**Program participation consent form**

Hualapai Tribe

Indian Health Service, Special Diabetes Program for American Indians/Alaska Natives

Hualapai Healthy Heart Program

Sandra Irwin, Program Director

## CONSENT FOR PROGRAM PARTICIPATION

## (Case Management)

# Program Description

You are being asked to participate in the Hualapai Healthy Heart Program. Its purpose is to determine if a program designed to prevent cardiovascular disease (heart disease), is helpful to people with diabetes or with metabolic syndrome.

Several studies have shown that you can reduce your risk of developing cardiovascular disease by treating and controlling your risk factors, such as blood pressure, cholesterol and tobacco use. In 2004, Congress funded the Indian Health Service to award funds to selected Indian Tribes to implement activities in communities to reduce the risk of cardiovascular disease in people with diabetes. In 2009, Indian Health Service expanded the eligibility criteria to include people with metabolic syndrome. Metabolic syndrome is a risk factor for diabetes

Diabetes is a disease of too much glucose (sugar) in the blood and can cause damage to blood vessels, heart, kidneys, eyes, and nerves. American Indians have higher rates of diabetes and cardiovascular disease than other racial/ethnic groups. Diabetes is a major risk factor for cardiovascular disease. Cardiovascular disease includes heart attacks, stroke and diseases of the blood vessels.

With this in mind, we are asking you to participate in our program to try to prevent cardiovascular disease through education, treatment of risk factors, and other prevention activities. Since you have diabetes or metabolic syndrome, we wanted to give you the opportunity to consider joining our program.

# Procedures

If you agree to participate, you will be asked to have a physical exam and laboratory tests to learn more about your health. This process will take about 1 hour.

You then will be scheduled for program activities. You will be scheduled to meet monthly with a trained case manager/health professional to assess your risk for cardiovascular disease to make a plan for reducing your risk. The case manager will monitor your blood pressure, cholesterol, weight, lab tests, and provide or refer you for education on healthy behaviors, such as weight loss, physical activity and healthy eating. In a year from now, you will be scheduled for another exam and some laboratory tests.

During the program, the following procedures will be carried out:

* A **physical examination** will be done when you first start in the program, and a physical examination will be repeated each year. This process will take about an hour. You may also need to receive a health clearance from a physician for physical activity and working out at the Fitness Center.
* During the above described clinic visit, a **blood sample** will be taken from your arm (about 2 tablespoons). This process will be done at your first examination, as needed for your routine care and then again once a year to access your progress. You will be asked to not eat or drink anything except water for 12 hours before some blood tests.
* **Blood pressure** will be measured at each visit with the case manager and during your first and annual clinic visits. This test will take about 5 minutes.
* **Body Measurements** will be taken. Your height will be measured when you start and your weight and waist size will be measured when you start and then again, once a year.
* You will be asked to fill out a **questionnaire** when you start and every 12 months. These questions have to do with your physical activity, food choices, health history and health status. This questionnaire will take about 15-20 minutes to complete.

Taking part in this program will require our knowing about any other medications that you might be using or might wish to use. While it should be ok for you to take your medications during this program, we will work closely with your own doctor to tell you which medications you may need to take or not take. It is likely that your medications will need to be modified to further reduce your risk of cardiovascular disease.

If you are a woman, you must notify the program staff immediately if you become pregnant. Your pregnancy may require changing the way you participate in the program activities and/or the medications that you are eligible to take. You must also notify the program staff if you are breastfeeding, because you may need to avoid some medications.

The program will last until 2012, so you will take part for up to 3 years depending on when you start.

**Risks and Discomforts**

The program requires that you attend regular meetings with program staff. The time involved may interfere with other activities in your life and you may need to adjust your schedule.

The program may require that your medications be changed from time to time, and it is possible you might have a serious reaction to these changes in medication. We will work closely with your doctor to try to avoid these types of side effects.

The risks of drawing blood include temporary discomfort from the needle stick and possible bruising or redness of the skin.

The risks of increasing your physical activity include fatigue, muscle soreness, and injury such as sprained ankle or pulled muscle. You will receive clearance from a physician to make certain that there are no health reasons why you should not exercise. Risks are reduced by proper warm-up and cool-down periods and careful planning of the exercise for each person. You can work with program staff to exercise and develop a plan that will work for you.

There may also be risks that are unknown at this time.

# Benefits

Volunteers in this program get a complete physical exam at the beginning of the program and each year. We will tell you if we find any health problems. Your health will be closely monitored during the program and problems such as heart disease might be found and treated sooner than if you were not a part of the program. Participation might improve your health and the activities of the program might reduce your risk of developing cardiovascular disease.

# Costs to Participants

There is no cost to you for participating in this program. There will be no charge for procedures required by the program. You will not be paid for your participation. You may receive some promotion items during the activities of the program.

# Source of Participates

Funding for this program is provided by the Indian Health Service, Special Diabetes Program for American Indians/Alaska Natives.

# Voluntary Participation and Withdrawal

Taking part in this program is voluntary. You have the right to choose not to take part in this program. If you do not take part, you will not lose any benefits or medical care to which you are entitled.

If you choose to take part, you have the right to stop at any time. You will be told if there are any new findings during the program that may affect whether you want to continue to take part.

# Injury and Compensation

You should inform your care provider(s) if you decide to participate in this program. If you have questions about injury related to this program, you may call Sandra Irwin, MPH at 928.769.2207 and/or your physician. Ms. Irwin should be informed about any injury you experience while you take part in this study.

If you are hurt as a direct result of the program, medical treatment will be done at no cost within the limits of the Indian Health Service compensation plan. Beyond this, treatment will be at your expense or that of your insurance carrier.

**Invitation to Ask Questions**

The person directing this program is Sandra Irwin, MPH, Health Department Director. You may ask any questions you have now. If you have questions later, you may call Karen Hays, RN at 928.769.1630. You will be given a copy of this form to keep.

If you have questions regarding your rights as a participant, please call Lynnae Lawrence, MD, CEO of the Colorado River Service Unit at 866.362.0712. This call is toll free and can be placed for you at the Healthy Heart Program facility.

# Confidentiality

# We will make every effort to keep your records confidential. Information from this program will be de-identified meaning that your name, address and contact numbers will be detached from the other information. Only your tribal affiliation will be maintained. This de-identified information will be sent to the Coordinating Center for the Special Diabetes Program for American Indians/Alaska Native Healthy Heart Program in Aurora, Colorado. The results of this program may be presented at meetings or in published articles. However, your identity will be kept private.

# Authorization

I have read this paper about the program or it was read to me. I understand the possible risks and benefits. I know that participating is voluntary. If I choose to take part in the program, I know I can stop at any time and I will still get usual medical care. I will get a copy of this consent form and have initialized all the previous pages of the consent form.

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

Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Consent form explained by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_