Consent to Participate in a Research Study

Title of Study: Dietary Patterns, Sodium Intake and Blood Pressure; Dietary Approaches to Stop Hypertension 2 (DASH2)

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PURPOSE AND DESCRIPTION OF DASH2

I am being asked to take part in a research trial that examines the effects of three levels of sodium intake and two dietary patterns on blood pressure. The purpose of this study is to determine if certain dietary patterns may be helpful in the prevention of the development of high blood pressure. Only volunteers who are not being treated for high blood pressure with medications are eligible to participate in this study. Individuals who enroll in the study will all be placed on the same diet for a two week run-in

period. Following the run-in period each participant will be randomly assigned to one of two possible diets and will eat those diets for three four week intervention periods at 3 varying levels of sodium. There will be no break between the run-in diet and the first treatment diet.

There will be a break of no greater than 5 days between the second and third feeding periods during which time you will not be provided food by Pennington and I will consume my own food. If I am eligible to participate in this trial the two possible dietary patterns which may be assigned to me are:

1. **Control diet**: This diet has approximately 37% of calories from fat and 15% of calories from protein. It has low to moderate levels of fruits and vegetables. This pattern is approximately that of the average American diet.

2. **Combination diet**: This diet is lower in fat (27% of calories from fat) higher in protein (18% of calories) and higher in fruits and vegetables.

Each of the two diets will be provided at the following three sodium levels:

1. "**Higher**" 150 mmol (about 3 teaspoons) This reflects current US consumption.

2. "**Intermediate**" 100 mmol (about 2 teaspoons) This reflects the upper limit of current US recommendations for sodium.

3. "**Lower**" 50 mmol (about 1 teaspoon) This reflects potential optimal sodium levels.

I understand that all of these diets include meat, and that I will be expected to consume all of my foods from the DASH 2 study menus. I also understand that the study requires me to maintain a stable weight during the fourteen week feeding period. I agree not to attempt a weight loss program during this time and to let staff know if I am receiving too little or too much food so that the amount can be adjusted. I also understand that it is important that I report any foods which I do not eat from among those given to me, and also that I report any foods that I eat which were obtained from other sources.

The specific diet assignment will be made at random (by chance) using a computer. Neither I nor the staff at the clinic will know in advance to which diet group I will be assigned. It is not possible for me to pick the diet I would prefer to receive, and if I agree to participate, I must be willing to consume either of the two diets for 12 weeks and each of the three sodium levels for a 4 week period.

400 participants will be enrolled in this trial at 4 centers. Participants must be 22 years or older with systolic blood pressure between 120 and 159 mm Hg and diastolic values between 80-95 mm Hg.

I understand I will be excluded if my blood pressure is outside the above listed parameters or if I have a pre-existing medical condition that would affect blood pressure or my ability to participate. I understand that I may be excluded at the Investigator's discretion for reasons of safety or compliance. I will also be excluded if I am not willing to alter my lifestyle to comply with study requirements for the duration of the study.

STUDY PROCEDURES

Prior to enrolling in the study, I must complete two additional screening visits that include the repeat measurement of my blood pressure, two fasting blood draws and the collection of a 24-hour urine specimen as well as the completion of various questionnaires. I agree to attend the DASH2 clinic five days per week and to eat one meal at the clinic on those days. My weight will by recorded at each clinic visit. At the beginning of the first feeding period my waist measurement will be taken. During my visits to the clinic, my blood pressure will be taken on several occasions using the same techniques as were used in the screening visits. I agree to wear an ambulatory blood pressure monitor for three 24-hour periods at the end of each of the three feeding periods. This will consist of carrying a small monitor box approximately the size of a Walkman radio on my belt and its attached tubing and blood pressure cuff on one arm, fitted and initialized at the Pennington Center. The cuff will inflate every 30 minutes while worn. I further understand I will receive instructions in its fitting and use. I will be asked to provide a 24-hour urine collection using containers provided to me and to also have a fasting blood sample drawn at the end of each feeding period.

BENEFIT AND RISKS

I understand that I have qualified for this study because I have high normal blood pressure or slightly elevated blood pressure. A potential benefit from the study is the identification of a dietary pattern which might reduce my future need for blood pressure medications. I may not receive a direct benefit from my participation in this trial but the knowledge gained from this trial may provide future benefit for patients with elevated blood cholesterol.

The DASH 2 study should not involve any major risk to participants. The most likely risks include gastrointestinal upset and increased frequency and bulk of stools. The risks of venipuncture (needle sticks into my vein for blood drawing) commonly include discomfort, and/or bruising at the puncture site and, less commonly, the formation of a small blood clot at the puncture site. I may also experience some momentary discomfort in my arm when blood pressure is taken.

ALTERNATE THERAPY

I do not need to participate in this study for treatment of my blood pressure. If I understand that this is research study and that if I do not wish to participate, there are alternative methods of treatment for elevated blood pressure including other kinds of change in diet, exercise, and prescribed medication.

VOLUNTEER REMOVAL

I do understand that should my blood pressure become elevated beyond safe levels during the course of the study, I will be referred to my physician for treatment of my blood pressure. The Investigator may

discontinue my participation if I am unable to follow the trial rules, have intolerable side effects to the diet, or unexplained laboratory results.

VOLUNTEER'S RIGHT TO REFUSE TO PARTICIPATE OR WITHDRAW

I understand I have the right to ask questions concerning any aspect of this trial at any time. My participation in this research trial is voluntary. I also have the right to withdraw from the trial at any time without penalty. Should I decide to withdraw I must immediately contact Dr. David Harsha at the Pennington Center at 763-0929. Should new significant findings develop during the course of the research which may relate to my willingness to participate, that information will be provided to me.

For any questions involving study participation , I may contact:

Investigator(s): Dr. George Bray (504) 763-2513 or Dr. Frank Greenway (504) 763-2576

Address: 6400 Perkins Rd. Baton Rouge, LA 70808 (same)

To contact Dr. Bray or Dr. Greenway in the event of an emergency please call:
(504) 765- 4644 where a 24 hour physician is available to respond to my questions.

If I have any questions about my rights as a research volunteer, I may contact either Dr. Bray at 763-2513 or the Institutional Review Board (IRB) office at:

Pennington Biomedical Research Center IRB (504) 763-2513

COMPENSATION FOR A STUDY RELATED ILLNESS OR INJURY

Pennington Biomedical Research Center is only a research facility and is not a source for medical treatment.

COST OF PARTICIPATION

I will receive $900.00 for the completion of this trial. If I am an employee of LSU or have been within the past year appropriate deductions will be withheld. All treatments, visits, and food that are a part of the study will be provided free of charge. At my request, my personal MD will be provided the results of all blood pressure and laboratory tests. However, I also understand that from the start of the feeding until the end of the study, the blood pressure and laboratory data will be kept from me unless they indicate the need for medical treatment. All of the data will be available at the end of the 14 week study.

CONFIDENTIALITY

Medical records which identify me and the consent form signed by me, may be inspected by the coordinating center for this national study and may be inspected by staff of the Institutional Review Board (IRB), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), or the Pennington Biomedical Reasearch Center. The results of this research project may be presented at meetings or in publications; however, my identity will not be disclosed in those presentations.

PATIENT'S CONSENT

Having carefully read and understood this consent form and being satisfied that I have had adequate opportunity to ask further questions, my signature indicates I voluntarily consent to participate in the DASH2 study.

I understand that I will be given a copy of this Patient Information and Consent Form.

_____ _____

Patient's signature **Date**

_____

Patient's Social Security Number

_____ _____

Witness **Date**

_____ _____

George A. Bray, MD (Investigator) **Date**

_____ _____

Frank L. Greenway, MD (Medical Investigator) **Date**