood to the heart).
  
  ▪ Congestive heart failure
  
  ▪ Cardiomyopathy (heart muscle becomes enlarged and does not work as well as it should)
  
  ▪ Stroke or transient ischemic attack (a "mini-stroke" that causes stroke-like symptoms, but no lasting damage)
  
  ▪ Chest pain or shortness of breath with activity (such as walking up stairs)
  
  ▪ Other heart conditions that require the care of a doctor
In addition, anyone with **3 or more** of the following risk factors should **NOT** get the smallpox vaccine:

- Have been told by a doctor that you have high blood pressure.
- Have been told by a doctor that you have high blood cholesterol.
- Have been told by a doctor that you have diabetes or high blood sugar.
- Have a first degree relative (for example, mother, father, sister or brother) who had a heart condition before the age of 50.
- Smoke cigarettes now

**Are Pregnant or Breastfeeding**

Babies of mothers who have been vaccinated while pregnant or during the month before they become pregnant can get a very rare but serious infection from the vaccine.

- **Do NOT** get the smallpox vaccine if you are pregnant, think there is a chance you are pregnant, or think you might become pregnant within 4 weeks after vaccination.

- Sexually active women are encouraged to take a pregnancy test before getting the vaccine. The test should be done the day their vaccination is scheduled. But be aware that even the best tests may not detect early pregnancies (those less than 2 weeks).

- Take steps to prevent pregnancy during the month before and the month after vaccination:
  - Do not have sex, or
  - Use effective birth control every time you have sex. Effective birth control methods include male or female sterilization, hormonal methods (such as birth control pills, implants, patches or injections) and intrauterine devices (IUDs). Condoms and the use of spermicide with diaphragms, sponges, or cervical caps are also acceptable methods, although they are less effective. Do **NOT** rely solely on the rhythm or 'natural family' planning method.

- **Do NOT** get the smallpox vaccine if you are breastfeeding. Follow this advice even if you are pumping and then bottle-feeding breast milk. It is not known if smallpox vaccine virus or antibodies can be passed to babies through breast milk.

- **Other Reasons—Do NOT Get the Smallpox Vaccine if You**
  - Are very allergic to polymyxin B, streptomycin, clindamycin, neomycin, or latex.
  - Had a bad reaction the last time you got the smallpox vaccine.
  - Are using steroid drops in your eyes.
  - Are moderately or severely ill the day of your vaccination appointment. Wait until you are better before getting the smallpox vaccine.

- **You should NOT get the smallpox vaccine if you live with or have close physical contact with anyone (such as a sex partner) who**
  - Has any of the skin problems listed above.
  - Has any of the immune system problems listed above.
  - Is pregnant or may become pregnant within 4 weeks of your vaccination.

The smallpox vaccine may pose a similar risk to them.

Smallpox vaccine is not routinely recommended for anyone under 18 years of age or for older people. People age 65 or older who do not have any of the conditions listed above should talk to their health care provider before getting the vaccine.

**If There IS a Smallpox Outbreak—**

These restrictions may not apply. Public health experts will say who should get the vaccine at that time.
WHAT SHOULD YOU EXPECT AFTER VACCINATION?

Normal Reactions

Week 1: Three or 4 days after vaccination, a red, itchy bump will form at the "vaccination site". Most times, this spot is about the size of a dime. It can be larger than 3 inches. The bump becomes a blister. It will fill with pus and then start to drain.

A health care provider should check your vaccination site 6-8 days after you get the vaccine to make sure the vaccination worked and everything is O.K.

Week 2: The blister will dry up and a scab will form.

Week 3: The scab will fall off. It will leave a small scar.

To Help Prevent Spread of the Virus:

- Cover the area loosely with a gauze bandage held in place with first aid tape. While at work, health care workers should also cover the gauze with a semi-permeable bandage (this type of bandage allows air to flow through but not fluids).
- Change the bandage often (at least every 3 days).
- Try not to touch your vaccination site.
- Do not let others touch the site or items that have touched it such as bandages, clothes, sheets, or towels.
- Always wash your hands with soap and water or alcohol-based hand wash if you touch the site or if you touch bandages, clothes, sheets, or towels that have touched the site.
- Keep the vaccination site dry. If the gauze bandage gets wet, change it right away. Cover your vaccination site with a waterproof bandage while bathing.
- Don’t scratch or put ointment on the vaccination site.
- Don’t touch your eyes, any part of your body, or another person after changing the bandage or touching the vaccination site until you have washed your hands.
- Wear a shirt that covers the vaccination site and bandage. This helps protect those you have close contact with such as young children or the person you share a bed with.
- Don’t share towels.
- Do your own laundry. Use a separate laundry hamper for clothes, towels, sheets, and other items that may come into contact with your vaccination site or pus from the site. Machine wash items that have touched the vaccination site in hot water with detergent and/or bleach.
- Put used bandages in plastic zip bags, then throw them away in the regular trash.
- After the scab falls off, put it in a plastic zip bag and throw it away.

If you do not feel like you can follow these instructions, do not get vaccinated.

The lymph nodes under your arm may swell and be sore. The vaccination site may itch. You may also feel tired, have a mild fever, headache, or muscle aches.

You may not get a blister if the vaccine did not work properly or if you are already immune to smallpox. In this case, you will need to get the vaccine again. If you still do not get a blister after getting the vaccine a second or third time, a health care provider will tell you if you are, or are not, considered immune.

What You Will Need to Do

The virus in the vaccine is alive. It can be spread from the vaccination site to other parts of your body or to other people through close physical contact. This can happen until the scab falls off.

In the past, the vaccine virus was spread from vaccinated people to others about 2 to 6 times out of every 100,000 people vaccinated for the first time (this usually happened between people who lived together).
WHAT ARE THE RISKS FROM THE SMALLPOX VACCINE?

A vaccine, like any medicine, can cause serious problems. There is a very small risk of smallpox vaccine causing serious harm, or death.

The following information is about known reactions to smallpox vaccine. There may be other unknown side effects.

<table>
<thead>
<tr>
<th>MILD TO MODERATE PROBLEMS</th>
<th>HOW OFTEN DID IT HAPPEN IN THE PAST!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feel sick enough to miss work</td>
<td>About 1 out of 10 to 20 people vaccinated</td>
</tr>
<tr>
<td>Fever of over 100°F</td>
<td>About 1 out of 10 people vaccinated</td>
</tr>
<tr>
<td>Mild rash that gets better without medicine</td>
<td>About 1 out of 12 people vaccinated</td>
</tr>
<tr>
<td>Blisters on other parts of the body</td>
<td>About 1 out of 10,000 people vaccinated</td>
</tr>
<tr>
<td><strong>MODERATE TO SEVERE PROBLEMS</strong></td>
<td><strong>HOW OFTEN DID IT HAPPEN IN THE PAST!</strong></td>
</tr>
<tr>
<td><strong>CALL OR VISIT A HEALTH CARE PROVIDER</strong></td>
<td></td>
</tr>
<tr>
<td>Eye infection from touching your eye if you have vaccine virus on your hand. This can lead to a loss of vision in the infected eye.</td>
<td>About 1 out of 45,000 people vaccinated</td>
</tr>
<tr>
<td>Rash on entire body which usually goes away without problems</td>
<td>About 1 per 15,000 people vaccinated</td>
</tr>
<tr>
<td>Inflamed heart (can be mild to life-threatening)</td>
<td>About 1 out of 10,000 people vaccinated for the first time</td>
</tr>
<tr>
<td><strong>SEVERE OR LIFE-THREATENING PROBLEMS</strong></td>
<td><strong>HOW OFTEN DID IT HAPPEN IN THE PAST?</strong></td>
</tr>
<tr>
<td><strong>GET TO A HEALTH CARE PROVIDER IMMEDIATELY</strong></td>
<td></td>
</tr>
<tr>
<td>Severe rash on people with eczema or atopic dermatitis, which can lead to scarring or death.</td>
<td>About 1 out of 26,000 people vaccinated</td>
</tr>
<tr>
<td>Encephalitis (severe brain swelling), which can lead to permanent brain damage or death.</td>
<td>About 1 out of 83,000 people vaccinated</td>
</tr>
<tr>
<td>Skin and tissue destruction starting at the vaccination site and spreading to the rest of the body, which can lead to scarring or death (usually happens in people with very weakened immune systems).</td>
<td>About 1 out of 667,000 people vaccinated</td>
</tr>
<tr>
<td>Vaccinia virus infection in unborn child that can lead to premature delivery, skin rash with scarring, stillbirth, or death of the child after delivery</td>
<td>Very rare, less than 50 cases have been reported throughout the world in the last 100 years</td>
</tr>
</tbody>
</table>

For every million people vaccinated in the past, up to 52 people had a life-threatening reaction to smallpox vaccine and up to 2 people died.

The numbers provided above for severe or life-threatening problems are from studies done in the 1960s when the smallpox vaccine was still routinely used in the U.S. The numbers reflect how often the problems occurred in infants, children, and adults.

The numbers provided for all other problems are from recent studies and experiences vaccinating members of response teams and the military.
8 WHAT IF SOMEONE HAS A MODERATE, SEVERE OR LIFE-THREATENING PROBLEM?

Within a Few Minutes to a Few Hours of Getting the Vaccination, Watch For—

- Trouble breathing, hoarseness or wheezing.
- Hives, pale skin, weakness, a fast heart beat, or dizziness.

These could be signs that you are having an allergic reaction to the vaccine.

For the Next 3 to 4 Weeks, Keep Watching For—

- A vaccination site that is not healing.
- A rash or sore on other parts of your body.
- An eye infection.
- A lasting headache or fever.
- Confusion, seizures, or trouble staying awake.
- Chest pain, shortness of breath, rapid or unusual heartbeat or unusual fatigue.
- Any unexpected health problem.

What Should You Do?
If you or a close contact have any of these problems, or if you are concerned about any health problem that you have after vaccination—

- Call or go to a health care provider right away.
- Tell the health care provider that you received the smallpox vaccine and when.
- Ask your doctor or nurse to file a Vaccine Adverse Event Report (VAERS form) and contact the health department. You can also file a report yourself by visiting the VAERS website at www.vaers.org or by calling 1-800-822-7967.

Treating Serious Problems
There are two drugs that may help people who have certain serious side effects from the vaccine: Vaccinia Immune Globulin (VIG) and cidofovir. These drugs are not licensed for this purpose, and may also cause side effects.

Cost of Treating Serious Problems
In the rare event that you have a serious reaction to the smallpox vaccine, a federal program has been created to help pay for related costs of medical care and lost wages. This program was created to compensate certain people, such as health care workers and emergency responders, injured by the vaccine. It will also cover certain people injured as the direct result of exposure to vaccinia through contact with certain people who received the smallpox vaccine (or with the contacts of such vaccine recipients). The program covers related costs of medical care and lost wages (usually starting after the first five days of missed work) after other available coverage, such as workers’ compensation or health insurance, has been used.

The Department of Health and Human Services will make more information about this program available soon, including how to request benefits and/or compensation. For more information contact Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Office of Special Programs, 888-496-0338 or go to www.hrsa.gov/smallpoxinjury.

9 HOW CAN YOU LEARN MORE?

- Ask your health care provider. They can give you more information, show you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Visit the Centers for Disease Control and Prevention (CDC) smallpox website at www.cdc.gov/smallpox
- Contact the (CDC):
  - Call 1-888-246-2675 (English)
  - Call 1-888-246-2857 (Español)
  - Call 1-866-874-2646 (TTY)

If you decide to get the smallpox vaccine, please KEEP THIS DOCUMENT for one month following vaccination.
APPENDIX D

Accidental Vaccinia Virus Exposure

- Information Sheet for Laboratory Workers
- Information Sheet for Healthcare Personnel
Accidental Vaccinia Virus Exposure:
Information Sheet for Laboratory Workers

If you have been exposed to vaccinia virus, or you have had a laboratory accident while working with vaccinia virus:

- **Irrigate the site of exposure**.
  - If exposure was by needle stick or other route which breaks the skin, wash with soap and water for 5-15 minutes and cover with a bandage.
  - If exposure was by splash to eyes or mucous membranes, irrigate thoroughly for 15 minutes at an appropriate eye wash station.

- **Report to your laboratory supervisor and occupational health IMMEDIATELY.**
  - The occurrence of vaccinia infection and its course will vary depending on route of exposure, the strain of vaccinia, the dose of exposure, your medical history and your "smallpox" (vaccinia virus) vaccine immunization status. Immediate medical "first-aid" interventions may help prevent or lessen the severity of infection.

- **In the weeks following infection take note of the following symptoms which may indicate a need for further medical attention:**
  - Lesions or swelling at the site of exposure
  - Rash
  - Fever

- **If you have already developed lesions that you suspect may be the result of a recent vaccinia Exposure:**
  - Cover the lesions with a bandage
  - Report to your laboratory supervisor and occupational health IMMEDIATELY (if it is after normal business hours, contact occupational health on-call)

- **Provide healthcare personnel with the following information:**
  - Whether or not you ever received a smallpox vaccination
  - Date of your last vaccination
  - The strain of vaccinia you were working with (ex. Western Reserve, Dryvax, MVA)
  - If the strain was recombinant, the identity of the inserted foreign gene
  - The dose/tier of vaccinia exposure (estimate based on concentration of virus suspension, and possible volume of inoculum)

- **The following medical conditions may increase the risk of serious complications. Notify your healthcare provider if you or any of your close contacts:**
  - Have a history of eczema/atopic dermatitis or other active skin conditions, such as acne or psoriasis
  - Have an immunodeficiency or immunosuppressive condition (taking steroids, etc.)
  - Have heart disease
  - Are currently pregnant (or could be pregnant) or nursing

![Progression of infection](image)
Accidental Vaccinia Virus Exposure: Information Sheet for Healthcare Personnel

If you are providing care to someone who has been exposed to vaccinia virus or who is suspected to have an active infection (e.g., a laboratory worker or recent recipient of "smallpox" (vaccinia) vaccine), you should know the following:

- Standard barrier precautions should suffice to minimize infection within the healthcare setting.
- If lesions are active, and mucosal contact may be possible, wear goggles and/or other mucosal protection (mask/face shield).
- Vaccinia is transmissible by direct CONTACT with lesions or contaminated materials. Risk of transmission immediately after an accidental lab exposure, before virus replication has occurred or lesions have developed, is very small. However, once lesions are present, risk of transmission is increased.
- In addition to barrier precautions, it is preferable that a patient with suspected vaccinia virus infection be cared for by someone who has a history of "smallpox" (vaccinia virus) vaccination.
- Certain medical conditions may increase the risk of serious complications. If vaccinated personnel are not available, it is preferable that the patient be cared for by a healthcare provider without any of the following conditions:
  - History of eczema/atopic dermatitis or other active skin conditions, such as acne or psoriasis
  - Immunodeficiency or immunosuppressive condition (taking steroids, etc.)
  - Heart disease
  - Currently pregnant (or could be pregnant) or nursing
  - In the instance that a lesion is present, specimens can be submitted to your state or local
- Laboratory Response Network for VACCINIA testing. Contact your local health department for more information.
(http://www.cdc.gov/mmwr/International/relres.html)
- Treatments that may be considered include vaccinia immune globulin (VIG) or post-exposure vaccination with smallpox vaccine. Contact your state health department or CDC with questions regarding treatment.

CDC Poxvirus Inquiry line: (404) 639-4129
CDC Emergency Operations Center: (770) 488-7100


Images sources:
APPENDIX E
UCSD Campus – Vaccinia Virus Medical Consult and Work Restriction Process

Vaccinia Virus Work with non-highly attenuated virus → Vaccinia Medical Consult by EHS OHN per UCSD Vaccinia Policy → Refer to Work Status/Vaccination Guidelines (App F) → Complete Vaccinia Pre-Screening Quiz

Emp or personal household contacts w/ medical contraindication per App F? Yes → Restriction for vaccinia work

No

Clearance for vaccinia work

Vaccination offered (Voluntary)

Emp requests vaccination? Yes

Provide work status clearance/restrictions to emp, PI, and EHS Biosafety.

No

Refer to COEM for vaccination

If work assignment assistance is needed for individual restrictions, refer to department HR.
# APPENDIX F

**Vaccinia Virus/Viral Vector Research**  
**Work Status and Vaccination Guidelines**

<table>
<thead>
<tr>
<th>WORK ASSIGNMENT</th>
<th>Highly Attenuated Strains</th>
<th>Non-Highly Attenuated Strains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(includes attenuated viral vectors, vaccine strains, and wild-type virus)</td>
<td></td>
</tr>
<tr>
<td>Research Lab/Vivarium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Lab/ACP: direct handling (agent/animal)</td>
<td>Medical Consult &amp; Work restriction if medical contraindication</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Vaccination</td>
<td>No</td>
</tr>
<tr>
<td>Research Lab/ACP: no direct handling of agent or animal; share equipment in lab area or present in lab area at time of virus manipulation</td>
<td>Medical Consult &amp; Work restriction if medical contraindication</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Vaccination</td>
<td>No</td>
</tr>
<tr>
<td>Research Lab/ACP: no direct handling of agent; no sharing of equipment; work in lab area only but not present during virus manipulation</td>
<td>Medical Consult &amp; Work restriction if medical contraindication</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Vaccination</td>
<td>No</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trial: direct agent contact/ administration (pharmacy; healthcare staff)</td>
<td>Medical Consult &amp; Work restriction if medical contraindication</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Vaccination</td>
<td>No</td>
</tr>
<tr>
<td>Clinical trial: direct care (treated patient) or present at time of agent administration</td>
<td>Medical Consult</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Work restriction if medical contraindication</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Vaccination</td>
<td>No</td>
</tr>
<tr>
<td>Clinical trial: ancillary personnel w/o pt contact (e.g., housekeeping); not present at time of agent administration or when patient is in room</td>
<td>Medical Consult &amp; Work restriction if medical contraindication</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Vaccination</td>
<td>No</td>
</tr>
</tbody>
</table>
1 Highly attenuated vaccinia strains are unable to replicate or replicate poorly in human cells.  
Per CDC, highly attenuated strains include only the following strains: MVA (Modified Vaccinia Ankara strain), ALVAC, TROVAC, and NYVAC strains

2 Work restrictions are required if an individual has the following medical contraindications which place them or their close contacts at increased risk for infection and/or serious complications of infection in the event of an accidental occupational exposure incident:
   - History of eczema, atopic dermatitis, exfoliative skin conditions
   - Immunocompromised conditions
   - Pregnancy/Breastfeeding
   - Close contacts (e.g., household contacts, intimate personal contacts) with the above medical contraindications
   - Infant < 1 years old in household

NOTE: See Appendix F-1 for work restriction exception for Jennerex JX594 Vaccinia Viral Vector Clinical Trials.

3 Medical consult regarding vaccination choice will include discussion of infection control practices and specific high risk tasks (e.g., work with sharps to prepare or administer the vaccinia agent, direct handling of research animals, potential for aerosol exposure). No work restriction is required if vaccination is declined and there are no medical contraindications.

4 A Staff Information Sheet explaining medical contraindications will be posted in the patient chart and on the patient room/treatment door. Staff with patient contact or who will be present in a room during clinical trial study drug administration, must first read the Information Sheet, and then self-assess for medical contraindications that require them to self-restrict (not have patient contact or be in the room during administration of the vaccinia study drug).
# APPENDIX F-1

IBC Modification to Vaccinia Policy, Appendix F
Clinical Trial – Jennerex JX594 Vaccinia Viral Vector
PI: T. Reid

## Work Status and Vaccination Guidelines

<table>
<thead>
<tr>
<th>WORK ASSIGNMENT</th>
<th>Occupational Health Requirements (in bold)</th>
<th>Jennerex JX594 (TK-deleted, attenuated viral vector)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Trials w/Jennerex JX594</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trial: Preparation of study drug (pharmacy staff)</td>
<td>Medical Consult &amp; Work restriction if medical contraindication¹</td>
<td>Required</td>
</tr>
<tr>
<td>Vaccination</td>
<td></td>
<td>Offered (Voluntary)²</td>
</tr>
<tr>
<td>Clinical trial:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Direct agent contact/handling contaminated materials/administration (healthcare staff);</td>
<td>Medical Consult</td>
<td>Not Required (available if requested)</td>
</tr>
<tr>
<td>- Direct care (treated patient);</td>
<td>Review &amp; sign-off on Staff Information Sheet: JX-594 Handling &amp; Patient Management Recommendations for HCWs. Self-assessment² for medical contraindication requiring work restriction¹.</td>
<td>Self-Assessment Required w/ Fit for Duty Evaluation at COEM if self-assessment identifies possible medical contraindication requiring work restriction.</td>
</tr>
<tr>
<td>- Present at time of agent administration.</td>
<td>Vaccination</td>
<td>No</td>
</tr>
<tr>
<td>Clinical trial: ancillary personnel w/o pt contact (e.g., housekeeping); not present at time of agent administration or when patient is in room</td>
<td>Medical Consult &amp; Work restriction if medical contraindication¹</td>
<td>Not Required (available if requested)</td>
</tr>
<tr>
<td>Vaccination</td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

¹ Work restrictions are required if an individual has the following medical contraindications which place them at increased risk for infection and/or serious complications of infection in the event of an accidental occupational exposure incident:

- History of eczema, atopic dermatitis, exfoliative skin conditions

² Offered is considered optional and voluntary according to the policy.
APPENDIX F-1

IBC Modification to Vaccinia Policy, Appendix F
Clinical Trial – Jennerex JX594 Vaccinia Viral Vector
PI: T. Reid

- Immunocompromised conditions
- Pregnancy/Breastfeeding

Note: Health care personnel who fit any of these categories are only precluded from:
- direct patient contact should any skin pustule(s) occur (includes contact with contaminated dressings/items), until complete resolution of the skin pustule(s)
- preparation or administration of JX-594
- direct handling of JX-594 contaminated material
- presence in room at time of JX-594 administration

2 Medical consult regarding vaccination choice will include discussion of infection control practices and specific high risk tasks (e.g., work with sharps to prepare or administer the vaccinia agent, direct handling of research animals, potential for aerosol exposure). No work restriction is required if vaccination is declined and there are no medical contraindications.

3 A Staff Information Sheet explaining medical contraindications will be posted in the patient chart and on the patient room/treatment door. Staff with patient contact or who will be administering JX594 or present in a room during JX594 administration, must first read the Information Sheet, and then self-assess for medical contraindications that require them to self-restrict (not have patient contact if pustules are present or be in the room during administration of JX-594). If a staff member self-assesses to have a work exclusion, they will be referred to UCSD Center for Occupational and Environmental Medicine for Fit For Duty evaluation to confirm work exclusion.
APPENDIX G

CENTERS FOR DISEASE CONTROL, EMERGENCY PREPAREDNESS AND RESPONSE
HTTP://WWW.BT.CDC.GOV/AGENT/SPECIALBOX/VACCINATION/CONTRAINdications-CLINIC.ASP

Smallpox (Vaccinia) Vaccine Contraindications

Because the vaccinia virus used in smallpox vaccine can be spread to others from the vaccine site of an immunized person, the contraindications below apply to both potential vaccinees and their household contacts ("household contacts" include persons with prolonged intimate contact with the potential vaccinee, including the potential for direct contact with the vaccination site, e.g., sexual contacts).

Eczema or atopic dermatitis and other acute, chronic, or exfoliative skin conditions

- Persons who have ever been diagnosed with eczema or atopic dermatitis should not be vaccinated, even if the condition is not currently active. These patients are at high risk of developing eczema vaccinatum, a potentially severe and sometimes fatal complication. Additionally, persons with household contacts that have a history of eczema or atopic dermatitis, irrespective of disease severity or activity, should not be vaccinated.

- If the potential vaccinee or any of their household contacts have other acute, chronic, or exfoliative skin conditions (e.g., burns, impetigo, chicken pox, contact dermatitis, shingles, herpes, severe acne, severe diaper dermatitis with extensive areas of denuded skin, or psoriasis), they are at risk for inadvertent autoinoculation of the affected skin with vaccinia virus and should not be vaccinated until the condition(s) resolves.

- Persons with Darier's disease can develop eczema vaccinatum and therefore should not be vaccinated.

Diseases or conditions which cause immunodeficiency or immunosuppression

- If a potential vaccinee or any of their household contacts have conditions such as HIV/AIDS, solid organ or stem cell transplant, generalized malignancy, leukemia, lymphoma, or agammaglobulinemia, they should not be vaccinated. People with these conditions are at greater risk of developing a serious adverse reaction resulting from unchecked replication of the vaccine virus (progressive vaccinia). It is also reported that some patients with severe clinical manifestations of some autoimmune diseases (e.g., systemic lupus erythematosus) may have some degree of immunocompromise as a component of the disease. These patients should not receive smallpox vaccine during the pre-event vaccination program.

- HIV testing should be readily available to all persons considering smallpox vaccination. HIV testing is recommended for persons who have any history of a risk factor for HIV infection and who are not sure of their HIV infection status. Anyone who is concerned that they could have HIV infection also should be tested. HIV testing should be available in a confidential or, where permitted by law, anonymous setting with results communicated to the potential vaccinee before the planned date of vaccination. Persons with a positive test result should be told not to present to the vaccination clinic for immunization.

Treatments which cause immunodeficiency or immunosuppression

- If a potential vaccinee or any of their household contacts are undergoing treatment with radiation, antimetabolites, alkylating agents, high-dose corticosteroids (i.e., > 2 mg/kg body weight or 20 mg/day of prednisone for > 2 weeks), chemotherapy agents, or organ transplant medications, they should not be vaccinated. People who are receiving these therapies are at greater risk of serious adverse reactions to the smallpox vaccine.
• People undergoing treatment with high dose corticosteroids, or who have household contacts undergoing such treatment, should not be vaccinated within one month of completing corticosteroid therapy. Persons undergoing other treatments which cause immunosuppression or who have household contacts undergoing such treatment should not receive smallpox vaccine until they or their household contact have been off immunosuppressive treatment for 3 months.

Pregnancy

• Live virus vaccines are generally contraindicated during pregnancy. Pregnant women who receive the smallpox vaccine are at risk of fetal vaccinia. Although this is a very rare condition (fewer than 50 cases have ever been reported), it usually results in stillbirth or death of the infant shortly after delivery.

• Before vaccination, people should be asked if they or any of their household contacts are pregnant or intend to become pregnant in the next 4 weeks; those who respond positively should not be vaccinated. In addition, women who are vaccinated should be counseled not to become pregnant during the 4 weeks after vaccination, and abstinence or highly effective contraceptive measures should be recommended to reduce the risk of pregnancy within four weeks of vaccination.

• Routine pregnancy testing of women of child-bearing age is not recommended.

• Any woman who thinks she could be pregnant or who wants additional assurance that she is not pregnant should perform a urine pregnancy test using a "first morning" void urine on the day scheduled for vaccination. However, women should be informed that a negative urine pregnancy test cannot exclude a very early pregnancy and therefore they and their healthcare providers should not base a decision about their pregnancy status solely upon a urine pregnancy test result.

• If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after vaccinia vaccination, she should be counseled regarding the basis of concern for the fetus. However, vaccination during pregnancy should not ordinarily be a reason to terminate pregnancy.

The contraindications above apply to potential vaccinees and their household contacts. The following additional contraindications apply only to potential vaccinees:

Previous allergic reaction to smallpox vaccine or any of the vaccine’s components

• Vaccinia vaccine (Dryvax®) contains small amounts of polymyxin B sulfate, streptomycin sulfate, neomycin sulfate, and phenol. Anyone who has experienced an anaphylactic reaction to these components should not be vaccinated.

• In addition, anyone who has experienced a previous allergic reaction to the smallpox vaccine should not be vaccinated.

Moderate or severe acute illness

• Moderate or severe acute illness is generally a contraindication to vaccination.

• Vaccination should be deferred until the acute illness has resolved.

Infants and children

• Smallpox vaccine is contraindicated for children under 12 months of age.

• The Advisory Committee on Immunization Practices (ACIP) advises against non-emergency use of smallpox vaccine in persons younger than 18 years of age.

Breastfeeding
• Breastfeeding mothers should not receive the smallpox vaccine. The close physical contact that occurs during breastfeeding increases the chance of inadvertent inoculation. It is not known whether vaccine virus or antibodies are excreted in human milk.

Heart disease, temporary deferral

• CDC recommends that persons with known cardiac disease such as previous myocardial infarction, angina, congestive heart failure, or cardiomyopathy not be vaccinated at this time. This recommendation follows reports of cardiac events following smallpox vaccinations including myocardial infarctions and angina without myocardial infarction. It is unclear whether or not there is any association between smallpox vaccination and these cardiac events. Experts are exploring these issues more in depth. This exclusion may be removed as more information becomes available.

General precautions:

• The vaccine vial stopper contains dry natural rubber that may cause hypersensitivity reactions when handled by, or when the product is administered to, persons with known or possible latex sensitivity.

• Persons with inflammatory eye diseases may be at increased risk for inadvertent inoculation due to touching or rubbing of the eye. Therefore it may be prudent to defer vaccination of persons with inflammatory eye diseases requiring steroid treatment until the condition resolves and the course of therapy is complete.

Contraindications to Vaccination During a Smallpox Emergency

During a smallpox emergency, all contraindications to vaccination would be reconsidered in the light of the risk of smallpox exposure. Persons would be advised by public health authorities on recommendations for vaccination.

Careful screening is essential to minimize complications from the smallpox vaccine. If you have any questions about whether or not someone should receive the smallpox vaccine, visit the CDC website at www.cdc.gov/smallpox.