ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

MHD in CKD Oral Consent Script and HIPAA Authorization

Introduction

You are being asked to participate in a research study called **Multicultural Healthy Diet in Chronic Kidney Disease.** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the

You can reach Dr. Johns at:

1300 Morris Park Avenue- Block
Bronx, NY 10461
718-430-8913

For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einsteinmed.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by The National Institute of Diabetes, Digestive and Kidney Diseases

My name is Lisandra Villalba, and I work at Montefiore Medical Center/Albert Einstein College of Medicine and would like to talk to you about a research study on Multicultural Healthy Diet in Chronic Kidney Disease.

Why is this study being done?

The goal of this study is to evaluate a culturally-tailored healthy diet among people with kidney disease. This diet is rich in foods which may reduce inflammation in the body and may be beneficial for people with kidney disease. The information from study will help to determine how feasible and safe the diet is for people with kidney disease.

Why am I being asked to participate?

You are being asked to participate in this study because you have kidney disease. You speak English or Spanish. You do not have an organ transplant or plans to start dialysis or move out of New York City in less than 2 months. You do not have special dietary restrictions or a history of high potassium level. You have been asked to participate because your kidney or internal medicine doctor has recommended you to the study. This study will enroll 20 adults at Montefiore Medical Center/ Albert Einstein College of Medicine. The study will last for a total of 2 months.

What will happen if I participate in the study?

If you decide to participate in the study, we will schedule you for an enrollment (baseline) visit where we will ask you to complete surveys and questionnaires, and give you instructions to complete two self-administered dietary intake assessments. After completing the enrollment visit and dietary assessments, all participants will have two sessions with a nutritionist with expertise in kidney disease nutrition. The first (lasting ~ 1hr) will occur about 1 week after enrollment and second (lasting ~ 30 mins) will occur about 4-5 weeks after enrollment. We will ask you to do a blood draw to measure your blood potassium level about 1 week after your session with nutritionist. To obtain the blood sample, we will wipe the skin on your arm with alcohol to clean it. Then, we will insert a small needle into a vein and 1 tube of blood will be drawn, about 1 tablespoon. We will also ask you to fill out surveys, questionnaires, and complete 2 self-administered dietary intake assessments at 2 months.

How many people will take part in the research study?

You will be one of about 21 people who will be participating in this study. **Will I be paid for being in this research study?**

You will receive a total of $100 for participating in study. You will receive $50 after completing the enrollment visit, first nutritionist session, and blood draw. You will receive $50 after completing the assessments at 2 months. In addition, you will receive a $14.50 Metrocard after completing blood draw visit and at 2 months. If you choose to withdraw from the study before completing all visits and assessments, you will be paid only for the visits you completed.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

Taking part in this study will not involve added costs to you. Nutrition counseling will be given free of charge. You and/or your insurance company will have to pay for any costs that are part of your regular medical care. **Confidentiality**

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

Information about your participation in this study will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, the information will be available to all of your providers who participate in the EMR system. The purpose of this entry is to provide research information that has the potential to impact your medical care.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Are there any risks to me?

We do not think there are any physical risks related to participating in this research study.

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

High potassium level

As a safety measure, you will undergo a blood draw to measure your blood potassium level about 1 week after your session with nutritionist. The potassium intake recommended by nutritionist will be low to moderate. While risk of developing a high potassium level from participating in this study will be very low, if a study participant develops a high potassium level,

they will be instructed to discontinue the diet immediately and counseled by Dr. Johns or nutritionist to avoid high potassium foods in their diet.

Blood Draw
Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless “black and blue” may develop. Very rarely, fainting may occur.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include receiving free dietary counseling on a healthy diet.

What choices do I have other than participating in this study?

You can refuse to participate in the study.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and **[**she/he**]** will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

Your participation will end if the investigator or study sponsor stops the study earlier than expected.

Do you have any questions? You may ask me now, or contact Dr. Johns about your questions or problems with this study.

May I begin?

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date
Printed name of the person conducting the consent process	Signature	Date