

Model Volunteer Consent Form, #2

Background

A team of service unit health care prevalence of diabetes in the community. The ultimate purpose is to determine geographic or demographic (age and gender) groups have the highest rates of undiagnosed diabetes, random serum glucose final diagnosis. The team obtained technical assistance for project design and sample size calculations.

General Methods:

The team members. The sampling office. This list every selected people and ask them to participate in the study. Anyone positive on a random serum glucose

Is an "Informed Consent" form necessary? Is this truly "research"?

Screening for diabetes is part of clinical care; a detailed process of informed consent is not usually done project really clinical care

Although the project includes clinical care, it is also research, due to its use of sampling and to the purpose of the project. Sampling is done to ensure that the prevalence rates found are valid for the entire community. But sampling is a method of research, not of clinical care. The undiagnosed diabetes, and ho purpose is research, although the research results care.

Informed Consent by potential volunteers:

Informed consent must be obtained before a person's participation. Although finding undiagnosed diabetes

*instance, driver license and insurability may be adversely affected by a diagnosis of diabetes.)
The consent must describe all benefits and risks.*

Community Diabetes Research Project Informed Consent for Volunteers

We ask you to take part in research for the Community Diabetes Project.

The Project is sponsored by the Tribal Health Program and IHS. We want to find out how many people have diabetes but do not know it.

Diabetes means that a person has too much sugar in the blood. Many people in this Tribe have diabetes. Although many people with diabetes are diagnosed in the Clinic, some people may not know they have it. If we know where most of those people live, we can set up stations to screen for diabetes in those Districts.

We want to check 200 adults for diabetes who live in all parts of the Reservation. We picked the people randomly from the Tribal Census, like picking bingo numbers out of a drum.

We want to check your height and weight, and do a blood test for sugar.

If you agree to take part, we will ask some questions about your health and how you are feeling. We then will check your height and weight, and get a drop of blood from you by a finger-stick. We will **test your blood for sugar right away, and tell you the results**. All this takes about 15 minutes of your time.

When we get back to the Clinic, we will put all the results in your chart, for the doctors to see.

If your test shows high blood sugar, we will ask you to go to the Clinic.

The test today does not diagnose diabetes. High blood sugar on the test today means just that you may have diabetes or tend to have it.

If the test today is high, we will make a Clinic appointment for you. **You can get the final tests to check for diabetes there.**

You and the community may benefit if you agree to take part.

You may benefit because you will learn if you have diabetes or not. If you have diabetes but do not know it, the Clinic can help you stay healthy. Our community may benefit because we will be able to plan for better health services.

We want you to know the risks for taking part, as well.

The finger-stick will sting for a couple of seconds.

Some people may worry a lot if the test today is high. But a high test today does not mean a person has diabetes for sure. The Clinic will do those tests. And if you have diabetes, the Clinic can help you return to good health

If you have diabetes, you may need to have the Clinic OK your Driver's License each year. Having diabetes also means it is more difficult to get insurance. (But most insurance companies test for diabetes when people apply, anyway.)

We will keep all your information confidential.

All results go right to your Clinic chart for your doctor's use. After that, the Community Diabetes Project will remove all names. Because there are no names, no-one can know what your results are from the Project.

If you have questions about this Project, please call Mary Doeswell at ____-____.

You may use a District or Clinic phone for the call, or you can visit her at Tribal Headquarters. If you have a **complaint, grievance, or other concerns** please call Ed Ethics at ____-____-____, or visit him in the Tribal Office. You may use a District or Clinic phone for the call.

Taking part in this study is voluntary.

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

We will give you a copy of this form.

*I agree to take part in the Tribal Diabetes Community Project. It
my blood for sugar, and put the results in my Clinic chart.*

Volunteer's Signature [or thumb-print]

Date

itness to Consent Procedures [optional for signature]

Date

Signature of Team Member

Date

.....

[Note: The readability of this Form is 7th grade. Consent Forms do not need to be un-understandable!]