PROTOCOL TITLE: REDUCING ASSESSMENT BARRIERS FOR PATIENTS WITH LOW LITERACY

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1.0 Purpose of the Study:

1.1 The purpose of this study is to determine the effects of health literacy on questionnaire based measurement.

2.0 Background / Literature Review / Rationale for the study:

2.1 Low health literacy as a barrier to healthcare. Health literacy is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[1] A vast body of research shows that lower health literacy is associated with poorer outcomes, including higher hospitalization rates, worse health, and greater mortality.[2-27] Approximately 75 million U.S. adults have low health literacy.[28] Worse yet, racial and ethnic minorities and older individuals (age 65+) are more likely to have low health literacy,[29] creating another mechanism for health disparities.[30-33] These data indicate that many people will have difficulties adhering to treatment regimens that require health literacy,[34] as well as completing questionnaires for public health and health research and care.

2.2 Improving self-report assessment. Health surveys are ubiquitous, but almost no questionnaires used across the country have been validated for use with people who have low health literacy. This is a glaring shortcoming in current survey validation methodology; inaccurate surveys lead to false conclusions and threaten the empirical foundation of everyone's efforts to understand and improve public health, healthcare, and health outcomes. Our goal is to rectify this shortcoming. This study will 1) determine the effect of health literacy on widely-used questionnaires, 2) determine the stability of psychometric properties of questionnaires over time, and 3) test various testing formats to determine which ones work best for people with low health literacy.

2.3 Reducing dementia-screening bias for people with low health literacy. Dementia screening tools are confounded with health literacy, but no means exist for correcting this test bias. Moreover, dementia-screening tools have not been validated for use by patients with low health literacy. Thus, screening may be inaccurate, leading to over-and under-diagnosis and in turn wasted resources on inappropriate care. A false-positive diagnosis is also extremely distressing for the patient. Thus, improvements in dementia screening are needed. Our goal is to determine differences in psychometric properties of dementia screening tools that are widely used in the clinical setting.

3.0 Inclusion and exclusion criteria:

Inclusion criteria:

1) Be 18 years of age or older
2) Be willing to provide informed consent, including signing the consent form
3) Be willing to be randomized to administration method
4) Be willing to complete questionnaires and interviews
5) Be fluent in English and/or Spanish
6) Be willing to attend three face-to-face sessions
7) Have no plans to move out of the study area in the next six months

Exclusion criteria:

1) Significant cognitive or neurologic impairment
2) Being a prisoner, detainee, or in police custody
3) Unable to complete the consent process
4) Inadequate vision to see study materials (worse than 20/80 corrected)
5) Inadequate hearing or manual dexterity to use the computer system

4.0 Procedures Involved:

4.1 Research setting: Participants will be recruited from clinics within Northwestern Medicine, or will be invited to come to our clinical research space on campus for three visits: Baseline, 3-month follow-up, and 6-month follow-up.

4.2 Study design and rationale: The study is a two-group, three time-point experimental design. The two study groups are paper-and-pencil questionnaires versus a computerized talking touchscreen interface. The three time points are baseline, 3-month follow-up, and 6-month follow-up. The rationale for this design is that it will allow us to compare two models of administration as well as to examine how the psychometric properties of questionnaires change over time.

4.3 Description of research procedures and activities: A research team member will screen potential participants for eligibility (see inclusion and exclusion criteria above). Eligible and interested participants will receive information about the study and will be invited to provide informed consent. Once informed consent is obtained, the research coordinator will administer a language assessment tool to participants to determine whether their testing needs to be conducted in English or Spanish. Next, participants will fill out the following assessments:

Visit 1	**Description of instrument**
Language Assessment	To determine testing in English or Spanish.
Single Item Health Literacy Screener	To screen for possible literacy status.
Short Portable Mental Status Questionnaire (SPMSQ)	To determine cognitive status to ensure the possible participant has sufficient mental status to participate.
Demographics	To assess participant characteristics.
Cognitive Screening questions	Unique items of the MoCA-B, MoCA 8.1 and RUDAS dementia screening tools
Health Literacy Assessment (Health LiTT)	Assessment of health literacy.
NUMI	Assessment of numeracy. That is, how well the person can process numerical information.
PROMIS Profile	To assess health-related quality of life.
PHQ-9	Self-report measure of depression.
Berlin Questionnaire (for sleep)	Self-report measure of sleep quality.
Purpose and Meaning (NIH Toolbox)	Self-report measure of the degree of meaning and purpose a person feels in their life.
Ruminative Responses Scale (RRS)	Self-report measure of negative, repetitive thoughts.
PTSD Checklist	Self-report measure of posttraumatic stress disorder symptoms.
* C-SSRS Lifetime	Self-report measure of recent history of suicidal ideation and behavior. (*This is not a variable of interest that will be used only to ensure patients' safety*).
*C-SSRS Last Contact	Self-report measure of suicidal ideation and behavior since the individual's most recent assessment. (*Used only as necessary to ensure patients' safety*).
Visit 2	
*Optional: Cognitive Screening questions	**If not administered at Visit 1
PROMIS Profile	To assess health-related quality of life.
PHQ-9	Self-report measure of depression.
Berlin Questionnaire (for sleep)	Self-report measure of sleep quality.
Purpose and Meaning (NIH Toolbox)	Self-report measure of the degree of meaning and purpose a person feels in their life.
RRS	Self-report measure of negative, repetitive thoughts.
PTSD Checklist	Self-report measure of posttraumatic stress disorder symptoms.
*C-SSRS Lifetime	Self-report measure of recent history of suicidal ideation and behavior. (*This is not a variable of interest that will be used only to ensure patients' safety*).

*C-SSRS Last Contact	Self-report measure of suicidal ideation and behavior since the individual's most recent assessment. (*Used only as necessary to ensure patients' safety*).
Visit 3	
*Optional: Cognitive Screening questions	**If not administered at Visit 1 ***or*** Visit 2
PROMIS Profile	To assess health-related quality of life.
PHQ-9	Self-report measure of depression.
Berlin Questionnaire (for sleep)	Self-report measure of sleep quality.
Purpose and Meaning (NIH Toolbox)	Self-report measure of the degree of meaning and purpose a person feels in their life.
RRS	Self-report measure of negative, repetitive thoughts.
PTSD Checklist	Self-report measure of posttraumatic stress disorder symptoms.
*C-SSRS Lifetime	Self-report measure of recent history of suicidal ideation and behavior. (*This is not a variable of interest that will be used only to ensure patients' safety*).
*C-SSRS Last Contact	Self-report measure of suicidal ideation and behavior since the individual's most recent assessment. (*Used only as necessary to ensure patients' safety*).
Exit Interview	

*Only those who endorse suicidality in the PHQ-9 will get either the C-SSRS Lifetime or the C-SSRS Last Contact.

At one of the time-points participants will complete a battery of cognitive screening questions. The cognitive screening questions are the unique variables from the following dementia screening tools: MoCA-B (Montreal Cognitive Assessment, Basic), MoCA 8.1 (Montreal Cognitive Assessment, Version 8.1), and RUDAS (Rowland Universal Dementia Scale). The cognitive screening questions will be administered to new study participants at Visit 1 after consenting. Previously enrolled participants will be offered the cognitive screening questions at their next visit (either Visit 2 or Visit 3). If a previously enrolled participant wants to complete the cognitive screening questions, they will be re-consented with the updated consent form and the cognitive screening questions will be administered at the visit when they are re-consented. If a previously enrolled participant does not want to participate in the cognitive screening questions, we will not re-consent them and they will complete the rest of the protocol as outlined in the original consent form, which contains all of the assessments in the table above with the exception of the cognitive screening questions.

Participants will be randomized into one of two testing schedule orders to receive the core battery for testing. The core battery includes the following questionnaires: PROMIS Profile, PHQ-9, Berlin Questionnaire, Purpose and Meaning (NIH Toolbox), RRS, PTSD Checklist. The following table indicates the two orders for core battery testing:

Order 1	**Order 2**
PROMIS Profile	PHQ-9
Berlin Questionnaire	RRS
Purpose and Meaning (NIH Toolbox)	PTSD Checklist
PTSD Checklist	Purpose and Meaning (NIH Toolbox)
RRS	Berlin Questionnaire
PHQ-9	PROMIS Profile

Next, depending on which randomized condition, the participant will complete all the questionnaires via paper-and-pencil or using a talking-touchscreen format which is computerized and give the participant the opportunity to have questions read aloud.

At the end of each visit, a research assistant will briefly speak with the participant to learn about their experience during the visit and to find out if those randomized to the talking-touchscreen format utilized the audio files. To assess this, we will ask the following questions and record the responses on REDCap:

1. How did the questionnaires go?
2. Did you use the audio? (all, some, none)
3. On a scale of 0-10 (with 0 being very unhelpful and 10 being very helpful), how helpful did you find the audio? (1-10)

At the end of the study, a research assistant will also debrief the participant about the purpose of the study, and conduct an exit interview to determine how comfortable the participant felt answering the questions and to learn what did and did not work well. As part of the exit interview, for participants that are 45 years of age or older, we will ask a short battery of questions about colon cancer screening and then all participants will be presented with a small set of questions to get detailed feedback from individuals on how they understood certain questions, what type of response format they prefer, and what was or was not confusing. These colon cancer screening questions relate to the Meaning and Purpose questionnaire that is already embedded in our study as individuals who report greater meaning and purpose are more motivated to engage in their healthcare and improve their overall health and wellbeing and are more likely to participant in preventive health services, including colonoscopies, etc. Based on screening recommendations from the American Cancer Society, we will be asking these additional questions to participants that are 45 years of age or older to determine if participants are adherent to the recommended screening timeframes. According to the guidelines from the United States Preventive Services Task Force and the American Cancer Society. Participants are classified as adherent if they reported receipt of either a FOBT within 1 year, colonoscopy within 10 years, sigmoidoscopy within 5 years, or both a colonoscopy and sigmoidoscopy within 10 years. We will then relate participant's adherence to their answers to the Meaning and Purpose questionnaire.

4.4 Monitoring of participant safety: This study involves the completion of questionnaires and literacy tests. As far as we know from our extensive experience with these tests, there are no psychological or physical risks. We will be asking questions about depression and anxiety. Thus, after each assessment, the research coordinator will review these questionnaires to determine whether significant depression or anxiety is present. All participants will be given a referral list at the end of each study visit in case the need ever arises for him or her to seek mental health treatment.

All research team members will be trained to assess suicidality using C-SSRS, a state-of-the-art and widely used suicide assessment tool. If any participant endorses suicidality on the PHQ-9, the research assistant/coordinator will notify any licensed psychologist or physician on the research team, either in person or via text page. Then the participant will be screened using the C-SSRS for further assessment. If the licensed psychologist/physician is immediately available they will assess the participant. If a licensed psychologist/physician is not immediately available, the research assistant/coordinator will begin the C-SSRS assessment until the licensed psychologist/physician can arrive. Suicide prevention steps will be taken in the unlikely event that a participant has active suicidal intentions; these

procedures include taking the participant to the Northwestern Medicine Emergency Department or notifying emergency services by calling 911.

4.5 Study Timeline. We anticipate recruitment of participants to begin March of 2018, preceded by a brief pilot-testing phase to ensure all procedures run smoothly. We aim to recruit 17 participants per month for three years to reach our local (i.e., Northwestern) target of N = 600. Each participant will be invited to complete a baseline (i.e., visit 1), three-month (i.e., visit 2), and six-month (i.e., visit 3) follow-up assessment. The first visit will take between 120-150 minutes and the second and third visits will last 60-90 minutes each. The final year of the project will be used for data analysis, manuscript writing, and study close-out.

4.6 Types of assessments completed. Participants will provide data via performance-based tests of health literacy. Depending on randomization, participants will also complete 1) paper-and-pencil questionnaires, or 2) a talking-touchscreen computer interface that allows the participant to have the computer read text aloud. As part of the exit interview, the research coordinator will also collect rating-scale data about different aspects of the testing environment. No specimens are collected as part of this study.

4.7 This is a multi-site study; the other site is Boston University Medical Center (BUMC). The research team at BUMC will submit the protocol to their IRB for approval.

4.8 Describe any approvals that will be obtained prior to commencing the research. None

4.9 Possible coercion in vulnerable individuals. This research does not include any coercive procedures. The total compensation is modest ($30 on average per 1-2-hour visit). During the informed consent process, it will be made unmistakable that participation is voluntary, and that individuals can stop participating at any time.

4.10 Participation of pregnant women. This study involves only answering questions via paper-and-pencil or computerized touchscreen, as well as some interview-based questions from a study team member. There are no known risks associated with these methods, either to a pregnant mother or to a fetus.

4.11 Neonates of uncertain viability or nonviable neonates. This is not applicable to the current protocol.

4.12 Participation of prisoners. Prisoners or other incarcerated persons are not eligible for participation.

4.13 Participation of children. Only adults, age 18 and older, are eligible to participate in this research.

4.14 Cognitive impaired adults. Participants with severe cognitive impairment will be considered ineligible for this study. The research coordinator will administer a cognition screener (i.e., SPMSQ) that assess for any severe cognitive impairment to determine eligibility for this study. Participants with known mild-to-moderate cognitive impairment may be referred by clinicians to enhance our participant sample for the dementia supplement. Only those deemed capable of providing consent (based on the SPMSQ score) will be considered for the study and their diagnosis of mild-to-moderate cognitive impairment will be noted in the study's REDCap project.

5.0 Multiple sites:

5.1 Study sites. This study is being conducted at two sites: Northwestern University and Boston University Medical Center (BUMC). Dr. Griffith is the PI of the Northwestern site and Dr. Michael Paasche-Orlow is the PI of the BUMC site. Northwestern is the grant-holding site with Dr. Griffith as the contact PI, but both PIs share overall leadership of the study. Both sites will recruit an equal number of participants (N = 608).

5.2 Required approvals. Recruitment will proceed at each individual site only when approved by the local IRB.

5.3 Site coordination. The sites are in frequency phone and email contact, and there is a weekly teleconference in place for the PIs and research coordinator to aid in consistency of study procedures. An all-team meeting is scheduled for once per month. To ensure that both sites are using the appropriate documents for the study, there is a shared, secure site on Box.com for all study materials (Note: No patient data or PHI is stored on Box, only study materials). Modifications to study protocols will be discussed among the team during the weekly teleconferences. These teleconferences will also be used to discuss problems, interim results, and eventual closure of the study.

5.4 Data management and security. The entire study team has been briefed on proper data management and security procedures. This includes the maintenance of data only on secure study trackers, managed via REDCap. Data security will be a weekly agenda item and data security will be routinely audited in terms of physical records (i.e., paper questionnaires and consent forms) as well as study files. Any and all non-compliance with the study protocol or applicable requirements will be reported to the appropriate IRBs in accordance with local policy.

6.0 Incomplete Disclosure or Deception:

There is no deception or incomplete disclosure as part of this study.

Recruitment:

We plan to recruit no more than 608 participants. They will be recruited through Northwestern Medicine with the assistance of our physician coinvestigator, Dr. O'Brien, and Northwestern Medicine Enterprise Data Warehouse (EDW). EDW contains clinical data from NMHC which is mined by a team of data analysts at Feinberg School of Medicine. The study team will work with the data analysts to define a cohort of patients to be recruited. Patients will then be contacted in accordance with NMHC and NU IRB policy including obtaining physician consent and sending an IRB and NMHC approved mailing (e.g., letter or email) before contacting patients either by phone or by email. The study team will screen for eligible participants using Epic, which is the electronic medical record that these clinics use. Via Epic, the research coordinator(s) will identify potential participants within our physician coinvestigator's schedule and request permission to approach their patients to assess eligibility and interest in the study. Participants will also be screened in clinic waiting rooms. Specifically, with approval from physicians and medical staff, research coordinators will approach potential research participants in Northwestern-affiliated clinics (e.g., Erie Family Health Center) and provide them with information about the study. The physician coinvestigators will also alert the coordinators of eligible participants. Interested participants will be invited to provide informed consent, and will then complete all the research measures relevant to the first visit in a private clinic room. Subsequently, they will be scheduled for their second and third visits. If needed, the research team will contact other physicians within General Internal Medicine at Northwestern Medicine for approval to contact their patients.

To enhance the study's sample of older adults and adults with mild-to-moderate cognitive impairment, the research team will collaborate with physicians that see these patients for recruitment into the study. The research team has requested access from the Mesulam Center for Cognitive Neurology and Alzheimer's Disease Center (CNADC) to use their registry of adults with mild-to-moderate cognitive impairment. We will also partner with other collaborators within NMHC, such as neuropsychologists, gerontologists, etc. to see if they would be interested in referring their patients to our study. The research team has also partnered with a Melvin Thompson who is a member of the advisory board at the Woodson

Regional Library, Chicago's first Dementia-friendly library in the Washington Heights neighborhood of Chicago. Mr. Thompson has agreed to provide recruitment support from members in the community he serves at Woodson Regional Library and via the Endeleo Institute.

Potential participants will also be recruited through community-based outreach methods, digital and print advertising (e.g., flyers, postcards, email outreach, web postings, ads on transit lines, newspaper ads, radio ads), and registries (e.g., Research Match, Illinois Women's Health Registry). Research Match is a secure online, national recruitment tool that is maintained by Vanderbilt University. ResearchMatch.org allows researchers to conduct feasibility or recruit potential study participants. Participants who are interested and released their contact information to the study team will be contacted via telephone or email. If participants cannot be reached via telephone, the Research Match follow-up email will be sent to them via email. The Illinois Women's Health Registry was established and overseen by Northwestern University's Women's Health Research Institute at the Feinberg School of Medicine to encourage investigator-initiated research targeting women's health. The role of the Registry is to facilitate the recruitment and identification of women who may be eligible to participate in IRB approved research being conducted at Northwestern University and other research institutions across the state of Illinois. Potential participants may also be recruited online through digital marketing tactics (e.g., GoogleAds, Facebook ads and posts, web display advertising) on websites (e.g., local digital news sources) and social media websites such as Facebook, Twitter, and Instagram. If potential participants are interested in the study, they will be able to contact the research staff via the telephone number given on the ads or click on a link to complete a brief online screener to be administered using Redcap. The online screener will be followed up with a more detailed pre-screening over the phone to assess and verify their eligibility to enroll. During pre-screening, we will explain the purpose of the study and will go over all inclusion and exclusion criteria as indicated in the protocol. Telephone and online pre-screening will be managed by the research team. If participants haven't already completed the brief pre-screener online, the study coordinator(s) will go over it with them over the phone after providing participants with more info about the study. If the individual is eligible and still interested in participating at the end of the phone screening procedure, the coordinator will schedule a time for them to come in for Visit 1.

Participants will receive $40 upon completion of the baseline visit, $50 after the 3-month visit, and $60 after the 6-month visit in the form of cash. In addition, they will receive parking passes at each one of their visits to cover the cost of their parking if they parked in a specified Northwestern garage. If needed, taxi or similar transportation (e.g., Lyft) will be arranged for participants, which will be paid for by the research project. Participants will receive up to $22.50 for transportation costs. Additionally, participants will receive $25 upon completion of the cognitive screening questions.

After Visit 1, the participant will receive the 1-page Summary Sheet of the research study as a retention material to remind participants of the importance of the research and what to expect next in the study. Additionally, after each visit the participant will receive a "Thank You Card" as a retention material. These "Thank You Cards" will be handwritten by the principal investigator to include the following text, "Thank you for your participation in our study. With your help, we will be able to talk to patients more clearly. We hope this work will help us provide better health care in the future. We couldn't do it without you!"

8.0 Consent Process

Consent will be obtained from the patient by bilingual (English/Spanish) research staff. The informed consent process is expected to take up to 20 minutes. Research coordinators obtaining consent will verbally explain the form and also allow time for the participant to read the form in its entirety. The participant will be free to consult with family if desired. After all the participant's questions have been

answered, the research staff will ensure the participant understands the purpose and procedures involved in the study by relying on the Informed Consent and Authorization Toolkit for Minimal Risk Research recommendations. Specifically, research staff will implement the teach-back method and ask participants questions about the consent process. Participants will be given time to make a decision about their enrollment once it is established that they possess an appropriate level of understanding of all aspects of the consent process. Otherwise, they will be screened out. The original signed written consent form will be kept separately from research data and a signed copy will be given to the patient. Spanish speaking participants will have access to translated Spanish translated materials and the Spanish-speaking research coordinators will ensure that they understand all aspects of the verbal and written information given to them during the informed consent process.

This research will not be recruiting neonates, prisoners, persons under the age of 18, or adults with severe cognitive impairment. Pregnant women will be eligible to participate with their informed consent. This study involves only the completion of self-report questionnaires. Thus, we do not foresee any risks to pregnant women or to the pregnancy. All participants will be screened for cognitive impairment by the research coordinator using the SPMSQ to determine eligibility for this study. Only those deemed capable of providing consent (based on the SPMSQ score) will be considered for the study and their diagnosis of mild-to-moderate cognitive impairment will be noted in the study's REDCap project. Any participant deemed to have severe impairment on this screening test will be deemed ineligible to participate.

9.0 Process to Document Consent:
We will be following "SOP: Written Documentation of Consent (HRP-091)."

10.0 Risks to Participants:
This study is low risk; only standard questionnaires and interviews are being used, none of which have significant risks beyond any discomfort associated with answering health questions. Some participants may experience some emotional distress when answering sensitive questions. Our team, however, has a high level of clinical experience and will be able to discuss these issues with participants as needed, and provide appropriate referrals if desired by a participant.

11.0 Adequacy of Protection against Risks:
All research proposals are submitted for approval to the Northwestern University Institutional Review Board and the Boston University Medical Campus (BUMC) Institutional Review Board. All research personnel are trained and certified in research and HIPAA regulations. Established policies and procedures allow for all individuals receiving healthcare at Northwestern Medicine and Boston Medical Center and affiliated Community Health Centers to be considered as potential candidates for research, with study personnel only approaching eligible patients after they have been informed of the study's nature by their healthcare provider, and agree to be approached.

Participants will be withdrawn at their request. If a participant wishes to withdraw, we will document the reasons for withdrawal for tracking purposes and for reporting to the IRB.

12.0 Financial Compensation:
Participants will receive $40 upon completion of the baseline visit, $50 after the 3-month visit, and $60 after the 6-month visit in the form of cash. In addition, they will receive parking passes at each one of their visits to cover the cost of their parking if they parked in a specified Northwestern garage. If needed, taxi transportation will be arranged for participants, which will be paid for by the research project.

Participants will receive up to $22.50 for transportation costs. Participants will also be compensated $25 upon completion of the cognitive screening questions.

12.1 Participants may be liable for covering transportation costs if those exceed $22.50. Further, they may be billed for research-related injuries. Specifically, all medical care will be billed to the participant, their insurance, or another third party. Northwestern Medicine has no program to pay for medical care for research-related injury. It is very unlikely that this study will cause any injuries; the study involves only completing standard questionnaires. If at any moment a participant refuses to answer a questions or withdraws from the study, they will still be compensated for that particular study visit.

13.0 Provisions to Protect the Privacy Interests of Participants:

Data on social and medical history (e.g., age, date of birth, gender, and race/ethnicity) will be obtained from the patient's electronic medical record to maintain privacy. Medical history data will be extracted from Epic via the EDW for purposes of calculating a single index of medical comorbidity, the Charlson Comorbidity Index. This index uses the presence versus absence of administrative codes in the medical record to determine certain diseases and syndromes that may be present; these include myocardial infarction, congestive heart failure, peripheral vascular disease or bypass, cerebrovascular disease or transient ischemic disease, hemiplegia, pulmonary disease/asthma, diabetes, diabetes with end organ damage, renal disease, mild liver disease, severe liver disease, gastric or peptic ulcer, cancer (lymphoma, leukemia, solid tumor), metastatic solid tumor, dementia or Alzheimer's disease, rheumatic or connective tissue disease, HIV or AIDS, hypertension, skin ulcers/cellulitis, depression, and warfarin use. These data will be combined into a single number that summarizes the degree of comorbidity faced by the individual patient. Data will be analyzed to determine whether health literacy and medical comorbidity interact in determining responses to questionnaires.

Other than the above-mentioned medical history and demographic variables, no other data will be retrieved from Epic.

Participants will interact with the study coordinator who will verify age, date of birth, race, and ethnicity date. The study coordinator will be the point person to answer any and all questions about the study. All study procedures will be conducted in a private space. Participants will be informed that they are allowed to skip any question that makes them feel uncomfortable or that they would not like to answer. Participants will be made aware of all of the examinations and research procedures that will take place ahead of time so that they are fully aware of what is required of them. The subject will be able to withdraw from the research study at any time. The research team is permitted to access the participants' medical records, which includes social and medical history. Only information that is pertinent to the research study will be viewed and collected. Any information that will be put into our databases will be collected from the EDW.

14.0 Confidentiality and Data Management:

Special procedures for ensuring patient confidentiality will be implemented. Data transmission and the distributed data systems will have multiple layers of security. All study data will be entered into the electronic data entry system by study coordinators at Northwestern. All databases will be on password protected computers, and the database will be password protected. The database will be stored on a Northwestern share drive, which is regularly backed up. Paper data (i.e. consent forms, data collection forms) collected from participants will be stored in a locked file cabinet at 625 N Michigan, 27th floor, in the department of Medical Social Sciences. Only authorized research personnel will have access to this data.

Each study subject will be assigned an identification number. Only this number will be used to identify subjects in any individual tabulation. The PHI that is collected will represent the minimum necessary to successfully execute the study.

Any PHI will be securely requested via the EDW. Only group-level data will be included in publications and presentations. If individual participated data are to be published, no identifying information will be included. The study files will be maintained in a secure location in our department. Access to computerized data will be restricted to study personnel. Password authorization will be enforced. Previous use of this security system and a secured server indicates that this technique is very successful in assuring the protection of confidential information.

The data will be stored on a secure server with restricted access. Nonetheless, there is always the possibility of unauthorized release of data about the participants. Such disclosure would be extremely unlikely to involve a threat to life, health, or safety. It is conceivable that such disclosure could have psychological, social, or legal effects on the patient. Using the standard security procedures (described above) can effectively minimize the risk of unauthorized disclosure of data. All study personnel who have access to patient data will be educated regarding the need to protect confidentiality and the procedures to be followed to ensure such protection. After the study is completed, the databases will be stored on public repositories. The databases in these repositories will be de-identified to obviate further privacy and security considerations.

Authorized representatives of the National Institutes of Health (NIH), as well as authorized members of the IRBs, will have also have access to study records.

There are no specimens associated with this study.

15.0 Data Monitoring Plan to Ensure the Safety of Participants:

We are asking questions about depression and anxiety, for which good treatments exists. As such, we will give all participants a referral list for possible mental health treatment, with information letting them know that they can contact us at any time for additional help finding a referral. Giving this information to <u>all</u> participants ensures that no person will be missed, and also reduces any feelings of stigma that might arise if the person felt singled out based on their responses. As described above, we will monitor the suicidality item of the PHQ-9 at each and every visit. Based on the PHQ-9, the coordinator will follow up as needed with the C-SSRS to assess whether additional assessment and/or intervention are needed. The C-SSRS will serve as the report form to document this additional information. For any participant with moderate or greater risk, a licensed psychologist or physician on the research team will talk to the participant to gather more information and make appropriate recommendations and referrals. As described above, any immediate suicidal intent will be treated as a life threatening emergency. We will take the person to the Emergency Department or involve emergency services from 911 if needed.

16.0 Data and if applicable, Specimen Banking: No
Biosample Storage and Shipment will be used

17.0 Qualifications to Conduct Research and Resources Available:
Our team includes the PI, a licensed clinical psychologist with extensive experience delivering psychotherapy as well as in health-related research. We also have licensed internists on the team. Our team has extensive experience working with patients across a variety of settings. Additionally, our

research coordinators have graduate degrees and extensive experience interpreting and translating documents from English to Spanish.

No additional psychological or medical resources should be needed as a result of this study. If further needs should arise, however, the study PI will assist the participant in getting connected with appropriate follow-up care. All participants will be given a referral list at the end of the study.

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