Compound Authorization and Consent for Participation in a Research Study

Yale School of Medicine

Study Title: Feasibility of the Elder Mistreatment VOICES Screening Tool

Principal Investigator: Fuad Abujarad, PhD
Department of Emergency Medicine
Yale University School of Medicine
464 Congress Ave, Suite 260
New Haven, CT 06519
(203) 737-5088

Please note: If you are a legally authorized representative reading this form on behalf on the subject, all procedures described in the form apply to the subject only.

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to test the feasibility of the VOICES tool.
- Study activities will include: use the VOICES Tool on a tablet in the presence of a researcher.
- The session will be videotaped for note-taking purposes.
- There may be some emotional distress risks from participating in this study.
- The study may have no benefits to you; however, your feedback may benefit the project and future users of the tool.
- At the beginning and at the end of the session you will be asked to complete a brief survey.
- Taking part in this study is your choice. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with Yale University.
- If you are interested in learning more about the study, please continue reading. Ask the study staff questions about anything you do not understand.
- If you agree to be in the study, we will give you a copy of the informed consent to keep.

Why is this study being offered to me?

We are asking you to take part in a research study because you are an English-speaking older adult age 60 or older. We plan to have 80 evaluation sessions with users like you.

Who is paying for the study?

The Claude D. Pepper Older Americans Independence Center at Yale School of Medicine, which is funded by the National Institute on Aging / National Institute of Health (NIH).

What is the study about?

The purpose of this study is to enhance a tablet-based health tool to screen for elder mistreatment. We hope that this tool will empower older adults to be their own advocates.

What are you asking me to do and how long will it take?

If you agree to participate, you will be asked to answer a demographics survey to learn more about you. Then, you will be asked to use the tool. Then, you will be asked about your opinion

on the tool through survey questions. At the end of the session, you will be asked to complete a brief survey. We will also record some basic health information from your medical record.

We think that the study will take 45-60 minutes of your time.

Are there any risks from participating in this research?

If you decide to take part in this study, you may experience emotional distress from the sensitive content of the discussion.

We do not expect any physical risks from taking part in this study. We will be asking questions about using a tablet, and the content of the tablet.

A potential risk to participants is the risk of a false positive, in which a participant who is not currently experiencing abuse is incorrectly identified as being at high risk for elder mistreatment from the questions asked. These participants and/or caregivers are at risk of harm from false accusation of mistreatment.

Identifying possible mistreatment can increase your risk of physical and emotional harm, or neglect. We will take all measures needed to lessen these risks. We are required to report any suspicion of mistreatment to your nurse.

The clinic, protective services for the elderly program, law enforcement, and the courts have systems in place to help keep you safe. If you feel that you are in urgent danger, your clinician will create a safety plan until a more permanent solution can be found.

It is important to know that recognizing mistreatment may lead to harm from the caregiver or loss of the caregiver. In some cases, the caregiver may be arrested. Identification of mistreatment may also lead to you being discharged to a long-term care or skilled nursing facility.

Answering personal and sensitive questions can make you feel anxious and uncomfortable. You may be distressed while, or after using the tool.

If you identify as a victim of elder mistreatment the research staff will notify your clinician at Yale Internal Medicine Associates (YIMA) to decide on the best approach to handle the case and if further action is needed.

There is the possible risk of loss of confidentiality.
There may also be risks of which we are not currently aware.

How can the study possibly benefit me or others?

Taking part in this study can give you a better understanding of what mistreatment is. Having a better idea of what mistreatment is can increase your emotional and physical health, your safety, and quality of life. Being in the study may also help us improve the safety of others in the future.

Are there any costs to participation?

You will not have to pay for taking part in this study.

Will I be paid for participation?

Yes, we will use a $75 Bank of America pre-paid debit card to provide the payment for taking part in the study. You will need to activate the card over the phone or via Internet.

You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What happens if I say: NO, I do not want to be in the study?
You can stop being in the study at any time.
You will not be penalized.
The care you get from your doctor will not change.
No one will treat you differently.

What are my alternatives?
Your alternative is to not take part in the study.

What should I do if I want to be in the study?
You will read the consent information on the iPad. By agreeing to the information and signing your signature on the iPad, you are saying that you agree to participate in the study.

Do I have to participate?
No, you do not have to participate in this study if you do not want to.

How will you keep my data safe and private?

Researchers are required by law to protect the privacy of your information. All health-related information that we gather about you for this research study will be kept in a locked cabinet and will remain confidential. The cabinet can only be opened using password-protected data entry. Only representatives from the National Institutes of Health, members of the research staff and researchers who have received the approval of the Human Investigation Committee (HIC) will know your identity. When the results of future research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent is obtained.

The health-related information that we gather about you in this study is personal. Your information is also known as protected health information (PHI). All reasonable efforts will be made to protect the confidentiality of your PHI. Your PHI may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Even with these protections, there is a possibility that information about you could be used or released in a way that it will no longer be protected.

What Information Will You Collect About Me in this Study?
Your PHI 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. Also, if you have any questions about the Privacy Rule and your rights, you can speak to the Yale Privacy Officer at 203-432-5919.

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

- The entire research record and any medical records held by the YIMA through December 31, 2022.

- Information obtained during this research about any referrals made to Protective Services of the Elderly.

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of this study.
- Co-Investigators and other investigators.
- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Health care providers who provide services to you in connection with this study.
- Others authorized to monitor the conduct of the Study

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. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you, or be used as evidence, for example, if there is a court subpoena, without your consent. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure; if you have consented to the disclosure; or if it is used for other research, as allowed by federal regulations protecting research subjects. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of cases of suspected elder abuse.

The Certificate cannot be used to refuse a request by National Institute on Aging/NIH which is funding this project if it is needed for auditing or program evaluation. A Certificate of Confidentiality does not prevent you from giving permission to release information about yourself or your involvement in this research. 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.

Why must I sign this document?

By agreeing to the information in this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record. You do not give up any of your legal rights by agreeing to participate.

What if I change my mind?

The permission to use and share your health information collected during your time taking part in this study will never expire. However, you may withdraw or take away your permission at any

time. You may withdraw your permission by telling the study staff or by writing to *Fuad Abujarad, PhD. 464 Congress Ave, Suite 264-J* at the Yale University, New Haven, CT 06520.

If you withdraw, you will not be able to stay in this study. The care you get from your doctor outside this study will not change. No new health information from you will be taken after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with the Yale-New Haven Health System or Yale University.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand. If you have questions later or if you have a research-related problem, you can call the Principal Investigator, **Fuad Abujarad, PhD, at (203) 737-5088.**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

Authorization and Documentation of Consent:

Your signature below indicates that you read and understand this consent form and the information presented and that you agree to be in this study.

We will give you a copy of this form for your records.

Participant Name (print)	Participant Signature	Date
Legally Authorized Individual Name (print)	Legally Authorized Individual Signature	Date
Person Obtaining Consent (Print)	Person Obtaining Consent Signature	Date

APPROVED BY THE YALE UNIVERSITY IRB 1/4/2022