ALBERT EINSTEIN COLLEGE OF MEDICINE

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called "Multicultural Healthy Diet to Reduce Cognitive Decline & Alzheimer's Disease Risk (MHD)**."** 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.

The researcher in charge of this project is called the "Principal Investigator." Her name is Yasmin Mossavar-Rahmani. You can reach Dr. Yasmin Mossavar-Rahmani at:
Office Address: 1300 Morris Park Ave.
City, State Zip: Bronx, NY 10461
Telephone #: 718-430-2136
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@einstein.yu.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 National Institute of Aging

Why is this study being done?

The purpose of this study is to better understand the relationship between the foods you eat and cognition—our ability to think, including memory. More specifically, we will study whether a diet that is high in anti-inflammatory foods (foods that reduce inflammation in your body) affects cognition, by improving it or delaying its decline.

Why am I being asked to participate?

You were selected because you are an adult within the age range of this study (40-65 yrs of age) and living, working, visiting or attending school in the area where our research takes place. If you agree to take part in this study, you will have tests and examinations to be sure that you qualify for the study and receive orientation on the things you will need to do during the study.

How many people will take part in the research study?

You will be one of about 408 people who will be participating in this study. Albert Einstein College of Medicine is the only site enrolling for this study.

Notice regarding research procedures during Covid-19 pandemic

Please note that the in-person procedures described in this written informed consent are only applicable when there are no restrictions for visiting the Albert Einstein College of Medicine ("Einstein") or attending group sessions at a local community site due to the Covid-19 pandemic. While restrictions are in effect, screening, clinic and group session visits will occur remotely by phone or video conference to the extent possible. At this time we have limited in-clinic visits for body measurements, blood draws and urine collection.

How long will I take part in this research?

It will take you about 27 months to complete this research study. During this time, you will have ongoing responsibilities related to what you eat and drink, self-reporting and brain games at home, as well as a total of 12 study visits to the Albert Einstein College of Medicine ("Einstein").

What will happen if I participate in the study?

Screening Visit 1 (2 hours)

If you are eligible and agree to take part in this research, you will be invited to visit the research offices at the Albert Einstein College of Medicine.

During this visit, you will:

- complete a brief questionnaire,
- receive an explanation of the full study by the study staff
- receive instruction in and have a chance to practice using the smartphone to review your activities, mood and play several brief "brain games"
- learn how to use the smartphone to track foods you eat and drink.

At home between the visits (1 hour per day for 2 days)

Beginning the next morning after the visit, you will be asked over two days to:

- complete a review of your activities and mood
- enter your food and drink intake using the smartphone
- complete a brief survey when you wake up in the morning and before going to bed
- upon receipt of a signal from the smartphone, play brief brain games several times during the 2 days
- answer follow-up questions by phone about the smartphone or study

You should allow about 20 minutes per day for the brain games and 40 minutes for entering your food and drink into the smart phone each day.

Screening Visit 2 (3-5 days after Screening Visit 1, 90 minutes)

During this visit, you will have to:

- return the smartphone.
- complete questionnaires and exercises that involve memory, attention, vocabulary and response speed.
- you may receive a follow-up phone call to complete a few additional questions.

After this visit, we will determine your eligibility to continue to the next part of the study.

If you are determined to be eligible for the main part of the study, we will assign you by chance (like a coin toss) to one of two groups: the Multicultural Healthy Diet group or the Usual Diet group. You and the study doctor cannot choose your study group. You will have an equal chance of being assigned to each group.

<u>If you are assigned to the Multicultural Healthy Diet, going forward in the study, you will:</u>

- follow an anti-inflammatory healthy dietary pattern
- attend four two hour groups sessions on shopping & cooking healthy diet in the first 2 months at Co-Op City or other convenient location (8hr)
- write down foods you eat 3 times/month for 18 months (18 hr)
- receive 16 monthly 20 minute phone calls and/or online program materials from coaches on following diet after the group sessions end. (5 hr, 20 minutes)

<u>If you are assigned to the Usual Diet, you will</u>:

- continue your usual diet
- attend four 2 hr group sessions at Co-Op City or other convenient location on topics related to aging (8hr)
- receive 16 monthly 20 minute phone calls and/or online program materials on topics related to aging (5 hr, 20 minutes)

<u>Clinic Visit #1 (Scheduled for eligible participants after Screening Visit #2, 2 hr)</u>

At this visit, you will:

- undergo cognitive testing at the clinic
- respond to questionnaires about medical history, moods & daily experiences
- have a refresher session on using the smartphone to review your activities, mood and play several brief “brain games”
- have a refresher session on using the smartphone to track foods you eat
- schedule a 30 minute visit for body measurements: blood pressure, blood draw, height, weight, waist/hip circumference, body composition, spot urine collection and eye test.

<u>At home after Visit #1 (1 hour per day for 7 days)</u>

You will be asked to do the following over the next seven days:

- enter your food intake using the smartphone
- complete a brief survey when you wake up in the morning and before going to bed
- play brief brain games five times during the day

- at the end of the 7 days, return the smartphone to the clinic after completing the exercises
- receive randomization assignment to Usual Diet or Multicultural Healthy Diet

Clinic Visit #2 (Scheduled 9 months after Visit #1, 2 hr)

This visit is identical to Visit #1.

At home after Visit #2 (1 hour per day for 7 days)

These activities are identical to at-home activities after Visit #1.

Clinic Visit #3 (Scheduled 9 months after Visit #2, 2 hr)

This visit is identical to Visit #1, except that there will be no blood tests or spot urine collection scheduled after the visit.

At home after Visit #3 (1 hour per day for 7 days)

These activities are identical to at-home activities after Visit #1.

Clinic Visit #4 (Scheduled 9 months after Visit #3, 2 hr)

This visit is identical to Visit #1, except that there will be no blood tests or spot urine collection scheduled after the visit.

At home after Visit #4 (1 hour per day for 7 days)

These activities are identical to at-home activities after Visit #1.

You do not have to commit at this time to returning for any 9 month follow-up visit to participate in this study, and you can decide to withdraw from the study at any time, without penalty.

Overall time commitment if selected for the Multicultural Healthy Diet:

***Total: 74 hr** over a 27 month period*

Overall time commitment if selected for the Usual Diet:

***Total: 56 hr** over a 27 month period*

A description of this clinical trial is 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.

Genetic Testing

Genes are made up of DNA, and have the information needed to build and operate the human body. Your blood or tissue will be tested for genetic changes that may relate to an increased risk of developing Alzheimer's Disease, in you. This is the APOE4 gene and can be tested by a blood test. The information obtained from these tests will include genetic information about you. To protect your identity, we will give your specimen(s) a code number. Genetic factors are inherited and run in families. Since genetic information is shared by family members, the information from these tests may apply to your family members, as well.

The meaning of the results of this genetic research is not known; therefore we will not give you the results of these studies. You should be aware that insurance companies sometimes use information from genetic testing to deny life insurance or disability coverage to applicants. If you decide to participate in this research study, if your insurance company asks, you should state that although you have had a genetic test performed as part of a research study, the test is investigational and has no clinical meaning, and you will not be provided with the results.

Specimen Banking (Future Use and Storage

We will store your specimens and information about you in a "biobank", which is a library of information and specimens (tissue, urine and blood) from many studies. These specimens and information cannot be linked to you. In the future, researchers can apply for permission to use the specimens and information for new studies to prevent, diagnose, or treat disease, including genetic research. Your specimens and information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the biobank and still be part of the main study.
INITIAL ONE (1) OF THE FOLLOWING OPTIONS

_____ I consent to have my specimens and information about me used for future research studies.
_____ I do NOT consent to have my specimens and information about me used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Please indicate your interest in participating in a future study described below.
INITIAL ONE (1) OF THE FOLLOWING OPTIONS:

_____ *I would be interested in being contacted for future studies that are sub-studies of the "Multicultural Healthy Diet Study to Reduce Cognitive Decline & Alzheimer's Disease Risk."*

_____ *I would NOT be interested in being contacted for future studies that are sub-studies of the "Multicultural Healthy Diet Study to Reduce Cognitive Decline & Alzheimer's Disease Risk."*

Will I be paid for being in this research study?

Your time is valuable so we want to provide a token of our appreciation.

You will receive $20 compensation for each of four completed clinic-based assessments (baseline, 9 month, 18 month and 27 month) and $80 for each battery of completed one-week cognitive tests and diet assessments. You will receive a $5 bonus for completing 80% of daily assessments and an additional $10 for completing 90% of all assessments.

If you complete the entire protocol for this study over the 27 month period, you will receive:

($20 X 4 clinic visits) plus ($80 X 4 for brain games/food tracking) = $400.00

Additionally you can receive bonus for completing 80% ($5 bonus) of assessments and additional $10 for completing 90% of assessments. So the maximum bonus you can receive if you complete 90% of assessments is: ($5 +$10) X 4 brain games/food tracking = $60.00

If you complete part of the study, you will receive partial payment depending on what you completed.

To compensate you for travel costs associated with with in-clinic visits, we will cover costs associated with transportation.

Payment will be provided to you shortly after your last visit to the research center. Receipt of payment is contingent on returning the smartphone and charger to our research staff.
If you were not eligible to participate in the study following your trial period at enrollment, you may be invited every 6 months to participate in other studies related to MHD study.

Some researchers may develop tests, treatments or products that have monetary value. 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?

There will be no cost to you to participate in the study. If you are randomized to the healthy diet, you may have additional costs due to the type of food you may have to eat during study participation.

What will happen if I am injured because I took part in this study?

If you believe that you have become ill or been injured from taking part in this study, treatment may be obtained through your regular doctor the treatment center or clinic of your choice. You may contact the researcher, Dr. Yasmin Mossavar-Rahmani, at 718-430-2136 to talk to her about your illness or injury**.** You or your insurance company will be billed for this medical care. Your insurance company may not pay for some or all of this medical care because you are participating in a research study. There are no plans for Albert Einstein College of Medicine to provide free medical care or to pay for research-related illnesses or injuries, or for Albert Einstein College of Medicine to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. By signing this form you will not give up any legal rights.

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.
- If you think you have become pregnant, contact your research study doctor immediately.
- You may carry out all your normal daily activities.

Confidentiality

We will keep your information confidential. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a secure manner and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information and specimens will be kept as long as they are useful for this research.

The only people who can see your research records are:

- The research team and staff who work with them
- The organization that funded the research: National Institute on Aging
- Organizations and institutions involved in this research: Albert Einstein College of Medicine, Pennsylvania State University, University of Pennsylvania, University of Minnesota, National Institute of Health/ National Institute on Aging.
- Connecting Health Innovations LLC
- Groups that review research (the Einstein IRB, and the Office for Human Research Protections.)
- Other institutions that collaborate with MHD investigators may be given portions of your data without information that can identify you.

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

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 was requested or subpoenaed by government agencies or the courts, we will use the Certificate to attempt to legally refuse to provide it. This is 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 that 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 a 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?

Here is a list of the known risks associated with this research:

- Completing questionnaires and making visits to Einstein will require a time investment.
- If you are in the special diet arm, you will likely require an extra investment of time.
- Making ratings on the computer and keeping record of your foods will result in a slight interruption in your daily activities.
- Completing the cognitive exercises may result in eye-strain, slight fatigue, and possible frustration from failing to remember items on a memory test.
- These risks will be minimized by frequent breaks to minimize fatigue, use of large print to prevent eyestrain, and by answering questions you have about your performance
- 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.

- You may not experience any direct benefit personally from participating in this study.
- If you are in the special anti-inflammatory diet arm of the study, you may experience some health benefits
- We hope you will participate because the study may generate important information about foods we eat and cognition.
- Your samples of blood will be used to look at markers of food that are associated with cognition

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. However, some of the information may have already been entered into the study and that will not be removed. The researchers and the sponsor 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 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.

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit and return the study smartphone if it is still in your possession.

Can the study end my participation early?

We will not let you participate in the study any more if you fail to follow the instructions given to you by the researcher. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

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