

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Verbal Consent_Care Partner Phone

STUDY TITLE:

PRINCIPAL INVESTIGATOR:

Researchers at [xx] ... are conducting a research study. To decide if you want to be part of this research, you should understand the risks and benefits so you can make an informed decision.

You have the right to know the purpose of this study, how participants are selected, what will happen during the study, what the possible risks and benefits are, what your other options might be, and what is expected of you as a study participant. You also have the right to know how your personal health information may be used or given to others during the study and after it is finished. This process is called "informed consent."

This consent form gives information about the research study. We will review this consent form with you. There may be words or phrases that you do not understand. Please ask us to explain anything you do not clearly understand. If you would like, we can give you a copy of this consent form to think about or to discuss with family or friends before making your decision. When you feel that you understand the study, and if you choose to participate, we will give you a copy of this consent form to keep.

The word *we* means the study researchers and other study staff.

Who is sponsoring this study?

The funding for this study came from the National Institute on Aging (NIA).

What is the purpose of this study?

The purpose of this study is to get advice on how to be sure that people with memory problems plus other health conditions are taking the right medicines for their needs. We will speak with patients, caregivers, doctors, and other health care workers. We are very interested in getting advice from patients and their caregivers on how doctors should talk about stopping medicines that may have unwanted side effects or are no longer helpful. Stopping medicines that may have unwanted side effects or are no longer helpful could prevent medical problems that are caused by these medicines.

Why are you asking me to take part in this study?

We are asking you to take part in this research study because you may have personal experience with memory problems, you have more than one medical condition, or you are a caregiver.

How many people will be in this study?

We anticipate 20-40 people will be enrolled.

If I agree to participate, how long will I be in this study?

We will ask you to come to one study visit. This study visit will last for 30-40 minutes.

What will happen if I agree to take part in this study?

If you agree to take part in this study, this is what will happen:

- Study team members will call you on a day and time that is convenient for you.
- We will ask for your ideas and suggestions about how doctors can best talk about medicines with their patients.
- We may show you some study information materials and ask you what you think about them.
- We will take notes during the meeting. We will also audio record our conversation to make sure we hear all your feedback. The recording from the meeting may be typed up later. If it is, we will remove any information that could identify you.

What are the possible risks, side effects, and discomforts of being in this study?

We do not anticipate any risks to you from participating in this study. However, talking about memory problems or medical conditions could make you uncomfortable. You may choose not to answer questions you don't want to answer.

Are there any benefits to being in this study?

We cannot predict whether you will receive any direct benefit from being in this study. However, we hope that the results of this study may help other patients in the future.

What are my choices if I do not want to be in this study?

You can choose not to participate in this study.

What if I am injured as a result of being in this study?

This study only involves collection of information and does not involve the use of any drugs, devices, or procedures. Therefore, we do not expect that you would experience any injury.

Am I required to be in this study?

Your participation in this study is completely voluntary. You can choose not to participate in this study. Your decision will not affect your medical care. If you decide to be in this study, you can change your mind at any time without any effect on your medical care or eligibility for future care or membership in.

Will it cost anything to be in this study?

There will be no cost to you to take part in this study.

Will I be paid to be in this study?

You will not be paid for your participation in this study, but you will receive a \$50 gift card as a thank-you for your valuable time and input.

Will my information be kept confidential?

All efforts will be made to keep your personal information confidential. We will not disclose it without your written permission unless the law requires it. Study information about you will be identified only by a unique study ID. No personally identifiable information such as your name or medical record number will be attached to your study information. However, your personal information may be disclosed if required by law.

The following people/organizations may look at and/or copy your research records to make sure the information is correct and to evaluate the conduct of the study:

- Institutional Review Board (a formal group of people that reviews research studies to protect the rights and welfare of participants)
- Food and Drug Administration (FDA); the Department of Health and Human Services (DHHS); or other regulatory agencies involved in keeping research safe for people.
- The sponsor of the study, the National Institute on Aging, and its representatives

If we are required to release information to these people/organizations, we cannot guarantee absolute confidentiality, but every effort will be made to maintain your privacy. Information that would reveal your identity (such as your name) would be removed before the copies are sent outside of.

Your research records will be identified only by a unique study number. The study team will ensure that the link between your name and these study numbers will never be released outside of the study.

Your identity will not be revealed in any publication or release of study results.

What if I have questions?

Any study-related questions, problems or injuries should be directed to the study investigator responsible for the study within
or the study project manager

Questions about your rights as a study participant, comments or complaints about the study also may be presented to the Institutional Review Board for the Protection of Human Subjects,

Verbal Consent:

Do you have any questions about this study? Are you satisfied with your understanding of possible benefits, risks, and alternatives and the voluntary nature of this study?

Do you consent to participate in this study?

Yes_____ No_____ Date_____

You will receive a copy of this form and the Research Participants Bill of Rights.

Name of person obtaining consent: _____

DO NOT REUSE

Research Participants' Bill of Rights

The following rights and privileges are guaranteed to all participants in medical research conducted within Program. If you have questions about these rights, please call the Institutional Review Board at.

Please note that items 5 and 6 below apply to clinical trials and may not apply to the research in which you are participating.

If you participate in medical research, you are entitled to certain rights that include but are not limited to the right to be:

1. Informed of the nature and purpose of the research.
2. Given an explanation of the procedures to be followed in the research and a description of any drug or device to be used.
3. Informed of any related discomforts and risks that can reasonably be expected from participation in the research.
4. Told of any benefits that can reasonably be expected from participation in the research.
5. Informed of any appropriate alternative procedures, drugs, or devices that might be advantageous to you and the relative risks and benefits of these alternatives.
6. If complications arise, informed of the availability of medical treatment, if any, after the medical research.
7. Given an opportunity to ask any questions concerning the research or about the procedures involved.
8. Told that you can decide to withdraw your consent to participate at any time with no effect on your health care benefits or medical care provided by.
9. Given a copy of the signed and dated written consent form.
10. Allowed to decide for yourself whether to participate in research without any force, fraud, deceit, duress, coercion, or undue influence by anyone.