

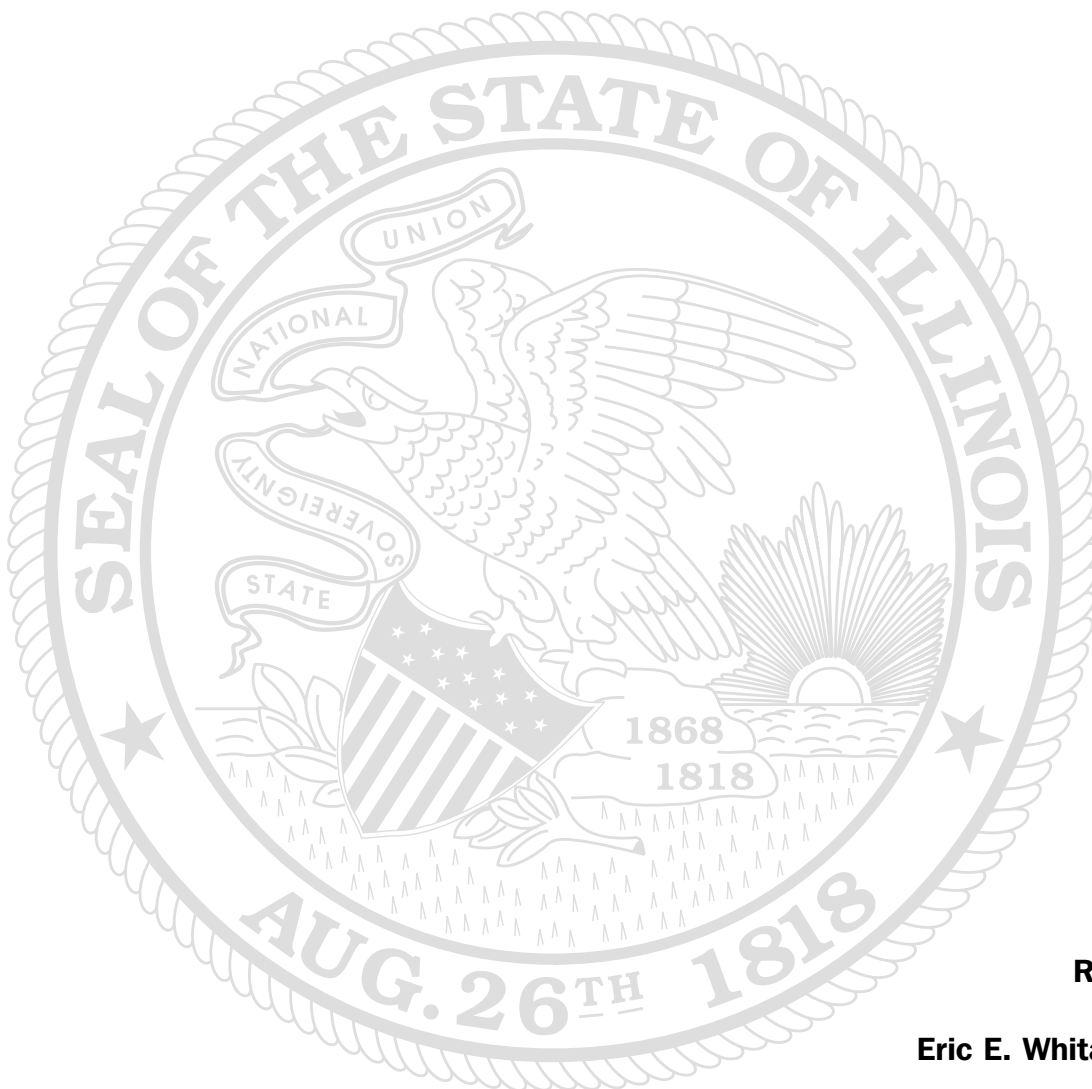


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# ***Smallpox Pre-Vaccination Information Package***

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July 2003 (Updated)



**Rod R. Blagojevich**  
Governor

**Eric E. Whitaker, M.D., M.P.H.**  
Director

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Dear Colleague:

You are considering whether to volunteer to be a member of a Smallpox Response Team as our country and our state prepare for a possible biological attack on our citizens. If you volunteer, you may want to be vaccinated against smallpox. Because a smallpox vaccination may expose you or members of your household to risks of adverse reaction, we recognize that the decision about whether or not to participate as a member of a SRT is difficult.

To help you decide whether you should volunteer, we are providing you with information prepared by the Centers for Disease Control and Prevention ("CDC") and additional information prepared by the Illinois Department of Public Health. This information is intended to help you understand the health risks to yourself and others, financial compensation issues should there be an adverse reaction, and how personal information concerning your vaccination will be maintained.

You have been given a lot of information to help you make your decision. Please take as much time as you need to read and understand all of this information before you volunteer. Share this information with members of your household and close physical contacts. Ask them to take as much time as they need to read and understand the information. Please consult your personal health care practitioner if you, a member of your household, or a close personal contact have any questions. In addition, if you are over 65 or have a chronic medical condition, you should seek guidance from your health care practitioner before you volunteer for smallpox vaccination. If you do not volunteer for vaccination, you will have other opportunities to participate in bioterrorism preparedness activities. As Dr. Julie Louise Gerberding, the Director of the CDC, has said in her enclosed letter of January 16, 2003, "We urge you to read, understand, and weigh all the information concerning your personal risks against your ability to help those in your community against a potential attack. We want you to err on the side of caution and not put you or your loved ones at risk of a serious adverse reaction."

Very truly yours,

A handwritten signature in black ink that reads "Eric E. Whitaker M.D." with a stylized flourish at the end.

Eric E. Whitaker, M.D.  
Director



Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

JAN 16 2003

Dear Colleague:

We are at a crossroads in public health. In 1980, we eradicated smallpox as a naturally occurring disease. Now this contagious, deadly disease may be brought back as a biological weapon. The most effective tool we have against the disease is the smallpox vaccine, a vaccine not without its own risks.

President Bush has initiated a national preparedness program to protect our citizens against smallpox as a biological weapon. Communities have been asked to form smallpox preparedness teams that are ready for a smallpox attack on this country. Some of you must now decide whether you will participate in this effort and receive the vaccination so that you might protect others. Your decision must be weighed carefully.

As you consider your participation on a smallpox preparedness team, please read the materials in the enclosed Smallpox Pre-Vaccination Information Package before making your decision. The Vaccine Information Statement (VIS) and supplemental fact sheets and forms are included in this package. A list of materials follows:

1. Vaccine Information Statement
2. Smallpox Vaccine Information Statement Supplement A: Reactions after Vaccination
3. Smallpox Vaccine Information Statement Supplement B: Vaccination Site Appearance and Care
4. Smallpox Vaccine Information Statement Supplement C: Skin Conditions That Mean You Should NOT Get Smallpox Vaccine
5. Smallpox Vaccine Information Statement Supplement D: A Weakened Immune System Means You Should NOT Get Smallpox Vaccine
6. Smallpox Vaccine Information Statement Supplement E: Pregnancy and Breastfeeding Mean You Should NOT Get Smallpox Vaccine
7. Pre-Event Smallpox Vaccination Screening Worksheet

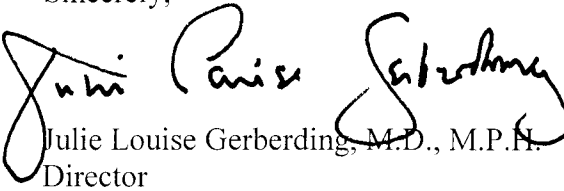
If you have any doubts, you may discuss these issues with your healthcare provider prior to vaccination. Your safety is our highest priority.

We recognize the decision about whether or not to participate in a smallpox preparedness team is difficult. We urge you to read, understand, and weigh all the information concerning your personal risks against your ability to help protect those in your community against a potential attack. We want you to err on the side of caution and not put you or your loved ones at risk of a serious adverse reaction.

Page 2 - Dear Colleague

On behalf of all of us in public health, we truly thank you for taking the time to make this important decision.

Sincerely,

A handwritten signature in black ink, reading "Julie Louise Gerberding". The signature is written in a cursive style with a large initial "J" and "L".

Julie Louise Gerberding, M.D., M.P.H.  
Director

Enclosure

# SMALLPOX VACCINE

## WHAT YOU NEED TO KNOW

### 1 What is smallpox?

Smallpox is a serious disease which kills up to 30% of people infected with it.

It is caused by a virus called **variola**, which is spread from person to person through close contact.

Smallpox can also cause:

- a severe rash, which can leave scars when healed
- high fever
- tiredness
- severe headaches and backache
- blindness

The world's last case of naturally-acquired smallpox was in 1977.

### 2 Why get vaccinated?

Smallpox vaccine protects people who work with smallpox or related viruses in laboratories.

It is believed that terrorists or governments hostile to the United States might also have the smallpox virus and could use it as a biological weapon. Smallpox vaccination can protect health care response teams, and other first responders, from smallpox disease. These teams will identify other people who need to be vaccinated to control outbreaks, and establish public vaccination clinics.

During an outbreak or emergency, smallpox vaccine can protect people exposed to smallpox virus.

### 3 Smallpox vaccine

Smallpox vaccine is made from a virus called **vaccinia**. Vaccinia virus is similar to smallpox virus, but less harmful. Vaccinia vaccine can protect people from smallpox. The vaccine does not contain smallpox virus.

Getting the vaccine *before* exposure will protect most people from smallpox. Getting the vaccine *within 3 days after exposure* can prevent the disease or at least make it less severe. Getting the vaccine *within a week after exposure* can still make the disease less severe. Protection from infection lasts 3 to 5 years, and protection from severe illness and death can last 10 years or more.

### 4 Who should get smallpox vaccine and when?

#### Routine Non-emergency Use (No Outbreak)

- Laboratory workers who handle cultures or animals contaminated or infected with vaccinia or other related viruses (e.g., monkeypox, cowpox, variola).
- Public health, hospital, and other personnel, generally 18-65 years of age, who may have to respond to a smallpox case or outbreak.

#### Emergency Use (Smallpox Outbreak)

- Anyone *directly exposed* to smallpox virus should get one dose of vaccine as soon as possible after exposure.
- Anyone *at risk of exposure* to smallpox virus may need to get one dose of vaccine when the risk occurs or becomes known.

*Vaccinated persons may need to be revaccinated after 3-10 years, depending on risk.*

### 5 After the vaccination

*See VIS Supplements A and B for more information.*

#### Expected Reactions

A blister should form at the vaccination site. Later it will form a scab. Finally the scab will fall off, leaving a scar.

You may also experience swelling and tenderness of the lymph nodes lasting 2-4 weeks after the blister has healed, itching at the vaccination site, fatigue, mild fever, headache, or muscle aches.

#### Care of the Vaccination Site

**Until the scab falls off, you can spread vaccinia virus to other people or to other parts of your own body.**

To prevent this, keep this area loosely covered with a gauze bandage. (While at work, health care workers will need additional measures, such as a semi-permeable dressing covering the gauze.)

Change the bandage as needed (every 1-3 days if using only gauze bandages, and at least every 3-5 days for semi-permeable dressings). Cover with a waterproof

Continued . . .

bandage while bathing. Don't touch the vaccination site and then another part of your body without washing your hands first. Don't scratch or put ointment on the vaccination site. **Don't touch your eyes or any part of your body after changing the bandage or touching the vaccination site.**

Wear a shirt that covers the vaccination site as an extra precaution, particularly in situations of close physical contact (for instance, parenting of young children).

Put used bandages in a plastic zip bag before throwing them away. Do the same with the scab when it falls off. Don't share towels. Launder items that have touched the vaccination site. Wash your hands after touching the vaccination site or bandages, clothing, sheets or towels that have touched the site.

**The vaccination site should be checked at around 7 days after the vaccination to make sure the vaccine is working.**

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**Some people should not get smallpox vaccine or should wait.**

*See VIS Supplements C, D, and E for more information.*

#### **Routine Non-emergency Use (No Outbreak)**

- Anyone who has eczema or atopic dermatitis, or has a past history of either condition, should not get smallpox vaccine.
- Anyone with a skin condition *that causes breaks in the skin* (such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne) should wait until the condition clears up before getting smallpox vaccine.
- Anyone whose immune system is weakened should not get smallpox vaccine, including anyone who:
  - Has HIV/AIDS or another disease that affects the immune system.
  - Has significant immune system suppression from a severe autoimmune disease, such as systemic lupus erythematosus.
  - Is being treated, or has recently been treated, with drugs that affect the immune system, such as steroids, some drugs for autoimmune disease, or drugs taken in association with an organ or bone marrow transplant.
  - Has leukemia, lymphoma, or most other cancers.
  - Is taking cancer treatment with x-rays or drugs, or has taken such treatment in the past 3 months.

- Pregnant women should not get smallpox vaccine.

- Women should avoid getting pregnant for 4 weeks after getting smallpox vaccine.

***Individuals who live with or have close physical contact with someone who falls into any of the above categories should not get smallpox vaccine, because of the risk it poses to that close contact. (Close contacts include anyone living in your household and anyone you have close physical contact with, such as a sex partner. They do not include friends or people you work with.)***

- Smallpox vaccine is not recommended for anyone under 18 years of age.
- Do not get smallpox vaccine if you have ever had a life-threatening allergic reaction to **polymyxin B, streptomycin, chlortetracycline, neomycin, or a previous dose of smallpox vaccine.**
- Breastfeeding mothers should not get smallpox vaccine.
- Persons using steroid drops in their eyes should not get smallpox vaccine.
- People who are moderately or severely ill at the time the vaccination is scheduled should usually wait until they recover before getting smallpox vaccine.

**If you have questions about any of the conditions described above, consult with your health care provider before getting smallpox vaccine.**

#### **Emergency Use (Smallpox Outbreak)**

- These restrictions may not apply in the event of a smallpox outbreak.

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**What are the risks from smallpox vaccine?**

*See VIS Supplement A for more information.*

The following information is about **known** reactions to smallpox vaccine. A vaccine, like any medicine, can cause serious problems, including those we do not yet know about, as well as severe allergic reactions. The risk of smallpox vaccine causing serious harm, or death, is very small.

#### **Mild to Moderate Problems**

- Mild rash, lasting 2-4 days.
- Fever of over 100°F (about 10% of adults).
- Blisters elsewhere on the body (about 1 per 1,900).

*About one-third of people getting the vaccine may feel sick enough to miss work or school or curtail recreational activities, or may have temporary trouble sleeping.*

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## Moderate to Severe Problems (That Need Immediate Medical Attention)

- Eye infection due to spread of vaccine virus to the eye, which can lead to loss of vision.
- Rash on entire body (as many as 1 per 4,000), which usually resolves without problems.

## Potentially Life-Threatening Problems

- Severe rash on people with eczema or atopic dermatitis (as many as 1 per 26,000), which can lead to scarring or death.
- Encephalitis (severe brain reaction) (as many as 1 per 83,000), which can lead to permanent brain damage or death.
- Severe progressive infection beginning at the vaccination site (as many as 1 per 667,000, mostly people with weakened immune systems), which can lead to scarring or death.

**For every million people vaccinated in the past, between 14 and 52 had a life-threatening reaction to smallpox vaccine and 1-2 died.**

*People who come in direct contact with the vaccination site of a vaccinated person, or with materials that have touched the site, also can have a reaction if they become infected with the vaccine virus.*

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## What if there is a moderate or severe reaction?

*See VIS Supplements A and B for more information.*

### Look for:

- A vaccination site that looks like it is not healing normally, a rash or sore on other parts of your body, an eye infection, a persistent headache or fever, confusion, seizures, difficulty staying awake, or another unexpected problem. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness occurring within a few minutes to a few hours after the vaccination.

**If you, or a close physical contact, experience any of these conditions, or if you are concerned about any condition that you experience after vaccination:**

- Call a health care provider, or get the person medical care right away.
- Tell the health care provider that you were vaccinated with smallpox vaccine and when.

- Ask your doctor or nurse to file a Vaccine Adverse Event Report (VAERS form) and contact their health department. You can also file a report yourself by visiting the VAERS website at <http://www.vaers.org> or calling 1-800-822-7967.

## Treating Serious Reactions

- Vaccinia Immune Globulin (VIG) can help people who have certain serious reactions to smallpox vaccine. A second drug, cidofovir, may be used in some situations. Neither drug is currently licensed for this purpose, and they may have side effects of their own.

## Cost of Treating Vaccine Reactions

- Treatment of severe reactions can be very expensive. Workers compensation or health insurance may not cover these expenses.
- There is no federal program to reimburse you for time lost from work, either because of illness due to vaccination or concern about spreading the virus to others. Your employer can tell you if they, or workers compensation, will cover these expenses.

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## How can I learn more?

- Read the VIS Supplements.
- Ask your doctor or nurse. They can show you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-888-246-2675** (English)
  - Call **1-888-246-2857** (Español)
  - Call **1-866-874-2646** (TTY)
  - Visit our smallpox website at <http://www.cdc.gov/smallpox/>



**U.S. Department of Health & Human Services**  
Centers for Disease Control and Prevention  
National Immunization Program

Smallpox (1/16/03)

Vaccine Information Statement



**SMALLPOX VACCINE INFORMATION STATEMENT (VIS):****IMPORTANT INTERIM SUPPLEMENTARY INFORMATION -- MARCH 31, 2003****SMALLPOX VACCINE AND HEART PROBLEMS**

There is evidence suggesting that smallpox vaccination may cause cases of heart inflammation (myocarditis), inflammation of the membrane covering the heart (pericarditis), and a combination of these two problems (myopericarditis). Most reported cases occurred in the military where approximately 325,000 doses of smallpox vaccine have been given between December 13, 2002 and March 31, 2003. Of the military cases, most had mild to moderate disease and have recovered. One became severely ill with heart failure on March 27, 2003 and remains hospitalized as of March 31, 2003. All of the military cases were among the approximately 225,000 people who received the vaccine for the first time, occurring at a rate of 1 in 20,000. Experts are exploring this more in-depth.

Heart pain (angina) and heart attack also have been reported in a small number of people following smallpox vaccination. Two of the people who had heart attacks have died. However, it is not known if smallpox vaccination caused these problems or if they occurred by chance alone (heart problems are very common). Experts are investigating this question also.

Reported events are not necessarily caused by the vaccine, and some or all of these events might be coincidental.

**As a precautionary step, if you have been diagnosed by a doctor as having a heart condition with or without symptoms you should NOT get smallpox vaccine at this time while experts continue their investigations. These include conditions such as:**

- **known coronary disease including:**
  - **previous myocardial infarction (heart attack)**
  - **angina (chest pain caused by lack of blood flow to the heart)**
- **congestive heart failure**
- **cardiomyopathy (heart muscle becomes inflamed and doesn't work as well as it should)**
- **stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage)**
- **chest pain or shortness of breath with activity (such as walking up stairs)**
- **other heart conditions under the care of a doctor**

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**In addition, you should NOT get the smallpox vaccine if you have 3 or more of the following risk factors:**

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

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

The presence of these conditions in a close contact (such as people you live with) is not a reason for you to defer vaccination.

If you have received the smallpox vaccine, you should see a health care provider right away if you develop chest pain, shortness of breath, or other symptoms of cardiac disease after vaccination.

If you have been diagnosed by a doctor as having a heart condition and have already received the smallpox vaccine, you should contact your heart disease specialist or regular health care provider if you have questions.

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY).

**SMALLPOX VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT A****Reactions After Vaccination**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective.

After smallpox vaccination, most people experience normal, typically mild reactions to the vaccine, which indicate that it is beginning to work. Some people may experience more severe reactions that may require medical attention. Consult the "Smallpox Vaccine Information Statement" (VIS), or relevant supplemental fact sheets for information on people who should not be vaccinated at this time.

Following are listings of what you may expect, and conditions that you should be watchful for:

**Normal, Typically Mild Reactions**

These reactions usually go away without treatment. They can start right away, or they may not start until a week or more after vaccination:

- The arm receiving the vaccination may be sore and red where the vaccine was given.
- The glands in the armpits may become large and sore.
- The vaccinated person may run a low fever.
- The vaccinated person may have other symptoms like fatigue, headache, or muscle aches.
- One out of 3 people may feel bad enough to miss work, school, or recreational activity or have trouble sleeping.
- The vaccination site may start itching after a few days, this could last until the scab falls off.

**Other Things to Expect with Normal Reactions**

A recent study found:

- The average size of the pustule (pus-filled blister) at the vaccination site was half an inch.
- The average size of the redness and/or swelling at the vaccination site was 2/3 of an inch.
- Up to 15% of people vaccinated had redness and/or swelling larger than 3 inches, sometimes involving the whole arm. This is usually seen around 7 to 10 days after vaccination.
- Up to 47% of people vaccinated reported pain at the vaccination site, but most said it did not keep them from normal activities.
- About 10% had a fever of 100°F or more. (This can be treated with ibuprofen or acetaminophen.)
- An allergic rash sometimes occurred where the first aid adhesive tape holding the gauze bandage in place touched the vaccine recipient's skin.

***If you are concerned about normal reactions:***

While these reactions usually go away on their own, if you are concerned about reactions of this type, call the phone number provided on the "Post-Vaccination and Follow-Up Information Sheet" given to you at the time of your vaccination, or call your health care provider.

## **VIS SUPPLEMENT A: Reactions after Vaccination**

(continued from previous page)

### **Symptoms That May Mean You Require Medical Attention**

Some people may experience more severe reactions that may require medical attention. You should be aware of symptoms that might indicate you are experiencing such a reaction.

Be watchful for the following symptoms:

- Your vaccine site doesn't look like it is healing normally.
- You develop a rash or sore on other parts of your body.
- You develop a persistent headache (lasting more than 24 hours) or high fever, confusion or seizures.
- You have difficulty staying awake.
- You have difficulty breathing, hoarseness or wheezing.
- You develop hives, paleness, weakness, a fast heartbeat or dizziness.
- You develop an eye infection.
- You develop some other atypical, unexpected problem.

If any of the above occur, call the phone number provided on the "Post-Vaccination and Follow-Up Information Sheet" given to you at the time of your vaccination, or call your health care provider.

### **Serious Reactions That Should Be Evaluated**

In the past, about 1,000 people for every 1 million people vaccinated for the first time had reactions that, while not life-threatening, were serious. These reactions may require medical attention:

- A vaccinia rash or outbreak of sores limited to one area (inadvertent inoculation). This is an accidental spreading of the vaccinia virus caused by touching the vaccination site and then touching another part of the body or another person before washing of hands. It usually occurs on the genitals or face, and can include the eyes, where it can damage sight or lead to blindness. Washing hands with soap and water after touching the vaccine site will help prevent this. **Note: If the eyes are affected, seek immediate attention.**
- A widespread vaccinia rash (generalized vaccinia). The virus spreads from the vaccination site through the blood. Sores break out on parts of the body away from the vaccination site.
- An allergic rash in response to the vaccine (erythema multiforme). This can take various forms such as red spots, bumps, or hives.
- Red streaks coming out from the vaccination site are most likely a normal reaction, but could be an infection and should be checked.

### **Life-Threatening Reactions That Need Immediate Attention**

Rarely, people have had very bad reactions to the vaccine. In the past, between 14 and 52 people per 1 million people vaccinated for the first time had potentially life-threatening reactions, and 1 or 2 died.

These reactions require **immediate** medical attention:

- Serious skin rashes (eczema vaccinatum). This is caused by widespread infection of the skin in people with skin conditions such as eczema or atopic dermatitis and can lead to scarring or death.
- Ongoing infection of skin at the vaccination site with tissue destruction (progressive vaccinia or vaccinia necrosum) that can lead to scarring or death.
- Inflammation of the brain (postvaccinal encephalitis) that can lead to disability or death.

## **VIS SUPPLEMENT A: Reactions after Vaccination**

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### **If you believe you are having one of the reactions above:**

Call the phone number provided on the "Post-Vaccination and Follow-Up Information Sheet" given to you at the time of your vaccination, call your health care provider, or visit an emergency room.

### **Treatment for Serious or Life-threatening Reactions**

Two treatments may help people who have certain serious reactions to the vaccine: Vaccinia Immune Globulin (VIG) and cidofovir. Neither drug is currently licensed for this purpose, and may have side effects of their own. More information on each will be available at the clinic facility or can be found at the website listed below.

### **Unsuccessful Vaccination**

Around 3% of people may have no reaction from the vaccine. This could mean that vaccination was not successful and you are not protected. In this case, you would need to be vaccinated again.

***Note:** Adverse events in the U.S. today may be higher than in the past because there may be more people at risk from immune suppression and eczema or atopic dermatitis. The outcome associated with adverse events may be less severe because of advances in medical care. Rates may be lower for persons previously vaccinated.*

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

(Version 1)

January 16, 2003

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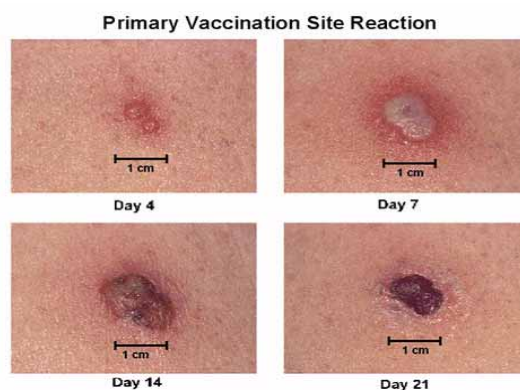
## SMALLPOX VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT B

### Vaccination Site Appearance and Care

#### Appearance

If the vaccination is successful, a red and itchy bump develops at the site of vaccination in 3 or 4 days. In the first week, the bump becomes a blister, fills with pus, and begins to drain. During the second week, the blister begins to dry up and a scab forms. The scab falls off in the third week, leaving a small scar. People vaccinated for the first time may have a stronger reaction than those who are being revaccinated.

The following pictures show the usual progression of the vaccination site:



Major (primary) reaction – Expected site reaction and progression over the three weeks following first-time smallpox vaccination, or following revaccination after a prolonged period. Source: CDC.

#### Vaccination Site Evaluation

**About 7 days after vaccination**, you will need to keep an appointment for a vaccination site exam so that someone can evaluate your vaccination site to determine whether the vaccination was successful. The details of this appointment are on the “Post-Vaccination and Follow-Up Sheet” given to you at vaccination.

#### Look-out for:

If your vaccination site doesn’t look like it is healing normally, or if you develop a rash or sore on other parts of your body, an eye infection, a persistent headache (lasting more than 24 hours) or high fever, confusion, seizures, difficulty staying awake, difficulty breathing, wheezing, hoarseness, hives, paleness, weakness, a fast heartbeat, dizziness or some other unexpected problem, call the phone number provided on the “Post-Vaccination and Follow-Up Information Sheet” or call your health care provider.

#### Site Care

There will be **vaccinia virus** at the site of your vaccination until the scab that forms after vaccination falls off on its own, between 2 and 3 weeks after vaccination. During this time, vaccinia can be spread to other parts of the body or to other individuals through direct contact (touching the vaccination site or a bandage or clothing contaminated with virus and then touching another part of your body or someone else before hand washing). You should avoid the spread of virus and keep the vaccination site clean and dry. Follow the instructions on the next page carefully.

## **VIS SUPPLEMENT B: Vaccination Site Appearance and Care**

(continued from previous page)

### **Site Care Instructions**

Follow these instructions until the scab that forms at the vaccination site has fallen off on its own.

#### **WHAT YOU SHOULD DO:**

- **When working in a health care setting, cover the vaccination site loosely with gauze, using first aid adhesive tape to keep it in place. Then cover the gauze with a semipermeable (or semioclusive) dressing. Change the bandage at least every 3-5 days in order to prevent build-up of fluids and irritation of the vaccination site. Also wear a shirt that covers the vaccination site** as an additional barrier to spread of vaccinia. (A "semipermeable dressing" is one that does not allow for the passage of fluids but allows for the passage of air.)
- **When not at work in a health care setting, you need only wear the gauze bandage secured by first aid adhesive tape** over the vaccination site. Change the gauze bandage frequently (every 1-3 days). As an **added precaution** against spread of transmission, **wear a shirt** that covers the vaccination site as well. This is particularly important in situations of close physical contact such as occurs in the household.
- **Wash hands with soap and warm water** or with alcohol-based hand rubs such as gels or foams after direct contact with vaccine, the vaccination site, or anything that might be contaminated with live virus, including bandages, clothing, towels or sheets that came in contact with the vaccination site. This is vital in order to remove any virus from your hands and prevent contact spread.
- **Keep the vaccination site dry.** Cover the vaccination site with a waterproof bandage when you bathe. Remember to change back to the loose gauze dressing after bathing. If the gauze covering the vaccination site gets wet, change it.
- **Put the contaminated bandages in a sealed plastic bag and throw them away** in the trash.
- Keep a **separate laundry hamper** for clothing, towels, bedding or other items that may have come in direct contact with the vaccination site or drainage from the site.
- **Wash clothing or any other material that comes in contact with the vaccination site** using hot water with detergent and/or bleach. **Wash hands afterwards.**
- When the scab falls off, **throw it away in a sealed plastic bag** (remember to wash your hands afterwards).

#### **WHAT YOU SHOULD NOT DO:**

- **Don't use a bandage that blocks all air from the vaccination site.** This may cause the skin at the vaccination site to soften and wear away. Use loose gauze secured with first aid adhesive tape to cover the site and then cover this with a semipermeable dressing and shirt when at work in a health care setting.
- **Don't put salves or ointments on the vaccination site.**
- **Don't scratch or pick at the scab.** The vaccination site can become very itchy but you should not scratch it.

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

**SMALLPOX VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT C****Skin Conditions That Mean You Should Not Get Smallpox Vaccine**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective. However, people with certain skin conditions are more likely to have rare and serious reactions to the smallpox vaccine, including bad skin rashes (eczema vaccinatum). This results when virus from the vaccine site gets into broken skin and causes a rash in that area. While most people recover from this rash with treatment, it can be quite severe, sometimes leading to scarring or even death.

**SKIN CONDITIONS THAT MEAN YOU SHOULD NOT BE VACCINATED:**

- Individuals who have ever been diagnosed with **eczema or atopic dermatitis**, (conditions involving repeated episodes of red, itchy or inflamed skin) even if the condition is mild, not presently active, or if you had it only as a child, **should not get the vaccine.**
- Individuals with **Darier's disease** should not get the vaccine.
- Individuals in **close contact** with someone who has ever been diagnosed with **eczema or atopic dermatitis**, even if the condition is mild, not presently active, or if they had it only as a child, **should not get the vaccine** because of the risk it poses to that close contact. (Close contacts include anyone living in your household and anyone you have close physical contact with such as a sexual partner.)

**SKIN CONDITIONS THAT MEAN YOU SHOULD WAIT BEFORE BEING VACCINATED:**

- Individuals with **breaks in their skin should not be vaccinated until the skin is fully healed.** Below are examples of skin conditions that can result in breaks in the skin.
- Individuals in **close physical contact with someone else who has breaks in their skin should not be vaccinated until the skin is fully healed.**

**Examples of conditions that can result in breaks in the skin include:**

- Impetigo (a skin infection)
- Varicella (chickenpox or shingles)
- Pityriasis rosea
- Acute contact dermatitis (e.g. poison oak or ivy)
- Recent significant burns (> about 1 inch x 1 inch) where skin has not completely healed
- Other conditions that cause significant rash or breaks in the skin, including moderate or extensive psoriasis, epidermolysis bullosa, severe acne (face or body) and pemphigus vulgaris.



## **VIS SUPPLEMENT C: Skin Conditions that Mean You Should NOT Get Smallpox Vaccine**

(continued from previous page)

### **What are eczema and atopic dermatitis?**

The word **eczema** describes certain kinds of inflamed skin. Early eczema can be red, blistering, or oozing areas of skin. Later on, eczema can be scaly, brownish, or thickened. Almost always, eczema itches. There are several different types of eczema. A special type of eczema called atopic dermatitis or atopic eczema has the greatest risk for severe rashes after smallpox vaccination.

**Atopic dermatitis** is a chronic disease that affects the skin. "Dermatitis" means inflammation of the skin. "Atopic" refers to a group of diseases that run in families and often occur together (including hay fever and asthma). In atopic dermatitis, the skin becomes extremely itchy and inflamed, causing redness, swelling, cracking, weeping, crusting and scaling. This often affects creases in the elbows or knees. Atopic dermatitis most often affects infants and young children, but it can continue into adulthood or appear later in life. In most cases, there are times when the disease is worse, called exacerbations or flares, followed by periods when the skin improves or clears up entirely, called remissions. Many children with atopic dermatitis will completely recover from this skin disease when they get older, although their skin often remains dry and easily irritated. Environmental factors can bring on symptoms of atopic dermatitis at any time in someone who has inherited the atopic disease trait.

Although it is difficult to know exactly how many people are affected by atopic dermatitis, an estimated 10% of infants and young children experience symptoms of the disease. Roughly 60% of these children continue to have one or more symptoms of atopic dermatitis into adulthood. This means that more than 15 million people in the United States have symptoms of the disease. None of these people should be vaccinated or be in close contact with someone who has been vaccinated because of the potential risk posed by exposure to the live virus in the smallpox vaccine.

### **What if there is an outbreak of smallpox?**

If there is a smallpox outbreak, recommendations on who should get vaccinated will change. Anyone who is directly exposed to smallpox should get vaccinated because the disease poses greater risk than the vaccine. Public health authorities will recommend who should be vaccinated at that time.

### **How can I learn more?**

- Talk to your health care provider if you have any questions or concerns about skin conditions.
- For more information on eczema and atopic dermatitis, visit <http://www.niams.nih.gov/hi/topics/dermatitis/> and <http://www.aad.org/pamphlets/eczema.html>

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

**SMALLPOX VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT D****A Weakened Immune System Means You Should Not Get Smallpox Vaccine**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective. However, people with immune system problems usually are advised to avoid live virus vaccines because their immune systems may not be able to stop the growth of the virus in their bodies. In the case of the smallpox vaccine, while the risk for severe complications for someone with a weakened immune system is unknown, there have been cases of serious reactions to the vaccine. Someone with a weakened immune system might develop a widespread, severe, vaccinia rash (generalized vaccinia), or ongoing severe skin destruction at the vaccination site (progressive vaccinia/vaccinia necrosum).

- Individuals with **suppressed immune systems should not get the smallpox vaccine.**
- Individuals who are **undergoing, or have recently undergone, medical treatment that can weaken their immune system should not get the smallpox vaccine.**
- Individuals **in close physical contact with someone who falls into these categories should not get smallpox vaccine** because of the risk it poses to that close contact. Close contacts include anyone living in your household or anyone you have close physical contact with such as a sex partner.

**What are some illnesses that can weaken the immune system?**

- HIV/AIDS
- Cancer
- Leukemia
- Lymphoma
- Multiple myeloma
- Primary Immune Deficiency disorders (such as Common Variable Immune Deficiency)
- Humoral (antibody) immunity problems (such as agammaglobulinemia or lack of normal antibodies)
- Some people with severe autoimmune diseases such as systemic lupus erythematosus (SLE) may have significant immune system suppression

**What else could cause a weakened immune system?**

Immunosuppressive medications or other treatments such as:

- High-dose oral or intravenous steroid therapy for 2 weeks or longer within the past month. (For example, with prednisone,  $\geq 2\text{mg/kg}$  per day for 2 weeks or longer within the past month is considered immunosuppressive.)

## **VIS SUPPLEMENT D: A Weakened Immune System Means You Should Not Get Smallpox Vaccine**

(continued from previous page)

- Cancer chemotherapy agents within the past 3 months
- Radiation therapy within the past 3 months.
- Organ or bone marrow transplant
- Medications that suppress the immune system, including steroids, some drugs for autoimmune disease, or drugs taken in association with an organ or bone marrow transplant (consult your health care provider)

**If you have questions about any of the above conditions, please consult your health care provider before being vaccinated.**

### **More on HIV/AIDS**

Up to 300,000 people in the U.S. may be infected with the HIV virus and not know it. You can have HIV infection and seem to be completely well. Although you may seem fine, if you have HIV, you are at risk for a bad reaction from smallpox vaccine. People with conditions such as HIV or AIDS that can suppress their immune system are at higher risk for having a severe skin rash or blood infection from the vaccine.

Below is a list of factors that may place you at higher risk for having HIV infection:

- Use of needles to inject anything not prescribed by your doctor
- Had an accidental needle-stick
- Had sexual contact with someone who has HIV/AIDS or has had a positive test for HIV/AIDS
- Had sexual contact with a prostitute or someone else who takes money or drugs or payment for sex
- Had sexual contact with someone who ever has used needles to inject anything not prescribed by a doctor
- For women: Had sexual contact with a man who has ever had sexual contact with another man
- For men: Had sexual contact with another man

If any of these situations apply to you, talk to your health care provider about getting tested for HIV before being vaccinated. In addition, since some people with HIV do not have these risk factors, if you have any concerns please get tested.

### **How can I learn more?**

If have any questions about whether your immune system may be weakened, consult your health care provider before getting vaccinated.

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

**SMALLPOX VACCINE INFORMATION STATEMENT (VIS) SUPPLEMENT E****Pregnancy and Breastfeeding Mean You Should Not Get Smallpox Vaccine**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective. In pregnant women, however, smallpox vaccination can cause an infection in the unborn child that can lead to premature delivery, skin rash with scarring, stillbirth, or death of the child after delivery. In addition, it is unknown whether vaccine virus or antibodies are excreted in breast milk. Also, the close physical contact that occurs during breastfeeding increases the chances of accidentally transferring the virus from the vaccination site to the baby.

**Pregnancy**

- **Pregnant woman should not get the smallpox vaccine.**
- Also, if someone you are in **close physical contact** with is **pregnant**, you should **not get the smallpox vaccine**. (Close contacts include anyone living in your household and anyone you have close physical contact with such as a sexual partner.)
- Women who are vaccinated should **avoid getting pregnant for 4 weeks**.

**If you want to get the smallpox vaccine**

- Any woman who thinks she could be pregnant or who wants additional assurance that she is not pregnant should perform a morning urine pregnancy test on the day vaccination is scheduled.

**After vaccination, prevent pregnancy for a month:**

You should wait until the vaccination site has completely healed and the scab has fallen off before you try to become pregnant after vaccination. Take measures to prevent becoming pregnant.

**Breastfeeding**

- **Women who are breastfeeding should not get the vaccine.** This applies to women who are breastfeeding as well as pumping and then bottle-feeding breast milk.
- Breastfeeding by a close contact is not a contraindication to vaccination. You can get vaccinated if a close contact is breastfeeding.

**What if there is an outbreak of smallpox?**

If there is a smallpox outbreak, recommendations on who should get vaccinated will change. Anyone who is exposed to smallpox should get vaccinated because they will be at greater risk from the disease than they are from the vaccine. Public health authorities will recommend who should be vaccinated at that time and what measures you can take to try to protect yourself from being exposed to smallpox.

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)



## Pre-Event Screening Worksheet for Smallpox Vaccine

The smallpox vaccine contains a live virus that is closely related to the smallpox virus. Most people who receive this vaccine will not have any adverse reactions. However, some people should not receive the vaccine because they are at risk of having problems following vaccination.

The smallpox vaccine is not like most other vaccines you may have received in the past. The vaccine virus can be spread from person to person, which means that problems following vaccination can occur both in the vaccinated person and his or her close contacts. Your close contacts include everyone who lives in your household and anyone that you have close, physical contact with (such as a sex partner). Before being vaccinated, you should find out if you and your close contacts have any of the conditions listed below. Also write down the names and doses of all prescription medications that you and your close contacts take. Talk with your doctor or pharmacist if you are not sure.

This worksheet contains questions designed to help you determine if you should not receive smallpox vaccine because of certain medical conditions that would place you or your close contacts at risk for a serious reaction from the vaccine. If you determine that you should not receive this vaccine, then you should not attend the vaccination clinic. Otherwise, you should bring the worksheet to the vaccination clinic after filling it out. If you are not sure about some responses, you should try to get the answers from your doctor before going to the vaccination clinic.

Some of these questions are of a personal and sensitive nature. This worksheet will not be collected by those administering the smallpox vaccine

### Who should not receive smallpox vaccine?

You should NOT receive the smallpox vaccine if you or a close contact has any of the conditions listed below. Close contacts include anyone living in your household and anyone you have close, physical contact with (such as a sex partner). Friends or people you work with are not considered close contacts.

- Known or suspected HIV/AIDS infection.
- A condition that impairs the immune system like leukemia, lymphoma, or a primary immune deficiency disorder.
- Some severe autoimmune diseases such as systemic lupus erythematosus (SLE) that may significantly suppress the immune system.
- Use drugs that affect the immune system, like oral steroids (prednisone and related drugs), some drugs given for autoimmune diseases, or drugs taken in association with an organ or bone marrow transplant.
- Are receiving or recently received chemotherapy or radiation therapy for cancer.
- Currently pregnant or might become pregnant within 4 weeks after smallpox vaccination. **Any woman who might be pregnant should perform a pregnancy test with a "first morning" urine sample on the day of vaccination.**
- Some skin diseases in childhood or adulthood, including atopic dermatitis or eczema.
- A history (as a child or adult) of a RECURRING itchy, red rash that lasted more than 2 weeks and was located in the creases of the arms or legs (even if currently resolved).

## Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

- Darier's disease (keratosis follicularis), a skin disease that usually begins in childhood.
- Had a serious, life-threatening reaction to smallpox vaccine in the past (does not apply to close contacts).

### Who should delay vaccination?

You should delay receiving the smallpox vaccine if you meet any of the following criteria:

- You are currently breastfeeding
- You (or a close contact) currently have a skin problem that causes significant breaks in the skin surface, such as burns, severe acne, impetigo, chickenpox, shingles, poison ivy, or other rashes (including those caused by prescription medications).
- You are currently using steroid drops in your eyes.
- You have a moderate or severe illness (including an illness with a fever).

You can receive the smallpox vaccine after the acute illness or rash goes away, or after you stop using these medications, and your doctor approves the vaccination.

### What about HIV infection?

Up to 300,000 people in the United States may be infected with the HIV virus and do not know it. You can have HIV infection and feel completely well. Although you may seem fine, if you have HIV infection you are at risk for serious, life-threatening reactions from this vaccine. If you do not know your HIV status, you should talk with your private doctor to decide if you should be tested before volunteering to get vaccinated. People with conditions such as HIV or AIDS that can suppress their immune system are at higher risk for having severe adverse events after vaccination.

**Below is a list of factors that may place you at higher risk for having HIV infection. If any of these apply to you, you should strongly consider being tested for HIV before getting the smallpox vaccine. In addition, since some people with HIV do not have these risk factors, if you have any concerns please get tested.**

1. Use of needles to inject anything not prescribed by your doctor
2. Had an accidental needle-stick
3. Had sexual contact with someone who has HIV/AIDS or has had a positive test for HIV/AIDS virus
4. Had sexual contact with a prostitute or someone else who takes money or drugs or payment for sex
5. Had sexual contact with someone who has ever used needles to inject anything not prescribed by a doctor
6. For women: Had sexual contact with a man who has ever had sexual contact with another male
7. For men: Had sexual contact with another man

### Screening questions

Please answer the questions on the following pages to help you determine if you should not get smallpox vaccine due to medical conditions or treatments that place you or your close contacts at greater risk for adverse reactions. Answer each question to the best of your knowledge. You may ask your health care provider or a clinic health care provider for assistance if you do not understand a question. If you need more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY).

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January 23, 2003

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**Pre-Event Screening Worksheet for Smallpox Vaccine**  
(continued from previous page)

<b>Conditions</b>	Do <b>you</b> have this condition?	Does a <b>close contact</b> have this condition?
1. Currently have cancer, or been treated for cancer within the past 3 months	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated
2. An organ or bone marrow transplant	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated
3. A disease that affects the immune system like lymphoma, leukemia, or a primary immune deficiency disorder	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated
4. An autoimmune disease such as systemic lupus erythematosus (SLE), that may suppress the immune system	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated until you check with your doctor	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated until you check with your contact's doctor
5. Currently pregnant or might be pregnant. <i>A pregnancy test is recommended if there is ANY chance you might be pregnant</i> (When did your last menstrual period begin? ____/____/____)	FEMALES ONLY: <input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated
6. Currently breastfeeding	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Delay vaccination until you are no longer breastfeeding	Not applicable
7. An allergy to polymyxin B, streptomycin, chlortetracycline or neomycin	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	Not applicable

**Pre-Event Screening Worksheet for Smallpox Vaccine**  
(continued from previous page)

<b>Conditions</b>	Do <b>you</b> have this condition?	Does a <b>close contact</b> have this condition?
8. Had a serious, life-threatening reaction to smallpox vaccine at any time in your life	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	Not applicable
9. Have Darier's disease, a skin problem that usually begins in childhood	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated
10. Ever given a diagnosis of atopic dermatitis or eczema by a doctor, including as a baby or child	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated
11. Currently have a skin problem that causes significant breaks in the skin surface. These problems include burns, severe acne, poison ivy, chickenpox, shingles, or other rashes (including those caused by prescription medications)	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Delay vaccination until your skin is healed	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Delay vaccination until your contact's skin is healed

Please answer 'yes' or 'no' to indicate if you or a close contact is currently receiving any of the following treatments or drugs. *Talk to a health care provider if you are not sure.*

<b>Treatments</b>	Are <b>you</b> receiving this medication or treatment?	Is a <b>close contact</b> receiving this medication or treatment?
12. Intravenous steroids or oral steroid pills or capsules (prednisone or related drugs) taken for 2 weeks or longer within the past month	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated <b>Name and dose</b> of medication:	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated <b>Name and dose</b> of medication:



**Pre-Event Screening Worksheet for Smallpox Vaccine**  
(continued from previous page)

<b>Treatments</b>	Are <b>you</b> receiving this medication or treatment?	Is a <b>close contact</b> receiving this medication or treatment?
13. Drugs that affect the immune system like methotrexate, cyclophosphamide, and cyclosporine, among others, within the last 3 months	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated <b>Name and dose</b> of medication:	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated <b>Name and dose</b> of medication:
14. Radiation therapy in the past 3 months	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated
15. Chemotherapy for cancer in the past 3 months	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated
16. Currently use steroid drops in your eyes	<input type="checkbox"/> YES <input type="checkbox"/> NO ↓ Do not get vaccinated	Not applicable

17. Do you currently have a moderate or severe illness?  
 YES → You must wait until this illness goes away before you get vaccinated  
 NO

**Some individuals may not be sure if they have had eczema or atopic dermatitis. The following questions are designed to help you determine if you should not get vaccinated because you or a close contact may have a history of atopic dermatitis or eczema.**

18. Do you currently have an **itchy red rash** that comes and goes but usually lasts more than 2 weeks, or did you have such a rash as a baby or child?  
 YES → You may have eczema or atopic dermatitis. You should discuss this possibility with your doctor. Please answer questions 19 and 20.  
 NO → **SKIP TO question 21**  
 Don't know → You should discuss any rashes you have with your doctor.

If you can, please write down any information given to you by a doctor regarding this rash:

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**Pre-Event Screening Worksheet for Smallpox Vaccine**  
(continued from previous page)

19. Did the itchy rash affect the creases of your **elbows** or **knees**?
- YES → You likely have eczema or atopic dermatitis and should **NOT** get vaccinated at this time
- NO
- Don't know
20. Did you have **food allergies** as a baby or child?
- YES
- NO → **SKIP TO question 21**
- Don't know
- IF YES** → Do you also have **asthma** or **hay fever**?
- YES → You likely have eczema or atopic dermatitis and should **NOT** get vaccinated at this time
- NO
21. Does a close contact currently have an **itchy red rash** that comes and goes but usually lasts more than 2 weeks, or did a close contact have this condition as a baby or child?
- YES → Your close contact may have eczema or atopic dermatitis. Discuss this possibility with a doctor.
- NO
- Don't know → You need to find out more about your contact's rash before getting vaccinated.

**If you answered 'YES' or 'Don't know' to question 21, more information is needed about your close contact before you get the smallpox vaccine. If you do not know the answers to the questions below, please ask the appropriate person to help you answer them. A parent should answer these questions if they apply to a child.**

22. Ask your close contact if he or she has an **itchy red rash** that comes and goes but usually lasts more than 2 weeks, or if this person had such a rash as a baby or child?
- YES → Your close contact may have eczema or atopic dermatitis. Please gather information so that questions 23 and 24 can be answered. Check with the contact's doctor about the rash.
- NO

If you can, please write down any information given by a doctor regarding this rash:

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23. Did the itchy rash affect the creases of the **elbows** or **knees**?
- YES → Your close contact likely has eczema or atopic dermatitis and you should **NOT** get vaccinated at this time
- NO
- Don't know

## Pre-Event Screening Worksheet for Smallpox Vaccine

(continued from previous page)

24. Did the person with the rash have **food allergies** as a baby or child?

- YES
- NO
- Don't know

**IF YES** → Does the person with rash and food allergies also have **asthma** or **hay fever**?

- YES** → Your close contact likely has eczema or atopic dermatitis and you should **NOT** get vaccinated at this time
- NO
- Don't know

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)



**Pre-Event Screening Worksheet for Smallpox Vaccine:**

**IMPORTANT INTERIM SUPPLEMENTARY INFORMATION -- MARCH 31, 2003**

There is evidence that suggests that smallpox vaccination may cause cases of heart inflammation (myocarditis), inflammation of the membrane covering the heart (pericarditis), and a combination of these two problems (myopericarditis). Experts are exploring this more in-depth.

Heart pain (angina) and heart attack also have been reported following smallpox vaccination. However, it is not known if smallpox vaccination caused these problems or if they occurred by chance alone (heart problems are very common). Experts are investigating this question also.

Reported events are not necessarily caused by the vaccine, and some or all of these events might be coincidental.

**As a precautionary step, people who have particular risk factors, as described below, or who have been diagnosed by a doctor as having a heart condition with or without symptoms should not receive smallpox vaccine at this time while experts continue their investigations.**

**Screening questions**

Please answer the questions on the following pages to help you determine if you should not get smallpox vaccine at this time due to heart disease that may place you at greater risk for adverse reactions. Answer each question to the best of your knowledge. You may ask your health care provider or a clinic health care provider for assistance if you do not understand a question. If you need more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY).

<b>Conditions</b>	<b>Do you have this condition?</b>
A previous heart attack (also called myocardial infarction)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Angina Pectoris (chest pain caused by lack of blood flow to the heart)	<input type="checkbox"/> YES <input type="checkbox"/> NO

**Pre-Event Screening Worksheet for Smallpox Vaccine:**IMPORTANT INTERIM SUPPLEMENTARY INFORMATION (continued from previous page)

Other coronary artery disease (disease in the vessels that bring blood to the heart)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Cardiomyopathy (heart muscle becomes inflamed and doesn't work as it should)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Congestive heart failure	<input type="checkbox"/> YES <input type="checkbox"/> NO
Chest pain or shortness of breath with activity (such as walking up stairs)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like but no lasting damage)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Other heart conditions under the care of a doctor	<input type="checkbox"/> YES <input type="checkbox"/> NO

**If you answered "yes" to any of the questions above, you should NOT receive the smallpox vaccine at this time while experts continue their investigations into these concerns.**

Please also answer the following questions about risk factors.

<b>Risk Factor</b>	<b>Have you been told by a doctor that you have this condition?</b>
High blood pressure	<input type="checkbox"/> YES <input type="checkbox"/> NO
High blood cholesterol	<input type="checkbox"/> YES <input type="checkbox"/> NO
Diabetes or high blood sugar	<input type="checkbox"/> YES <input type="checkbox"/> NO

**Pre-Event Screening Worksheet for Smallpox Vaccine:**

IMPORTANT INTERIM SUPPLEMENTARY INFORMATION (continued from previous page)

<b>Risk Factor</b>	<b>Does this risk factor apply to you?</b>
Have a 1 <sup>st</sup> degree relative (such as a mother, father, sister, or brother) who had a heart condition before the age of 50	<input type="checkbox"/> YES <input type="checkbox"/> NO
Smoke cigarettes now	<input type="checkbox"/> YES <input type="checkbox"/> NO

**If you answered "yes" to 3 or more of the above questions about risk factors, you should NOT get the smallpox vaccine at this time.**

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY).



## Pre-Event Screening Worksheet for Smallpox Vaccine

### (Illinois Supplement)

The Centers for Disease Control and Prevention (CDC) Pre-Event Screening Worksheet for Smallpox Vaccine contains recommendations on who should not receive smallpox vaccination. In addition, the Illinois Department of Public Health (IDPH) recommends the following:

#### **Who should delay vaccination?**

- Anyone who lives with, or has close physical contact with, a child less than one year old, or who has close physical contact with a person who lives with or has close physical contact with a child less than one year old, should not receive the smallpox vaccine. Young infants may be at higher risk for side effects if they are exposed to the vaccinia virus in smallpox vaccine.

Anyone who has inflammatory eye disease (e.g. conjunctivitis), or anyone who lives with or has close physical contact with individuals with inflammatory eye disease (e.g. conjunctivitis) should not receive the smallpox vaccine until the condition has resolved. Inflammatory eye disease may make the eye more vulnerable to autoinnoculation by the vaccine virus, and will make it more difficult to distinguish eye disease related to vaccine adverse reaction from underlying eye inflammation.

- Anyone who has taken or who lives with/has close personal contact with individuals who have taken immunosuppressive drugs in the last three months should not receive the smallpox vaccine. Immunosuppressive drugs might include such drugs as intravenous or oral steroids (e.g. prednisone or related drugs), chemotherapeutic agents for cancer treatment, or anti-rejection medications following organ or bone marrow transplantation.

#### **What allergies exclude a person from vaccination?**

- The currently available smallpox vaccine vials contain a rubber stopper. The vial stopper contains dry natural rubber that may cause hypersensitivity reactions when handled by, or when the vaccine is administered to, persons with known or possible latex sensitivity. IDPH recommends that individuals who have ever had an anaphylactic reaction to latex not be vaccinated.

## Who should not get vaccinated at the pre-event setting?

- Coronary heart disease occurs considerably more often in diabetics than in the general population. If you have diabetes, you should not get vaccinated at this time.

Conditions	Do <b>you</b> have this condition?	Does a <b>close contact</b> have this condition?
1. Living with or in close physical contact with a child less than one year old	<input type="checkbox"/> YES <input type="checkbox"/> NO If yes, delay vaccination until all children are at least one year old	Delay until all children are at least one year old
2. Inflammatory eye disease (i.e., conjunctivitis)	<input type="checkbox"/> YES <input type="checkbox"/> NO If yes, delay until eye condition has resolved	Delay until eye condition has resolved
3. Immunosuppressive drugs such as intravenous or oral steroids	<input type="checkbox"/> YES <input type="checkbox"/> NO If yes, delay until more than 3 months after last administration of immunosuppressive drug	Delay until more than 3 months after last administration of immunosuppressive drug
4. Anaphylactic reaction to latex	<input type="checkbox"/> YES <input type="checkbox"/> NO If yes, do not get vaccinated	Not applicable
5. Diabetes	<input type="checkbox"/> YES <input type="checkbox"/> NO	Not applicable





## **Present Day Risk of Adverse Reaction to Smallpox Vaccination (Illinois Supplement)**

The U.S. population now has many more people at high risk for serious adverse reactions to the smallpox vaccine compared to the 1960s, when most data concerning the safety profile of the vaccine was collected. Although the vaccine to be used in the first two phases of the smallpox vaccination program is the vaccine stored since the 1970s, the characteristics of the population have changed significantly. First, a high proportion of the population has not been immunized against smallpox, and there is some evidence that primary vaccinees are more likely to experience serious adverse reactions compared to those being revaccinated. The vaccine also carries significant risks for some members of the population – those with various types of immune suppression, such as HIV infection or due to cancer chemotherapy, those with certain diseases such as eczema and atopic dermatitis, and close physical contacts of vaccinees who have such conditions. It is thought that with rigorous efforts at screening those at risk and with intensive efforts at educating vaccinees about caring for the vaccination site, accidental inoculation of high-risk contacts of vaccinees can be reduced. However, the actual risks will only be known after the vaccination program is operative for some period of time.



## Smallpox Vaccination and HIV Testing (Illinois Supplement)

People who have HIV infection (HIV or AIDS), whether diagnosed or undiagnosed, are at increased risk of serious complications from smallpox vaccine and should not be vaccinated, unless they have been exposed to the smallpox virus.

Those who are most at risk for HIV infection are men who have sex with men, individuals who inject drugs, and the sex partners of these individuals. HIV does occur, though less frequently, among other groups as well. If you have had sexual contact or shared needles with someone who is HIV-infected or whose HIV status is unknown, you may have been infected with HIV. Please refer to the CDC's "**VIS Supplement D: A Weakened Immune System Means that You Should Not Get Smallpox Vaccine**" for additional information.

- If you are considering getting the smallpox vaccine and are unsure of your HIV status or concerned about your risk, the Illinois Department of Public Health (IDPH) strongly recommends that you first be tested for HIV before getting the smallpox vaccine. Be aware that the return of test results may take up to two weeks.
- You can obtain an HIV test at your doctor's office or clinic. HIV testing is also available in Illinois at publicly funded HIV testing sites.

You can get more information about HIV/AIDS, how it is transmitted, and where to get tested (if not at your doctor's office) by calling Illinois Department of Public Health at:

800-243-2437 (English/Spanish)  
800-782-0423 (TTY)

or the **Illinois Department of Public Health Website:**  
<http://www.idph.state.il.us/aids/default.htm>

or contact the  
**Centers for Disease Control  
and Prevention 24 hour hotline:**  
800-342-2437 (English)  
800-344-7432 (Spanish)  
800-243-7889 (TTY)

**The CDC Website is:**  
<http://www.ashastd.org/nah>



## **Smallpox Vaccine and Pregnancy (Illinois Supplement)**

The unborn child of a pregnant woman is at increased risk of serious complications from smallpox vaccine including premature delivery, skin rash with scarring, stillbirth or death of the child after delivery. Pregnant women, women trying to become pregnant, individuals living in the same household as a pregnant woman or individuals in close physical contact with a pregnant woman should not be vaccinated.

- For more information, please refer to the CDC's **"VIS Supplement E: Pregnancy and Breastfeeding Mean You Should Not Get Smallpox Vaccine"**.
- If you are unsure whether you are pregnant, the Illinois Department of Public Health (IDPH) strongly recommends that you consult with your personal health care provider and/or perform a self-administered pregnancy test before you receive smallpox vaccine.



## **Smallpox Vaccine and Individuals with Diabetes (Illinois Supplement)**

In early 2003, heart pain (angina) and heart attacks have been reported following smallpox vaccination. At this time, it is unclear if smallpox vaccination is responsible for the occurrence of these events. Initial analysis by the Centers for Disease Control and Prevention (CDC) suggests that the number of angina episodes and heart attacks that have occurred in vaccinated individuals may be no greater than the number of such events expected to normally occur during this time period. **However, analysis of these events is still not complete, and a possible link between smallpox vaccination and cardiac events cannot be ruled out at this point.** Therefore, CDC has recommended that any individual with three or more cardiac risk factors should not get the smallpox vaccine at this time.

In addition, IDPH advises that individuals with diabetes should not be vaccinated at this time, even in the absence of other known cardiac risk factors. The risk for coronary heart disease (CHD) is increased substantially in many individuals with diabetes. Many experts believe that the chance that someone with diabetes will have a heart attack is similar to the risk of a heart attack in an individual of the same age with known CHD, who does not have diabetes.<sup>1</sup> Although proper management of other cardiac risk factors can reduce the risk of cardiac events in individuals with diabetes, in the interest of caution, IDPH has recommended excluding individuals with diabetes from smallpox vaccination at this time.

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<sup>1</sup> Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, National Heart, Lung, and Blood Institute, National Institutes of Health, 2002. NIH publication No. 02-5215



## **Smallpox Vaccine and Individuals with Chronic Health Conditions**

### **(Illinois Supplement)**

IDPH advises that any individual with questions about the decision to volunteer for smallpox vaccination should obtain consultation from a physician. It is prudent for every individual with a chronic medical condition to discuss the decision whether or not to be vaccinated with a physician who understands his/her medical history. Such consultation can provide assistance in determining if a chronic medical condition represents a contraindication to vaccination. In addition, even in the absence of a medical condition that is a contraindication, discussions with a physician may provide valuable guidance regarding the decision to volunteer for, or decline vaccination.



## **Smallpox Vaccine and Individuals Age 65 and Older (Illinois Supplement)**

The CDC recommends that individuals over 65 who have been asked to participate in a public health or health care smallpox response team and do not have a risk factor for an adverse reaction to the vaccine should be allowed to volunteer for vaccination. In the interest of caution, IDPH advises that any individual over age 65 should obtain consultation from his/her physician prior to volunteering for vaccination.



## SMALLPOX FACT SHEET (FOR CLOSE CONTACTS OF PEOPLE CONSIDERING VACCINATION)

### Someone You Are Close to May Get Smallpox Vaccine: What You Should Know and Do

If someone you have close, physical contact with (your spouse, partner or other member of your household) is considering getting the smallpox vaccine, there are some things you should know.

#### **Before Vaccination: What You Should Know**

The smallpox vaccine contains a live virus called vaccinia, which is related to smallpox, though milder. The vaccine helps the body develop immunity to smallpox. And while the smallpox vaccine is safe and effective for most who receive it, people with certain health conditions are more likely to have serious reactions to the smallpox vaccine. These people should not be vaccinated and they should not be in close contact (household or similar intimate physical contact) with someone who has been vaccinated.

Careful screening measures are in place to help ensure that people who are more susceptible to serious reactions, or who live with others who are more susceptible to serious reactions, are not vaccinated. As your close contact considers vaccination, it's important that you actively participate in this screening process. Inform your close contact if you have any of the conditions listed below, or even if you have any concerns about any of the conditions listed below.

#### **Health conditions that would mean you should not be in close contact with someone who has been vaccinated are:**

- A diagnosis of eczema or atopic dermatitis, past or present
- A weakened immune system, for whatever reason (HIV, cancer and cancer treatment, some autoimmune diseases and some treatments for autoimmune conditions can weaken the immune system)
- A skin condition with breaks in the skin (chickenpox, shingles, burns, severe acne, etc...) or
- Pregnancy

If any of these conditions apply to you, you should not be in close contact with someone who has gotten smallpox vaccine because of the risk it poses to you (or your fetus if you are pregnant).

#### **After Vaccination: What You Should Know**

If neither you nor your close contact has any condition that might place you at increased risk from a serious reaction, and that close contact decides to get vaccinated, there are still some things you should keep in mind.

The main concern for people who have close, physical contact with someone who has gotten the vaccine is that the vaccinia virus can be spread from the vaccination site, causing rash (mild to severe), fever, and head and body aches. Vaccinia is spread by touching a vaccination site before it has healed or by touching bandages, clothing, or other material contaminated with live virus from the vaccination site and then touching another part of the body or touching someone else. The vaccination site often becomes itchy, which may lead to scratching, rubbing, or touching the site.

## Someone You Are Close to May Get Smallpox Vaccine: What You Should Know and Do

(continued from previous page)

In the past, when vaccinated persons spread vaccinia to other parts of their body, it often was to their eyes or their genitals. Vaccinated persons also can spread vaccinia to other individuals. In the past, this was reported to occur between 20 and 60 times out of 1 million people vaccinated for the first time and often involved children. Most of the time, this took place in situations of close contact, such as happens in a household, or in similar situations involving close physical contact where careful hand hygiene and site care may not be followed.

### **After Vaccination: Taking Care**

People getting the vaccine will receive instructions for special care to minimize the risk of spreading vaccinia by touch, but you also can take precautions to protect yourself. These measures should be followed until the scab that forms at the vaccination site after vaccination falls off on its own (in 2 to 3 weeks).

- Do not touch the vaccine site or any materials that might be contaminated with live virus from the site (such as bandages, towels, clothing, or washcloths used by the person who got the vaccine).
- If you accidentally come in contact with the vaccine site, or something that may be contaminated with live virus, immediately wash with soap and warm water.
- If you share a bed with the vaccinated person, be sure that they are wearing a gauze bandage held in place with first aid adhesive tape over the vaccination site. As an extra precaution, the person who got the vaccine can wear a shirt or pajamas that cover the bandaged vaccine site. If they do not, you may choose to sleep in a separate bed. (When involved in direct patient care, healthcare workers should cover the gauze with a semipermeable dressing as an additional barrier.)
- Keep a separate laundry hamper for items like clothing, towels, or bedding that have come in direct contact with the vaccine site or drainage from the site. Launder these items, using warm water with detergent and/or bleach and wash hands carefully afterwards.
- Remind the person who got the vaccine to follow site care and hand washing instructions. If their hand is contaminated and they touch you, you can contract vaccinia.

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)





## **Compensation in the Event of an Adverse Medical Reaction (Illinois Supplement)**

This Supplement is intended to address common questions about certain financial considerations for individuals deciding whether to participate in the federal smallpox vaccination program. It is important to emphasize that there may be adverse financial consequences associated with receipt of the vaccine. At the present time, these adverse financial consequences are difficult to assess. Prior to vaccination, you, your household members and close physical contacts should consider these possible adverse financial consequences, and raise any resulting questions with your employer, insurer or with others who may be able to address your concerns.

### **Will the government compensate me if I or a close contact have an adverse reaction to the vaccination?**

If you or a close contact have an adverse reaction to the smallpox vaccination, it is possible that you or a close contact will be eligible for benefits and/or compensation under the provisions of the Smallpox Emergency Personnel Protection Act of 2003.

As described in materials published by the CDC ([www.bt.cdc.gov/agent/smallpox/vaccination/bene-comp.asp](http://www.bt.cdc.gov/agent/smallpox/vaccination/bene-comp.asp)), on April 30, 2003, the President signed into law the Smallpox Emergency Personnel Protection Act of 2003 ("SEPPA"), which established a no-fault program ("the Program") to provide benefits and/or compensation to certain individuals, including health-care workers and emergency responders, who are injured as the result of the administration of smallpox countermeasures, including the smallpox (vaccinia) vaccine. The Program will also provide benefits and/or compensation to certain individuals who are injured as a result of accidental vaccinia inoculation through contact.

This program will allow the Federal Government to reimburse eligible individuals for the costs of reasonable and necessary medical treatment. Such payments will be secondary to any other coverage available to the individual (e.g., health insurance benefits). Compensation for lost employment income (beyond the first 5 days of work missed, except that the 5 day waiting period for compensation does not apply if the loss of employment extends beyond 9 work days) will also be available for certain eligible individuals. As with the Program's medical benefits, such payments will be secondary to other available coverage. The SEPPA provides parameters for determining, based on lost wages, the amount of lost employment income that will be available to particular eligible individuals. The Program may also provide a lump sum death payment in

circumstances in which the eligible individual's death is determined to have resulted from a covered injury. This benefit, which will be paid to survivors, is modeled on the award available to police officers and firefighters killed in the line of duty under the Public Safety Officers Benefit Program ("PSOB"), administered by the Department of Justice. Such payments will be secondary to benefits that are paid or payable under the PSOB if an injured party is already eligible for the PSOB. As an alternative, a lost wages death benefit including payment options in the case of individuals who are survived by at least one dependent under the age of 18 will be available. SEPPA gives the Federal Government considerable discretion as to the method and frequency of payments made by the Program (e.g., the Secretary of Health and Human Services could purchase an annuity or medical insurance policy or execute a structured settlement agreement for the award of benefits and/or compensation under the Program in specified circumstances).

HHS will publish, by interim final rule, a vaccine injury table and the procedural process for filing a request for benefits and/or compensation under the Program in the near future. The vaccine injury table will list the injuries and conditions that will be presumed to be caused by the smallpox vaccine, together with the time frame in which the presumption applies. Other injuries and conditions, or injuries and conditions outside of the published time frame, may still be eligible for benefits, but the requester will need to provide evidence of causation. The provisions included by interim final rule will be immediately effective and will cover injuries that occurred since the beginning of the Program.

Section 304 of the federal Homeland Security Act will allow some monetary claims to be filed under the Federal Tort Claims Act ("FTCA") by injured parties against certain entities and individuals involved in the federal smallpox vaccination plan. At this time, it is uncertain what, if any, compensation might be received by an injured party under the FTCA.

### **Will Workers' Compensation benefits be available?**

Typically, if you sustain a work related illness or injury through your employment, Workers' Compensation will cover some or all of the medical costs and lost wages resulting from that work related illness or injury. However, it is presently uncertain whether Workers' Compensation will cover you if you suffer any adverse reaction to your smallpox vaccination. If you have any questions or concerns about this issue, you should consult with your employer's human resources office. Even if Workers' Compensation covers costs associated with an adverse reaction to you, it will not cover or provide compensation to anyone to whom you might transmit vaccinia. As noted above, if you are eligible for certain benefits and/or compensation under the provisions of the SEPPA, such benefits and/or compensation may be secondary to other available coverage.

**Will I be compensated if I am required to take leave from work?**

As discussed in the materials you have received, for a period of time after your vaccination, there are risks of adverse reaction to you and others with whom you may come into contact. Although the CDC Advisory Committee on Immunization Practices has not recommended that a vaccinated employee be asked to stay home during this time, your employer may ask you not to report for work for some time. If you are asked to stay home, it will be up to your employer to decide whether you will be compensated.

**Will I be compensated for lost work time if I suffer an adverse reaction to my vaccination?**

If you have an adverse reaction to smallpox vaccine, you may be absent from work for an unknown period of time. As indicated above, it is uncertain whether you will be compensated for this time through Workers' Compensation. It is also uncertain whether you will receive compensation for lost time in excess of those days provided for by your employer's regular sick time/vacation policy, or any short term or long term disability plans or programs that you may have through your employment. You are advised to consult with your employer's human resources office regarding whether there will be compensation. It is possible that you will be eligible for compensation for lost employment income under the provisions of the Smallpox Emergency Personnel Protection Act of 2003. As noted above, if you are eligible for certain benefits and/or compensation under the provisions of the SEPPA, such benefits and/or compensation may be secondary to other available coverage.

**Will medical insurance cover the costs of treatment if I suffer an adverse reaction to my vaccination?**

The federal government will provide specialized medications to treat certain smallpox vaccine related complications. If you suffer an adverse reaction, you may have to file a claim with your own health insurance company for payment of the costs of care and treatment. You should consult with your employer's human resources office or your insurance representative for more information about whether your health insurance will provide coverage. There may be no coverage for treatment under any Federal or State medical insurance program (i.e., Medicare or Medicaid.) It is possible that you will be eligible for federal payment or reimbursement for certain medical items and services as reasonable and necessary to treat certain adverse reactions under the provisions of the Smallpox Emergency Personnel Protection Act of 2003. As noted above, if you are eligible for certain benefits and/or compensation under the provisions of the SEPPA, such benefits and/or compensation may be secondary to other available coverage.

**SMALLPOX SUPPLEMENTAL FACT SHEET****Investigational Vaccinia Immune Globulin (VIG) Information**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective. Some people, however, are at greater risk for serious side effects from the smallpox vaccine. Vaccinia Immune Globulin (VIG) may help people who have certain serious reactions to the smallpox vaccine. VIG is an investigational new drug (IND) made from plasma from the blood of people who have immunity to smallpox. If you develop a serious reaction to the smallpox vaccine, you may be offered VIG.

**VIG Information**

- VIG is an immune globulin made from the blood of people who have gotten the smallpox vaccine more than once (usually many times). The part of the blood (antibodies) that gives protection from vaccinia infection is taken out, purified (cleaned), and bottled. It is called the immune globulin.
- VIG is not licensed (approved) by the Food and Drug Administration (FDA). It is "investigational."
- There are two available types of VIG: VIG-intramuscular (VIG-IM) and VIG-intravenous (VIG-IV).
- VIG might be used in cases of generalized vaccinia, eczema vaccinatum, or progressive vaccinia.

**How is VIG administered?**

VIG is given by a needle in the muscle in the arm (VIG-IM), or by a needle in a vein in the arm (VIG-IV). The type of VIG (IM vs. IV) given will depend on which is available.

**Side Effects**

- VIG is made from human blood plasma. Products made from human blood may contain infectious agents, such as viruses, that can cause disease. To decrease the chance that such products carry viruses, plasma donors are checked for prior contact with certain viruses, the collected plasma is treated for the presence of certain viruses, which are killed and/or removed from the plasma.
- Immune globulin products like VIG may cause allergic reactions that can be mild or may be serious and cause life-threatening breathing and heart problems. If you have a serious or life-threatening reaction, medical care and drugs are available to treat you.
- People who have a problem making a certain antibody called IgA or who have had a serious allergic reaction to human antibody products before are at risk for an allergic reaction to VIG.
- Most side effects from similar products are mild and do not last for very long. You may experience back pain, chills, headache, muscle pain, joint pain, itching, weakness, fever, nausea, vomiting, abdominal cramps, flushing, tightness of the chest, sweating, changes in blood pressure, dizziness, paleness, shortness of breath, and wheezing. Rashes occur rarely.
- Some people experience pain and soreness at or near the site where VIG is given. While this is unpleasant, it is not serious and can be treated with common pain relievers.

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

**SMALLPOX SUPPLEMENTAL FACT SHEET****Investigational Vistide® (Cidofovir) Information**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not smallpox virus). The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. For most people, live virus vaccines are safe and effective. Some people, however, are at greater risk for serious side effects from the smallpox vaccine.

Vistide (cidofovir), a drug licensed to treat serious viral infections of the eye in HIV-infected people, may help people who have certain serious reactions to the smallpox vaccine. If you develop a serious reaction to the smallpox vaccine, and VIG (another medicine used to treat bad reactions to the smallpox vaccine) is not available or is not working, you may be offered cidofovir. While this drug has not been used to treat patients with bad reactions to smallpox vaccine, early results from laboratory studies suggest that cidofovir may work against the vaccinia virus. Use of cidofovir would be administered under an Investigational New Drug (IND) protocol.

**Cidofovir Information:**

- Vistide® (Cidofovir) is licensed to treat cytomegalovirus (CMV) retinitis (a serious eye infection) in HIV-infected people. It is not licensed to treat the problems caused by smallpox vaccine so it is only available through a special protocol called an Investigational New Drug (IND) protocol.
- Use of cidofovir to treat smallpox vaccine reactions should be evaluated and monitored by experts at the National Institutes of Health and the Centers for Disease Control and Prevention.
- Cidofovir might be used to treat generalized vaccinia, eczema vaccinatum, or progressive vaccinia.

**How is cidofovir administered?**

Cidofovir is injected through a needle in the vein. Fluids will be given through the vein and another medication (probenecid) given by mouth both before and after cidofovir. These may help decrease the side effects of cidofovir.

**Side Effects:**

- Kidney problems that can lead to kidney failure.
- Low white blood cells.
- Pressure in the eye.
- Swelling and tenderness of the eye.
- Build up of acid in the body that can result in liver problems and inflammation of the pancreas that can result in death.
- Other problems include fever, infection, pneumonia, shortness of breath and nausea with vomiting.
- Cidofovir can cause headache, weakness, rash, hair loss, diarrhea, pain, lowered number of red blood cells, loss of appetite, chills, coughing, and infections in the mouth.

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)



## Supplemental Site Care Instructions (Illinois Supplement)

Live vaccinia virus will be present at the site of your vaccination until the scab falls off. This virus is infectious. The main goals in caring for your smallpox vaccination site are to avoid the spread of virus from the vaccination site to another area of your body (i.e., eyes or genitalia), to avoid spread of virus to another person, and to keep the vaccination site clean and dry so it can heal.

- **Keep your hands clean!**

Until your scab falls off you **must** use scrupulous hand hygiene so that vaccinia virus does not spread to other parts of your body or to your contacts. Hands **must** be cleaned with antimicrobial soap and warm water (for 20 seconds) or an alcohol-based hand rub. Alcohol-based hand rub should only be used if hands are not visibly soiled. Perform hand hygiene after applying the new dressing, after touching the vaccination site, or after touching items that have been in contact with the vaccination site.

Always clean your hands before inserting, removing, or manipulating contact lenses. You may wish to wear glasses until your scab falls off to prevent accidental inoculation of your eyes.

Wash your hands as soon as you wake up, because you may have touched your bandage or the vaccination site while sleeping.

- **Special instructions for healthcare workers who provide direct patient care and public health workers:**

A gauze and semipermeable dressing will be placed over your vaccination site at the time you are vaccinated. Gauze and semipermeable dressings can remain in place up to 3-5 days at a time, but should be changed sooner if significant drainage is noted on the gauze.

If you work at a healthcare facility other than the one that sponsored you for vaccination, you **must** inform them that you have been vaccinated for smallpox, and follow any instructions they may give.

Your vaccination site **must** be covered with the gauze and semipermeable dressing when you are at work. To provide another layer of protection, long sleeves must be worn when providing direct patient care. The vaccination site must be covered in this manner while you are at work until the scab falls off.

Before beginning each work shift you **must** report to the person designated in your facility to check vaccination site dressings. Your dressing will be visually assessed for barrier quality and will be changed if necessary.

Do not touch your dressing while at work. If your dressing needs attention during your work shift, please see the person designated by your facility to check vaccination sites.

- **When you are not at work:**

According to CDC guidelines, semipermeable dressings are not required in non-patient care settings. The CDC recommends you should use gauze and tape to cover the site when you are not at work. Gauze and tape dressings typically need to be changed more frequently than gauze and semipermeable dressings (e.g., every 1-2 days vs. every 3-5 days).

When changing dressings at home, remove the dressing and place it in a sealed plastic bag before placing it in the trash. When the scab falls off also put it in a sealed plastic bag before placing it in the trash. If there are young children, pets, or others in your household that might play with or “inspect” garbage, do not leave garbage containing gauze, bandages, or your scab in an accessible location.

- **General instructions:**

- Unvaccinated persons must not touch the vaccination site or things that have touched the vaccination site, like bandages or clothing.
- Keep your vaccination site dry.
- Do not take a bath until the vaccination scab has fallen off.
- Cover the vaccination site when you shower with a waterproof bandage or plastic wrap (e.g. Saran wrap).
  - Do not run shower water directly on the vaccination site.
  - Do not scrub the site when showering
  - Do not touch the site and then touch another area of the body (i.e., eyes or genitalia).
  - Wash and dry the vaccination site area carefully so that the washcloth or towel does not rub or spread virus elsewhere.
  - Do not reuse wash cloths or towels until they have been laundered.
  - Change the dressing or bandage if it becomes saturated with water.

- Clothing, bedding, towels, wash cloths, or other items that may have come in contact with the vaccination site or drainage should be handled carefully and contact with these items should be kept to a minimum. Keep these items in a separate hamper until they are laundered (preferably by the vaccinated person) to reduce the chance of an unvaccinated person having contact with these items.
- Launder clothing, bedding, towels, washcloth, or other items that may have come in contact with the vaccination site or drainage in the warm water cycle for  $\geq 10$  minutes with laundry detergent, followed by hot air drying; bleach is not required. Hands should be cleaned after contaminated items are handled.
- When you are in close contact (such as sharing a bed) with a household member or other close contact, cover the vaccination site with gauze and tape and long sleeves.
- Do not share towels, napkins, or clothing you have used with anyone until the vaccination site scab has fallen off.
- If you wear contact lenses, care must be taken to clean hands thoroughly before handling lenses.
- Do not scratch the vaccination site. Antihistamines such as Diphenhydramine Hydrochloride (Benadryl®) and analgesics (e.g. acetaminophen, or ibuprofen) at recommended doses may be used when you are at home to reduce itching. Inform staff providing vaccination site care if you are using any medications to reduce vaccine related side effects. Do not put salves or ointments on the vaccination site.

**Recreational activities:**

- Do not engage in contact sports (e.g., wrestling) until your scab falls off.
- If you use shared equipment at a gym or health club, wear the gauze and semipermeable dressing or a waterproof bandage and long sleeves. Do not use equipment that rubs against the vaccination site.
- Do not use swimming pools, hot tubs, saunas, gym or health club showers/towels until scab falls off.



## Patient Medical History and Consent Form

For Administrative Use Only:

Initial Vaccination:

Revaccination:  (Initial Patient Vaccination Number (PVN) \_\_\_\_\_)

Date: \_\_/\_\_/\_\_\_\_ (mm/dd/yyyy)

For Administrative Use Only: Place  
Patient Vaccination Number (PVN)  
Sticker here

Please fill out sections A, B, and D of this form. Please use ink and print.

### SECTION A: PATIENT DEMOGRAPHIC INFORMATION

(To be filled out by the patient. Please use ink and print)

Title: \_\_\_\_\_ First Name: \_\_\_\_\_ Middle Name \_\_\_\_\_

(Mr., Ms., Mrs., Dr., etc.)

Last Name: \_\_\_\_\_ Suffix (Jr. Sr., M.D., etc.): \_\_\_\_\_

SSN: \_\_\_\_ - \_\_\_\_ - \_\_\_\_ Date of Birth: \_\_/\_\_/\_\_\_\_ (mm/dd/yyyy)

Gender:  Male  Female

Street Address: \_\_\_\_\_ Apt. #: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip code: \_\_\_\_\_

County \_\_\_\_\_

#### Contact Information:

Home Phone: (\_\_\_\_) \_\_\_\_ - \_\_\_\_

Work: (\_\_\_\_) \_\_\_\_ - \_\_\_\_ ext. \_\_\_\_

Cell Phone: (\_\_\_\_) \_\_\_\_ - \_\_\_\_

Fax: (\_\_\_\_) \_\_\_\_ - \_\_\_\_

E-Mail Address: \_\_\_\_\_

Occupation: \_\_\_\_\_ Employer \_\_\_\_\_

Employer's Address \_\_\_\_\_

Ethnicity/Race:  Hispanic or Latino  Asian  African American  Hawaiian

American Indian or Alaskan  White

May we contact you in the future?  Yes  No

---

### SECTION B: VACCINATION AND MEDICAL HISTORY

(To be filled out by the patient. Please use ink and print)

#### Vaccination History

**Did you ever receive the smallpox vaccine?** Use the most recent date if you were vaccinated more than once.

I have documentation that I was vaccinated on this date: \_\_/\_\_/\_\_\_\_ (mm/dd/yyyy)

I recall that I was vaccinated on this date, but I don't have documentation: \_\_/\_\_/\_\_\_\_ (mm/dd/yyyy)

I was vaccinated in childhood, but I don't know the date.

No, I was never vaccinated or I don't know.

**Do you have a vaccination scar?**  Yes  No or Don't Know

**Did you have any bad reactions to the vaccine (adverse events)?**  Yes  No or Don't know

If yes, please describe the reaction \_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_ (mm/dd/yyyy)

Patient Name: \_\_\_\_\_ PVN: \_\_\_\_\_

### Medical History

Have you received chickenpox (varicella) vaccination in the last month?  Yes  No

Are you currently taking medication?  Yes  No

If yes, please list medications: \_\_\_\_\_

Are you sick today?  Yes  No

If yes, please describe your illness (you may need to wait to be vaccinated until you get better )

\_\_\_\_\_

Do any of the following apply to YOU? Yes  No

1. Do you have any conditions that weaken the immune system such as HIV/AIDS; leukemia, lymphoma, or most other cancers; organ transplant; or primary immune deficiency disorders?
2. Do you have a severe autoimmune disease such as lupus that may weaken the immune system?
3. Are you now taking, or have you recently taken, drugs that can weaken the immune system like steroids (e.g. prednisone), medicines for autoimmune disease, or medicines taken after an organ transplant?
4. Are you now taking cancer treatment with drugs or radiation or have you taken such treatment in the past 3 months?
5. Do you now have, or have you ever had eczema or atopic dermatitis (even as a baby or child and even if the condition is mild)?
6. Do you now have other skin problems that have made many breaks in your skin such as a rash, severe burn, impetigo, chickenpox, shingles, herpes, psoriasis, or severe acne?
7. Are you now being treated with steroid eye drops?
8. Are you pregnant, breastfeeding, or planning to become pregnant in the next month?
9. Have you ever had a life-threatening allergic reaction to smallpox vaccine, latex or the antibiotics polymixin B, streptomycin, chlortetracycline, or neomycin?
10. Have you ever been diagnosed by a doctor as having heart disease with or without symptoms such as previous myocardial infarction (heart attack), angina (chest pain caused by lack of blood flow to the heart), congestive heart failure, or cardiomyopathy?
11. Have you ever had a stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage)?
12. Do you have chest pain or shortness of breath when you exert yourself (such as when you walk up stairs)?
13. Do you have any other heart condition for which you are under the care of a doctor?
14. Do you have three or more of the following risk factors?
  - a. You have been told by a doctor that you have high blood pressure.
  - b. You have been told by a doctor that you have high blood cholesterol.
  - c. You have been told by a doctor that you have diabetes or high blood sugar.
  - d. You have a first degree relative (for example mother, father, brother, or sister) who had a heart condition before the age of 50.
  - e. You smoke cigarettes now.

**IF YOU ANSWERED YES TO ANY OF THE QUESTIONS ABOVE,  
YOU SHOULD NOT GET THE SMALLPOX VACCINE AT THIS TIME.**

(Continues on next page)

Date: \_\_\_/\_\_\_/\_\_\_ (mm/dd/yyyy)

Patient Name: \_\_\_\_\_ PVN: \_\_\_\_\_

Do any of the following apply to your **CLOSE CONTACTS**? Yes  No

(A close contact is someone you live with or have close physical contact with, such as a sex partner. Close contacts do not include friends or co-workers.)

1. Do any of your close contacts have conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers; organ transplant; or primary immune deficiency disorders?
2. Do any of your close contacts have a severe autoimmune disease such as lupus that may weaken the immune system?
3. Are any of your close contacts now taking, or have they recently taken, drugs that can weaken the immune system like steroids (e.g. prednisone), medicines for autoimmune disease, or medicines taken after an organ transplant?
4. Are any of your close contacts taking cancer treatment with drugs or radiation or have they taken such treatment in the past 3 months?
5. Do any of your close contacts now have, or have they ever had eczema or atopic dermatitis (even as a baby or child and even if the condition is mild)?
6. Do any of your close contacts now have other skin problems that have made many breaks in their skin such as a rash, severe burn, impetigo, chickenpox, shingles, herpes, psoriasis, severe diaper rash, or severe acne?
7. Are any of your close contacts pregnant or planning to become pregnant in the next month?

**IF YOU ANSWERED YES TO ANY OF THE QUESTIONS ABOVE,  
YOU SHOULD NOT GET THE SMALLPOX VACCINE AT THIS TIME.**

<p><i>Screener comments/notes for clarification (for administrative use only)</i> _____</p> <p>_____</p> <p>_____</p>
---

**SECTION C: CURRENT VACCINATION INFORMATION AND TAKE EVALUATION**

(This section will be filled in by clinic staff)

Date: \_\_\_/\_\_\_/\_\_\_ (mm/dd/yyyy)

Patient Name: \_\_\_\_\_ PVN: \_\_\_\_\_

**DISPOSITION**

<input type="checkbox"/> <b>Referred for Vaccination</b>	<input type="checkbox"/> <b>Deferred due to medical contraindications</b>
<input type="checkbox"/> <b>Vaccination refused</b>	

Clinic personnel should pre-enter or attach this information before printing and copying the form.

Vaccination Clinic Information		Vaccine Batch Information			
Name:		Vaccine Type:		Batch #:	
Contact:		Program:		Batch Date:	
Phone:		Dilution Strength:			
Fax:		Vaccine Lot#:		Diluent Lot #:	
Address:		Vaccine Lot Manufacturer:		Diluent Lot Manufacturer:	

Referring Organization _____ Address _____  Date of Vaccination: ___/___/___  Arm inoculated: <input type="checkbox"/> Left <input type="checkbox"/> Right  Vaccine Administered by: _____ (please enter first name, last name, and professional suffix (M.D., R.N., etc))
--

**Take Response**

**If take response evaluation is going to be conducted at another clinic site, please copy this page and send it to that location.**

Take Response Clinic: Name _____ Address _____ Take Response Exam performed by: _____ (please enter first name, last name, and professional suffix (M.D., R.N., etc))	Exam Date: ___/___/___ <input type="checkbox"/> Major <input type="checkbox"/> Equivocal <input type="checkbox"/> No Take
Additional Comments	

**Adverse Events should be recorded in VAERS**

**SECTION D: CONSENT SIGNATURE  
(TO BE RETAINED BY THE VACCINATION CLINIC)**

**Date:** \_\_\_/\_\_\_/\_\_\_ (mm/dd/yyyy)

**Patient Name:** \_\_\_\_\_ **PVN:** \_\_\_\_\_

I have:

- received, read and understand the Smallpox Pre-Vaccination Information Package, including 1) the Vaccine Information Statement (VIS), 2) the VIS supplements (A-E) on reactions after smallpox vaccination, vaccination site appearance and care, skin conditions, weakened immune system, pregnancy and breastfeeding, 3) the March 31, 2003 VIS supplement on smallpox vaccine and heart problems, and 4) the pre-event screening worksheet;
- considered my own health status as well as the health status of my household members and close physical contacts;
- had the opportunity to discuss my medical concerns with my health care provider or a health care provider at the vaccination clinic;
- had the opportunity to obtain a referral to seek confidential laboratory testing for medical conditions that may increase my risk for adverse reactions from the vaccine;
- responded to the questions above to the best of my ability.

**I understand the decision to be vaccinated is voluntary and agree to proceed with smallpox vaccination.**

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Medical Screener

\_\_\_\_\_  
Date

**Privacy Act Statement**

The information requested on this form, including the Social Security Number (SSN), is collected under the authority of Section 311 of the Public Health Service Act (42 U.S.C. 243), the NCVIA (42 U.S.C. 300aa-2(a)), and Section 304 of the Homeland Security Act of 2002 (Pub. L. No. 107-296). The information will be used in the analysis and follow-up of significant events associated with smallpox vaccination and to assure availability of smallpox response teams. The SSN is being collected for identity verification purposes. Furnishing the requested information, including SSN, is voluntary; however, with more complete information, public health objectives, such as adequate monitoring and follow-up of potential adverse events, are more readily achievable. Identifiable information may be shared with authorized U.S. Department of Health & Human Services' personnel and public health or cooperating medical authorities.



## Patient Medical History and Consent Form (Illinois Supplement)

Date: \_\_\_/\_\_\_/\_\_\_ (dd/mm/yyyy)

Patient First Name:

Middle Name:

Last Name:

**SECTION B SUPPLEMENT: VACCINATION AND MEDICAL HISTORY  
DO YOU HAVE ANY OF THE FOLLOWING CONDITIONS?:  
(To be filled out by the patient. Please use ink and print.)**

Is any household member or close physical contact a child less than one year of age? Yes  No

Do you have inflammatory eye disease ( e.g. conjunctivitis)? Yes  No

Have you had intravenous or oral immunosuppressive drugs in the last 3 months (e.g. steroid based medications)? Yes  No

Have you ever had an anaphylactic reaction to latex? Yes  No

Do you have diabetes? Yes  No

**DO ANY OF YOUR HOUSEHOLD MEMBERS OR CLOSE PHYSICAL CONTACTS HAVE ANY OF THE FOLLOWING CONDITIONS?:**

Does any close physical contact have another household member or close physical contact who is less than one year of age? Yes  No

Do any household members or close physical contacts have inflammatory eye disease (e.g. conjunctivitis)? Yes  No

Has any household member or close physical contact taken intravenous or oral immunosuppressive drugs in the last 3 months (e.g. steroid based medications)? Yes  No

**IF YOU ANSWERED YES TO ANY OF THESE QUESTIONS, YOU CANNOT GET THE VACCINE AT THIS TIME.**

**Patient Signature:**

**Date:**

**Medical Screener Signature:**

**Date:**



## **Consent To Smallpox Vaccination (Illinois Supplement)**

I understand that this Consent to Smallpox Vaccination (Illinois Supplement) is in addition to and does not replace the Patient Medical History and Consent Form I have signed today. By signing this Consent, I am confirming my desire to volunteer for receipt of the smallpox vaccine. Receipt of the smallpox vaccine will facilitate my serving as a member of a Smallpox Response Team (“SRT”) so that I may contribute to the public’s health and national security. I understand that receipt of the smallpox vaccine exposes me, my household members and close physical contacts to risks of adverse reaction including severe illness and death.

Before making my decision to volunteer and consent to receive smallpox vaccine, I was given the materials in the Smallpox Pre-Vaccination Information Packet prepared by the Centers for Disease Control and Prevention (“CDC”) (including the opportunity to view the CDC Videotape entitled “Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate”), and the materials in the Supplemental Illinois Information Packet. All of these materials are listed on Index A.

### **RISKS, CONTRAINDICATIONS AND RESTRICTIONS AFFECTING ME**

- I have had adequate time to read the materials listed on Index A, consult with my personal health care provider, and secure any desired medical screening. If I am unsure whether smallpox vaccination is contraindicated for me, or if I have a chronic medical condition or am over the age of 65, I have consulted with my health care provider.
- I understand that in addition to the contraindications identified by the CDC, the State of Illinois has further restrictions on the availability of smallpox vaccine to certain members of the population. To the best of my knowledge, none of the contraindications or restrictions described in the CDC’s **“Pre-Event Screening Worksheet for Smallpox Vaccine”** or the **“Pre-Event Screening Worksheet for Smallpox Vaccine (Illinois Supplement)”** apply to me, or, as applicable my household members or close physical contacts.
- I have read the **“Present Day Risk of Adverse Reaction to Smallpox Vaccination (Illinois Supplement)”**. I understand that the U.S. population now has many more people at high risk of serious adverse reaction to the smallpox vaccine as compared to the 1960’s, when most data concerning the safety profile of the vaccine was collected.

- Any questions or medical concerns about smallpox vaccination have been answered to my satisfaction.

### **RISKS, CONTRAINDICATIONS AND RESTRICTIONS AFFECTING MY FAMILY AND CLOSE PHYSICAL CONTACTS**

- I have given copies of the materials listed on Index A to my adult household members and close physical contacts for their review. These household members and close physical contacts have had adequate time to read the materials, consult with their personal health care provider about the risks my vaccination may pose to them, and secure any desired medical screening. They have been told that they should consult with their personal health care provider if they are unsure whether they have conditions which would make my smallpox vaccination contraindicated. To the best of my knowledge, none of my adult or minor household members or close physical contacts have any known contraindication to my vaccination.
- I have reviewed and I understand the **“Supplemental Site Care Instructions” (Illinois Supplement)**. I understand that if I follow all appropriate site care precautions I will reduce but not eliminate the risk of transmitting vaccinia to others. I have discussed this possibility with my household members and close physical contacts.

### **COMPENSATION ISSUES**

- I have reviewed the information contained in the document **“Compensation in the Event of Adverse Medical Consequences (Illinois Supplement)”**. I understand that there are uncertainties and limits to financial compensation, if any, that may be available in the event a household member, a close physical contact or I suffer an adverse consequence of smallpox vaccination.

### **PRIVACY ISSUES**

- I have reviewed the document **“Privacy Rights: Smallpox Screening and Vaccination (Illinois Supplement)”** and I understand that in the interests of public health and national security, personal information about my vaccination and any adverse reactions may be shared with others. I have reviewed and signed the **“Permission for Release of Smallpox Vaccination Information (Illinois Supplement)”**.



**I understand that the decision to receive the smallpox vaccine is completely voluntary on my part. I have given complete and accurate information to the personnel screening me for smallpox vaccination. To the best of my knowledge, neither I nor any household member or close physical contact has any known contraindication for this vaccine.**

Vaccinee Signature

Date

Vaccinee Name (printed)

Vaccinee Employer (printed)

Witness Signature

Witness Name (printed)

Witness Employer (printed)

## **INDEX A**

### **MATERIALS IN CDC INFORMATION PACKET**

Cover letter from Dr. Julie Louise Gerberding, M.D., MPH, Director of the CDC

Smallpox Vaccine Information Statement (VIS)

Smallpox Vaccine and Heart Problems: Important Interim Supplementary Information – March 31, 2003

VIS Supplement A: Reactions After Smallpox Vaccination

VIS Supplement B: Vaccination Site Appearance and Care

VIS Supplement C: Skin Conditions that Mean You Should Not Get Smallpox Vaccine

VIS Supplement D: A Weakened Immune System Means that You Should Not Get Smallpox Vaccine

VIS Supplement E: Pregnancy Means You Should Not Get the Smallpox Vaccine

Pre-Event Screening Worksheet for Smallpox Vaccine

Pre-Event Screening Worksheet for Smallpox Vaccine: Important Interim Supplementary Information – March 31, 2003

Someone You are Close to May Get Smallpox Vaccine: What You Should Know and Do

Fact Sheet: Investigation Vaccinia Immune Globulin (VIG) Information

Fact Sheet: Investigational Vistide (Cidofovir) Information

Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate (Videotape)

Patient History and Consent Form

Post-Vaccination and Follow-up Information Sheet

## **MATERIALS IN ILLINOIS SUPPLEMENTAL INFORMATION PACKET**

Consent to Vaccination (Illinois Supplement)

Smallpox Vaccination and HIV Testing Information Sheet (Illinois Supplement)

Smallpox Vaccination and Pregnancy (Illinois Supplement)

Privacy Rights: Smallpox Screening and Vaccination (Illinois Supplement)

Permission for Release of Smallpox Vaccination Information (Illinois Supplement)

Compensation in the Event of an Adverse Medical Reaction (Illinois Supplement)

Present Day Risks of Adverse Reaction to Smallpox Vaccination (Illinois Supplement)

Pre-Event Screening Worksheet for Smallpox Vaccine (Illinois Supplement)

Patient Medical History and Consent Form (Illinois Supplement)

Site Care Instructions (Illinois Supplement)

Smallpox Vaccine and Individuals with Diabetes (Illinois Supplement)

Smallpox Vaccine and Individuals with Chronic Health Conditions (Illinois Supplement)

Smallpox Vaccine and Individuals Age 65 and Older (Illinois Supplement)



## **Privacy Rights: Smallpox Screening and Vaccination (Illinois Supplement)**

Thank you for considering receipt of the smallpox vaccine. The United States Department of Health and Human Services, through its Centers for Disease Control and Prevention (“CDC”), is responsible for implementing this federal smallpox vaccination program throughout the United States in order to protect the public health and national security. Pursuant to the direction of the United States government, the Illinois Department of Public Health (“IDPH”) is administering this federal smallpox vaccination program in Illinois, with the involvement of local public health agencies, hospitals, and other health care providers. Various types of information will be requested from you in connection with the vaccination program. This statement of privacy rights describes what information will be requested, who will have access to the information, and how it will be used.

You will be asked for medical and other information about yourself, about other persons in your household and about your close physical contacts. This will include information related to the health risks associated with smallpox vaccine made with live vaccinia virus. This information will be used to advise you of the health risks associated with taking the vaccine and to advise you as to whether you should avoid the vaccination or not. There is no legal obligation for you to provide this information. However, without it, the smallpox vaccine will not be given.

If you decide to receive the smallpox vaccine, information will be obtained from you about whether the smallpox vaccination has “taken” (in other words, whether the appearance of the vaccination site indicates that the vaccination has worked for you), about whether you have any adverse reactions to the vaccination, and about other aspects of your vaccination experience. This information will be used to determine whether you need to be revaccinated, to determine whether you need treatment for any adverse reaction, and to determine what portion of smallpox vaccinations “take.” This information will also be used to analyze and follow-up on significant events associated with smallpox vaccination, to assure the availability of smallpox response teams, to respond to any smallpox emergency, and for other public health purposes. There is no legal obligation for you to provide this information.

All of the information obtained from you in connection with the smallpox vaccination program will be maintained at the public health agency clinic where you obtain your smallpox screening and vaccination. You will have access to this information. IDPH and CDC will have access to the Patient Medical History record in the event access is needed to protect the public health. While IDPH cannot control the actions of other parties, IDPH will preserve the privacy of the information it receives in accordance with

applicable state and federal law. Other parties who might have access to this information include staff and consultants of the public health agency clinic where you obtain the smallpox screening and vaccination, staff and consultants of any party that is assisting with the administration of the vaccination process at that clinic, and, under appropriate circumstances, a treating hospital or other treating health care provider. These parties should have access to this information only to the extent that they need to know it in order to perform their job duties in protecting the public health. All parties who have access to this information are expected to preserve the privacy of the information in accordance with applicable state and federal law. Please consult with their privacy notice for information on how they will protect the privacy of your information.

If you are successfully vaccinated and Illinois later faces a public health emergency related to smallpox or a threat of smallpox, the local public health agency and IDPH might share your vaccination status with local, state and federal government agencies.

Except as described above, IDPH will share with your employer only your patient identifying information and information on whether you have been vaccinated unless you consent to release of additional information.



## Permission for Release of Smallpox Vaccination Information (Illinois Supplement)

Name: \_\_\_\_\_ PVN: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Gender:    M     F

Employer Name and Address (or name and address of organization that referred you for smallpox vaccination, if other than your employer)

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I have read and understand “Privacy Rights: Smallpox Screening and Vaccination (Illinois Supplement)”. In addition to the consent that I signed on the “Patient Medical History and Consent Form” and the “Supplemental Illinois Consent to Vaccination”, I give my permission for release of the following information to my employer or other organization listed above: my name, address, patient vaccination number (PVN) and social security number. I understand the organization that referred me for smallpox vaccination (if other than my employer) and public health agencies will use this information to assure the availability of smallpox response teams and to respond to any smallpox emergency.

I understand that any medical and other information I provide in connection with the smallpox vaccination program is voluntarily given. As described in this document and in “Privacy Rights: Smallpox Screening and Vaccination (Illinois Supplement)”, I further understand and acknowledge that this information may be accessed by local public health agencies, local, state and federal government agencies, treating hospitals and other treating health care providers if necessary to protect the public health.

I understand that signing this permission does not relieve me of my responsibility to provide notification of my vaccination status to my employer and to any other facility where I perform healthcare work.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_



## **Post-Vaccination and Follow-Up Information Sheet**

**IMPORTANT: KEEP THIS FORM. BRING IT WITH YOU TO YOUR VACCINATION SITE EXAM.**

You have just been vaccinated with Smallpox Vaccine; please do not throw this sheet away. This sheet will serve as your proof of vaccination until you come back to the clinic for your vaccination site exam. On that date, you will get your permanent immunization card.

### **INTERIM PROOF OF VACCINATION:**

Name: \_\_\_\_\_

Date vaccinated: \_\_\_\_\_

Clinic: \_\_\_\_\_

Clinic Telephone No.: \_\_\_\_\_

### **APPOINTMENT FOR REQUIRED VACCINATION SITE EXAM:**

Date of Appointment: \_\_\_\_\_

Clinic: \_\_\_\_\_

Clinic Telephone No.: \_\_\_\_\_

### **WHAT TO DO IF YOU THINK YOU ARE HAVING A BAD REACTION TO THE VACCINE:**

Call: \_\_\_\_\_, call your health care provider, or visit an emergency room.

**IMPORTANT: DO NOT DISCARD THIS FORM. YOU WILL NEED TO BRING IT WITH YOU WHEN YOU RETURN FOR YOUR VACCINATION SITE EXAM.**

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox), or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)