Anthrax Vaccine and Drugs Availability Program for Persons Possibly Exposed to Inhaled Spores

Adolescent Assent Form (Ages 13-17)

Background:

People who breathe in large numbers of anthrax spores may be at risk for developing anthrax infections in their lungs. Such infections are very serious and possibly fatal. As you know, you may have been exposed to spores during the recent anthrax attack.

Antibiotics (drugs) can prevent anthrax infection in people exposed to spores. Not much is known about people who may have been exposed to very large numbers of spores, such as those in post offices or government buildings during the recent attacks. The current recommendation to try to prevent infections in exposed individuals is to take drugs for 60 days. Some scientists and doctors have recommended the drugs be taken for longer than 60 days. Whether or not 60 days of drugs is enough is not known, because spores can stay in the body for a long time and may be hard to get rid of. FDA has not approved use of any drug for more than 60 days to prevent anthrax disease. There are risks from taking drugs for a long time.

There is also a vaccine for anthrax to immunize persons at risk of exposure to anthrax spores. We don't know if giving anthrax vaccine along with drugs after a person is exposed to anthrax spores is better than giving drugs alone to prevent the disease. The Food and Drug Administration (FDA) has not approved anthrax vaccine for this use. There are risks to taking the vaccine.

Because people like you may have been exposed to large numbers of anthrax spores, the Department of Health and Human Services (DHHS) is making anthrax vaccine available to those exposed who may want to take it to prevent anthrax disease, even though it has not been tested or shown to be effective for this use.

Purpose of the Program:

This program is intended to make the vaccine and additional drugs available to all people who may have been exposed to anthrax spores and who were advised to complete a 60-day course of drugs. It is very important that you understand that this use of the vaccine has never been tested in people and no one knows if it offers any additional protection from infection. The vaccine is only available through this program.

Description of the Program:

Although the current recommendation to prevent anthrax is to take drugs for 60 days, everyone who decides to take part in this program will receive an additional 40 days of drugs to try to reduce the chances of anthrax infection. You may also take the vaccine if you wish.

You do not need to take the vaccine to receive the drugs. In addition, you can choose to stop taking drugs at the end of 60 days and not take part in this program.

Before you decide to take part in this program, there are several important things that you should know. You should read this form very carefully with a member of the program staff or your doctor and make sure that you know the risks and possible benefits before you agree to take part in this program.

- **Anthrax vaccine has <u>not</u> been studied in persons under 18 years of age.**
- **Anthrax vaccine has <u>not</u> been shown to prevent infection when given to people after exposure to anthrax spores.**
- **The FDA has <u>not</u> approved the use of any antibiotic for more than 60 days or the use of amoxicillin for the prevention of anthrax.**
- **The vaccine that you will receive in this program has <u>not</u> been approved by the Food and Drug Administration (FDA) for this use and is considered investigational.**
- **FDA has not approved this lot of vaccine (Lot FAV-063) because the company's license to produce the vaccine is under review. This lot of vaccine has passed all of the vaccine maker's tests for use in humans.**
- **You should not consider the vaccine as treatment for anthrax. The vaccine as given in this program has not been shown to give long term protection against anthrax.**
- **You may have undesirable side effects from taking the vaccine.**

Because the vaccine is not approved for this use, FDA considers this a clinical investigation and regulations require the collection of health information from you in order to watch for side effects or other problems. In addition, we will watch for any cases of anthrax.

DHHS is <u>not</u> making any recommendation whether you should or should not take this vaccine. DHHS is making the vaccine available to you to allow you to decide whether or not you wish to use the vaccine.

If you decide to take the vaccine, you will get three shots of vaccine in the muscle of your upper arm. You will get one shot every two weeks. Each shot is small (0.5cc), one-tenth of a teaspoon. You will get all of your vaccine shots in one month.

In addition to the vaccine, you will also be given a 15-day supply of drugs. You will be asked to return for a follow-up visit two weeks later to get the rest of your 40-day supply.

Do not stop taking the drugs without first talking to program staff or your doctor.

Everyone in the program will be asked to keep a diary about their health for the first six-weeks after starting the program. You will also receive a phone call from the CDC staff at 2-months, 6-months, 1-year and 2-years after joining the program to keep track of how you are doing and any problems you may have.

You will be asked to take part in this program for a period of two years. Your taking part in this program is completely voluntary.You may drop out any time without penalty or loss of benefits to which you are entitled.

Possible Risks:

Anthrax Vaccine:
The most common side effects are a sharp stinging or burning in your arm right after the shot. This pain usually goes away within a minute. Like many vaccines, the anthrax vaccine can cause soreness, redness, itching, and swelling in the arm that can last up to a week. A lump at the site is common.It usually goes away in a few weeks without treatment. From 5% to 35% of people who get the vaccine will have muscle aches, joint aches, headaches, malaise, rashes, chills, low-grade fever, nausea, or related symptoms. These usually go away within a week.

Any vaccine can cause serious problems, which may require a hospital stay. For anthrax vaccine, these serious problems, such as allergic reactions, happen less than once in every 100,000 doses. Some people have reported serious chronic illnesses like Guillan-Barre Syndrome (a muscle weakness disease), chronic joint diseases or had miscarriages and infertility after getting the anthrax vaccine. Data from over 500,000 people world wide who did get the anthrax vaccine so far suggests that people who get the vaccine have the same chance of getting these health problems as people who don't get the vaccine.

The anthrax vaccine cannot give you anthrax disease.

Although unconfirmed, a recent preliminary study suggests that the vaccine may be linked with an increase in the number of birth defects when given during pregnancy. At this time no one knows for sure whether this vaccine can cause fetal harm.

If you have the Human Immunodeficiency Virus (HIV) or another health problem that affects your immune system (such as if you are being given drugs to treat cancer), seek the advice of your vaccine provider or your personal doctor about how any medical problems you might have may be affected by receiving anthrax vaccine. New findings that we discover in this program will be reported to the site program coordinator and provided to you by them.

Antibiotic Use:
Drugs may have side effects. Read the fact sheets on the three drugs. These describe the risks from taking each drug. Women should take note of potential problems to use of drugs during pregnancy. Follow medical advice carefully.

Please report any side effects you have in the first 6 weeks to your site program coordinator (as listed on your emergency contact sheet). After 6 weeks, please report side effects that you have by mailing a Vaccine Adverse Events Reporting Form (VAERS) to the address on the form (PO Box 110 Rockville MD 20849-1100) and fax the VAERS form and Cover Sheet to the CDC's Central Processing Center at 1-404-639-8548. You will also need to report these side effects to MedWatch by calling1-800-FDA-1088 or by faxing the MedWatch form to 1-800-FDA-0178.

Possible Benefits

We do not know if there is a risk of disease among people who have been exposed to anthrax spores and have taken 60 days of antibiotics. However, if there is such a risk, then either 40 days

of additional antibiotics or 40 days of additional antibiotics and the vaccine may be of benefit in reducing the risk of disease.

Alternatives

Anthrax vaccine is only available to you at this time through this program.

If you do not want to take the vaccine, you may continue to take drugs either through this program or through your doctor.

You also have the choice to not take extra drugs.

Costs

Participants in this program will receive free of charge the vaccine and/or drugs and all services necessary to administer the vaccine. You will be responsible for your routine medical costs and charges not related to this program.

Injury

If you are hurt as a result of being in this program, treatment will not be provided by HHS and may not be provided by [this site]. You (or your insurer, Medicare, or Medicaid) will be expected to pay for any care that is needed. By signing this consent form and agreeing to be in this program, you are not giving up any of your rights. If you believe that you have been injured, please contact the National Immunization Information Hotline at 1-800-232-2522 (for Spanish speakers, call 1800-232-0233) for information on your rights and advice on how to proceed.

Privacy

Your privacy will be protected to the extent legally possible. Information obtained from this program may be published. We would not publish your name or other information that would identify you personally. The CDC, (local site), the vaccine maker, and the FDA will be allowed to review medical and program records as part of their duty to protect people involved in this program.

<u>If you have any questions:</u>
If you have any questions about this program or want to report any side effects, you may contact the site program coordinator. If you have questions regarding your rights as a program participant, you may contact CDC Deputy Associate Director for Science (1-800-584-8814).

Consent

A member of the program staff has explained this document in detail to me, and I freely consent to join this program. I understand the following:

- I may continue to take drugs alone to prevent anthrax disease and that these are likely to be effective so long as I continue medication.

- If I choose to receive the vaccine as given in this program, I am unlikely to develop long-lasting immunity to anthrax.
- There have been no human studies to date that have shown whether the vaccine can be effective when given after exposure to anthrax spores.
- The anthrax vaccine or the drugs can cause rare serious adverse reactions.
- The doctors in charge may remove me from the program without my consent, if it is in my best interest medically.
- The risks and benefits of taking this vaccine.
- That I may refuse to join or may drop out at any time without penalty or loss of benefits.

I have been given the time to ask questions freely and had them answered to my satisfaction. I have been given a copy of this informed consent form. I understand that nothing contained in this informed consent waives any of my legal rights as a volunteer.

Please check one:

___ I choose to be in the program and get 40 extra days of drugs

___ I choose to be in the program and get 40 extra days of drugs and vaccine

Printed Name of Volunteer Subject	Date of Birth (dd/mm/yy)	
Signature of Volunteer Subject	Date/Time	
Permanent Street Address of Volunteer Subject		
Permanent City, State, Zip Code of Volunteer Subject		
Printed Name of Person Conducting Consent Interview	Signature of Person Conducting Consent Interview *	Date
Printed Name of Witness	Signature of Witness **	Date

*** If the consent information was provided to a volunteer who does not speak or read English, the person conducting the interview should indicate that the information was presented in the subject's language: _____.**

** Witness should be able to understand both English and the volunteer's language.