VERBAL INFORMED CONSENT FORM SCRIPT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR PARTICIPATION IN A RESEARCH STUDY

Sponsor / Study Title:	**National Institute on Aging / "FY19_Pilot2_Hwang: Pathway to Detection & Differentiation of Delirium & Dementia in the Emergency Department (PD4ED)"**
Principal Investigator: (Study Doctor)	**Dr. Ula Hwang** A convenience sample of total of 100 eligible subjects will be contacted by telepho up and informed telephone assent with a waiver of written consent to participate i surveys and medical record review.
Telephone:	**203-737-7158**
Address:	**464 Congress Ave. Suite 260** **Dept. of Emergency Medicine** **New Haven, CT 06519**

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. When the subject cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the subject rather than the person (legally authorized representative) who is signing and dating this form for the subject. In cases where the subject's representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the subject regains the capacity to consent, informed consent will be obtained from the subject and the subject offered the ability to leave the study if desired.

Key Information:
We are asking you to join a research study.

The purpose of this research study is to assess undiagnosed cognitive impairment by talking to people that have come into the Emergency Department at Yale New Haven Hospital who are over the age of 65. This study will look at the screening and referral process for cognitive impairment in the ED.

Researchers will enroll a total of fifty people that come into the ED at Yale New Haven Hospital between January 2021 and December 2021. Approximately 100 subjects will take part in this study. Subjects participate in a short phone interviews, and asked questions about their health, memory and any outpatient referrals after their ED visit.

Participation will last a total of 3 months. Should you participate, a research assistant will call you twice – today and in a couple of months. The first phone interview is today and takes place 4-6 weeks after your ED visit. The second takes place 3 months after your ED visit. Each call should take no more than 20 minutes.

Risks and Benefits:

For this study, we will collect information about you, your health and the care you recently received in the ED. As with all studies that collect personal information, there is always the possible risk of loss of confidentiality. There is also a risk the questions may make you feel uncomfortable. If that happens at any point during an interview, you can skip the questions or stop the interview altogether. There may be risks that are unknown.

The study may or may not have no direct benefit to you. Instead, we hope the information we gather from this study will help other older patients in general improve care in the ED.

Compensation and Costs:

There are no costs to you and you will not be paid participate in this study.

Your Information:

All your responses are anonymous**.** Only the researchers on this study and those responsible for research oversight, such as the National Institutes of Health, will have access to any information that could identify you. We will only share it with others with your permission or if we must do it because U.S. or state law requires it. We will do many things to protect your information. Data will be stored on secured servers. Data will be stored by subject ID and not with any of your identifiers (like your name). Any linking information we need will be stored separately to prevent any linkage on password protected devices. Any paper research forms will be stored in a locked file cabinet in a secure room with access limited to the study doctor and study staff.

We may share research information for future research, but we will not use your name or anything that might identify you. If we publish any information about the study or talk about it in conferences, we will not use your name. We will not ask you for any additional permission.

Certificate of Confidentiality:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). Any research information, documents, or biospecimens that may identify you cannot be used in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, without your permission. This information that is protected by this Certificate cannot be shared anyone else who is not part of this study. The only exception is if the US federal or state law or government requires it, or you give permission for the information to be released.

Voluntary Participation and Withdrawal:

Taking part in this study is your choice. You can choose to or not to take part. Whatever your decision, this will not have any effect on your future medical care. However, please note that the NIH requires that any information collected up to the point of your withdrawal cannot be removed from the study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with [Name of the study site hospital]. You do not

give up any of your legal rights by giving your verbal agreement to participate. Please feel free to ask about anything you don't understand.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

Alternatives to Participation:
This study is for research purposes only. The only alternative is to not participate in this study.

New Findings:
Any new important information that is discovered during the study that may influence your willingness to continue participation in the study will be provided to you.

Whom to Contact About This Study:
During the study, if have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subjects, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00048377.

Authorization to Use and Disclose Protected Health Information:
The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule.

The specific information about you and your health that we will collect, use, and share includes:

- Information from your electronic health records, such as medical history, diagnoses, medication,

- Referrals from the Emergency Department
- Research study information:
    - The entire research record and any medical records held by the study site created from January to December 2021
    - Attempted phone calls to reach you made as part of this research

Who will have access to your data:

- The research team, including the study doctor, study coordinators, and personnel responsible for the support or oversight of this study.
- The U.S. Department of Health and Human Services (DHHS) agencies and the NIH.
- Representatives from the study site and the Institutional Review Boards at Advarra and the study site (the committees that review and monitor research on human subjects), who are responsible for ensuring research compliance.

These individuals are required to keep all information confidential. We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule.

By giving permission for the use of your health information, you are allowing researchers to use your information described we just described for this study. This is to make sure the research information is available to those who may need it for research purposes. If you decide not to give your permission, you will not be able to take part in the study. You always have the right to review and copy your health information in your medical record.

The authorization to use and disclose your health information collected for this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by writing to the study doctor and her information that we gave at the start of this discussion.

Statement of Authorization
Do you have any questions?

If speaking with subject:
Do you agree to the use and disclosure of your protected health information? Y/N

If speaking with legally authorized representative:
Do you want to authorize the use and disclosure of (subject name)'s protected health information? Y/N

_____ _____
Printed Name of the Person Conducting the Authorization Discussion

_____ _____
Signature of the Person Conducting the Authorization Discussion Date

Statement of Consent
Do you have any questions?

If speaking with subject:
Do you want to participate in our research study? Y/N

If speaking with legally authorized representative:
Do you authorize (subject name) to participate in our research study? Y/N

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date