DVA COOPERATIVE STUDY #996 - Information About the DVA Cooperative Study

"Prevention and Treatment of Hypertension Study" (PATHS)

FORM 88 - STUDY CONSENT

Medical Center Name _____ Medical Center No. ___ ___ ___

Participant Name _____ Participant No. ___ ___ ___ ___ ___

PURPOSE: Researchers are currently studying the relationship of many "lifestyle" factors, such as diet, smoking, drinking alcohol, and exercise, to diseases of the heart and blood vessels ("cardiovascular" diseases). You are being asked to participate in a study designed to determine how alcohol intake is related to blood pressure and other risk factors for cardiovascular diseases. The information learned from this study should be useful in treating people with mild high blood pressure as well as in "public health" recommendations and measures to reduce cardiovascular disease risk. Approximately 600 individuals will participate in this study.

PROCEDURES: All participants in this study will be randomized (by chance, like the flip of a coin) to one of two groups. One group will be asked to lower the amount of alcohol they drink each week and will attend sessions with an instructor where strategies and methods to reduce drinking are taught. The first five (5) sessions will be scheduled during the first three months and will take about one hour for each session. Then sessions may be scheduled at one to three month intervals for the remainder of the study. If you are randomized to the second group you will not attend the instruction sessions nor will you be asked to change the amount of alcohol that you drink.

For all participants there will be six visits one month apart over a period of six months. At these visits, you will have your blood pressure, pulse and weight measured. Occasionally, we will ask you questions about various health practices. At three visits, you will have blood samples drawn (about 4 teaspoons). You will also undergo two (2) echocardiograms (ultrasound examinations of your heart); at the beginning and near the end of the six-month period. This test takes pictures of the heart using sound waves, is safe, and requires about 45 minutes.

After the initial six-month period, you will be followed every three months for an additional eighteen (18) months. During this time, you will come to the clinic six times, at three-month intervals, for measurements and questions similar to the first part of the study. Blood samples will be drawn three times during the 18-month follow-up period.

At each of the visits described above, you will be given $10.00 for your attendance to help defray expenses related to the visit.

During your participation in this study, we will check your blood pressure many times but will not inform you of the results except at the beginning of your participation in the study. However, if your blood pressure goes above the mildly hypertensive range at any time or rises into or remains in the frankly hypertensive range after the initial six-month period, we will notify you and begin or refer you for appropriate treatment, but we will continue to follow you in the study. If any other medical or psychological problems occur during the course of the study, the participating investigator will refer you for appropriate treatment.

_____

(Participant's Signature)

RISKS: The intervention sessions and the evaluation sessions offer no risks to you other than the possibility of tiredness, frustration or anxiety on answering questions. The staff will provide you rest time as needed. Drawing blood may cause pain or bruising at the site of the needle stick. You will be monitored for physical or psychological health problems that might pose a risk for you. There is a very small possible risk of a medical complication occurring during the time when your blood pressure may be mildly elevated. If your blood pressure rises into or remains in the frankly hypertensive range we will watch you very closely and, if necessary, will refer you for appropriate treatment or treat your blood pressure ourselves.

BENEFITS: No benefits can be promised from your participation in this study. However, you may benefit from information derived by monitoring of your health and from the special tests (such as the echocardiogram). You may also feel some satisfaction from knowing you have contributed to medical research which may benefit others in the future.

MONITORING: In order to insure your safe participation during the course of the study, your medical and study records may be monitored by a member of the DVA Cooperative Studies Program. At all times, your records will be kept confidential and your identity will not be revealed to anyone outside the program.

WITHDRAWAL/REFUSAL: You do not have to participate in this study if you do not want to. You may also withdraw at any time during the study and discontinue participation without jeopardizing the medical care to which you may be entitled.

ALTERNATIVE TREATMENT: If you have a cardiovascular risk factor such as high blood pressure, abnormal blood fats (such as cholesterol), or cigarette smoking, there are many ways to improve your risk, including medications.

YOU WILL RECEIVE A COPY OF THIS FORM.

ALL OF MY QUESTIONS RELATING TO THIS STUDY HAVE BEEN ANSWERED TO MY SATISFACTION. I UNDERSTAND THAT IF I HAVE ANY ADDITIONAL QUESTIONS, I MAY CALL:

_____ AT _____.

IF I HAVE ANY QUESTIONS ABOUT MY RIGHTS AS A STUDY PARTICIPANT OR ABOUT A STUDY RELATED INJURY, I CAN CALL:

_____ AT _____.

HAVING READ AND UNDERSTOOD THE ABOVE INFORMATION, I FREELY AGREE TO PARTICIPATE IN THIS STUDY.

_____ _____

(Participant's Signature) (Date)

_____ _____

(Witness' Signature) (Date)

_____ _____

(Participating Investigator's Signature) (Date)