

Model Volunteer Consent Form, #1

Background

Goodvacc Vaccine Research Study

We ask you to take part in a research study of a new vaccine for Severe-disease.

The NoName IHS Service Unit, Topdrug Pharmaceutical Company, and Academia University are doing this research. The study has 2 purposes:

- 1] to see if Goodvacc vaccine can prevent Severe-disease; and
- 2] to see if the vaccine is safe.

Goodvacc is an experimental vaccine. 2,500 adults have received it without problems.

Goodvacc is an "Investigational New Drug," because it is still being studied. That is, it has not been licensed by the FDA (Food and Drug Administration) for general use. The FDA may use this study to decide if it should be licensed.

Goodvacc has been given to more than 2,500 adults. Almost all of them made antibodies to Severe-disease. (Antibodies are what the body makes to fight infections.) So far, no serious side-effects were seen in any of the people given the vaccine.

There is no other way to prevent Severe-disease.

Severe-disease is an infection that hits mostly elders. About one-third of elders with Severe-disease die even though we give them the best medical treatment known. So we want to prevent the disease from hitting the elders, but there is no way known to prevent it now. If Goodvacc vaccine works, it would be the only way to prevent it.

We want to find out if this vaccine works, and to be sure it is safe.

This study will find out if Goodvacc, and the antibodies it produces, do prevent Severe-disease. We also want to check for side-effects. We are testing Goodvacc vaccine here because many elders of NoName Reservation get Severe-disease, and more than one-third of them die from Severe-disease.

If you volunteer to take part, we will give you a shot either Goodvacc vaccine,or sterile water (a "placebo") that does not produce antibodies.

We ask all patients age 60 or older, who come to NoName Clinic, if they want to take part in this study. We will check to see if there is a medical reason that they should not take part.

If you volunteer to take part, we will put you in one of 2 groups. Groups are assigned by chance or randomly, as by a flip of a coin. People in one group will get a shot of Goodvacc vaccine; people in the other group will get a shot of sterile water ("placebo"). You will not know which shot you get, the vaccine or the water. All shots are given by trained nurses.

We will draw one tube of blood three different times.

If you volunteer to take part, a skilled lab tech will draw one tube of blood (about two teaspoonfuls). We will draw the blood before the shot, in 1 month, and in 1 year. We use the blood tests to see if you already have, or make, antibodies to Severe-disease. To draw the blood from you, we will ask you to come back to the NoName Clinic in 1 month and 1 year.

When you come back, a nurse will ask you a few questions to find out if you had any side-effects after the shot, and if you had Severe-disease. The questions take about 10 minutes. The nurse will also check your medical chart at the Clinic to see if you had Severe-disease.

We will give you \$10 for today's blood draw, and \$20 each for the second and third draw, to pay for time, gas, and other expenses.

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Schedule

Date	Type of visit	What will be done
Today	Clinic	health questions; blood draw; shot; \$10
1 month	appointment with us	health questions; blood draw; \$20
1 year	appointment with us	health questions; blood draw; \$20

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The vaccine may have side-effects.

So far, the side-effects of the 2,500 people given Goodvacc vaccine have been the following.

Local reactions at the shot:
redness or soreness or swelling.

General reactions:
fever for about 1 day.

Less than 4% (1 person in 25) of the people who received the vaccine had any of those reactions.

As with all blood draws, you may get a bruise where the blood was taken. It is very rare to get an infection at the site of the blood draw.

The vaccine may have risks that we do not know about.

Goodvacc may have a side-effect or reaction that we do not know about. Other vaccines have had rare severe allergic reactions, long-term muscle weakness, and very rare death from reactions.

The vaccine may benefit those who get it.

If you get the Goodvacc vaccine shot, you may be protected from Severe-disease. We hope Goodvacc vaccine protects against the disease, because it protected animals in tests. However, we do not know for sure if it protects human beings from Severe-disease. The purpose of this study is to find out if it does protect.

If you get the "placebo" shot, you will not get benefit now. But if this study shows that Goodvacc protects against Severe-disease and is safe, we will offer to give you the vaccine immediately.

NoName Reservation may also benefit from this study. If the vaccine protects elders from Severe-disease, NoName elders will be the first to be protected. When we get the results of the study, we will report them to the Tribal Council first, before releasing the information to the general public.

We will guard your confidentiality.

We protect all information about you and your taking part in this study as much as we can. We have trained all staff not to tell anyone outside the study any information about a participant. Medical records are held in a secure room. The FDA may examine our records of those who take part in the study. It is possible but unlikely that a court order may force us to reveal medical records to other people, as is true for all medical records.

In case of injury or reaction, call Dr. Ida H. Service at ____-____-____.

If you have an injury or reaction that may be caused by your shot or study procedures, please call Dr. Service immediately. Her telephone number is ___-___-____. You may use the NoName Clinic phone, or call collect, to make the call.

The NoName IHS Clinic will provide medical care for any injuries or reactions caused by the Goodvacc vaccine or study procedures. The Topdrug Pharmaceutical Company will pay for needed medical care that IHS does not provide.

If you have questions about the research, call Dr. Service at ___-___-____, or write her:

NoName Clinic, NoName Indian Nation
1000 Named Street
NoName City, XX 12345-6789

You may use an NoName Clinic phone for the call.

You have rights as a research volunteer.

Taking part in this study is voluntary. If you do not take part, you will have no penalty and lose no care or services by IHS or others. You may stop taking part at any time, with no penalty or loss of any care or service to which you are otherwise entitled.

We may contact you later about taking part in other studies related to Goodvacc vaccine or Severe-disease. You may choose to take part or not at that time. Your decision to take part or not in the future will not affect any care or services by IHS or others.

You may stop taking part in this study at any time. You will be reimbursed for each blood draw taken. We may end your participation in this study at any point if we feel it is in your best interests for your health. We will tell you any information we find that may affect how willing you are to continue in the study.

If you have a **complaint, grievance, or other concern**, call or write Ed Ethics:

NoName IRB, NoName Tribal Office
1000 Happy Ave
Happy City, XX 12398-7654
(telephone ___/___/____)

You may use an NoName Clinic phone for the call.

*I agree to take part in
questions have been ans*

Signature: _____
[or thumb-print]

itness: _____

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*[Note: The readability of this Volunteer Consent Form is 8th grade. No sentence is 30
are 14*