INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Digital Detection of Dementia (D^3) Studies: Clinical Validation (stage III) Study

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 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 STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with Indiana University.

STUDY SUMMARY

The Clinical Validation study is aimed at early detection of Alzheimer's Disease and Related Dementia (ADRD) through early screening in older adults aged 65 years and older. Possible participants will be identified from primary care practices and the research team will conduct ADRD screening on all eligible patients. ADRD assessments will be performed face to face or via zoom teleconference and may also be performed at the subject's home if the participants prefer. We anticipate early detection of ADRD in some patients enrolled in this study, who undergo the screening process. Patients enrolled in the study who screen positive for ADRD will be referred for further appropriate diagnostic testing if they are interested.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to help older adults ages 65 and older, through early detection of ADRD. Currently, many Americans living with Alzheimer's Disease and Related Dementia (ADRD) never received a diagnosis. For those who receive a diagnosis, it often occurs 2 to 5 years after the onset of symptoms. The inability to diagnose and treat cognitive impairment results in prolonged expensive medical care, but early detection could help persons with dementia and their care partners plan for the future. In addition, if the development of ADRD symptoms management treatment is successful, those detected with dementia early may benefit at a very early stage of ADRD. Also, the current methods of cognitive testing or use of biomarkers for early detection of ADRD cannot be expanded due to low acceptance, their cost,

being invasive in nature and are not accessible by those people who live in rural or underserved areas.

You were selected as a possible participant because you are an older adult aged 65 years and older. The study is being conducted by Malaz Boustani, MD, a geriatric physician at Indiana University School of Medicine. It is funded by National Institute of Health (NIH).

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 400 participants. This study is being conducted at Indiana University site and at University of Miami in South Florida.

WHAT WILL HAPPEN DURING THE STUDY?

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

- You will receive screening for ADRD by answering some questions in form of a questionnaire and interviews
- We will collect some information from you and from your medical record
- A detailed neurological examination will be completed by certified research staff
- You will need a study partner/caregiver who can discuss a shared experience with you. We will not collect personal information on the study partner/caregiver. We can talk with them in person or by telephone.
- When relevant for making diagnosis, we might draw blood for some laboratory tests or Magnetic Resonance Imaging (MRI). The blood draws will be one time draw of 2 tablespoons of blood.
- This is a one time visit type of a study without follow ups. However, you might have another appointment if you are one of those who will require blood draw for labs or MRI
- If you require blood draw or MRI, we will contact you to schedule an appointment and we will provide you with directions to the clinic location for these procedures
- You will not be charged for the labs or MRI

Your doctor will discuss the next steps with you

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

This is a very low risk study. No experimental pharmacological or nonpharmacological intervention will be used in this study. However, in our recent published ADRD screening trial that evaluated the potential benefits and harms of ADRD screening, there were no differences between the screened and the control group in quality of life, depressive symptoms or anxiety.

<u>Assessment questions</u>

But if some of the assessment questions cause discomfort or anxiety, research personnel will be trained to recognize and minimize any discomfort. While completing the survey and interviews, you can tell the researcher that you feel uncomfortable or do not want to answer a particular question.

Blood Draws

There following are possible risks when your blood is being drawn:

- You may experience pain while your blood is being drawn
- You may bruise on your skin after blood draw
- Some people bleed from the site after blood has been drawn
- There may be other risks associated with blood draw which we may not be aware of

Blood draw risks are minimized by using staff members experienced in drawing blood.

Magnetic Resonance Imaging (MRI)

Because radiation is not used, there is no risk of exposure to radiation during an MRI procedure. However, due to the use of the strong magnet, MRI cannot be performed on patients with internal metallic objects such as implanted pacemakers, intracranial aneurysm clips certain prosthetic devices. Please let us know if you have any type implants. If you have any type of implants, a CT scan without contrast may be performed.

Subjects may also experience discomfort due to the tightness of space. Some people feel nervous in tight spaces. If you feel uncomfortable, we can pause and try the MRI again.

Loss of Confidentiality

Loss of confidentiality is another possible risk. Our data management and quality assurance techniques have proven effective in past trials in maintaining confidentiality and all study personnel have completed training in Human Subjects Research and HIPAA standards.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

We hope to learn things which will help scientists in the future through your participation in this study.

There are possible benefits to participation in the study that are reasonable to expect. These are:

- Patients screening may identify a need for referral for appropriate diagnostic services.

WILL I RECEIVE MY RESULTS?

If you participate in this study, we may learn things about you from the study activities that could be important or interesting to you. We will share some of that information with you. Depending on the information, you might need to meet with professionals with expertise to help you learn more about next steps. The study team/study will not cover the costs of any follow-up consultations or actions. We will share the following information with you:

- Any information that might be immediately critical to your health will be shared with you or your health care provider.
- We will share information that may be helpful for your health in the future. Getting this information could help you protect your health, but you will decide to take action or not.
- Information on results will be shared by phone, zoom, or physical letter. If your brain health evaluation indicates a possible cognitive impairment, we will attempt to reach you by phone. If we cannot reach you after three attempts, we will share your results with your primary care physician to ensure you receive them.

HOW WILL MY INFORMATION BE PROTECTED?

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. No information which could identify you will be shared in publications about this 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, NIH, and any state or federal agencies who may need to access your medical and/or research records (as allowed by law). State and federal agencies may include the Office for Human Research Protections (OHRP), and National Institutes of Health (NIH).

A description of this clinical validation study 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.

WHAT FINANCIAL INTEREST DOES THE RESEARCHER HAVE?

Drs. Boustani and Ben Miled have outside interests in DigiCARE Realized, Inc. as shareholders and co-founders of the company. This company seeks to commercialize digital therapeutics which may be developed from the research. We are giving you this information so you can decide if this affects your willingness to participate in this study. If you would like more information, please ask the researchers or study staff.

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 or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?

As a thank you to you for participating, you will receive $50. Your study partner/caregiver will also receive $50. No payment will be made for partially completed interviews.

WILL IT COST ME ANYTHING TO PARTICIPATE?

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

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study contact the researcher, Malaz Boustani, MD, MPH at 317-274-8536 during business hours. If you cannot reach the researcher during regular business hours

(i.e. 8:00AM-5:00PM), please call 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 Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?
If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, please let the research staff know. Your participation may be terminated by the investigator without regard to your consent if your continued participation poses risk to your health. You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

PARTICIPANT'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.

Participant's Printed Name:_____

Participant's Signature:_____**Date**:_____

Printed Name of Person Obtaining Consent:_____

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