Study Title: Decisions About Cancer Screening in Alzheimer's Disease (DECAD)

ClinicalTrials.gov ID: NCT03282097

Document Names:

1. DECAD Participant Assent

Version Date: 01.06.2017

2. DECAD Informed Consent - Participant

Version Date: 04.28.2022

3.DECAD Informed Consent-Caregiver

Version Date: 04.28.2022

Indiana University Assent to Participate in Research

DEcisions about Cancer screening in Alzheimer's Disease (DECAD)

We are doing a research study. A research study is a special way to learn about something. We are doing this research study because we are trying to find out more about decision aids and how they help caregivers and patients make decisions about cancer testing**.** We would like to ask you to be in this research study.

Why am I being asked to be in this research study?

You are being asked to be in this research study because you have someone assisting you in making medical decisions about cancer testing.

What will happen during this research study?

We want to tell you about some things that might happen if you are in the study. If you agree to participate, we will check your medical records to see if you have had certain cancer tests. We will check your medical record after you have had a visit with your doctor. We will ask you some questions two different times. These questions will be about your health and how you like to make decisions. Each interview will take about 10 to 15 minutes. After your first interview, you will get an educational brochure to look through.

Are there any bad things that might happen during the research study?

Sometimes bad things happen to people who are in research studies. These bad things are called "risks." The risks of being in this study is that someone may know you are a part of this study and sees your medical record information.

You may feel bored or uncomfortable answering the questions. If you do not want to answer the questions you do not have to. You can leave the study any time.

Not all of these things may happen to you. None of them may happen. Things may happen that the researchers don't know about yet. If they do, we will make sure that you get help to deal with anything bad that might happen.

Are there any good things that might happen during the research study?

Sometimes good things happen to people who are in research studies. These good things are called "benefits." The benefits of being in this study might be more discussion about your health.

We don't know for sure if you will have any benefits. We hope to learn something that will help other people some day.

Will I get money or payment for being in this research study?

No, you will not receive anything for participating in the study.

Who can I ask if I have any questions?

If you have any questions about this study, you can ask the researcher. Also, if you have any questions that you didn't think of now, you can ask later. You can do this by Calling Nicole Fowler at 317-274-9021.

What if I don't want to be in the study?

If you don't want to be in this study, you don't have to. It's up to you. If you say you want to be in it and then change your mind, that's OK. All you have to do is tell us that you don't want to be in it anymore. No one will be mad at you or upset with you if you don't want to be in it.

My choice:

If I write my name on the line below, it means that I agree to have my legal representative provide consent to access my medical records for this research study.

_____ _____
Subject's Signature Date

_____
Subject's Name

_____ _____
Signature of person obtaining assent Date

_____
Name of person obtaining assent

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Decisions about Cancer screenings in Alzheimer's Disease (DECAD) Decision Aid-Patient
Indiana University IRB Study #1501278953

ABOUT THIS RESEARCH
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent and authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to gain an understanding about the use of educational pamphlets by caregivers of women with dementia. This study will randomize caregivers to receive one of two different educational pamphlets and is designed to gather information on how caregivers make health care decisions for someone with dementia after reading them.

The study is being conducted by Dr. Nicole Fowler, the Regenstrief Institute and the Indiana University School of Medicine. The study is funded by the Indiana University School of Medicine and the Indiana University Center for Aging Research.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of up to 450 caregivers and 450 patients who will participate in this research.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will do the following things:

Grant permission to the research team to access your medical records.

You will be asked to complete two interviews for the study. Your first interview will take place in person or over the phone. Next, we will ask you to look through a pamphlet after you receive it from us in the mail. Your second interview will happen after you see your primary care doctor. Each interview takes about 10 to 15 minutes to complete.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
While on the study, there are two risks. One, a risk is possible loss of confidentiality. Two, a risk of being bored or uncomfortable answering the questions.

To minimize these risks we will do two things. One, keep all information stored either in locked cabinets in a locked building or on a password protected encrypted computer and server with firewalls. Two, inform you that you have the right to refuse to answer any question that you do not want to answer. The study is completely voluntary and you have the right to leave the study at any time.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

We don't think you will have any personal benefits from taking part in this study, but we hope to learn things that will help other people in the future.

WILL I BE PAID FOR PARTICIPATION?

You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?

The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. This may include accessing your records to find reports of breast cancer screening imaging and/or breast cancer treatment and colon cancer screening and/or colon cancer treatment, or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include:

- Medical orders for cancer screening tests
- Radiology records for cancer screening tests
- Medical history form
- Consultations for oncology
- Radiology films (like X-rays or CT scans)
- Laboratory / diagnostic tests
- Pathology reports
- Pathology specimen(s) and/or slide(s)
- Diagnostic imaging reports

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Indiana University Health Physicians
- IUMG – Primary Care Physicians
- Eskenazi Health
- Indiana Network for Patient Care (INPC)
- Other: _____

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study

- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - Office for Human Research Protections (OHRP)
    - National Institutes of Health (NIH)

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. 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.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information, documents, or specimens that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research when allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Dr. Nicole Fowler, at 317-274- 9021. After business hours, please call the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

In the event of an emergency, you may contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Indiana University Health or Eskenazi Health.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, you can call or email our study team and end your participation. You can also call Dr. Nicole Fowler at 317-274- 9021.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Nicole Fowler, PhD at 1101 West 10th Street, Indianapolis IN 46202. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

The researchers may stop your participation in the study even if you do not want to stop if you move into a nursing home, move out of Indiana, or have a new breast cancer diagnosis.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Research Participant's Printed Name

Research Participant's Address

Printed Name of Legally Authorized Representative (LAR) **Date**

Signature of LAR

OR

Participant's Printed Name **Date**

Participant's Signature

Participant's Address

Printed Name of Person Obtaining Consent **Date**

Signature of Person Obtaining Consent

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Decisions about Cancer screenings in Alzheimer's Disease (DECAD)
Decision Aid-Caregiver
Indiana University Center for Aging Research

You are invited to participate in a research study about the use of decisions aids for caregivers of women with dementia. You were selected as a possible subject because you are a caregiver of a woman 75 years of age or older with a diagnosis of Alzheimer's disease or a related dementia**.** We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Dr. Nicole Fowler, of the Regenstrief Institute and the Indiana University School of Medicine. The study is funded by the Indiana University School of Medicine and the Indiana University Center for Aging Research.

STUDY PURPOSE

The purpose of this study is to gain an understanding about the use of educational pamphlets by caregivers of people with dementia. This study will randomize caregivers to receive one of two different educational pamphlets and is designed to gather information on how caregivers make health care decisions for someone with dementia after reading them.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of up to 450 caregivers and 450 patients who will participate in this research.

PROCEDURES FOR THE STUDY:

If you agree to be in the study, you will do the following things:

You will meet with us at least three times either in person or by phone. The first interview will last about 45 minutes and will include questions about medical decision-making. You will then receive one of two informational pamphlets which we will ask you to read on your own. We will make every effort to meet with you before your loved one's next primary care visit to review the pamphlet. Afterwards we will meet you in person or by phone to complete the second interview that will take about 30 to 45 minutes. The third and final interview will take place 15 months after the second interview. If we are unable to reach you by phone, we will send a written survey to be completed and mailed back in a self-addressed, stamped envelope. This last interview may be audio recorded with your permission. We will follow your loved one's medical records for up to 24months to see if they had a mammogram or breast cancer testing. If we are unable to determine this from their electronic medical records, we may call you.

RISKS OF TAKING PART IN THE STUDY:

While on the study, the risks are:

The risk of possible loss of confidentiality.

The risks of completing the survey are being bored or uncomfortable answering the questions.

To minimize these risks we will:

Keep all information stored either in locked cabinets in a locked building or on a password protected encrypted computer and server with firewalls.

Inform you that you have the right to refuse to answer any question that you do not want to answer. The study is completely voluntary and you have the right to leave the study at any time.

BENEFITS OF TAKING PART IN THE STUDY:

The benefits to participation that are reasonable to expect are you may find some of the educational pamphlets we are using for the study useful for you as provide care for your loved ones in dealing with their illness and their health care.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Instead of being in the study, you have these options: The only option to taking part in this study is to not take part, which you have the right to do so at any time.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results will be stored. Tape recordings will be used by study staff only for the further development of the educational pamphlets. All tape recording will be destroyed seven years after the end of the study.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor, the Indiana School of Medicine Faculty Research, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), who may need to access your medical and/or research records.

A description of this clinical trial will be available on **ClinicalTrials.gov**, as required by U.S. law. 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.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

PAYMENT

You will receive payment for taking part in this study. You will receive a $25 Kroger gift card after completing each interview (Initial Interview, Second Interview (after doctor's appointment), Third Interview (15 months after second interview)).

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher Dr. Nicole Fowler at 317-274-9021. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM) or for an emergency please call the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Healthy Aging Brain Clinic (HABC), ABC Med Home, Indiana Alzheimer's Disease Center (IADC), or any other health organization affiliated with your loved one's health care.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name:_____

Subject's Signature:_____ **Date**:_____
(must be dated by the subject)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____