PURPOSE:
You are being asked to join DASH (Dietary Approaches to Stop Hypertension), a study of the effects of diet on blood pressure. The goal of this study is to learn whether eating certain foods, such as more fruits and vegetables, lowers blood pressure. To accomplish this goal, we will study the blood pressure of 120 volunteers who are provided with all of their meals for 11 weeks. Each volunteer will be in the study for 3 to 6 months.

FOR VOLUNTEERS TAKING BLOOD PRESSURE MEDICINES:
In order to join this study, you must be willing and able to stop your blood pressure medicines for up to 6 months. With your permission, we will contact the doctor who prescribed your medications to see if he/she thinks this would be safe for you. If you and your doctor agree, and if you have no history of severe high blood pressure or serious consequences of high blood pressure, these medicines will be carefully discontinued under our supervision. We will check your blood pressure regularly to make sure that it does not go too high. Three to 5 weeks after stopping your blood pressure medicine, if your blood pressure is in the range to qualify, you will enter the study as described below.

STUDY DESIGN:
The study is divided into the following phases:

PHASE I: Screening 3 weeks to 3 months
PHASE II: Feeding:

Baseline period	3 weeks
Treatment period	8 weeks

PHASE I: SCREENING PERIOD: The purpose of the 3 screening visits is to determine if you qualify for the study. At each visit, blood pressure and weight will be carefully measured. In addition, at Screening Visit 2, a medical history, and laboratory evaluations (requiring urine and 2-3 teaspoons of blood) will be performed.

One of these blood tests will be saved for possible future DNA analysis. We will store this particular blood sample in a central laboratory, and will use it in the future if we think that the effects of the diets may have been influenced by certain genes. As you may know, DNA is the genetic material, and contains all your chromosomes. If, in the future it seems likely that certain genes may affect the blood pressure response to diet, then we will use these specimens for looking at those particular genes. These specimens will be identified by code number, so that your confidentiality will be maintained. The results of any genetic analysis we perform in the future will be identified by this code number only, and will not be associated with your name or any other identifying information.

_____
Patient's Initials

For Screening Visit 3, you will be asked to complete questionnaires about your diet and exercise habits. Body measurements will be taken using a procedure called DEXA scan. This is a painless test much like an X-ray which measures the amount of bone, muscle, and fat in your body. You will need to lie very still on a table for approximately 10 minutes to complete this test. The DEXA uses about 1/6 the radiation of a regular chest X-ray. In addition, blood tests (requiring 2-3 teaspoons of blood) will be done.

If your blood pressures at the 3 screening visits are in the range required for the study and if no other significant health problems are found, you will continue into the feeding periods.

PHASE II: FEEDING PERIOD: During the 11-week feeding period, all of your food will be provided to you. You will be required to eat your evening meal on weekdays at the Sarah W. Stedman Nutrition Center at the Duke Center for Living on Morreene Road. Your other meals will be packaged for you to take with you. Some beverages including coffee, sodas, and alcoholic drinks may be consumed on a limited basis that will be explained to you.

You will be asked to eat only the food provided by the study and to not eat any additional food or beverages. It is important that you understand that following these guidelines is essential to the study. If you do not feel that you can eat only the food provided by the study and no others for this time period, please discuss this with one of the investigators before joining the study. We will ask you daily to report foods eaten.

Since it is already known that losing weight lowers blood pressure, we will not be studying weight loss in this study. Therefore, if you join this study, your diet will be adjusted so that your weight will not change.

You will be weighed and asked to fill out a brief checklist daily. Your blood pressure will be checked every week. During the third and eleventh weeks of the feeding phase, your blood pressure will be checked every weekday. We will also ask you to wear a 24-hour ambulatory blood pressure monitor on two separate days. This monitor will automatically measure your blood pressure every 30 minutes during your usual daily activities. During both the third and the last week
of the study, laboratory evaluations (requiring 2-3 teaspoons of blood) will be performed once more. You will also be asked to collect all of your urine for 24 hours on 4 occasions during the study.

The 11-week feeding period is divided into a 3-week baseline period and an 8-week treatment period.

BASELINE PERIOD: During the first 3 weeks of the feeding phase, all volunteers will receive the same "baseline" diet, which is designed to resemble the "standard American diet". The purpose of this baseline period is to stabilize all volunteers on the same diet and to make sure
that you are willing and able to continue into the "treatment" portion of the study. You should understand that your eligibility to proceed to the final 8-week treatment period is determined in part by how well you comply with the requirements of the 3-week baseline period.

TREATMENT PERIOD: For the final 8 weeks of the feeding phase, you will be assigned randomly by computer to one of the following 3 diets:

1. Standard American diet
2. Low fat, high fruit and vegetable, high dairy
3. Standard American diet with high fruit and vegetable

There is a one in three chance that you will be assigned to any one of these diets. It is not possible to know which diet you will be assigned to in advance. If you agree to participate, you should be willing to consume any of the three diets for the entire eight weeks. If you normally have trouble digesting dairy products, we can supply you with a medication (lactaid) which may help you tolerate the milk products if you are assigned to the high-dairy diet.

During the feeding phase, we will check your blood pressure often and will let you know if it needs immediate treatment. Otherwise, the results will be available to you after the study. At the end of the study, we will advise you to return to your physician for regular follow-up.

POTENTIAL RISKS:
It is possible that your blood pressure could get higher during the study. If your blood pressure goes too high, we will refer you to your physician for treatment. In order to minimize the risk of high blood pressure, we will check your blood pressure often and perform a careful review of your medical history before you join the study. If you have had severe high blood pressure or any consequences from high blood pressure in the past, you will not be eligible for the study.

If you are already on a low-fat diet, it is possible that your cholesterol levels could go up during the study since the "standard American" study diet has about 37% of calories from fat. If you have significant high cholesterol during the screening phase, you will not qualify for the study.

As always, when blood is drawn, there is a chance of pain, bleeding, infection, or fainting. Serious complications are very rare. As a result of participating in this study, you will receive a radiation dose less than 1/2% of the annual occupational exposure limit. The National Committee on Radiation Protection has set annual 'occupational exposure limits' for the many radiologists, technologists, and scientists who work with radiation and are exposed nearly everyday. These limits are defined as 'the dose of radiation that, in the light of present knowledge, is not expected to cause appreciable bodily injury to a person at any time during his/her lifetime'. The risks of this amount of occupational exposure to radiation are thus considered to be very small and, at these levels, which have been in effect since 1957, there is no indication of harmful effects to the worker or his/her offspring. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received or will receive from other tests.

There are no known risks of wearing the ambulatory blood pressure monitor.

POTENTIAL BENEFITS TO SOCIETY:
The DASH study may lead to the development of dietary recommendations that will prevent or reduce the development of high blood pressure. It may also establish new diet treatments for high blood pressure.

POTENTIAL BENEFITS TO YOU:
Participation in DASH may help you learn more about your diet and blood pressure. Copies of your study records will be available to you and your physician at the end of the study upon request. You will not have to buy groceries for yourself and will be paid for your participation during the feeding period.

COMPENSATION:
You will be paid $30 per week during the feeding period, for a possible total of $350. If you are unable to complete the study, payment will be prorated. Since many people spend $50 or more per week on groceries, you could save an additional $550 during the course of the study.

COSTS:
During this study, all research costs will be paid by research funds. Participants are responsible for transportation costs and the costs of routine medical care not related to the study.

FOR WOMEN OF CHILDBEARING POTENTIAL:
By signing this consent form, you agree to the following: "I understand that special diets are required during pregnancy and, therefore, that this research may have an adverse reaction on an unborn child and should not be done during pregnancy. I understand that it is necessary that a pregnancy test (using two teaspoons of blood drawn from a vein by needlestick) will be done before DASH feeding begins. To my knowledge, I am not pregnant at this time. If sexually active, I will take contraceptive measures for the duration of the research."

INFORMATION ABOUT STUDY PARTICIPATION:
It is important that you understand several principles that apply to all who take part in this study:

a) Taking part in this study is entirely voluntary. Refusal to participate will not affect your medical care.

b) This study may or may not help you personally but knowledge may be gained that will help others.

c) You may refuse to join or may withdraw from the study at any time without affecting your regular medical care.

d) The investigators may end your part in the study for administrative reasons or if they feel that it is in the best interest of your health. They will then make arrangements for your continued care.

e) The confidentiality of this study's records identifying you will be maintained within Duke University Medical Center. Your name will remain confidential if this information is used for publication or for education.

f) Any significant new findings developed during this research, which may affect your condition or change your willingness to continue in the research, will be provided to you and your doctor.

g) Research related injuries: Immediate necessary care is available if an individual is injured because of participation in a research project. However, there is no provision for free medical care or for monetary compensation for such injury. Further information about the rights of patients in research can be obtained from the Hospital Risk Management Office, 684-3277.

_____

Patient's Initials

PARTIES TO CONTACT:
You have the right at any time to ask questions concerning this study. If you have questions or feel you may have sustained a research related injury, you may contact Melvania Williams, PA-C or Laura P. Svetkey, M.D. at (419-5840) on weekdays. For emergencies at other times, you may page Dr. Svetkey by calling the Duke paging operator at 919-684-8111 and asking for Duke ID# 2602.

CONSENT:
"I have read and understood this consent form. I have been given the opportunity to ask questions. I consent and volunteer to take part in this study with the understanding that I may withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I will be given a signed copy of this consent form."

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Obtaining Consent Date