



Cardiovascular Health in the African American Population (CHAAP) in West Michigan

CONSENT FORM

Heart disease has been the leading cause of death in Kent County. In Kent County, African Americans have an about 30% greater chance of dying from heart disease than do Caucasians. About 25% of all African American deaths in Kent County are because of this disease.

The Grand Rapids African American Health Institute (GRAAHI) is working to determine why African Americans in Kent County have a higher risk of getting and dying from heart diseases. GRAAHI hopes to use this information to improve African American's chances of avoiding and surviving heart disease. To do this, GRAAHI is developing a registry with information about the health of African Americans in Kent County. It will also send important information to local doctors.

You are being asked to participate in this research because you are an African American at least 18 years old and live in Kent County. It is planned that 200 people will enroll in this project during the first 14 months and to continue this study for an additional nine (9) years. After 14 months GRAAHI hopes to enroll 800 more people. If you agree to be part of this research, you will meet with GRAAHI researchers for a series of interviews. You may be asked to go to planned educational programs (not more than four times a year) to help you lower your risk for heart disease. These programs will not last more than one hour and attendance will be strongly recommended but not required. You may also be asked to make changes in your lifestyle to decrease your risk of heart disease.

At the first interview, you will be asked to give GRAAHI researchers information about you. This will include your medical history and health care treatment. You will be asked about your health and family history, have a sample of your blood and urine taken for laboratory analysis, and have your blood pressure measured. You will also have an *electrocardiogram*. An electrocardiogram is a test where wires are pasted on your chest and a recording of your heartbeat is made. An *echocardiogram* may also be done at this time, or later. An echocardiogram is when an ultrasound picture of your heart is taken. Echocardiograms may be done twice a year. GRAAHI researchers may not need to do these tests if you have had them done in the past two months. Except for the echo- and electrocardiograms, all appointments will take place at the site or institution where you signed the consent form. The echo- and electrocardiogram will be performed at a local health care facility or doctor's office.

Your health history and tests will be used to determine your risk for heart disease. You will receive information about your blood pressure and your risk for heart disease. These results also will be used to compare the treatment you are currently receiving from your doctor to nationally accepted treatment recommendations. Information about your risk for heart disease and the national recommendations will be sent to your doctor. However, GRAAHI will never in any way attempt to replace your physician's role as care provider. If you do not have a regular doctor you will be encouraged to find one. One way to do this is by using the yellow pages or hospital referral lists.

After your first meeting with the research nurse, you will be asked to come back for regular follow up visits. These visits are to check your blood pressure and have a blood sample taken for testing (usually not more than twice a year). You will also be asked to give information about your medications, your current health and the last visit to your doctor. The questions asked could sound like: "Have any of your medications changed? Do you take any new medications? Did you experience any health problems since our last meeting? Have you seen your doctor? Why?". Answers to these questions and any information about visits to the emergency room or hospitalizations will be recorded, but will have no effect at all on your participation in this research program. Depending on your blood pressure, these visits may be scheduled as often as every two weeks, or as seldom as every three months.

You will be given a confidential study code number to identify your health information. Your name will never appear on your health information. All of the information you give to GRAAHI will be confidential. Except for the information that is sent to your doctor, only research personnel will see your information. All public reports will use information that has been combined with information about everyone in the project. There will be no way to identify you in these reports.

If you agree to be part of this research, you may benefit from GRAAHI's close monitoring of your blood pressure and other factors related to your heart. The educational programs you go to may help you improve your health. The information GRAAHI sends your doctor may help him care for you better. You will experience the usual pain of being stuck by a needle when giving blood. You may experience some mild discomfort when the wires are removed from your chest after your electrocardiograms. It may be necessary to shave small sections of chest hair to apply the adhesive contacts for the electrocardiograms. Although project personnel will take all possible precautions with the information you give them, there is a very small chance that others may see it.

You will not be charged for any of the visits, tests, or items related to educational programs done for this project. If you are injured as a result of your participation in this project, care may be provided to you. However, GRAAHI will not be responsible for paying the cost of that care.

If you have questions about this study or your role in it, you may call Kim Ludwig, M.D. or Khan Nedd, MD at the Grand Rapids African American Health Institute (ph: 331-5831).

If you have any questions about your rights as a research subject, you may call Paul Reitemeier, Ph.D. Dr. Reitemeier is the Chairman of the Grand Valley State University Human Research Review Committee (ph: 331-3417).

Your participation in this research project is voluntary. Because this is a long-term project, we plan that your participation will last for 10 years. However, you may withdraw from this research at any time and for any reason. You will not be penalized by GRAAHI if you withdraw.

By signing this form I acknowledge that I understand the above information. I agree to become a subject in this research project. I also agree to allow the Grand Rapids African American Health Institute to contact my doctor and get information about me that is important to this project. I also understand that the Grand Rapids African American Health Institute will be sending my doctor information about my health.

Subject's Name – printed

Date

Subject's Signature

Witness's Signature

