IRB Protocol # 2000030574

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE –Saint Raphael Campus Emergency Department

Study Title: **Feasibility of the VOICES Elder Mistreatment Screening Tool**

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Research Study Summary:

- Please take your time considering if you want to take part in this study.
- The purpose of this study is to get your feedback on using the VOICES computer program.
- Study activities include: Using the VOICES computer program on a tablet in the presence of a researcher.
- There may be some emotional distress risks from participating in this study.
- Your feedback may benefit the project and future users of the program.
- You will be asked to complete two brief surveys before and after using the program.
- 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 want to learn more about the study, please continue reading. Ask the Researcher questions about anything you do not understand.

What is involved in this study?

What happens if I say "YES, I want to be in the study"?
If you agree, you will be asked to participate during your visit at the Saint Raphael Campus Emergency Department today.

How long will the study take?
The study will take an additional 25-40 minutes of your time and will be completed today. Participation will not make your stay at the emergency department any longer.

How many patients are expected to take part in the study?
About 80 patients will be included in this study.

What is the study about?
The mistreatment of older adults is a serious and widespread public health problem. The purpose of this study is to help older adults learn about different kinds of mistreatment and to ask you questions about mistreatment on the iPad.

What is involved in the study?

1. We will obtain informed consent.

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2. We will ask you to complete a demographics survey to learn more about you.
3. We will ask you to use the iPad to test a new computer program that screens for elder mistreatment.
4. We will ask you to complete a survey about your experience using the program.

You will be asked questions related to different types of mistreatment, such as: Neglect and abandonment, financial exploitation, emotional abuse, physical abuse, and sexual abuse.

If the questions you answer on the iPad mean that you may be mistreated, the research assistant will talk to the attending doctor who will come in and talk to you to learn more about your experience. This may require a report to the Protective Services for the Elderly. A report may cause risks as described on the next page.

Who is paying for the study?
The National Institute on Aging of the National Institutes of Health.

What are my risks if I take part in the study?
The direct medical risks involved in this study are very small.

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 care team.
Saint Raphael Campus Emergency Department, 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 care team will create a safety plan until a more permanent solution can be found. If you wish to disclose mistreatment, the Research Assistant will stay with you until a member of your care team comes in.

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 us feel anxious and uncomfortable. You may be distressed while, or after using the tool.

The Research Assistant will give you a brochure on resources that can offer help with mistreatment. These items can be kept with study staff until you leave the Emergency Department if you do not want anyone else to see them.

There is a risk that the privacy of your personal information can be compromised. To lower this risk, you will be labeled by only a study number. All study-related information will be stored securely and only people who are part of the study can view it. All electronically stored data will be encrypted, and password protected.

Other Risks
As with all research, this study may involve risks that are currently unknown.

What are my benefits if I take part in the study?
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.

Will I be paid for my time?

Yes, we will give you:

- $75 gift card

If you participate fully in the study and complete the survey.
We will use a Bank of America pre-paid debit card to provide the payment for taking part in the study. You will receive the card directly after participating in the study. You will need to activate the card over the phone or online.

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.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, if you are being hurt or if you hurt someone else.
All information collected about you will be kept in a secure, password-protected database and locked cabinet that is only accessible by the research team on this study. Identified data will be destroyed in 2 years and the de-identified data will be destroyed in 5 years.

When we publish the results of the research, we will not use your name. If we want to use your name, we will ask you for your permission.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission or require additional informed consent from you or a legally authorized representative.

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 Yale New Haven Hospital.
- 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:

- Members of the research team 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, without your permission. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research. The exception to this Certificate is if there is a federal, state, or local law that requires disclosure; if you have given permission to the disclosure; or if it is used for other research. 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 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.

We will also share information about you with other researchers for future studies, but we will not use your name or any other identifiers.

Why must I sign this document?

By signing this form, you will allow researchers to use and share your information described above for this research study. This is to make sure 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.

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 your permission, 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.

Voluntary Participation and Withdrawal

This study will be done during your visit at Saint Raphael Campus Emergency Department. This study may also be stopped, or your participation ended at any time by your doctor, or study principal investigator without your consent.

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). You do not give up any of your legal rights by signing this form.

To withdraw from the study, you can call a member of the research team (203-737-4498) at any time and tell them that you no longer want to take part. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits. Your decision will not affect your future relationship with the Yale School of Medicine or Saint Raphael Campus Emergency Department.

What will happen with my data if I stop participating?

Your data collected up to the point of withdrawing from the study will remain with the study and will be unable to be withdrawn. No data will be collected from you after stopping participation.

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) 737-5788.**

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.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorization and Permission

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

Person Obtaining Consent (Print)	Person Obtaining Consent Signature	Date