Title: Virtual cOaching in making Informed Choices on Elder Mistreatment Self-Disclosure (VOICES)

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Document: Protocol (amended SAP separately submitted)

HRP-503B – BIOMEDICAL RESEARCH PROTOCOL
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Protocol Title: Virtual cOaching in making Informed Choices on Elder Mistreatment Self-Disclosure (VOICES)

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(*If applicable***) Clinicaltrials.gov Registration #:** NCT03834870

INSTRUCTIONS

This template is intended to help investigators prepare a protocol that includes all of the necessary information needed by the IRB to determine whether a study meets approval criteria. **Read the following instructions before proceeding:**

1. Use this protocol template for a PI initiated study that includes direct interactions with research subjects. Additional templates for other types of research protocols are available in the system Library.
2. If a section or question does not apply to your research study, type "Not Applicable" underneath.
3. Once completed, upload your protocol in the "Basic Information" screen in IRES IRB system.

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SECTION I: RESEARCH PLAN

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested.

The purpose of this study is to develop an interactive tool to screen for Elder Mistreatment (EM) in the emergency department. EM is a major public health problem with prevalence estimate ranges from 7.6% to 12.7% among older adults. EM causes serious adverse outcomes for its victims including injury, increased service utilization, mental distress and increased mortality. A major barrier in overcoming EM is the inability to accurately identify EM victims. It is estimated that only 1 in 24 cases become known to authorities. This is problematic as older adults are not likely to report that they are being mistreated. To improve the screening for EM and promote self-disclosure we will study the Feasibility of Virtual cOaching in making Informed Choices on Elder Mistreatment Self-Disclosure (VOICES). The overarching aim of this project is to develop VOICES that runs on tablet and is used by older adults to screen for EM. VOICES will utilize virtual coaching, interactive multimedia libraries (e.g. graphics, video clips, animations, etc.), techniques form electronic screening for intimate partner violence, and brief motivational interviewing designed to enhance identifying EM among older adults. This project includes developing new screening framework, as well as a study to examine the feasibility of complex interventions in real-world settings.

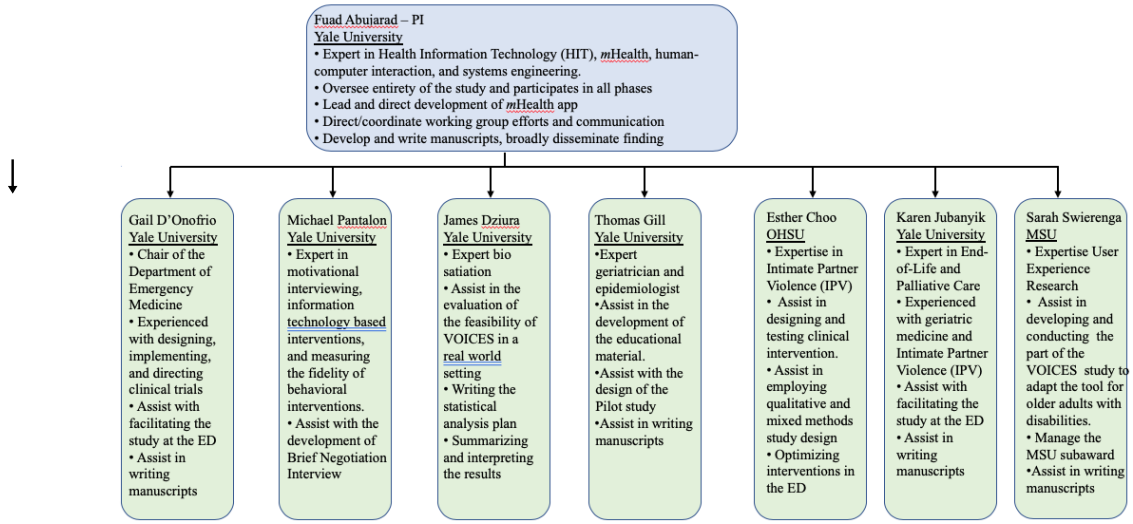
The scientific aims are:

Aim 1. Tool Development: To develop and refine the interactive VOICES tool, which will promote self-identification and self-disclosure to increase reporting of EM at point-of-care in the ED setting.

Aim 2. Feasibility Study: To conduct a feasibility study (N= 800) examining the use of VOICES in a busy ED.

Aim 3. Exploratory Aim: To perform a preliminary evaluation of the accuracy of VOICES as a screening tool in correctly classifying EM cases that were referred to Adult Protective Services (APS).

Organization Structure with Expertise/Role Contribution and Communication Pathways



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2. **Probable Duration of Project:** State the expected duration of the project, including all follow-up and data analysis activities.

   4 Years

3. **Background:** Describe the background information that led to the plan for this project. Provide references to support the expectation of obtaining useful scientific data.

   Magnitude of Problem: Elder mistreatment (EM) is a major public health problem with prevalence estimate ranges from 7.6% to 12.7% among older adults.[1,2] We have systems in place, such as Adult Protective Services (APS), specifically designed to support older adults who have been subjected to mistreatment. However, it is estimated only 1 in 24 cases of EM become known to authorities.[1,3] This means the vast majority of older adults subjected to EM are going without services that could help stop the mistreatment. If we want to prevent this trend of failing to connect victims of EM from turning into a health inequity, more research is needed to examine the complex causes and consequences of elder mistreatment to inform the future design of evidence-based guidelines on screening for individuals at risk of mistreatment in the older adult population. [2,4-8] Therefore, we will study the feasibility of Virtual cOaching in making Informed Choices on Elder Mistreatment Self-Disclosure (VOICES), as a strategy for increasing identification of victims of EM.

   Empowering Older Adults with tools to help them self-identify and self-disclose EM is significant: There is a literature gap in the research to support older adults in making decisions about self-disclosure (informing others about the EM experiences) of mistreatment. Victimized older adults often are not likely to disclose that they are being mistreated, despite having a general understanding of what constitutes mistreatment behavior.[4] There are several perceived barriers to self-disclosure that limit help-seeking behaviors of older adult victims. These perceived barriers include fear of nursing home placement, fear of losing autonomy, and fear that if the abusive caregiver is fired, there would be no one to take care of them. There are also concerns about getting an abusive family member in legal trouble. Importantly, some of these perceived barriers are based on stigma and misunderstanding of how the APS response works and are actually rare outcomes of seeking help for EM. Additionally, most older adults say if they were a victim and were to ask for help they would go to a family member as they aren't aware of the professional services available to them. VOICES will close this gap by integrating the best available evidence from multidisciplinary fields to relay the fact that mistreatment is rarely an isolated incident and it usually escalates in severity and intensity over time. In addition, it will educate older adults on common misunderstandings of the EM response processes, that are usually the main barriers to self-disclosure.

   Barriers to Effective EM Screening: All efforts-to-date are focused on increasing identification of EM victims by educating healthcare professionals and developing screening tools to be administered by professionals with limited input from older adults. Provider performed screening processes are important, however, the alternative approach we propose seeks to include the older adults in the screening process. We are aiming to empower them to be their own advocates and to be able to scale to the increase in demand for such service since 25% of the U.S. population will be age 60 or older by 2030.[5] Additionally, it was reported that healthcare providers generally rely on patient self-reporting.[6] Integrating Health Information Technology (HIT) into point-of-care visits for screening, brief intervention, and referral to APS addresses provider barriers of time, training (by provider prompts), resources (by automating the screening processes), and satisfaction (a senior-friendly tool).

   ED Visit for EM Screening: In other areas of mistreatment research such as intimate partner violence (IPV) and child abuse and neglect, the ED is the standard catchment area and the health care providers are gatekeepers for screening for all types of mistreatment.[7-9] Older adults subject to EM frequently have high rates of medical co-morbidities and are more likely to present to healthcare systems than any other service system. [10-13] For most of these victims the ED visit could be the only opportunity for them to get help.

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Furthermore, Fulmer reported that it is feasible to implement health care provider based-protocol in a busy ED.[14] The impact of VOICES can help identify those who do not, will not, or cannot speak on their own behalf and be their own voice.

HIT Success in Screening IPV and Child Abuse: Advances in computer-based IPV screening at the ED has been demonstrated to produce significantly higher rates of reporting (19% with the tool vs. 10% with a paper survey vs. <1% usual ED care) and has made routine screening for high-risk activities easier to report.[15] Other studies show that computer-based tools for instances of IPV among women ED patients increased the rates of domestic violence discussion between patient and physician (56% vs. 45%), disclosure (14% vs. 8%), and services provided (8% vs. 4%).[16] Digital tools which offer the opportunity to confidentially self-disclose risky or stigmatize behavior or treatment significantly increase the opportunity of identification.

Older-Adults Centered-Framework: Little has been done to support older adults in making decisions about self-disclosure of victimization or to support their help-seeking behaviors. This study is innovative because it focuses on the older adults themselves. This project will instigate a paradigm shift by being the first to put the EM screening process in *the hands of the actual older adult patient*, rather than the healthcare provider, through the use of a patient-centered virtual-coaching digital health app. Currently, only patients with clear signs of abuse and neglect get the in-person screening from their provider or social worker. One of the innovations, in our approach includes: *standardization* of intervention delivery and greater *efficiency* and use of limited resources in U.S. EDs. The *anonymity* supported by the tool on tablets is expected to motivate more patients to self-disclosure of sensitive or taboo subjects. In addition, we believe older adult's input is vital to understanding this sensitive topic, therefore we included *three* older adults on our research team as **Co-researchers**. An important innovative aspect of this proposed framework is that it is easily modifiable to create culturally appropriate versions and easily replicable in other care settings. Although the first version will be in English, the software architecture and development techniques will allow us (with minimal effort) to produce multilingual versions of VOICES (e.g. Spanish). The language adaptable screens and the automated text-to-speech models will be able to produce text and audio in different languages. We are also hoping to create a version of the tool designed specifically for patients that are blind, have low vision, are deaf, or are hard of hearing.

Innovative use of the Brief Negotiation Interview (BNI): This is a specialized "brief intervention" for the medical setting based on motivational interviewing techniques. The BNI has been effective in promoting a variety of positive *help-seeking* behavior changes. In this project, the purpose of the BNI is to assist patients to self-disclose experiences of abuse and/or neglect. Patients who screen with *suspicion* of EM and do not want to self-disclose EM to their providers will receive an automated BNI to motivate them to self-disclose. VOICES is innovative in delivering the BNI with the virtual coach. By using tablets, BNI, and virtual coaching VOICES is a complete process of screening and intervening, not just a screening tool.

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2. Wiglesworth A, Mosqueda L, Mulnard R, Liao S, Gibbs L, Fitzgerald W. Screening for abuse and neglect of people with dementia. *Journal of the American Geriatrics Society.* 2010;58(3):493-500.
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7. Ziminski CE, Phillips LR, Woods DL. Raising the Index of Suspicion for Elder Abuse: Cognitive Impairment, Falls, and Injury Patterns in the Emergency Department. *Geriatric Nursing.* 2012;33(2):105-112.
8. Fulmer T, Paveza G, Abraham I, Fairchild S. Elder neglect assessment in the emergency department. *Journal of Emergency Nursing.*26(5):436-443.
9. Beach SR, Carpenter CR, Rosen T, Sharps P, Gelles R. Screening and detection of elder abuse: research opportunities and lessons learned from emergency geriatric care, intimate partner violence, and child abuse. *Journal of Elder Abuse & Neglect.* 2016;28(4-5):185-216.
10. Rosen T, Bloemen EM, LoFaso VM, Clark S, Flomenbaum NE, Lachs MS. Emergency Department Presentations for Injuries in Older Adults Independently Known to be Victims of Elder Abuse. *The Journal of Emergency Medicine.* 2016;50(3):518-526.
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12. Dong X, Simon MA. Association between elder abuse and use of ED: findings from the Chicago Health and Aging Project. *The American Journal of Emergency Medicine.* 2013;31(4):693-698.
13. Rovi S, Chen PH, Vega M, Johnson MS, Mouton CP. Mapping the elder mistreatment iceberg: U.S. hospitalizations with elder abuse and neglect diagnoses. *J Elder Abuse Negl.* 2009;21(4):346-359.
14. Fulmer T, Paveza G, Abraham I, Fairchild S. Elder neglect assessment in the emergency department. *Journal of Emergency Nursing.* 2000;26(5):436-443.
15. Rhodes KV, Drum M, Anliker E, Frankel RM, Howes DS, Levinson W. Lowering the threshold for discussions of domestic violence: A randomized controlled trial of computer screening. *Archives of Internal Medicine.* 2006;166(10):1107-1114.
16. Rhodes KV, Lauderdale DS, He T, Howes DS, Levinson W. "Between me and the computer": Increased detection of intimate partner violence using a computer questionnaire. *Annals of Emergency Medicine.* 2002;40(5):476-484.

4. **Research Plan:** Summarize the study design and research procedures using non-technical language that can be readily understood by someone outside the discipline. **Be sure to distinguish between standard of care vs. research procedures when applicable and include any flowcharts of visits specifying their individual times and lengths**. Describe the setting in which the research will take place.

The purpose of this study is to develop the tool "VOICES" and pilot it in the ED setting. This study will utilize best practices, advances, and innovations in the design and development of digital health tools. It incorporates evidence HIT research and lessons learned from evidence-based IPV practices to build a tool that will increase *help-seeking* behaviors associated with better patient outcomes. As an easy-to-use senior-friendly HIT tool, VOICES will run on an iPad and the information and messages are displayed on the screen and spoken through headphones for patient privacy. We will build VOICES to promote help-seeking behaviors among victims of EM by promoting self-identification of victimization and supporting decisions regarding self-disclosure to increase reporting of EM. We will conduct three focus groups to enhance the initial concept and improve the content of the tool. The first focus group will have four older adult participants, two caregivers, two ED providers, and two ED social workers. The second and third focus groups will have 6-8 older adult participants in each. Participants for the focus group will be English speaking and age 60+ and one of the focus group will also include two caregivers, two ED providers, and two social workers from the YNHH-ED. They will be asked questions about what features are important when designing a mistreatment screening tool for older adults? They will also be asked how should the educational content be designed to help motivate older adults? At the end of the focus group session, participants will be asked to complete a brief survey. It will be completely voluntary, and all surveys are anonymous. We will have an envelope at designated area in the room from the focus group where the participate can leave their survey. Surveys will be stored in a locked cabinet in our locked office. Participants will be told that their information is confidential. Participants will be compensated with a $30 gift card. In our approach for Aim 1, we make a

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clear distinction between the content development and the App development. In Aim 2, we will conduct a study with eight hundred (N=800) eligible participants in order to evaluate the feasibility of implementing this innovative screening process into the ED with older adults. We will conduct the feasibility study across five important areas including: acceptability, demand, implementation, practicality, and limited efficacy. In Aim 3, we perform a preliminary evaluation of the accuracy of VOICES as a screening tool in correctly identifying EM cases that were referred to APS. Finally, we will analyze the data, disseminate findings, and plan a study to test the effectiveness of VOICES in more diverse, multilingual, and multi-center settings throughout the country that allows for assessment of impact on outcomes.

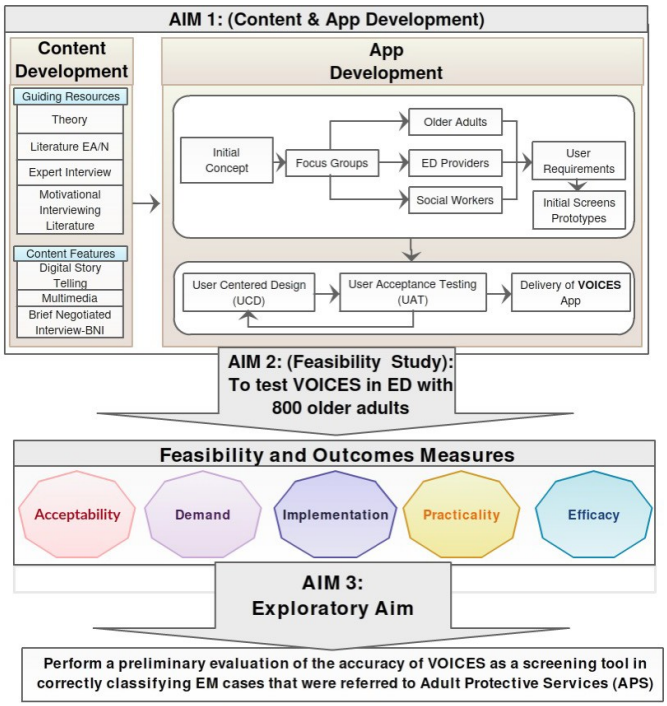

Figure 2: Project Design and Methods

Ethical issues and the unique challenges. We pay special attention to the ethical issues and the unique challenges of EM research and to consenting and enrolling the elderly in our study. We designed a detailed process on how to evaluate capacity, determine competence, and obtain informed consent from older adults. Evaluating the capacity of the participants to understand the purpose, risks, benefits, confidentiality, and privacy associated with this study is vital for valid informed consent. We will use standardized criteria to determine if the potential participant is capable of providing consent. Members of the study team who are responsible for participant recruitment and consent will be highly trained in obtaining informed consent. They will receive training by the Yale Program on Aging in determining capacity to consent in aging populations. Ability to provide informed consent will be assessed using the Abbreviated Mental Test 4 (AMT-4) to assess cognitive status designed to assess decision-making capacity for research participation according to NIH standards. Additionally, we will employ evidence-based practices from the fields of IPV and geriatrics to correctly address these challenges. While at the initial stages in our research, we will focus on older adults who are alerted and oriented, our future plans include patients suffering from cognitive impairments. We are only excluding them at this early stage of the research, to demonstrate proof of concept through a traditional highly controlled research design. This sequencing approach is in line with the NIA stage model for behavioral interventions.

AIM 1: App Development: To develop, test, and refine the interactive VOICES which will promote self-identification and self-disclosure to increase reporting of EM at the point-of-care setting.

We will build the tool VOICES to promote help-seeking behaviors among victims of EM by promoting self-identification of victimization and supporting decisions regarding self-disclosure to increase reporting of EM. In the software development, we will ensure that VOICES has a *senior-friendly, self-driven*, and *step-by-step* interface that seamlessly engages *seniors* in the screening process. The way older adults use technology is different, and VOICES will satisfy the highest standard for usability, accessibility, and acceptability as stated in "Web Content Accessibility Guidelines (WCAG) 2.0", to ensure effectiveness, efficiency, and satisfaction. We will develop a digital informed consent process that pays special attention to the ethical issues and the unique challenges posed by conducting EM research. This digital informed consent process will cover all aspects of the consent and utilize multimedia, animation, audio and visual components to enhance the participants' understanding of the study. The consent process will be performed on an iPad, and developed with the same user-friendly and target population

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specific approaches used with VOICES. Moreover, we will implement comprehensive security strategies that will guarantee the confidentiality and privacy of the patient and clinical information.

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The VOICES system initial concept and content will be developed based on the literature, findings in EM research, older adults input, and subject matter expert interviews. The concept will then be used to create content, conceptual model, and requirements. We will adapt the User-Centered Design (UCD) approach to develop VOICES, that is, an iterative multi-stage design approach which involves the user's input throughout the development process. UCD gives extensive attention to the user's needs, wants and limitations at each stage of the design process and allows *User Experience* (UX) evaluations to be incorporated into the design. We will conduct a series of older adults' UX evaluations that map on to the development cycle, i.e., user requirements analysis, conceptual design, detailed design, implementation, quality assurance testing, launch and maintenance. The result will be a tool that is built and optimized around how older adults *can*, *want*, or *need* to use it.

SPECIFIC AIM 2 (Feasibility Study): To conduct a feasibility study examining the use of VOICES in a busy ED.

In this Aim, we will conduct a study with eight hundred (N=800) eligible participants in order to evaluate the feasibility of implementing this innovative screening process into the ED with older adults. Our study will be designed based on rigorous scientific methods and will enable us to produce unbiased experimental design, methodology, analysis, interpretation and reporting of results. We expect this project will lead to a future comparative effectiveness research study comparing (VOICES + in-person screening) to the standard-of-care (in-person screening) in EM. Currently, patients with clear signs of abuse and neglect get the in-person screening from their provider or social worker. The advantages to our approach, in *addition* to the in-person approach, includes: *standardization* of intervention delivery and greater *efficiency* and use of limited resources in a busy ED. The *anonymity* supported by the tool on tablets is expected to motivate more patients to self-disclosure of sensitive or taboo subjects.

Study Setting: The Department of Emergency Medicine (DEM) at Yale School of Medicine (YSM) will serve as the study sites. Subjects for VOICES study will be recruited from the large and diverse patient population that visit the Yale-New Haven Hospital Emergency Department on the Saint Raphael's Campus (YNHH-ED-SRC).

Screening/Data Collection Description: The anticipated process for the screening and data collection is as follows and expected to take 45 minutes. After obtaining consent via the digital informed consent tool on the iPad, the RA will assist the older adult with putting on the headphones; orient them to the iPad screen, and explain the process that will follow. First, participants will complete a demographic pre-survey. Next, they will begin VOICES with an interactive educational session about EM and APS response, and will be screened for EM. For participants who screen positive, VOICES will ask them if they would like to self-disclose. If they choose to disclose VOICES will stop and thank them for participating. If they choose not to disclose EM, they will then complete the BNI and be asked again if they would like to self-disclose.

VOICES is not intended to replace the existing protocols for handling EM in EDs. Rather it is intended to help screen and identify cases of suspected EM that otherwise will be missed. The established protocol at YNHHS when EM is suspected requires notifying the ED social worker who will conduct an in-person evaluation and decide on the best approach to handle the case. VOICES will first screen for EM and administer an interactive educational session. It will then ask if the older adult would like to self-Identify with EM. If the patient does not want to self-identify, VOICES will administer BNI and ask again if the older adult want to self-identify with EM. If the patient chooses to identify with EM, the research assistant (RA) will notify the provider/social worker and say, "The patient wants to disclose EM". When the older adult is finished they will signal to the RA who will collect the iPad, complete a brief post-survey, administer the $20.00 incentive and (if needed) will notify their provider.

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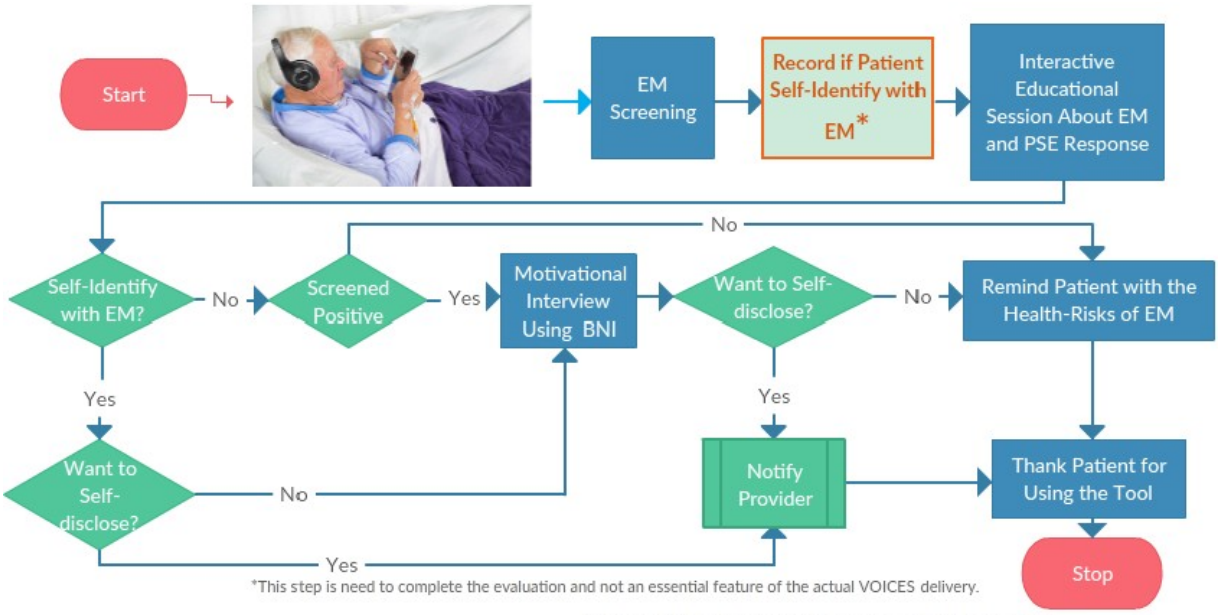

Figure 3: High Level Flow Chart of VOICES

Data Analysis, Measurement and Analysis of Outcomes: The purpose of this Objective is to understand important areas of feasibility, including *acceptability, demand, implementation, practicality, and limited efficacy* (Table 1). Data for the completion of this Objective comes from the following sources: (1) Participant demographic data obtained on pre-survey, (2) participant responses given to questions during VOICES (EM screener, self-identification, self-disclosure), (3) participant responses on participant satisfaction given to questions on post-survey, and (4) observations made by the RA on enrollment, VOICES administration, and data collection for each participant.

For the data collected during VOICES completion, the exact phrasing of the self-identification and self-disclosure questions will be decided upon during completion of Objective 1 following the focus groups and expert interviews. For the EM screener used in VOICES to determine whether there is suspicion of probable EM victimization, we will use the Self-Administrated Elder Abuse Suspiscion Index (EASI-sa) 5-item scale which asks about items related to physical and psychological aggression. The EASI-sa has adequate internal. In our study design and analysis, we will observe and report sex-based data. Moreover, we will look for differences on how **sex and other biological variables**, such as age, weight, and underlying health conditions, plays role in the outcome and the percentage of older adult that chooses to self-disclose EM.

Data analysis will be conducted with help of the Yale Center for Analytic Sciences (YCAS and will be performed using SAS v9.4 (SAS Institute, Cary, NC). Analysis of feasibility will be primarily descriptive. Numeric summaries including frequencies for categorical outcomes and means, medians, standard deviations and interquartile ranges for continuous feasibility outcomes will be presented. Graphical summaries will be used to describe distributions of outcomes and relations of outcomes with baseline characteristics. 95% confidence intervals for means and proportions will be estimated to describe uncertainty from sampling variation for feasibility outcomes.

Concept	Question	Outcomes of Interest
Acceptability	To what extent is VOICES satisfying to end-users?	Participant satisfaction measured using post-use satisfaction survey with a 7-point Likert response set, developed based on the focus group analysis

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Demand	To what extent is VOICES likely to be used?	Size of target population of EM victims in the ED measured by % who screen positive for EM and % who receive the BNI portion of VOICES
Implementation	To what extent can VOICES be delivered to participants in the defined, but not fully controlled, context of the ED?	Degree of execution measured by % of potential participants approached who consent to participate in the pilot study Success of execution measured by # of participants who used the tool to completion and reasons for not completing the tool as reported on post-survey
Practicality	To what extent can VOICES be carried out with intended participants without outside intervention?	Efficiency of implementation measured by the average time (1) to consent & orient participants to the tool and (2) needed to complete VOICES documented by the RA; and (3) patients perceived time of VOICES as measured on post-survey Factors affecting implementation measured by the number and source of interruptions during participation documented by the RA; The number of participants who want their caregiver/family member present during study as documented by the RA Positive/Negative effects of VOICES measured by participants' perceptions of safety concerns vs. benefits as reported on post-survey
Limited Efficacy	Does VOICES show promise of being successful?	Observed trends in proportions of reported (1) portion of participants who change their self-identification response after completing the education (2) portion of participants who change readiness to disclose after completing the BNI (3) exploration of whether self-identification impacts likelihood of self-disclosure Effect-size estimation measured by change in the % of patients who disclose Potential sources of bias measured by (1) sample representativeness & (2) observed group differences of participants measured by demographic data determine through t-tests and chi-square analyses

Table 1: Planned Data Analyses and Interpretation

Data Management. Study data will be entered into the VOICES by the patients through direct use and by the RA through data entry. We will use VOICES Back-end for the study management needs.

SPECIFIC AIM 3: Exploratory Aim: To perform a preliminary evaluation of the accuracy of VOICES as a screening tool in correctly classifying EM cases that were referred to Adult Protective Services (APS).

In this exploratory aim, we will evaluate the *positive predictive value* of VOICES as a screening tool in correctly identifying EM cases. This could serve as preliminary test for the accuracy of VOICES in correctly classifying victims/non-victims. It will be estimated through the measure of positive predictive value (PPV) using the APS case outcomes as the gold standard comparison.

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Design and rational:

In Connecticut, reported cases of EM are investigated by the Protective Services for the Elderly (PSE), commonly known as APS, which is administered by the Division of Social Work Services within the Connecticut Department of Social Services (please see letter of support). PSE is designed to safeguard people age 60 and older from EM. Pursuant to State Code 2012-R-0437, mandatory reporters are able to know outcomes of their report (see letter of support from PSE). If a case was opened by PSE this means the case met the state's determined threshold for a situation requiring an investigation so reporting was valid. Often times, if a case was opened regardless of EM determination services are provided to the older adult. For our purposes, PPV is a measure of VOICES ability to correctly classify cases of clinically significant EM (true positive rate). Determination by PSE will serve as our gold-standard criterion for comparison. Ideally, VOICES would only refer cases which would require an investigation and have a positive finding of EM as this would represent true validity in identifying positive cases.

VOICES-C Study: (01/10/2020 to 03/01/2020) completed

We will conduct this activity to formally evaluate the usability of the VOICES tool. Usability refers to how easily a specific task can be accomplished with a specific tool. The International Organization for Standardization (ISO) defined usability as the "extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" (ISO, 1998). Hypothesis 1a: users will report a high level of ease of use of VOICES. Hypothesis 1b: Users will report a high level of satisfaction in using VOICES.

What will subjects be asked to do?

Subjects will be asked to review the VOICES Tool on the iPad in the presence of a researcher, while being videotaped, and share their perceptions of the application by speaking out loud. After completing a series of tasks, they will be asked to fill out a brief questionnaire and answer some follow-up questions.

Where will this take place?

At Yale School of Medicine at Yale Center for Medical Simulation (YCMS).

How long with the research activities take the subject?

Participation will take approximately 30-40 minutes

What will happen if one of VOICES-C subjects identify as a victim of elder mistreatment?

The PI will notify Yale New Haven Hospital social worker to decide on the best approach to handle the case as per usual clinical practice that includes notifying Connecticut Protective Services for the Elderly (PSE).

VOICES-D Study: (01/10/2020 to 03/01/2021) ongoing at Michigan State University

The added supplemental study (VOICES-D) will be conducted at Michigan State University and will evaluate the usability of VOICES tool by older adults with **visual** and **hearing** disabilities to enhance and refine the EM screening tool to be useable by persons with disabilities. **Specific Aims of the Supplement:**

Aim 1. To perform a preliminary evaluation of the usability of the VOICES screening tool for older individuals with visual or hearing disabilities.

Aim2. To enhance and refine the interactive VOICES tool to be usable and acceptable for older adults with visual or hearing disabilities.

What will subjects be asked to do?

Subjects will be asked to review the VOICES Tool on the iPad in the presence of a researcher, while being videotaped, and share their perceptions of the application by speaking out loud. After completing a series of tasks, they will be asked to fill out a brief questionnaire and answer some follow-up questions.

Where will this take place?

At Usability/Accessibility Research and Consulting, 93 Kellogg Center, 219 S. Harrison Rd., Michigan State University, East Lansing, MI 48824;

How long with the research activities take the subject?

Participation will take approximately 60 minutes

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The PI will oversee the conduct VOICES-D supplemental study with collaboration with Michigan State University Usability/Accessibility Research and Consulting (MSU UARC) and the Site PI Dr. Swierenga. The data will stay at MSU and will be analyzed there. Summative results will be sent to Yale.
The MSU-Site PI will submit the VOICES-D protocol to MSU IRB for review and approval of their role in the research.
We will evaluate the ease of use and usefulness of VOICES as a screening tool for older adults who are blind, have low vision, are deaf, or are hard of hearing to assess the degree to which this tool is appropriate for these potential populations of users. Based on the findings and recommendations from the usability evaluation in, we will utilize a User-Centered Design (UCD) approach to enhance and refine VOICES tool to make it usable by older adults with visual or hearing disabilities.

VOICES-Feasibility Study: (07/10/2020 to 03/01/2023) to be initiated
We will conduct this study to formally evaluate the feasibility of the VOICES tool with 800 older adults in the YNHH-ED-SRC.

What will subjects be asked to do?
Subjects will be asked to fill out a pre-study survey, use the VOICES Tool on the iPad in the presence of a RA, then asked to fill out a brief questionnaire and answer some follow-up questions.
Where will this take place?
YNHH-ED-SRC.
How long will the research activities take the subject?
Participation will take approximately 45 minutes.
What will happen if one of VOICES-D subjects identify as a victim of elder mistreatment?
The RA will notify a Yale New Haven Hospital social worker to decide on the best approach to handle the case as per usual clinical practice that includes notifying Connecticut Protective Services for the Elderly (PSE).

5. Genetic Testing N/A ☒

A. Describe
- *i.* the types of future research to be conducted using the materials, specifying if immortalization of cell lines, whole exome or genome sequencing, genome wide association studies, or animal studies are planned *Write here*
- ii. the plan for the collection of material or the conditions under which material will be received *Write here*
- *iii.* the types of information about the donor/individual contributors that will be entered into a database *Write here*
- *iv.* the methods to uphold confidentiality *Write here*

B. What are the conditions or procedures for sharing of materials and/or distributing for future research projects? *Write here*
C. Is widespread sharing of materials planned? *Write here*
D. When and under what conditions will materials be stripped of all identifiers? *Write here*
E. Can donor-subjects withdraw their materials at any time, and/or withdraw the identifiers that connect them to their materials? *Write here*
- *i.* How will requests to withdraw materials be handled (e.g., material no longer identified: that is, anonymized) or material destroyed)? *Write here*

F. Describe the provisions for protection of participant privacy *Write here*
G. Describe the methods for the security of storage and sharing of materials *Write here*

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6. **Subject Population:** Provide a detailed description of the types of human subjects who will be recruited into this study.
Participants for the focus groups will be identified as English speaking and age 60+. The first focus group will have four older adult participants, two caregivers, two ED providers, and two ED social workers. The second and third focus groups will have 6-8 older adult participants in each. Participants will be recruited from the community and YNHH, by the research team and by the Agency on Aging of South Central Connecticut.

VOICES-C (completed): Participants of the VOICES-C usability evaluation study will be identified as English speaking and age 60+ volunteers. Participants must be able to consent and communicate in English. The sample size will be 12 participants. Participants must be computer tablet users who can use the accessibility features on the device. To the extent possible with the New-Haven area, participants will be recruited to include diverse racial and ethnic backgrounds. The duration of our study is estimated to be approximately 6 months.

VOICES-D: Participants of the VOICES-D usability and accessibility evaluation study will be identified as English speaking and age 60+ volunteers with visual or hearing disabilities. Participants must be able to consent and communicate in English. The sample size will be 24 participants. Participants must be computer tablet users who can use the accessibility features on the device. To the extent possible with the mid-Michigan area, participants will be recruited to include diverse racial and ethnic backgrounds. The duration of our study is estimated to be approximately 9 months.

VOICES-Feasibility Study: In the YNHH-ED-SRC setting we will seek to enroll eligible older adults (N=800). The participants in the pilot study will be ED patients age 60 and above in non-trauma track. Participant will need to be alerted and oriented to person, place and time with AMT-4 score of 4, able to consent and communicate in English, and agrees and able to use the iPad.

Recruitment for VOICES will take place over 21 months.

7. **Subject classification:** Check off all classifications of subjects that will be <u>specifically recruited for enrollment</u> in the research project. Will subjects who may require additional safeguards or other

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considerations be enrolled in the study? If so, identify the population of subjects requiring special safeguards and provide a justification for their involvement.

☐Children	☒ Healthy	☐Fetal material, placenta, or dead fetus
☐Non-English Speaking	☐ Prisoners	☐Economically disadvantaged persons
☐Decisionally Impaired	☐ Employees	☐Pregnant women and/or fetuses
☐Yale Students	☐ Females of childbearing potential	

NOTE: Is this research proposal designed to enroll children who are wards of the state as potential subjects?
Yes ☐ No ☒

8. **Inclusion/Exclusion Criteria:** What are the criteria used to determine subject inclusion or exclusion?

For VOICES-C Sub Study:

Inclusion Criteria. Inclusion criteria are as follows: (1) Age 60 years or older (EM age per Connecticut law);), (2) Able to consent and communicate in English; and (3) Agrees and able to use the iPad

- **Exclusion Criteria:** Exclusion criteria are as follows: (1) Patient refusal to participate;

For VOICES-D Sub Study:

Inclusion Criteria. Inclusion criteria are as follows: (1) Age 60 years or older (EM age per Connecticut law); (2) hard of hearing, deaf, blind, or 20/70 to 20/200 vision (after correction, if applicable), (3) Able to consent and communicate in English; and (4) Agrees and able to use the iPad

- **Exclusion Criteria:** Exclusion criteria are as follows: (1) Patient refusal to participate;

For VOICES-Feasibility Study:

Inclusion Criteria. Inclusion criteria are as follows: (1) Age 60 years or older (EM age per Connecticut law); (2) Non-trauma track; (3) Alert and oriented to person, place and time; (4) AMT-4 score of 4; (5) Able to consent and communicate in English; and (6) Agrees and able to use the iPad, (7) Not in police custody

- **Exclusion Criteria:** Exclusion criteria are as follows: (1) subjects who live in nursing homes or other long- term care sitting and do not reside in community setting; (2) at the discretion of the clinician, patient will be excluded if they cannot safely undergo the studies required for participation; (3) subjects with clear signs of EM; (4) Patient refusal to participate; (5) severe hearing and vision impairment; (6) presenting with active psychotic symptoms; (7) presenting with acute intoxication.

9. How will **eligibility** be determined, and by whom?

VOICES-C Sub Study:
The eligibility be determined by the PI and If the patient meets the initial screening eligibility, and none of the exclusion criteria as described above for VOICES-C.

VOICES-D Sub Study:
The eligibility be determined by the MSU PI and If the patient meets the initial screening eligibility, and none of the exclusion criteria as described above for VOICES-C.

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VOICES-Feasibility Study:

Eligibility and Capacity Evaluation: We will use standardized criteria as described below to determine if the potential participant is capable of providing consent. The RAs will be highly trained in obtaining informed consent. They will receive training by the Yale Program on Aging for determining capacity to consent in aging populations. Evaluating the capacity of the participants to understand the purpose, risks, benefits, confidentiality, and privacy associated with study is vital for valid informed consent. The RAs will determine if the subject can participate based on their degree of alertness and if they are oriented to person, place and time and if they are able to communicate in English.

If the patient meets the initial screening eligibility, and none of the exclusion criteria as described above, the RA will approach the patient and check if they are well enough to participate in the study. The RA will then check if the patient is alert and oriented to person, place, and time. Then, the RA will use Abbreviated Mental Test 4 (AMT-4) to assess cognitive status. If the patient scores < 4 on the AMT-4 then s/he will not be eligible to be enrolled in the study. If the patient scores 4 on the AMT-4, then the RA will introduce the study and ask if s/he is interested in participating in the study. Factors to be considered include the ability to articulate a choice regarding study participation, understand its purpose, and comprehend that participation does not constitute medical treatment. If the patient is deemed capable and chooses to participate in the study, then the RA will perform the informed consent process to find out if the individual is still interested in participating in the study. The timing of the informed consent will take place as described below:

1. The RA goes to the older adult's room, if the caregiver is there, S/he will be asked to wait in the ED waiting room.
2. Escort the caregiver (if any) to wait in the waiting area
3. Introduce the study to the older adult when s/he is alone
4. If the older adult agrees to participate, conduct the bedside screening that includes these questions: Is the patient well enough to participate? Is the patient able to hear the instructions from the iPad through the headphone provided? Is the patient able to see instructions and demonstrations on the iPad screen? Is the patient alert and oriented to person, place, and time? Does the patient have a AMT-4 score of 4)?
5. If all of the above was completed and the older adult is eligible and agrees to participate, start the informed consent process that will include all the eight basic elements of informed consent mentioned above and the additional elements of informed consent.

Connecticut law requires reporting of the abuse of persons above the age of 60. During the consent process, participants will be notified of this legal requirement but reassured that investigators will make every effort to make the process confidential and comfortable for the participant, including a) keeping the participant's reporting confidential and b) involving the care team (clinician, nurses, and attendings), who can address patient's concerns around reporting, immediate safety concerns, and any concerns for retaliation or abandonment.

At the end of the consent process, the RA will review the subject's understanding of the study by asking the following question:

- What are you being asked to do?
- What questions is this study trying to answer?
- What are the potential risks and benefits of participating in this study?
- Can you withdraw from the study, and what should you do if you decide to withdraw?
- Do you understand that participation in this study is voluntary and is not part of your medical treatment?

10. **Risks:** Describe the reasonably foreseeable risks, including risks to subject privacy, discomforts, or inconveniences associate with subjects participating in the research.

There are no medical interventions in this study, the direct medical risks are minimal. However, identification of potential EM without adequate safeguards could increase the risk of physical harm, emotional harm, risk of neglect, and financial loss to the victim. In addition, EM Identification can potentially lead to adverse events

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including:

- retaliation of a family member,
- an older adult may lose the caregiver or be abandoned by a caregiver, a family member or paid caregiver may be arrested / incarcerated.
- discharge of a patient to a long-term care or skilled nursing facility, which they may not be able to afford and the setting of which could be problematic for them,
- distress/anxiety during and/or after using the VOICES tool is a potential risk given the complex emotions typically associated with this phenomenon,
- participant may suffer from distress and/or anxiety when reviewing information and answer questions about EM during the study session,
- participant may suffer from distress and/or anxiety when he or she realizes that he she is a victim of EM based on the information received from VOICES,
- because participants will review the VOICES tool and answer questions on the iPad with the help of the RA, there is a risk of compromised security of personal information,

Many of these adverse events would likely occur as a result of the mandatory report to PSE that the ED would make. However, during this study the ED is expected to discover information that will require the ED to make a report to PSE even if the patient does not want them to do so (and, as noted above, this report may have significant consequences).

11. **Minimizing Risks:** Describe the manner in which the above-mentioned risks will be minimized.

The Yale ED has a comprehensive, protocolized, and multi-disciplinary process for dealing with EM identification and disclosure and the appropriate next steps and interventions after EM disclosure or identification according to laws, local regulations, and statutory mandates, both on a federal- and state-level. After the start of the study and in the Yale ED, there will be two groups of EM victims: A) those who were identified by VOICES and B) those who were identified by ED providers as part of usual care. The two groups may have similar risks for adverse events, but they are different in one important way. For patients with EM identified by VOICES, the risk is created because of the research intervention and wouldn't occur if VOICES didn't exist or if they declined to participate. Our research team is aware of the potential for the occurrence of adverse events that may be the result of the VOICES screening process. The subsequent ED multi-disciplinary response to EM identification, whether initially identified through VOICES or through ED usual care, is comprehensive and protocolized.

Risks will be minimized through appropriate participant exclusions and close medical supervision throughout the protocol. We will inform all participants that there is a chance that they may experience AE or SAE by participating in the study and that their participation is voluntary. We will also remind participants that they can discontinue participation at any time. In the Yale ED and when a member of the health care team has any suspicion of EM, he or she will notify the ED social worker who has a well-established multi-disciplinary and comprehensive protocol on how to handle the EM cases. The protocol includes any combination of the following: interview, screening (if EM is suspected but not yet identified), referral to community service provider, safety admission to the hospital, or reporting to CT Protective Services for the Elderly (PSE). The hospital, the community, PSE, and the law enforcement agencies have systems in place to maintain the abuse victim's safety.

In Summary: VOICES' goal is to help identify cases of EM within the ED visit. The subsequent procedures for the EM identification are important but are similar to the case when a provider identify suspicion of EM during normal clinical care:

- the ED already (before conducting the VOICES study) has a comprehensive and protocolized multi-disciplinary approach to respond when elder mistreatment is suspected by ED providers during usual clinical care.
- all patients who screen positive with the VOICES tool will receive a similar response.

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- while the research team recognizes that the EM identified through the VOICES tool may lead to adverse events for patients associated with EM identification, we anticipate that the Yale ED's response will minimize the possible adverse events due to the EM identification.

We will train all RAs to detect common signs of distress and anxiety. If any are even suspected of being observed, our Co-I (Dr. Pantalon), who is a licensed clinical psychologist, will be contacted immediately for consultation and next steps, which could include counseling, referrals or a psychiatric evaluation

Moreover, a licensed clinical psychologist will be available for consultation to the staff and patient, if needed, during most hours of recruitment. When this level of back-up is not available, we will have psychiatry back-up for any distressed reactions that require mental status evaluation. Thus, some psychological or psychiatric evaluation will be available during all study assessments and during all recruitment periods of the project to facilitate stabilization and necessary referrals for participants who report distress during assessment procedures.

If the older adult screens positive on the VOICES for EM or the older adult wants to self-disclose EM, the RA will notify the care team in the ED that there is suspicion of EM. Also, if the tool fails to identify EM but the patient would like to disclose EM, the RA will notify the care team. The RA will stay with the participant until a member of the care team arrives and implements existing protocols for handling EM in the ED.
The care team can address each patient's concerns around reporting, immediate safety concerns, and any concerns for retaliation or abandonment. The care team will contact the social worker by calling Mobile Heart Beat or his/her cell phone. The social worker will perform the Social Worker Assessment. If the assessment indicates suspicion of abuse, then the social worker will work with members of the multi-disciplinary team to handle the mistreatment case. If the case gets reported to PSE, usually PSE will arrive at the hospital within 12 hours to take care of the case. While waiting for PSE, the health care team members will discuss safety issues with the patient. If the older adult feels s/he is in immediate danger or does not feel safe going home, the care team will create a safe disposition plan that can include safety admission to the hospital until PSE can implement a more permanent solution.

We will protect against psychological distress by informing all participants that there is a chance that they may experience some negative emotions while completing the surveys, after completing survey, or when they leave the hospital, but that they do not have to answer questions that they find distressing. We will also remind participants that they can discontinue participation at any time. We will also provide all older adults that we approach with the brochure on resources for aging well that also include free referral line. These options will be discussed with participants during initial recruitment.
Although privacy and confidentiality will be preserved to the utmost extent possible, participants will be informed that, should EM be identified, the RA will report this to the care team in the ED. For example, if in the course of research procedures, a participant reveals elder abuse to the RA, the RA will discuss with the participant his/her responsibility to report the abuse to the care team in the ED. The care team will do its EM assessment and if they find suspicion of abuse, they will intervene to ensure that ED's EM protocol is implemented. Also, if the participant divulges suicidality, the RA must report this to the care team in the ED and notify the PI.
We will follow standard hospital operating procedures to guard against the possibility of study coercion, loss of confidentiality, psychological distress, and escalation of abuse, acknowledging that awareness or suspicion of reporting may anger the abuser but can also empower the patients and ultimately, make them safer.

Our intent is to conduct a VOICES study session **without the presence** of the caregiver. From our experience, family members usually volunteer to leave the room once the health care provider walks in. When they are asked to leave the room, they usually do so. We will ask the caregivers to leave the room before engaging the older adults in the study and before consenting them. If the older adult wants the caregiver to remain, we will respect their wishes, but that patient will be excluded from the study and no study information will be presented.
Given the sensitive nature of the study topics, along with the safety concerns surrounding elder abuse, RAs will discuss the risk should study materials (e.g., copies of the consent form) be seen by the abuser and will suggest

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that such materials be discarded or kept with study staff after review but before leaving the ED.
Risks to participants, including pregnant women and their fetuses, are minimal given that this tool will be provided to adults aged 60 years or older. Subjects experiencing adverse events will have access to full in-patient medical facilities of the Yale-New Haven Hospital should intensive treatment be necessary to reverse any complications during the study.

If a participant reveals depression, the research assistant will provide a referral to a mental health agency accessible to the subject. If a participant reveals severe depression or suicidality, or requests immediate psychiatric care for any reason, the RA will alert the patient's clinician to initiate an immediate psychiatric evaluation.

The RAs will receive training for all procedures related to suicidality and elder abuse.
Since the VOICES tool is a web-based application in nature, **no information** will be stored on the tablet. If the tablet gets lost or stolen, the patient's data will not be compromised. All iPads contain encryption software, per University Policy 5100.

12. **Data and Safety Monitoring Plan:** Include an appropriate Data and Safety Monitoring Plan (DSMP) based on the investigator's risk assessment stated below. (Note: the HIC will make the final determination of the risk to subjects.)

The DSMP will be monitored by the study team. The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis. To ensure that we are identifying both the adverse events that we might anticipate as well as those that you might not, the PI will review each case where either: (1) a report was made to PSE or (2) a patient was admitted to the hospital for safety to assess for any potential adverse events. The Data and Safety Monitoring Team (DSMT) will consist of Drs. Fuad Abujarad, Thomas Gill, James Dziura, Karen Jubanyik, and Esther Choo; this team will monitor participant safety, evaluate the progress of the study, and review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. They will monitor the study for reports of any adverse or unexpected events. Study participants will be advised to contact the study team to report any adverse events or concerns. VOICES will only be administrated for the intervention group, and there will be no control groups. The PI and investigative team will monitor data and safety at the monthly study team meetings. The following will be reviewed:

- Cumulative accrual
- Enrollment of subjects who meet the study eligibility criteria only
- Recruitment is proceeding as planned
- The informed consent process is conducted appropriately; informed consent is obtained
- Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcome
- Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial
- Review study performance, make recommendations, and assist in the resolution of problems reported by the PI
- Evaluate data completeness and quality and as specified in the protocol.

Prior to proceeding with any study procedures

- Review the research protocol, informed consent documents and plans for data safety and monitoring
- Protect the safety of the study participants
- Ensure the confidentiality of the study data and the results of monitoring
- Review procedures for the privacy and confidentiality of subjects
- Review cumulative attrition and attrition by gender and race/ethnicity
- Review dropouts and reason for withdrawal from the study are documented

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The principal investigator will be responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews. During the review process the principal investigator will evaluate whether the study should continue unchanged, require modification/amendment, or close enrollment.

The principal investigator and the Institutional Review Board (IRB) and the NIA have the authority to stop or suspend the study or require modifications.

12.1 Adverse Event and Serious Adverse Event Collection and Reporting

Serious Adverse Event (SAE): Any adverse event that results in any of the following outcomes: death, a life-threatening experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

Adverse Event (AE): An undesirable and unintended, although not necessarily unexpected, as direct result of using the VOICES tool.

Reportable Adverse Event
An adverse event that must be reported to the IRB and the NIA Program Officer because it is all of the following:
1. Serious or life-threatening; AND
2. Unanticipated (unexpected) OR anticipated but occurring with a greater frequency than expected; AND
3. Possibly, probably or definitely related to the intervention.

This section describes the procedures and timelines for adverse events (AE) and serious adverse events (SAE), collection and reporting.

- No SAEs are expected from the direct use of VOICES tool on the iPad, but when SAEs occur as result of EM identification and disclosure that are related to the VOICES tool, they will be reported to the NIA Program Officer, Yale IRB, and to the research team within 48 hours of study's knowledge of the SAE.
- AEs will be reported per YALE IRB policies. They will also be reported to the NIA Program Officer and the study's team at frequency requested by NIA. At minimum, semi-annual reports.
- In the unlikely event that such events occur, Reportable Events (which are events that are serious or life-threatening and unanticipated and possibly related) or Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) that may require a temporary or permanent interruption of study activities will be reported immediately to the NIA Program Officer, Yale IRB, and to the research team, followed by a written report within 5 calendar days of the Principal Investigator becoming aware of the event to the IRB and any appropriate funding and regulatory agencies.
- The PI will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project through regular study meetings and via email as they are reviewed by the PI.
- All deaths will be reported within 24 hours of study's knowledge of death.
- The report of death will be submitted to NIA Program Officer, Yale IRB, and to the research team.
- Since the VOICES tool is a web-based application in nature, no information will be stored on the tablet. Data will be stored on Yale secure servers. If the tablet becomes lost or stolen, the patient's data will not be compromised. All iPads contain encryption software, per University Policy 5100.

12.2 Frequency of Data and Safety Monitoring
The data and safety monitoring reviews will take place during monthly meetings of the study team monthly meetings. In addition, the DSMT will meet twice annually, either in-person or by teleconference call to review

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study progress, data quality, and participants safety.

12.3 Data Analysis and Coordination

Data analysis will be conducted with the help of the Yale Center for Analytic Sciences (YCAS) and will be performed using SAS v9.4 (SAS Institute, Cary, NC). Analysis of feasibility will be primarily descriptive. Numeric summaries including frequencies for categorical outcomes and means, medians, standard deviations and interquartile ranges for continuous feasibility outcomes will be presented. Graphical summaries will be used to describe distributions of outcomes and relations of outcomes with baseline characteristics. 95% confidence intervals for means and proportions will be estimated to describe uncertainty from sampling variation for feasibility outcomes.

The research team seeks to broadly disseminate the study results through publication in peer-reviewed journals and presentations at national meetings to share and demonstrate the findings and the lessons learned from this project. We plan to present at conferences such as the Gerontological Society of America annual meeting, the American Geriatrics Society annual meeting, and the National Association of Adult Protective Services annual meeting.

In accordance with the National Institutes of Health (NIH) policy to promote broad and responsible dissemination of information from NIH-funded clinical trials, we are registered VOICES trial on ClinicalTrials.gov (https://clinicaltrials.gov/ct2/show/NCT03834870). In addition, we will submit the VOICES trial results information to ClinicalTrials.gov.

The informed consent documents for the VOICES trial will include a specific statement that states the posting of clinical trial information at ClinicalTrials.gov and the trial number.

13. **Statistical Considerations:** Describe the statistical analyses that support the study design.

VOICES-C and D:
Data collection instruments for usability are tools that help us analyze the design, implementation, and integration process. Usability data analysis will include percentage of successfully completed tasks; number and types of errors; time to successfully perform a particular task; user satisfaction ratings; and verbal and written feedback from the sessions. Quantitative data will be analyzed as numerical indicators and summarized using common descriptive statistics appropriate for discrete and continuous data. Non-numerical indicators will be analyzed using qualitative methods. Key results will be used to 1. Modify the VOICES tool to make it more usable and acceptable in terms of system's design; and 2. Normalize VOICES by reducing process and structural problems. We will conduct data analysis by using Camtasia 2®, a package that allows simultaneous video recording, user screen capture, note-taking, and participant survey. Key usability measures will include both qualitative and quantitative outcome measures. These include effectiveness (i.e., how well a system does what it is supposed to do), efficiency (i.e., the way a system supports users), and satisfaction (i.e., subjective responses from users about the system).

VOICES Feasibility Study:
Sample size calculations were performed using PASS v2012. The objective of this study is to evaluate markers of feasibility rather than to determine the efficacy of VOICES. The sample size was therefore determined based on the practical considerations of time and availability of subjects as well as the precision by which feasibility parameters will be estimated. We estimate EM prevalence to range from 7% to 12% among adults age 60 and above since the reported numbers in literature were for ages 65 and above. In addition, if we also assume that 20% of them may not participate in the study based on cognitive ability, then we can expect the EM prevalence in our eligible sample to range from 6% to 9.6%.

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If we also exclude subjects with clear signs of EM (1 in 24) 5%, as they will be immediately identified and reported by health care provider, then we are left with EM prevalence estimation of 5.7% - 9.12%. A sample size of eight hundred subjects (N=800) should thus result in 45-72 adults from whom we can estimate the proportions who change their self-identification response and who are ready to self-disclose after using VOICES. This will be a sufficient size to estimate a 95% confidence interval around a proportion with a width of no greater than 0.3. A sample size of 800 will provide a precision of +/- 0.14 standard deviations for the 95% confidence interval around a mean for continuous feasibility outcomes (e.g. acceptability, time to completion). This sample size will also produce precision of no worse than +/- 14% in the estimation of a 95% confidence interval around a proportion for dichotomous feasibility outcomes (e.g. demand, implementation).

SECTION II: RESEARCH INVOLVING DRUGS, BIOLOGICS, RADIOTRACERS, PLACEBOS AND DEVICES

If this section (or one of its parts, A or B) is not applicable, check off N/A and delete the rest of the section.

A. RADIOTRACERS ☒N/A

B. DRUGS/BIOLOGICS ☒N/A

B. DEVICES ☒N/A

SECTION III: RECRUITMENT/CONSENT AND ASSENT PROCEDURES

1. Targeted Enrollment: Give the number of subjects:

a. Targeted for enrollment at Yale for this protocol: 800

b. If this is a multi-site study, give the total number of subjects targeted across all sites:

2. Indicate recruitment methods below. Attach copies of any recruitment materials that will be used.

VOICES Feasibility Study:

☐ Flyers
☐ Posters
☐ Letter
☐ Medical record review*
☐ Departmental/Center newsletters
☐ YCCI Recruitment database
☒ Other: Coordinator/Research Assistant will be stationed in the ED and will work with designated nurses and social workers to identify potential participants.

☐ Internet/web postings
☐ Mass email solicitation
☐ Departmental/Center website
☐ Departmental/Center research boards
☐ Web-based clinical trial registries
☐ Social Media (Twitter/Facebook):

☐ Radio
☐ Telephone
☐ Television
☐ Newspaper
☐ Clinicaltrails.gov

For VOICES C- D:

☒Flyers
☒Posters

☒Internet/web postings
☐ Mass email solicitation

☐ Radio
☐ Telephone

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☐ Letter	☐ Departmental/Center website	☐ Television
☐ Medical record review*	☐ Departmental/Center research boards	☐ Newspaper
☐ Departmental/Center newsletters	☐ Web-based clinical trial registries	☐ Clinicaltrails.gov
☐ YCCI Recruitment database	☐ Social Media (Twitter/Facebook):	

*** Requests for medical records should be made through JDAT as described at**
http://medicine.yale.edu/ycci/oncore/availableservices/datarequests/datarequests.aspx

3. Recruitment Procedures:

a. Describe how potential subjects will be identified.

Subjects for the focus group will be identified as English speaking and age 60+.
The first focus group will have four older adult participants, two caregivers, two ED providers, and two ED social workers. The second and third focus groups will have 6-8 older adult participants in each.
Participants will be recruited from the community and YNHH, by the research team and by the Agency on Aging of South-Central Connecticut.

VOICES-C: 12 subjects will be recruited to participate in this usability study. We seek a purposive sample of adult male and female age > 60 years. We will recruit participants primarily from the New Haven area, inviting them to participate in the usability evaluation of the VOICES tool; participation in this study will be completely voluntary. Participants will receive a $25 VISA gift card per session as a thank you for their time.

VOICES-D: The supplemental disabilities study will be used to evaluate the accessibility of VOICES tool by older adults with **visual** and **hearing** disabilities. We plan to recruit 24 older adults (up to 6 per group, i.e., blind, have low vision, are deaf, or are hard of hearing).

We will recruit participants primarily from the mid-Michigan area, inviting them to participate in the usability evaluation of the VOICES tool; participation in this study will be completely voluntary. Participants will receive a $75 VISA gift card per session as a thank you for their time and to reduce the likelihood of "no-shows."

For VOICES Feasibility Study: In the ED setting, we will seek to enroll eligible older adults (N=800). Working with the ED, we will develop a rotating schedule for the Study Coordinator/Research Assistant that varies shifts and days to get a more representative ED sample. The Study Coordinator/Research Assistant will be stationed in the ED and will work with designated nurses and social workers to identify potential participants.

b. Describe how potential subjects are contacted.

The research team will present a flyer/brochure regarding the focus groups to AASCC and ask them to post it at their location. Interested participants can contact the research team for more information about participating in the focus groups.

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Participants of VOICES-C will be recruited in a variety of ways, e.g., through notices on information boards, retirement and/or assisted living facilities, local/professional organizations, and YCCI networks and website.

Participants of VOICES-D will be recruited in a variety of ways, e.g., through notices on information boards, retirement and/or assisted living facilities, local/professional organizations, and MSU Outreach and Engagement networks, MSU Resource Center for Persons with Disabilities, and the MSU UARC networks and website. An eligibility survey will be used to screen participants.

Participants of VOICES Feasibility will be recruited in the ED. The Study Coordinator/Research Assistant will approach all potential participants, screen for eligibility and obtain informed consent via the digital informed consent tool on the iPad.
All recruitment material will be submitted to the IRB for review and approval prior to using

Who is recruiting potential subjects?

Participants of VOICES-C will be recruited by the Yale team. Participants of VOICES-D will be recruited by the MSU UARC team with significant assistance from Yale team.
Participants of VOICES Feasibility Study will be recruited by the Study Coordinator/Research Assistant of the Yale team.

4. **Assessment of Current Health Provider Relationship for HIPAA Consideration:**
Does the Investigator or any member of the research team have a direct existing clinical relationship with any potential subject?
☐Yes, all subjects
☐Yes, some of the subjects
☒No

If yes, describe the nature of this relationship.

5. **Request for waiver of HIPAA authorization:** (When requesting a waiver of HIPAA Authorization for either the entire study, or for recruitment purposes only. Note: if you are collecting PHI as part of a phone or email screen, you must request a HIPAA waiver for recruitment purposes.)
Choose one:

☐ For entire study
☒ For recruitment/screening purposes only
☐ For inclusion of non-English speaking subject if short form is being used and there is no translated HIPAA research authorization form available on the University's HIPAA website at hipaa.yale.edu.

i. Describe why it would be impracticable to obtain the subject's authorization for use/disclosure of this data:
We are requesting a HIPPA waiver for recruitment purposes only. The RA will review the ED Track Board in EPIC and will then check the demographic and chief complaint for patient 60 years or older. They will then approach the patients identified as EMR screening eligible to ask additional screening questions. We don't have resources and staffing to approach every ED patient and ascertain eligibility. Using Epic is more efficient for the RAs.

The RA will track and document each HER that the RA access using the HIPAA Disclosure Tracking Spreadsheet found at https://hipaa.yale.edu/policies-procedures-form.

ii. If requesting a waiver of **signed** authorization, describe why it would be impracticable to obtain the subject's signed authorization for use/disclosure of this data:

The investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

Researchers are reminded that unauthorized disclosures of PHI to individuals outside of the Yale HIPAA-Covered entity must be accounted for in the "accounting for disclosures log", by subject name, purpose, date, recipients, and a description of information provided. Logs are to be forwarded to the Deputy HIPAA Privacy Officer.

6. **Process of Consent/Assent:** Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure subjects' independent decision-making.
   We will be enrolling older adults age 60 or above who are alert and oriented to person, place and time and if they are able to communicate in English. We will develop a user-friendly digital informed consent process on the iPad that will pay special attention to the ethical issues and the unique challenges posed by conducting EM research. Moreover, we will implement comprehensive security strategies that will guarantee the confidentiality and privacy of the patient and the clinical information.

   We will be recruiting older adults age 60 or above who are able to communicate in English for our three focus groups. We will develop an informed consent process to explain the purpose of the focus group and how participants information will be kept confidential.

   We will be recruiting older adults age 60 or above who are able to communicate in English for our VOICES-C study. We will develop an informed consent process to explain the purpose of the usability evaluation and the participant confidentiality and privacy measures.

   We will be recruiting older adults age 60 or above who are able to communicate in English for our VOICES-D study. We will develop an informed consent process to explain the purpose of the usability evaluation and the participant confidentiality and privacy measures.

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7. **Evaluation of Subject(s) Capacity to Provide Informed Consent/Assent:** Indicate how the personnel obtaining consent will assess the potential subject's ability and capacity to consent to the research being proposed.
   The Study Coordinator/Research Assistant will determine if the subject can participate based on if they are alert and oriented to person, place and time and if they are able to communicate in English. In addition, we will design a detailed process on how to evaluate capacity, determine competence, and obtain informed consent from older adults (please see the DSMP). Evaluating the capacity of the participants to understand the purpose, risks, benefits, confidentiality, and privacy associated with study is vital for valid informed consent. We will use standardized criteria to determine if the potential participant is capable of providing consent. Members of the study team who are responsible for participant recruitment and consent will be highly trained in obtaining informed consent and with using the iPad that the consent will be conducted on. They will receive training by the Yale Program on Aging in determining capacity to consent in aging populations. Ability to provide informed consent will be assessed using the Abbreviated Mental Test 4 (AMT-4) to assess cognitive status designed to assess decision-making capacity for research participation according to NIH standards. Additionally, we will employ evidence-based practices from the fields of IPV and geriatrics to correctly address these challenges.

8. **Non-English Speaking Subjects:** Explain provisions in place to ensure comprehension for research involving non-English speaking subjects. If enrollment of these subjects is anticipated, translated copies of all consent materials must be submitted for approval prior to use.
   N/A

As a limited alternative to the above requirement, will you use the short form* for consenting process if you unexpectedly encounter a non-English speaking individual interested in study participation and the translation of the long form is not possible prior to intended enrollment? YES ☐ NO ☒

Note* If more than 2 study participants are enrolled using a short form translated into the same language, then the full consent form should be translated into that language for use the next time a subject speaking that language is to be enrolled.

Several translated short form templates are available on the HRPP website (yale.edu/hrpp) and translated HIPAA Research Authorization Forms are available on the HIPAA website (hipaa.yale.edu). If the translation of the short form is not available on our website, then the translated short form needs to be submitted to the IRB office for approval via modification prior to enrolling the subject. ***Please review the guidance and presentation on use of the short form available on the HRPP website.***

If using a short form without a translated HIPAA Research Authorization Form, please request a HIPAA waiver in the section above.

9. Consent Waiver: In certain circumstances, the HIC may grant a waiver of signed consent, or a full waiver of consent, depending on the study. If you will request either a waiver of consent, or a waiver of signed consent for this study, complete the appropriate section below.

☐ **Not Requesting any consent waivers**

☒ **Requesting a waiver of signed consent:**

☒ **Recruitment/Screening only** *(if for recruitment, the questions in the box below will apply to recruitment activities only) for focus groups only*

☐ **Entire Study (**Note that an information sheet may be required.)

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For a waiver of signed consent, address the following:

- Would the signed consent form be the only record linking the subject and the research? YES ☒ NO ☐
- Does a breach of confidentiality constitute the principal risk to subjects? YES ☒ NO ☐

OR

- Does the research pose greater than minimal risk? YES ☐ NO ☐
- Does the research include any activities that would require signed consent in a non-research context? YES ☐ NO ☐

☒ **Requesting a waiver of consent:**

☒ **Recruitment/Screening only** *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ **Entire Study**

For a full waiver of consent, please address all of the following:

- Does the research pose greater than minimal risk to subjects?
  - ☐ Yes ***If you answered yes, stop. A waiver cannot be granted.***
  - ☒ No
- Will the waiver adversely affect subjects' rights and welfare? YES ☐ NO ☒
- Why would the research be impracticable to conduct without the waiver? *it is not feasible to consent ever ED patient in order to review the patient demographics in EPIC. Once we verify age, language,* not live in nursing homes or other long-term care sitting, *no recorded signs of EM in Epic, we will then ask 3-4 questions to the patient to determine eligibility.*
- Where appropriate, how will pertinent information be returned to, or shared with subjects at a later date? *Write here*

SECTION IV: PROTECTION OF RESEARCH SUBJECTS

Confidentiality & Security of Data:

This is a single center study. All data will be entered into databases that are protected with appropriate passwords and routine backups of all data will be carried out. All data collected on the subjects will be coded with numbers to maintain confidentiality. Access to the files will be restricted to the investigators and study personnel on this protocol. It is possible that the Human Investigation Committee, YCCI, or the NIH, may review study results during auditing procedures but these individuals are required to keep all information confidential.

Clinical data will be stored with specific patient identifiers, (de-identification of samples), and maintained in a locked file, separate from any other clinical records with limited access, to assure patient confidentiality. Results will be assembled with confidential clinical research records, but will be unidentifiable without these files, to assure confidentiality. The only data that will be used in this study is the information directly obtained from the subjects.

1. What protected health information (medical information along with the HIPAA identifiers) about subjects will be

collected and used for the research? Medical records will be reviewed to collect the following variables: MRN, DOB, Not in full trauma track on arrival, Able to communicate in English, Not in police custody? Living in community dwelling? No signs of elder mistreatment? No active psychotic symptoms? No intoxication? Clinician approves? No severe hearing/vision impairment?Passed Abbreviated Mental Test 4 (AMT4) (which asks the patient to report their age, date of birth, current location, and year) .

2. How will the research data be collected, recorded and stored? We will have shadow files on each subject. Data of the study will be entered into a secure database. In this study, the following materials will be collected from human subjects: questionnaire, study subject's study ID, and signature. All paper documents will be maintained in a locked file, separate from other clinical records to assure confidentiality. All electronically stored data will be encrypted and password-protected. Only the primary investigator, co-investigators, study coordinator and programmers will have access to subjects' data. All datasets will be de-identified and only known to study investigators involved in consent and data acquisition. All information relating to participating subjects will be deidentified.
3. How will the digital data be stored? ☐CD ☐DVD ☐Flash Drive ☐Portable Hard Drive ☐Secured Server ☐Laptop Computer ☐Desktop Computer ☒Other on secure database server.

4. What methods and procedures will be used to safeguard the confidentiality and security of the identifiable study data and the storage media indicated above during and after the subject's participation in the study?

   The VOICES system will be designed to ensure compliance with good research practice regarding the management of research data containing Protected Health Information (PHI). VOICES will adopt comprehensive security strategies that will assure the confidentiality and privacy of the patient and clinical information. Only authorized users will have access to patient PHI, which will help assuage concerns participants may have regarding the privacy and security of their data. The guidelines contained in the Common Framework give a detailed specification of technical architecture, privacy safeguards, and several approaches to health information exchange. We will utilize this framework to protect patient privacy and keep PHI under strict local control. We will continuously evaluate our security practices in order to quickly identify any new vulnerabilities that could compromise VOICES integrity and privacy. We will utilize the Yale Information Technology Services (ITS) existing privacy and security practices and technology, and incorporate Yale ITS-consistent policies into VOICES development and implementation. In addition to tier separation and firewall protection, the three-tiered architecture maintains VOICES security, confidentiality, and privacy. VOICES will maintain data security with appropriate encryption, system controls and audit trails. *Paper surveys will be stored in a locked area. All electronic data will be de-identified and stored in secure database.*

All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url http://its.yale.edu/egrc or email it.compliance@yale.edu

5. What will be done with the data when the research is completed? Are there plans to destroy the identifiable data? If yes, describe how, by whom and when identifiers will be destroyed. If no, describe how the data and/or identifiers will be secured.
   Data will be stored in safe secure server.
6. If appropriate, has a Certificate of Confidentiality been obtained? *YES*

SECTION V: POTENTIAL BENEFITS

Potential Benefits: Identify any benefits that may be reasonably expected to result from the research, either to the subject(s) or to society at large. (Payment of subjects is not considered a benefit in this context of the risk benefit assessment.)

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Although there are risks to the subjects, the benefits outweigh the risks. EM can have profound medical consequences for victims, significantly increasing their risk for mortality, exacerbations of chronic illnesses, and depression. EM is very seldom identified, and low rates of identification and reporting have likely led to much of the associated morbidity and mortality. Therefore, by increasing identification of this morbid and mortal phenomenon, the VOICES tool may offer significant benefits to patients. A potential benefit for the participants is that they will gain better self-awareness, enhance and support self-disclosure, and improve reporting of EM at the point-of-care setting, which may result in, better emotional and physical health, increased safety, and quality of care.

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SECTION VI: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

1. **Alternatives:** What other alternatives are available to the study subjects outside of the research?
   Currently, there are limited measure for EM screening in the ED and only the patients with clear signs of abuse and neglect get the in-person screening from their provider or social worker. The alternative is to decline participation in the study.
2. **Payments for Participation (Economic Considerations):** Describe any payments that will be made to subjects, the amount and schedule of payments, and the conditions for receiving this compensation.
   Participants will received $20 compensation for their participation.
3. **Costs for Participation (Economic Considerations):** Clearly describe the subject's costs associated with participation in the research, and the interventions or procedures of the study that will be provided at no cost to subjects.
   There will be no cost to subjects for participation in the study.
4. **In Case of Injury:** This section is required for any research involving more than minimal risk, and for minimal risk research that presents the potential for physical harm (e.g., research involving blood draws).

   a. Will medical treatment be available if research-related injury occurs? *Write here*
   b. Where and from whom may treatment be obtained? *Write here*
   c. Are there any limits to the treatment being provided? *Write here*
   d. Who will pay for this treatment? *Write here*
   e. How will the medical treatment be accessed by subjects? *Write here*

IMPORTANT REMINDERS

APPROVED BY THE YALE UNIVERSITY IRB 7/16/2020

Will this study have a billable service? **Yes** ☐ **No**☒

A billable service is defined as any service rendered to a study subject that, if he/she was not on a study, would normally generate a bill from either Yale-New Haven Hospital or Yale Medical Group to the patient or the patient's insurer. The service may or may not be performed by the research staff on your study, but may be provided by professionals within either Yale-New Haven Hospital or Yale Medical Group (examples include x-rays, MRIs, CT scans, specimens sent to central labs, or specimens sent to pathology). Notes: 1. There is no distinction made whether the service is paid for by the subject or their insurance (Standard of Care) or by the study's funding mechanism (Research Sponsored). 2. This generally includes new services or orders placed in EPIC for research subjects.

If answered, "yes", this study will need to be set up in OnCore, Yale's clinical research management system, for Epic to appropriately route research related charges. Please contact oncore.support@yale.edu

Are there any procedures involved in this protocol that will be performed at YNHH or one of its affiliated entities? **Yes** ☐ **No** ☒

If Yes, please answer questions a through c and note instructions below.

a. Does your YNHH privilege delineation currently include the **specific procedure** that you will perform? **Yes** ☐ **No** ☐

b. Will you be using any new equipment or equipment that you have not used in the past for this procedure? **Yes** ☐ **No** ☐

c. Will a novel approach using existing equipment be applied? **Yes** ☐ **No** ☐

If you answered "no" to question 4a, or "yes" to question 4b or c, please contact the YNHH Department of Physician Services (688-2615) for prior approval before commencing with your research protocol.

IMPORTANT REMINDER ABOUT RESEARCH AT YNHH

Please note that if this protocol includes Yale-New Haven Hospital patients, including patients at the HRU, the Principal Investigator and any co-investigators who are physicians or mid-level practitioners (includes PAs, APRNs, psychologists and speech pathologists) who may have direct patient contact with patients on YNHH premises must have medical staff appointment and appropriate clinical privileges at YNHH. If you are uncertain whether the study personnel meet the criteria, please telephone the Physician Services Department at 203-688-2615. **By submitting this protocol as a PI, you attest that you and any co-investigator who may have patient contact has a medical staff appointment and appropriate clinical privileges at YNHH.**

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