RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Diet and Dementia Prevention in Ischemic Stroke Patients
Sponsor(s): National Institute on Aging, Washington, D.C.

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

Previous studies suggest that stroke and having a poor diet may increase one's risk of Alzheimer's disease and cognitive decline with aging. The purpose of this study is to conduct a randomized controlled trial to test whether the degree to which changing certain foods you eat can have positive effects on the brain and your thinking.

If you agree to participate in this study, your participation may last up to 3 years and you will be asked to complete a total of 6 study visits (baseline and 3, 6, 12, 24, and 36 months). Each visit will take approximately 2 hours to complete.

During these visits, you will be seen by the research assistants or data collectors for measurement of brain health, blood pressure, body measures, diet, physical activity, health events, medication use, along with a blood draw and spot urine collection. You will also complete a COVID-19 questionnaire at each visit to document potential exposure to COVID-19 and the impact it has had on your health and cognition.

All participants will be randomly assigned to eat either a special diet (this group is called "Coach NOURISH") or your usual diet (this group is called "Self NOURISH") for a period of up to 3 years. We have no control over which group you will be in. Your group assignment is decided by a random process, like a coin flip. Regardless of what group you are in, you will be given education about how to eat healthy and take care of yourself after a stroke. You will talk to a study case manager regularly during the 3 years of the study. The counseling sessions will be audio or video recorded to be sure that the information shared with you is of the highest quality. The audio and video recordings will be destroyed at the end of the study.

Do you agree to have your counseling sessions with the case manager audio or video recorded?

_____ _____ Yes, I agree to have my counseling sessions audio or video recorded.

Initials Date

_____ _____ No, I do NOT agree to have my counseling sessions audio or video.

Initials Date

For the first 90 days, and at no cost to you, meals will be delivered to your home by a well-established meal delivery company that has agreed to provide meals approved by the NOURISH study's lead dietitians. Case managers will help you to choose meals, confirm meal delivery and monitor satisfaction with meals delivered using video communication, like Zoom, or by telephone during the 90 days of meal delivery. You will also be sent newsletters every three months or so with information about how to take care of yourself after a stroke.

To ship and track the meal deliveries, we will share only the following contact information with the meal delivery company:

- Your first and last name
- Your mailing address
- Your telephone number
- Your email address

If you are assigned to the ***Coach NOURISH group*** (the special diet group), you will talk with your case manager every week for the first 6 months of the study, then twice a month beginning in month 7 of the study and continuing until the end of the study. You will be given specific foods every month that your case manager will help you to add to meals you prepare for yourself. You must complete each telephone or Zoom communication with your case manager to receive the specific foods every month.

If you are assigned to the ***Self NOURISH group*** (usual diet group), you will talk with your case manager every week for the first 14 weeks of the study, then once during months 10, 13, 16, 19, 22, 24, 28, 31, 34 and 36. Instead of specific foods, you will be given a $30 gift card after each month of communication with your case manager. You must complete each scheduled telephone or Zoom communication with your case manager to receive the $30 gift card.

You may be invited to participate in a second study that involves brain magnetic resonance imaging (MRI). You will be asked to sign another consent document if you are asked and agree to participate in that study.

There are risks to you for participating in this study.

The risk of participating in the assessments and evaluations is small. A blood specimen will be obtained by an experienced professional trained to perform these blood collections. This procedure involves a risk of slight discomfort, bleeding and bruising at the site the needle enters the body, and in rare cases, fainting or infection. We will be analyzing your blood tissue for certain genes associated with Alzheimer's disease risk.

You may not directly benefit from taking part in this study, but we hope that knowledge gained from this study may be of benefit to people who have suffered a stroke and may be at risk for cognitive decline and Alzheimer's disease. Alzheimer's disease poses a large and growing problem for older adults, and the proposed study offers the possibility of greatly increased understanding of this condition in the future.

This is not a treatment study. Your only other option to participating in this study is not to participate.

<u>Detailed Information</u>: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

<u>Why are you being invited to participate in this study?</u>

You are being asked to participate in this study because you are 55 years of age or older, not cognitively impaired, and you were admitted to one of the medical centers in Chicago for an acute ischemic stroke and discharged home.

How many participants will take part in this study?
Approximately 500 participants are expected to take part in this study (200 participants from Rush University Medical Center, 200 participants from Advocate Christ Hospital, and 100 participants from the University of Chicago).

Does this study involve tissue/blood banking?
Yes, it does. Tissue and/or blood banking is the long-term storage of your samples into a repository (or sample bank). Your samples will be stored by the repository manager at Rush University Medical Center indefinitely or until you request your samples be withdrawn from the repository.

_____ _____ Yes, I agree to have my samples stored in a repository
Initials Date

_____ _____ No, I do NOT agree to have my samples stored in a repository
Initials Date

Does this study involve genetic testing?
Yes, this study involves genetic testing. We will be analyzing your blood tissue for certain genes associated with Alzheimer's disease risk. The use of genetic material in research to study the causes of disease and to help understand how individuals respond to lifestyle or drug treatments is called genetic research. The cells of your body contain a molecule called deoxyribonucleic acid (DNA). DNA is received from your parents and carries a code in the form of genes, which determine your physical characteristics such as the color of your hair and eyes. Ribonucleic acid or RNA for short also acts as a messenger to tell your cells to produce certain features. Just as differences in our genetic codes help explain why we all look different, these differences can also help explain why some people develop certain diseases and others do not. They may also help explain why some drugs are safe and effective for some people but not for others.

What do you need to know regarding the collection of biospecimens?
Biospecimens may include blood, tissue, urine, bone marrow, saliva, cells, etc. In this study, we will collect urine and blood tissue.

Most biospecimens contain DNA. We will not use biospecimens collected as a part of this study for whole genome sequencing, which involves mapping (identifying the location of genes and the distance between them) of all of your DNA.

Will your information or biospecimens be used for research in the future?
Information or biospecimens collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information or biospecimens are shared. Since identifying information will be removed, you will not be asked for additional consent.

_____ _____ Yes, I agree to have my unidentified samples kept for future research.
Initials Date

_____ _____ No, I do NOT agree to have my unidentified samples kept for future research.
Initials Date

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks involving genetic information?
While we believe that the risks to you and your family are very low, we are not able to know all of the risks from taking part in genetic research. Your privacy will be protected to the fullest extent possible. Certain health concerns that affect you and your blood relatives might be found as inherited traits are studied. Even though your genes are unique, you share some of the same genes with your blood relatives. Genetic information is considered health information and is protected under the Health Insurance Portability and Accountability Act (HIPAA) as is your other health information. While very rare, information could be misused by employers, insurance companies and others. For example, life insurance companies may charge a higher rate based on this information. A federal law called the Genetic Information Non-Discrimination Act (GINA) should help lower the risk from unfair health insurance or employment policies. To learn more about the GINA Law, please go to http://www.ginahelp.org/GINAhelp.pdf or ask the study staff.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Neelum Aggarwal and Dr. Christy Tangney, the study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Aggarwal, Dr Tangney and their study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Medical history
- Physical examination and laboratory test results

Dr. Aggarwal and Dr. Tangney and the study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- The Researchers at Advocate Christ Medical Center and the University of Chicago Medical Center;
- The study Sponsor, National Institutes of Health, National Institute on Aging and its representatives, and the Data Safety and Monitoring Board;
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Aggarwal and Dr. Tangney are not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential.

Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Aggarwal at 1750 W. Harrison St, Suite 1000, Chicago, IL 60612 or Dr. Tangney at 600 S Paulina St, Room 716 ACC, Chicago, IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. Minimizing risks to confidentiality is assured by methods used during data collection. Information will be obtained and recorded by participant number and analyzed as such for statistical purposes only. All staff will undergo training that will include strong emphasis on strict confidentiality of all study data. No personal identifier will be stored electronically with your personal information.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This research study can be found by searching for the following Clinical Trial Registry Number (NCT#): NCT04337255. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What are the costs to participate in this study?

There are no costs to you for participating in this research. All costs for the required study visits, examinations and laboratory procedures will be paid by the National Institute on Aging.

Will you be paid for your participation in this study?
We will pay you up to $375 in the form of gift cards over the course of the study if you successfully complete every follow-up visit. Payment for successful completion of each follow-up visit is as follows: $25 gift card for the 3-month visit, $50 gift card for the 6-month visit, $75 gift card for the 12-month visit, $100 gift card for the 24 and $125 gift card for the 36-month visit. You will only be paid for the follow-up visits you complete.

If you participate in the MRI sub-study, you will receive an additional $50 gift card for successful completion of each of the two MRI sessions. Therefore, your total compensation for completing the study will be gift cards that total $475.

What if you are injured as a result of your participation in this study?
If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Aggarwal or Dr. Tangney at 708-660-6463.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call the program manager, Pyone Maung at 312-947-2157 or email her at pyone_maung@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Aggarwal or Dr. Tangney in writing at the address on the first page. Dr. Aggarwal and Dr. Tangney may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature