

BAYLOR SCOTT & WHITE RESEARCH INSTITUTE
Baylor Scott & White Health and Wellness Center
Dallas, TX

CONSENT FORM AND PRIVACY AUTHORIZATION

PROJECT TITLE: Fruit and Veggies for Health

PRINCIPAL INVESTIGATOR: Dr. Donald Wesson

TELEPHONE NUMBER: (214) 865-3064

INTRODUCTION:

Before you say that you will be in this research study you need to read this form. It is important for you to understand all the information in this form. This form will tell you what the study is about and how it will be done. It will tell you about some problems that might happen during the study. It will also tell you about the good things that might happen for you during the study. When you read a paper like this to learn about a research study it is called "informed consent." The people who are doing this research study are giving you very important information about the study. When you give your consent for something, it is the same as giving your permission. This consent form may contain words that you do not understand. Please talk with someone from the research staff if you have questions. Do not sign this consent form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the form to keep.

You are being asked to take part in this study because you have elevated measures that could increase your risk of developing or progressing chronic kidney disease (CKD).

Why Is This Study Being Done?

This study is being done to evaluate the feasibility and effect of providing fruits and vegetables (F&V) to reduce the risk of developing or progressing CKD.

What is the Status of the Procedures or Techniques Involved in this Study?

Standard approved procedures will be used to investigate the effect of providing fruits and vegetables (control) and fruits and vegetables plus education on how to prepare fruits and vegetables (study). This study involves collecting a small amount of urine that will be tested for protein. You will be asked to complete a questionnaire to collect your contact information and



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specifics about your past medical history. Your blood will be collected by a finger prick. Your blood pressure will be taken with an automated blood pressure device. This study also involves measuring your height with a stadiometer and your weight will be measured with a digital scale. Your waist circumference will be measured with a measuring tape.

How Many People Will Take Part In The Study?

About 140 people will take part in this study worldwide/nationwide. About 140 of these people will take part at this location.

What Is Involved In The Study?

You will be assigned to a F&V Group or a F&V+ Cook Group. Neither you nor your doctor will choose which group you will be in.

You will be asked to complete several questionnaires which will ask you questions about fruits and vegetable eating habits. Once you have completed these questionnaires you will give them to the researcher or his/her staff so that they can review them for their research report.

You will be asked to allow the researcher to collect one drop of blood from you by a finger prick to define your risk of diabetes, CKD and cardiovascular disease.

You will be asked to allow the researcher to collect a urine sample to define risk of developing of CKD.

You will be asked to allow the researcher to measure your blood pressure to define risk of progressing CKD.

You will be asked to allow the researcher to measure your height and weight. These measurements will be used to calculate your body mass index (BMI) to define your risk of being overweight or obese.

You will be asked to allow the researcher to measure your waist circumference to define your risk of developing obesity-related CKD, diabetes, or cardiovascular disease.

You will be asked to take part in a specific group activity. Fruit and Vegetable Only: This group will receive a prescribed amount of free F&V for 6 weeks through pick-up at a farm stand, or direct free delivery. After 6 weekly pick-up/deliveries, participants will be provided vouchers and reminders to obtain F&V at farm-stands for an additional 18 weeks.

F&V + Cook: In addition to free F&V, participants will receive 6 weekly (once per week), group nutrition and cooking education classes based on “The Happy Kitchen/La Cocina Alegra®”



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(Sustainable Food Center, Austin, TX). 6 classes will be led by community health workers and held at the Baylor Scott and White Health and Wellness Center.

How Long Will I Be In The Study?

You will be in the study for 6 weeks of the F&V program. Follow up measures will be taken at the close of the 6 week program and again at 6 months post program.

The researcher may decide to take you off the study if s/he feels that it is in your best interest, if you are not able to follow the rules of the study, if the study is stopped before it is finished or if new information becomes available that indicates it would be best for you to stop being in the study.

You can stop taking part in this study at any time. If you decide to stop taking part in the study, you should let the researcher or his/her staff know so that they can make sure you are safely taken out of the study.

What Are The Risks of The Study?

It may hurt when you are having your blood drawn using a finger prick. There is also a chance that you will have a bruise at the place where the needle is stuck into your finger. There is also a slight chance that the place where the needle is stuck will become infected. It may be uncomfortable to have your blood pressure measured as the automated device will briefly apply pressure to your arm.

What are the Benefits of The Study?

Subjects will benefit from the access to and supply of F&V, educational classes, and cooking instruction. Subjects will also benefit from access to recorded health measures.

What are the Alternatives to Being in the Study?

Your other option is to not be in the study. Being in the study is completely voluntary and you do not have to take part.

What If I am Injured While Taking Part in This Study?

The people doing this research project will do everything they can to make sure you do not get hurt during the project. If you do get hurt, you should tell the researcher or his/her staff and they will help you to get necessary medical care. You or your insurance company may need to pay for



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the medical care. Baylor Scott and White Health, Baylor Scott and White Research Institute and Baylor Scott and White Health and Wellness Center have not set funds aside to pay you money if you are hurt. You have not given up any of your legal rights by signing this form.

What About Confidentiality?

You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on this study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Scott & White Research Institute (“BSWRI”) and your doctors and other health care providers and facilities that have provided services to you, which could include physicians that work for the Scott & White Clinic, HealthTexas Provider Network or Texas Oncology, P.A., Baylor University Medical Center, Scott & White Medical Center – Temple and other health care providers depending on where you have received care (collectively, “Your Health Care Providers”) get your permission before giving any of your health information to other people. There are people who need to review your information to make sure this study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to BSWRI and Your Health Care Providers to give other people information about your health as needed for the research project. These groups include people who work for BSWRI (including the Institutional Review Board), Baylor Scott and White Health, the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. This also includes the following groups of people who are working with the sponsor of the study: National Institute of Health. Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also include notes and other information in your medical records. We may ask for these notes and other information in your medical records from Your Health Care Providers. This means that the records of your care and information about you maintained by Your Health Care Providers may be given to the people mentioned above and, by signing this form, you are agreeing that Your Health Care Providers may release this information to these people .

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for BSWRI and Your Health Care Providers to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in this study.

If you give permission to BSWRI and Your Health Care Providers to give other people information about your health and the other people are not part of the group that must obey the privacy law,



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your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused.

If you change your mind and later want to withdraw your permission, you may do so. You must notify BSWRI in writing at 2001 Bryan St, Suite 2200, Dallas, TX 75201. Please be sure to tell us the name of this study and the PI for this study for which you are withdrawing your permission. BSWRI will provide your withdrawal notice to Your Health Care Providers promptly after BSWRI receives your withdrawal notice. While not required, you should also talk to your PI and Your Health Care Providers and make sure they are aware you are withdrawing your permission. If you withdraw your permission, it will not apply to information that was given to others by BSWRI before you withdrew or to information given to others by Your Health Care Providers before Your Health Care Providers receive your notice withdrawing your permission. If you withdraw your permission, you will no longer be able to take part in this study.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after the study is completed.

Unless permission is withdrawn, this permission will not expire at the end of the study. A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What Are the Costs and Will I be Paid?

There are no costs to you for being in this study and you will be paid \$40 for the time you spend in this study. This payment is to help cover your expenses for coming to this study visit(s). Your payment will be made from Baylor Scott & White Research Institute and is considered taxable income. You must be eligible to be paid in the United States and willing to complete all the necessary tax/legal paperwork to receive this payment.

What are My Rights As a Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason.

Deciding not to be in the study, or leaving the study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.



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All of the people working on the project must be careful not to carelessly harm you. If you are hurt during this project, you have the right to seek legal counsel. Nothing in this consent form takes away that right if you are hurt during this research.

Whom Do I Call If I have Questions or Problems?

If you have concerns, complaints or questions about the study or have a research-related injury, contact the principal investigator Dr. Donald Wesson at (214) 865-3084. For after hours access contact Dr. Heather Kitzman at (214) 865-3082.

For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff, contact the IRB Office at (214) 820-2687 (for NTX Studies)

Statement of Person Obtaining Consent:

I have explained to _____ the purpose of the research project, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part.

Signature of Person Obtaining Consent

Date

Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this research study. You will be asked to give your written consent if you want to be in the study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all the pages in this form. If you cannot read, then someone can read the form to you. Make sure that all your questions about this research project have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ has explained to me the purpose of the research project, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about the research study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research.

Therefore, I agree to give my consent to take part as a subject in this research project.



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Signature of Subject*

Date

Time

Printed Name of Subject



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