CONFIDENCE-AI Financial Education for Caregivers (CONFIDENCE-AI)

Study Protocol and Statistical Analysis Plan

NCT0613418

May 19, 2025

[USE THIS TEMPLATE IF YOUR PROJECT INCLUDES SURVEY, INTERVIEWS, FOCUS GROUPS OR EDUCATIONAL RESEARCH ACTIVITIES WITH NO BIOMEDICAL/CLINICAL COMPONENTS]

INSTRUCTIONS:

- *Use this template to prepare your IRB Protocol.*
- *Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, please mark as N/A.*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *Consider using a different color font for your answers.*

PROTOCOL TITLE:
Include the full protocol title.
CONFIDENCE 2 Financial Education Program Evaluation.

PRINCIPAL INVESTIGATOR:
Name: Kylie Meyer

DATE: 5/19/2025

Indicate the origin of this protocol (who conceived of and leads the development of the protocol regardless of funding):
☒ Investigator initiated *(Investigator(s) developed protocol, regardless of funding)*
☐ Industry *(Pharmaceutical, Device, etc.) (Industry developed protocol)*
☐ Federal *(NIH, DOD, etc.)*
☐ Cooperative Group *(SWOG, GOG, etc.)*
☐ Other - Please specify: Click here to enter text.

Has this study been disapproved by or withdrawn from any other IRB?
☐ Yes ☒ No
If so, please explain: .

Does this study involve cancer research or cancer-related issues?
☐ Yes ☒ No
If yes, indicate the PRMC number: Click here to enter text.

Is this a student led study?
☐ Yes ☒ No
If yes, is the student: ☐ Undergrad ☐ Graduate Student ☐Other Click here to enter text.
If yes, is the project: ☐ Capstone ☐ Master's thesis ☐ PhD dissertation
☐Other Click here to enter text.

Is this work part of a larger collaborative research project where more than one institution is participating in the research? (*In collaborative projects, data/specimens/results are often shared between researchers at the participating institutions, and they will publish together.)*

☐ **No** ☒ **Yes**

If yes, please explain.

We are collaborating with the University of Southern California, where the intervention is being administered as a part of a social service program for caregivers (USC Family Caregiver Support Program). USC may participate in the publication of findings but is not involved in data collection procedures, other than registration data used as a part of regular programming. We are also working with Amicus Brain Innovations as a study partner. Amicus Brain Innovations is responsible for building out technology components of the CONFIDENCE program. They will store data such as utilization data (e.g., receipt of text messages) from caregivers in the NeuViCare app that we are integrating into the intervention.

1.0 Funding

If this study is grant funded, is the money coming directly to CWRU from the study sponsor?

☒ Yes ☐ No ☐ N/A, not grant funded

2.0 Objectives

Directions: Describe the purpose, specific aims or objectives. Be sure to also include the hypothesis being tested. The *overall objective* of this project is to test the feasibility, acceptability, and preliminary efficacy on an AI-enhanced psychoeducational intervention to reduce financial strain among Latino/Hispanic family caregivers to people living with dementia (PLWD) by supporting resource access called CONFIDENCE 2. The *central hypothesis* is that caregivers who participate in the CONFIDENCE intervention will report higher levels of resourcefulness and self-efficacy following participation in the CONFIDENCE intervention that will reduce financial strain among caregivers of PLWD.

3.0 Background

Directions: Describe the relevant prior experience and gaps in current knowledge describing how this study will add to existing knowledge. Include any relevant preliminary data. Family caregivers to people living with dementia encounter financial strain, including material, psychological, and behavioral components. Caregivers to PLWD also spend an average of $8,978 per year out-of-pocket on caregiving expenses, which is around $1000 more than caregivers to persons without dementia. Research findings support that caregiving places individuals at increased risk of poverty, due to factors such as reduced ability to engage in employment and spending down one's own savings to cover costs. Financial strain is also a risk factor for caregiver depression and burden which affects 1 in 5 family caregivers to PLWD. Financial strain disproportionately affects Latino/Hispanic family caregivers to PLWD. They spend 47%of their annual household income on out-of-pocket costs of caregiving, compared to 18% among non-Hispanic white, 34% among African American, and 22% among Asian American caregivers. These differences in out-of-pocket expenses are partially due to cultural preferences to provide care at home, such that Latino/Hispanic families provide more intensive care that is more likely to disrupt employment and increases out-of-pocket costs. Further, U.S. Latino/Hispanic households have a median net worth of $52,190 (four times lower than U.S non-

Latino/Hispanic households), which makes it more difficult to absorb out-of-pocket costs when they occur. The impact of financial strain on Latino/Hispanic families is likely to grow substantially, given an anticipated 832% increase in the number of Latinos/Hispanics LWD in 2060. However in 2022 only two studies were found to examine intervention effects on financial strain of Latino/Hispanic caregivers.

To address the need for programs to reduce financial strain among Latino caregivers, we developed the Confidently Navigating Financial Decisions and Enhancing Financial Wellbeing in Dementia Caregiving (CONFIDENCE) program with support from AARP Foundation from 2020 to 2023. The original version of CONFIDENCE includes a 5-week, group-based psychoeducational intervention delivered by Zoom. Most data for the evaluation of the CONFIDENCE original program have been collected. Initial findings indicate high satisfaction with the program among participants (100% "Agree" or "Strongly Agree" they would recommend the program to other caregivers), but also lower-than-anticipated uptake and adherence. For example, only 51% of caregivers registering for CONFIDENCE at the USC Family Caregiver Support Center attended at least one session. Of those who attended at least one session, average attendance was 3.1 out of 5 sessions. These findings suggest high acceptability but limited feasibility.

The second version of CONFIDENCE aims to build on lessons learned from the original CONFIDENCE program with the goal of improving program feasibility prior to testing the program's efficacy. To improve uptake and adherence, we have shortened the number of group-based Zoom discussion sessions from 5 to 4 to reduce the time required to participate. Content covered in the sessions removed from the core program will be delivered by asynchronous, technology-driven means. Participating caregivers will have a chance to decide which topics to focus on based on their current needs and will receive informational text messages covering these topics. Caregivers will also have access to a conversational AI assistant ("Keiko") that will draw from hand-picked and trusted resources to devise answers to questions caregivers may have about topics such as how to find reduced-cost home modifications, how to prepare for retirement, and how to prevent financial scams. To support learning between discussion sessions, NeuViCare also will host a moderated community forum where caregivers can connect with other participating caregivers .

Please add relevant references at the end of the protocol, not at the end of this section.

4.0 Inclusion and Exclusion Criteria

Directions: Describe how individuals will be screened for eligibility.

Participants will be asked to either complete an online self-administered survey to determine their eligibility, or to complete eligibility questions by telephone.

Using the tables below, describe the inclusion and exclusion criteria that will define who will be included and excluded in your final study sample.

	Inclusion
1.	Age range: from 18 to not upper limit
2.	Has been at least 6 months since the care recipient began to experience dementia symptoms
3.	Person living with dementia meets stage 4 to 6 criteria on Global Deterioration Scale according to family caregiver
4.	Latino/Hispanic ethnicity

	Exclusion
1.	Individuals who plan to place their family member in a nursing home in the next 3 months
2.	Unreliable access to internet, tablet or smart phone, and email
3.	Does not agree to participate in at least 3 of the 4 group sessions and/or register for the NeuViCare app
4.	Unable to read and speak in English or Spanish

5.0 Number of Research Participants

Directions: Indicate the target number of research participants to be accrued locally, and, if this is a multi-site study, indicate the total number of research participants to be accrued across all sites.

Example language that can be used: We will enroll 25 subjects at CWRU and plan to enroll 150 subjects study wide. We will recruit 42 family caregivers to account for the anticipated 20% attrition before and after participation in CONFIDENCE 2. Moreover, at least 12 participants will complete qualitative interviews.

6.0 Special/Vulnerable Populations

Indicate specifically if you will include each of the following special populations by checking the appropriate box:

- ☐ **Adults unable to consent**
- ☐ **Minors (infants, children, teenagers)**
  - ☐ Wards of the state (e.g. Foster Children)
- ☐ **Pregnant Women** (only if targeted)
- ☐ **Neonates**
- ☐ **Neonates of Uncertain Viability**
- ☐ **Employees**
- ☐ **Prisoners**
- ☐ **Illiterate Individuals**
- ☒ **Non-English Speaking**
- ☐ **Students**
- ☐ **None**

1. If the research involves students or employees, describe how you will recruit so that:
   a) Employers or educators do not know if someone participated (until after grades have been assigned in the case of educators)
   b) Employers or educators do not *directly* recruit their own students or employees, and anything else to prevent feelings of coercion to those subordinate to their employer or educator.

2. If the research involves individuals that are included in a special/vulnerable population, describe the additional safeguards included to protect the rights and welfare of the individuals for each population indicated. Click here to enter text.

3. If excluding pregnant women, illiterate or non-English speaking individuals, provide a scientific rationale for the exclusion. Inconvenience or cost is not an acceptable rationale. Persons who are illiterate are excluded from the study due to an inability to engage with the program materials, such as the written workbook and text materials.

7.0 International information

☒ This is **not** an international study – *please leave rest of this section blank.*

☐ We will be conducting this research at the following international sites:
Click here to enter text.

☐ We are recruiting participants outside of the US from the following locations:
Click here to enter text.

☐ We are sending data outside of the US to the following locations:
Click here to enter text.

☐ We are receiving data from outside of the US from the following locations:
Click here to enter text.

8.0 Recruitment Methods

Note: Attach all applicable recruitment materials to the last section of the Smart form under "Recruitment Materials."

1. Which of the following methods will be used to recruit research participants? – *Select all that apply*
   - ☒ Email
   - ☒ Phone call
   - ☐ Letter
   - ☒ Advertisement (e.g., poster, flyer, etc.)
     - ☒ I attest that advertisements will only be placed **with permission**
   - ☒ Social media
     - Indicate the platform(s): Facebook
     - ☒ I attest that recruitment information will only be posted **with permission**
   - ☐ Other. *Please specify:* *Click here to enter text.*

2. Describe when, where, how and by whom potential research participants will be recruited. Individuals involved in recruitment should be identified by role and not by name (e.g. study coordinator, co-investigator, research assistant).
Information about CONFIDENCE will be shared by email blast sent to caregivers in the USC FCSC mailing list. USC FCSC Family Consultants will also share information about the program with clients who may benefit (See Talking Points document.). Caregivers may also learn about the study on the Alzheimer's Association TrialMatch

site. Participants who register on Eventbrite and indicate interest in learning more about the study will receive calls and emails from the study team with information about the study. If interested, eligibility screening will be conducted by phone and they will be sent an email with a REDCap consent form to review. Participants who complete the eligibility screening online will receive a link to the consent form and a telephone confirmation. Once enrolled, participants will receive a baseline survey up to 3 weeks before their first scheduled CONFIDENCE session.

3. Describe the feasibility of recruiting the required number of suitable research participants within the agreed recruitment period. For example, how many potential research participants do you have access to?
   The anticipated recruitment period will begin in March 2024 to August 2025. We aim to enroll 5-6 caregivers per cohort. Each cohort will take 4-5 weeks to complete. We aim to use the same recruitment approach as was done in the original CONFIDENCE study, relying heavily on the USC FCSC client list. USC FCSC serves over 500 caregivers yearly, among whom 60% are Latino/Hispanic and 38% care for someone living with AD/ADRD. Although recruitment into the initial study was far lower than anticipated, multiple factors are expected to contribute to higher enrollment in this study, including 1) reduced burden of participation in the intervention (e.g., reduction of synchronous sessions from 5 to 4), 2) reduced burden of study participation (e.g., removal of daily spending diary component), and 3) expansion of age eligibility criteria from caregivers ages 50+ to 18+ in the current study. Further, we have expanded our recruitment approach during the initial CONFIDENCE study.

9.0 Setting

Directions: Describe the sites and locations where your research team will conduct the research.

All research will be conducted at Case Western Reserve University where the study team has lab space to collect data by telephone, REDCap, and Zoom in a private space. Some data on app utilization will be collected by Amicus Brain Innovations for use by Case Western Reserve University researchers.

10.0 Consent Process

Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes, answer the following questions:

1. Describe who will consent the subjects and where the consent process will take place: The consent process will be completed using an online consent form completed in REDCap, wherein participants will be asked to review a written consent form and answer 5 true or false questions about participation to check understanding. If these questions are not answered correctly, a study team member will contact the participant to clarify information and resend the consent form. If

answers are still incorrect, the participant will be deemed ineligible to participate and notified of their removal from the study.

2. The time that will be devoted to the consent discussion: The time to complete the online consent form will vary among participants, though we anticipate it will take no more than 1 hour and, for most participants, around 20 minutes.

3. Any waiting period available between informing the prospective subject and obtaining the consent: There is no required waiting period between informing the participant of their eligibility and the consenting process. However, participants may choose to delay consent following notification of eligibility, such as by taking additional time to complete the online consent form.

4. Steps that will be taken to ensure the research participants' understanding: Participants will be asked to complete 5 questions about what is involved in the study to ensure understanding of the written consent form. They may also contact members of the study team with any questions they may have.

5. Any process to ensure ongoing consent: We will assume ongoing consent if the participant chooses to complete surveys. At the top of each survey, participants will be reminded that participation is voluntary

6. Steps that will be taken to minimize the possibility of coercion or undue influence to the subjects: While consenting participants, we will remind them that participation is voluntary and that they are welcome to participate in CONFIDENCE regardless of their choice to participate in the research study

For Adult Participants

Indicate if you will be asking for a waiver or alteration of consent process or documentation (consent will not be obtained, or written consent will not be documented)

☒ Yes ☐ No

If yes, explain how the research involves no more than minimal risk. We are requesting a waiver of consent related to provision of a signature for a sub-study, wherein we will ask caregivers who are not in the parent study to participate in a qualitative interview. The interview content focuses on their experience in the CONFIDENCE program and is aligned with the goals of program evaluation/quality improvement. It is unlikely private or embarrassing information would be shared.

Indicate which part of the consent process you are requesting be waived or altered and the rationale for requesting the waiver or alteration:

☒ I will obtain consent, but not participant's signature.

1. Give the rationale for the request of a waiver of signed consent. Those individuals who did not enroll in the study are likely busier than those who are enrolled in the parent research study. Asking for a consent signature may add additional burden to a minimal-risk component of the study.

2. Please describe how you will be documenting that a participant has consented. The interviewer will ask the participant if they consent to participate at the beginning of the interview. They interview will not proceed unless consent is given

3. Indicate if the subjects will be provided with written information about the study, and provide justification if you will not be providing a written explanation of the research. Caregivers will be sent a copy of the information sheet prior to the scheduled interview, if they agree to be interviewed. This will be reviewed at the beginning of the interview.

☐ I will obtain consent, but request a waiver of some of the elements of consent (e.g. use of deception).

☐ I will not obtain any consent, and I am requesting a full waiver of consent.

If you are requesting an alteration of consent, or a waiver of consent, please answer the following:

1. Give the rationale for the request of a waiver or alteration of the consent process. See above

2. Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants. The questions asked in the qualitative interview are unlikely to result in disclosure of sensitive information, and are more aligned with the goals of program evaluation or quality improvement than research.

3. Explain why the research could not practicably be carried out without the waiver or alteration of consent. Requiring a signature would put additional burden on caregivers without necessarily reducing already minimal risks.

4. Indicate if the subjects will be provided with additional information about the study after participation. Caregivers will be provided additional

information at the end of the study, including a written summary and invitation to view a presentation about results

**Be sure to upload a consent script or information sheet with your study protocol*

Additional Considerations for Consent Process with Adults

Non English Speakers *(Please select one)*

☐ I am **not** enrolling non-English speaking individuals in this research study. The following is justification for why non-English speaking individuals cannot be enrolled: Click here to enter text.

☒ I will be targeting non-English speaking adults

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study. Study, intervention, and communicative documents have been translated from the English version to Spanish by a professional translation service and checked by research assistants that are fluent/native in both English and Spanish languages. When available, we use validated translations of scales; for those scales that are not validated, we use forward and back translation with at least two study team members fluent in Spanish. Qualitative interviews will also be translated by a professional translation team (ASTA USA). Interventionists responsible for delivering the Spanish version of CONFIDENCE at the USC Family Caregiver Support Center are fluent in Spanish. Study team members who conduct enrollment of participants and review the consent process will also be native Spanish speakers. Three RAs have been hired to ensure sufficient coverage for this,

2. List the language(s) other than English that will be targeted: Spanish

☐ I am **not** targeting non-English speaking individuals. If a non-English speaking individual is eligible for the study, we will use the following procedures to enroll:

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study. Click here to enter text.

2. List the language(s) other than English that will be targeted: Click here to enter text.

Adults Unable to Consent

☒ I am **not** enrolling adults unable to consent in this research study *– please leave the rest of this section blank.*

☐ There is an anticipated direct benefit to the subject. Explain: Click here to enter text.

☐ There is NOT an anticipated direct benefit to the subject. Explain: Click here to enter text.

1. Describe the process to determine whether an individual is capable of consent. Click here to enter text.

2. List the individuals from whom permission will be obtained in order of priority (e.g. durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child). Click here to enter text.

3. For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in the research. Click here to enter text.
   ☐ N/A

4. Describe the process for assent of the research participants. Indicate:
   - Which subjects that are unable to consent will be required to give assent? If not all, explain why. Click here to enter text.

   - Describe whether assent of the research participants will be documented and the process to document assent. Click here to enter text.

   ☐ The subject will be informed about the research to the extent compatible with the subject's understanding.
   ☐ Subjects will be closely monitored.
   ☐ The subject will be withdrawn if they appear unduly distressed.

Research Participants Who Are Not Yet Adults (infants, children, teenagers)

☒ I am not enrolling participants who are not yet adults in this research study. *– please leave the rest of this section blank*

1. Will parental permission be obtained from:
   ☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child
   ☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child
   ☐ Requesting a waiver of parental permission

   If you are getting parental/guardian permission:
   a. Indicate how you will be documenting the permission:
   ☐ Signed consent form

☐ Requesting a waiver of documentation of parental permission

b. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's participation in research. Click here to enter text.

If a waiver of parental permission is being requested:

a. Describe how the study is designed for a subject population for which parental/guardian permission is not a reasonable requirement to protect the subjects, if applicable. Click here to enter text.

b. Describe how the research could not practicably be carried out without the waiver of parental permission. Click here to enter text.

c. Indicate if the subjects will be provided with additional information about the study after participation. Click here to enter text.

2. Will assent be obtained from:
   ☐ all of the children
   ☐ some of the children
   ☐ none of the children

   If assent will be obtained from some children, indicate which children will be required to assent. Click here to enter text.

   If assent will be obtained from none of the children, indicate the rationale. Click here to enter text.

   When assent of children is obtained, describe how it will be documented. Click here to enter text.

3. For children who are pregnant, describe how assent and permission are obtained. Click here to enter text.
   ☐ N/A

11.0 Sharing of Results with Research Participants

Individual test or research results will be shared with research participants (this is not referring to sharing through standard academic channels, e.g., publishing, presentation, etc.):

☐ Yes ☒ No

If yes, describe how the results will be shared. *Click here to enter text.*

Individual test results will be shared with others (e.g., lab results given to a primary care physician):

☐ Yes ☒ No

If yes, describe with whom and how the results will be shared. Click here to enter text.

12.0 Study Design/Procedures

Directions:

1) Describe the overall study design (e.g.: single visit, single-blind, double-blind, non-randomized, randomized, blood draw, investigational drug, device etc.).
2) Provide a description of all study-related research procedures being performed, including the length of time involved.
3) Include procedures being performed to monitor research participants for safety or minimize risks.
4) Describe the source records including medical or educational records, which will be used to collect data about subjects.
5) Include a description of any device being used to collect data (e.g., eye tracker, step counter). If the device itself is being studied, include additional information in Section 29.

Overall design. A single-arm pre- and post-test clinical trial of the CONFIDENCE intervention will be conducted. This study builds on the original CONFIDENCE study (STUDY20221010), but with a modified version of the intervention and minor updates in data collection protocols to reduce participant burden. Participation will be offered to any caregiver of persons living with dementia nationally who register for the program via the USC Family Caregiver Support Center (USC FCSC) Eventbrite. Study participation is optional. CONFIDENCE will be delivered in English and Spanish, and participants may participate in the study in either language.

Intervention The intervention includes participation in four, 1.5 hour group discussion sessions delivered by Family Consultants from the USC Family Caregiver Support Center. Zoom sessions will be attended by other caregivers and will feature vignette-style videos featuring family caregivers as well as peer-learning activities. Between the sessions, caregivers will receive text messages from NeuViCare™ with informational tips and reminders to complete practice exercises. They may also choose to interact with Keiko, the apps conversational AI assistant that generates responses to questions based on sources selected or created by the study team. Caregivers can also participant in a monitored community forum, wherein they will be able to communicate with other caregivers in the program. Participants will be sent instructions on how to register for the NeuViCare App, and will have a dedicated "NeuViCare champion" at the USC FCSC who they can turn to if they need additionals support. Total time for intervention participation in 8 to 10 hours over 4 weeks.

Recruitment strategy. Caregivers will primarily be recruited from the USC FCSC by sending information about CONFIDENCE via email blast, as well as individual email invitations and follow-up calls sent to participants who are likely to be eligible for the study. The USC FCSC may also advertise this program via social media channels and with community partners, as they would any program they offer to the community. Caregivers may also learn about the study on the Alzheimer's Association TrialMatch

site.

Enrollment and consenting. Participants who register on Eventbrite and are interested in learning about the study will receive up to four calls and emails by a study team member to learn more about the study. If interested in participating, eligibility screening and a review of the study consent information will be conducted by phone with the PI or a trained study team member. (Participants may complete the screening process online, but are asked to complete a telephone follow up where they will be asked the screening item about the Global Deterioration Scale and other questions they did not respond to.) Participants will then be sent an email with a REDCap consent form to review and signature. Total enrollment and consenting time is estimated to take up to 1 hour.

Survey administration. Once enrolled, participants will receive the baseline survey up to 3 weeks before their first CONFIDENCE session by email, which includes questions about spending on out-of-pocket care costs, financial strain, resourcefulness, self-efficacy, and information about the caregiving context and use of supports. The first follow-up survey will be sent mediately post-intervention (i.e., within 1 week). A second follow-up survey will be sent two months following intervention completion to understand the maintenance of outcomes. We estimate follow up surveys take about 30 to 45 minutes to complete.

Qualitative interviews. In-depth, open-ended, semi-structured qualitative interviews will be conducted with at least 12 participants by phone and/or Zoom, both in Spanish and English. Questions will be based on caregiver's experiences and opinions about their participation in CONFIDENCE 2. The interview guide will be based on the seven components of the Theoretical Framework of Acceptability. This guide will be previously reviewed by an advisory council. Questions about the theory of resourcefulness will be also included to better understand its application. Depending on how much participants would like to share, we estimate interviews will last 15 minutes to 1 hour. Update 9/2/2024: The research team may also follow up with caregivers who participated in CONFIDENCE but did not enroll in the research study to conduct qualitative interviews. The process for these interviews are consistent with those used for caregivers enrolled in the parent study. We will use purposeful sampling according to engagement int the program (e.g., attended all four sessions).

NeuViCare Utilization data. Data on app utilization will be available on a dashboard viewable to the study team and facilitator on the NeuViCare App. They PI will be able to view and record data stored in the secure NeuViCare Google Cloud on a secure dashboard using a unique login. Aggregated information on Care Advisory search subject will be shared by email; that is, we will not see questions individuals submitted to Keiko.

Payment. Participants will receive up to $160 for their participation using emailed Amazon Gift Cards. They will receive $50 for the baseline survey completion and $50 and $60 for the first and second follow-up survey, respectively.

Fidelity monitoring. Fidelity will be monitored using a form developed for the initial CONFIDENCE intervention with additional refinements from talking to interventionists. This form will be completed by an observer who views a video recording of selected sessions. Questions will be based on adherence to the session agenda, timing, participant experience, and quality of delivery. One session per cohort will be randomly selected for fidelity monitoring.

Attendance. Attendance to each session will be recorded by facilitators and shared with Case Western using a Box folder. The average number of sessions attended by participants and the standard deviation will be reported and compared between the English and the Spanish sessions. Another comparison, in the form of percentage based on the different number of possible sessions to attend, will be made on attendance between CONFIDENCE vs CONFIDENCE.

Participant safety monitoring. *Confidentiality*. All survey data will be de-identified and only the PI will have access to the identifier information. NeuViCare user data will be tracked using an email address and phone number. Only the PI will have access to the study key that will allow link study data to contact information, and will not share this with other study team members to prevent breach of privacy. *Transient emotional distress*. If caregivers experience emotional distress while interacting with a study team member, they will be referred to resources of self-care, community support and the Alzheimer's Association 24/7 Helpline. **Adverse events.** All suspected study adverse events will be reported using a standardized form in REDCap. These will be tracked and monitored by the PI. All study team members will be trained to identify on risk management protocols, such as when to immediately contact the PI about a suspected adverse event. See the Adverse Event Form.

13.0 Study Timeline (optional)

	Pre-Screening	Visit 1	Visit 2	Visit 3	Six week Follow up
Estimated time requirement of visit					
Data Collection					
Study Procedure 1					
Study Procedure 2					
Study Procedure 3					
Phone Call Questionnaire					

14.0 ClinicalTrials.gov Information

Directions: If this study has been registered on ClinicalTrials.gov, provide the ClinicalTrials.gov identifier and the investigator/sponsor responsible for registering. If this study has not been registered on ClinicalTrials.gov, provide the rationale as to why and if/when it will be. If it does not meet the requirement for being registered on ClinicalTrials.gov, please state that.

Unique Protocol ID: STUDY20230876.

15.0 List of Data to be Collected

1. *Indicate what identifiers you will collect*

☒ Name
☒ Address *(e.g., Zip code, other geographical designation, etc.)*
☐ Dates related to an individual *(e.g., Date of admission, birth, surgery, etc.)*
☒ Telephone number
☐ Fax number
☒ Email address
☐ Social security number
☐ Medical record number
☐ Health plan beneficiary number
☐ Account number
☐ Certificate/license number
☐ Any vehicle or other device serial
☐ Device identifiers or serial numbers
☐ Web URL
☐ Internet protocol (IP) address
☒ Finger or voice prints *(includes audio recordings)*
☒ Photographic images *(includes video recordings)*
☐ Other: Any characteristic that would uniquely identify the individual
If other, please explain: Click here to enter text.

2. List all other data to be collected for the research study. Attach all data collection tools on the Local Site Documents page of the SpartaIRB smart form (Other Attachments). Baseline, Follow Up 1, and Follow Up 2 Surveys; Qualitative interviews (recordings and transcripts); Utilization of NeuViCare App including logins, completion of activities, receipt of text messages, community forum posts, and AI prompts (de-identified; includes non-study participants); Intervention fidelity, including selected CONFIDENCE session recordings; Characteristics of study participants and non-study participants (USC FCSC Eventbrite registration); intervention attendance; Study adverse events; Study retention

16.0 Online Data Collection

☐ We will not collect data through an online platform.

1. List the online platform to be used. The preferred platforms are REDCap and Qualtrics, as these provide good data security and have options for collecting data without individually identifiable information.
   All survey data will be collected through REDCap. Qualitative interview data will be collected on an institutional Zoom account and recorded. Eventbrite data will also be downloaded on registrants, regardless of study participation. Eventbrite data, also collected in the previous CONFIDENCE study, includes information such as demographics information to help us understand the characteristics of those who participate in the CONFIDENCE program when delivered in a community setting. Finally, app utilization data in the NeuViCare program will be stored in a dashboard and made accessible to the study team by individual password protected accounts.

2. If your intent is to collect the data without identifiers linked to an individual (including IP addresses), describe how you will ensure that no identifiable information will be associated with the data.
   - ☐ Qualtrics: enable Anonymize Responses setting (removes IP addresses and location data)
   - ☐ REDCap: use of the Public Survey Link
   - ☐ REDCap: use of a Participant List without a Participant Identifier field
     (Note: this does maintain a connection between the data and the individual, but it is only accessible to REDCap support personnel and not the researchers. Data collected in this manner should not be referred to as anonymous, but rather as data that is deidentified to the researchers).
   - ☐ Other: Click here to enter text.

17.0 Data Analysis Plan

Directions: Describe the data analysis plan, including any statistical procedures. If applicable, provide a power analysis, and study/safety endpoints.

Outcome measures. *Resourcefulness (primary outcome*). Resourcefulness skills help family caregivers lower material out-of-pocket costs through identification of community resources and alternative ways of managing costs. This will be measured using Resourcefulness Scale, a 28-item scale used to measure potential and social resourcefulness (alpha=0.83; range: 0 to 140). *Self-efficacy (second primary outcome)* is measured using the Caregiver Self-Efficacy Scale. This 8-item scale combines domains of self-efficacy (e.g., managing behavioral symptoms, accessing respite, and controlling upsetting thoughts. It demonstrates high reliability (alpha=0.89) and good test-retest reliability (0.73). Scores range from 8 (lowest) to 80 (highest). *Financial strain (secondary outcome)*. Interventions to reduce caregiver financial strain are needed across multiple levels, individual-level behavioral interventions are needed given the slow pace of policy change to promote caregiver's financial security. This will be primarily measured using the 11-item Comprehensive Score for Financial Toxicity (COST) Scale, which has been modified from the cancer field, which demonstrates validity and reliability (a=0.91; range: 0 to 44). We will also use a secondary measure of psychological financial strain that was used in the initial CONFIDENCE study. (See NCT05292248 for details on this measure.) *Community Resource Access (ancillary outcome)*. This author made item asks about caregivers'

access to community resources that may reduce the costs of caregiving. We will assess whether or not caregiver accessed 1 or more new community resources since beginning CONFIDENCE.

Outcome Analysis. Scores for resourcefulness, self-efficacy, and financial strain will be analyzed using t-test analyses, where we will compare baseline scores to scores from each follow-up survey. If there is a p-value <0.05, this indicates that there was a statistically significant difference between scores. Mean scores and standard deviation for all scores on each scale will be also examined. (We will use descriptive statistics alone to assess whether or not a caregiver accessed new resources following program participation.)

Satisfaction surveys. To analyze Likert responses to satisfaction surveys, a percentage for each response will be provided. Each item will be compared to items collected for the initial CONFIDENCE study, as well as scores for items of CONFIDENCE between Spanish and English intervention.

Attendance. We will report the average number of sessions attended (range 0 to 4) and the standard deviation. Comparison on the number of sessions attended will be compared between the English and the Spanish sessions as well as between the earlier and current version of CONFIDENCE in the form of percentages to allow us to draw preliminary comparisons, given the different number of possible sessions to attend (3 vs. 5). The average number of sessions will be calculated both with and without accounting for make-up sessions. (i.e., giving credit for attendance in Session 1 if the caregiver attended the makeup session for this lesson.)

App Utilization. Usage data from NeuViCare™ Care and Resources Advisors will be reported in aggregate Individual-level data will be collected on the average number of text received, average interactions on the Community Hub, and average number of practice activities completed on NeuViCare.

Fidelity. Fidelity reports will be evaluated using total scores averaged across all CONFIDENCE sessions observed. Sub scores will be reported for adherence to the facilitator guide, participant experience, and quality of delivery. These will be reported separately for English and Spanish participants by using a percentage, as well as means and standards of deviation, to examine variability.

Qualitative interviews. Qualitative interviews will be transcribed verbatim, and for the ones conducted in Spanish, they will be previously translated. Transcription and translation of interviews conducted in Spanish will be by ASTA-USA. English Transcriptions will be done by GMR. A preliminary code book will be developed by at least two research members and will be refined prior to applying codes to the remaining interviews. At least two coders will analyze each transcript independently and will meet to compare the codes. The second round of coding will be conducted to integrate new codes if needed.

18.0 Confidentiality of Data

1. To maintain the confidentiality of the data:

   ☒ I will use a unique study identifier to code individuals' identifiable data and will store the master list separate from the study data.

   ☐ I will use a unique study identifier to code individuals' data, but it will never be linked to a master list.

   ☒ Other- please explain: Utilization data collected from the NeuViCare app will be manually entered into study survey linked with individual contact information. The PI will, using the study key, merge data on app utilization with study data to examine "exposure" to the intervention prior to analysis. Aggregate deidentified data about questions asked to the conversational AI assistant will be shared by Amicus Brain by email. By limiting who has access to utilization data from NeuViCare, reporting questions to NeuViCare in aggregate, and storing data in secure locations, we will protect participant confidentiality. Caregivers who participate in the CONFIDENCE will be notified that their app utilization data will be recorded.

   Provide a plan to maintain or destroy identifiers once analysis of identifiable information is complete. All identifiers will be removed by the PI from study data prior to long-term storage in an encrypted Box folder. For survey data, this will be done first by downloading data in REDCap using the "Remove Identifiers" function, followed by visual examination to confirm all variables with identifying information is removed. Columns in Eventbrite (e.g., email addresses) will be manually deleted prior to saving. The electronic study key will be deleted.

   ☒ I attest that any recordings (audio or video) saved to a portable device will be deleted by formatting the device's storage memory.

How are you storing your electronic data?

☒ CWRU Redcap

☐ CWRU Secure Research Environment (SRE)

☒ CWRU Box

☐ OnCore

☐ CWRU Secure Network Drive

☐ Zoom Cloud

☒ Portable device (must be encrypted, not just password protected)

☒ Other - List storage method and provide justification: Downloaded data is stored in Box on portable devices, rather than in less secure locations (e.g., Documents or Desktop). Eventbrite information on program registrations is maintained by USC; USC will share login information with the PI so she can manually download data on registrants for analysis to reduce the need for data transferring by email. Intervention recordings will be temporarily stored in a Case Western's Box drive with limited access while the study team checks for fidelity, and then deleted at the end of this research study. Electronic data on caregiver utilization of the NeuViCare app is maintained by Amicus Brain in a HIPAA compliant Google Drive Folder. The PI will have access to user data via a dashboard with a unique

login. See attached NeuViCare s security information.

Please note: if you're storing or entering your electronic data in any system other than an approved system listed above, please contact the CWRU IRB (cwru-irb@case.edu).

2. ☐ I acknowledge that paper research data and documents will be stored in a double-locked secure environment in the following **location:** Click here to enter text.
   ☒ We will not have paper research documents.

3. Will data be shared?
   ☒ Yes
   - List the exact data elements that will be shared: De-identified survey data from the surveys will be shared, as well as de-identified qualitative interview transcripts with investigators at the University of Southern California, led by Donna Benton, PhD, who co-developed CONFIDENCE with the PI. The Case Western study team will also provide "over the shoulder" (i.e., Zoom share screen) access to review de-identified data to other investigators to support analyses. Further, screening and enrollment data will be shared with the National Institute on Aging, the study's funder, which requires these data to be uploaded as a part of their CROMS requirements on a monthly basis: https://www.nia.nih.gov/research/grants-funding/nias-clinical-research-operations-management-system-croms

     Data sharing with NeuViCare: Identifiable information about participants will be shared with the NeuViCare app to administer the CONFIDENCE study. With the participant's consent, we will add their email and phone number to register them for the CONFIDENCE app. We will also add their preferred topics on financial well-being in order to send tailored text messages. This information will be drawn from the baseline survey and Eventbrite registration, and will be entered directly into the NeuViCare app. The research team will also be able to view the app participant's completion of activities.

     Data sharing with USC Family Consultants: In order to administer the CONFIDENCE program to caregivers, we will share the names, email addresses, and phone numbers of eligible caregivers with the USC Family Consultants. Family consultants will receive an affiliate ID at Case Western to receive emails about participant information, and to deliver sessions using at Case Western HIPAA-compliant Zoom account. Recordings for fidelity monitoring and attendance reports will be stored in a Case Western Box folder.

- Describe how data will be sent: De-identified data will be shared by email

  Contact information to use the app will be entered directly into the app

  Affiliate accounts will be set up for USC Family Consultants to receive names by email, and for them to store recordings and attendance information in Boxl

☐ No

☐ N/A

If sharing data, please complete a request to ensure the proper contracts/agreements are in place: https://case.edu/research/faculty-staff/technology-transfer/material-transfer-data-use-agreements

18.0 HIPAA Authorization

Does this study collect, access, use, or distribute any Protected Health Information (PHI)?
Protected Health Information (PHI) is (1) any individually identifiable health information transmitted or maintained in a medical record, paper or electronic, or (2) designated data set that was created, disclosed, or used in the course of providing a health care service such as diagnosis, payment or treatment.

☐ Yes ☒ No

If yes, indicate how HIPAA authorization will be obtained (check all that apply):

- ☐ HIPAA authorization is in the consent form
- ☐ I am receiving a Limited Data Set under a Data Use Agreement (DUA)
- ☐ Requesting a full or partial waiver of HIPAA for prescreening
  - ☐ I will complete the Request for Waiver of HIPAA Authorization form. *See SpartaIRB Library*
- ☐ Requesting a full or partial waiver of HIPAA
  - ☐ I will complete the Request for Waiver of HIPAA Authorization form. *See SpartaIRB Library*

19.0 FERPA Authorization

Does this study collect, access, use, or distribute any personally identifiable information from student records or personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education)? This includes, but is not limited to, classroom assignments and course evaluations.

☐ Yes ☒ No

If yes, how do you plan to get written authorization from the student (or parent if the student is a minor)?

☐ I will incorporate FERPA language* into the consent and obtain written and dated signature or authorized electronic signature using REDCap

☐ I will incorporate FERPA language* into a separate form and obtain written and dated signature or authorized electronic signature using REDCap

20.0 Risks to Research Participants

1. List the reasonably foreseeable risks such as breach of confidentiality, discomforts, hazards, or inconveniences to the research participants related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Include the physical psychological, social, legal, and economic risks.
   Breach of confidentiality. This is unlikely to occur, as all the research data collected will de de-identified and each participant will be assigned a different ID that only the PI will have access to. Emotional distress, such as finding intervention activities and survey questions uncomfortable or upsetting is also unlikely but possible. Participants will be reminded that participation is voluntary in each moment, and survey questions can be chosen to be skipped. Finally, there is a slight possibility that participants would receive information that is incorrect for their individual situations while using the NeuViCare app. The most likely outcome, if this occurs, is inconvenience, such as applying for a financial aid program that is not relevant to the caregiver. It would be unlikely that a caregiver would receive information that would harm them financially, given that all sources from which the AI responses will be drawn are either hand-picked (e.g., Department of Labor's information on Family Medical Leave) or developed by the research team. Further, multiple elder law professionals were involved in generating or reviewing intervention materials. However, we include language in the consent form notifying participants of this possibility.

2. If applicable, indicate which experimental procedures may have risks to the research participants that are currently unforeseeable. We cannot identify any unforeseeable risks to participation
   ☐ N/A
3. If applicable, describe the risks to others who are not research participants. Click here to enter text.
   ☒ N/A
4. Describe the availability of medical or psychological resources that research participants might need. As a part of the CONFIDENCE intervention, participants are provided with multiple resources to help with caregiving, including information about how to access counseling, support groups, and respite care for caregiver stress
   ☐ N/A

21.0 Provisions to Protect the Privacy Interests of Research Participants

* FERPA language: 1. Specify the educational records that may be both accessed and used in the research. 2. State the purpose of the access and use of records. 3. Identify to whom the records disclosure may be made.

Directions: Indicate the measures that will be taken to protect research participants' privacy interests. Select all that apply:

☐ In person interactions will be conducted in a private space where conversations would not be overheard by others -- this could be at a specific location determined by the research team or at a location that the participant chooses.

☒ For online/remote data collection, participants will be advised to choose a location that would be private.

☐ Researchers will only contact participants if permission has been given to do so.

☒ Other: Participants will be notified both during an initial telephone call, in the consent form, and when registering for the NeuViCare app that their information, including inquiries submitted to "Keiko" will be stored for the purpose of evaluation. These reminders are intended to prevent caregivers from providing personal information they would not wish to share when communicating with the AI assistant. Even if this does occur, these entries will be reported in aggregate and will not be linked to individual participants.

22.0 Potential Benefit to Research Participants

☒ There is potential benefit to research participants.

Describe the potential benefits that individual research participants may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits. *Do not list compensation.* Participants will learn about resources on how to reduce caregiving costs (e.g., reduced cost home modifications) and they may discuss challenges experienced with other caregivers, which could be therapeutic.

☐ There is **no** direct benefit to research participants.

If no direct benefit, state the potential benefit to society or others. *Do not list compensation.* Click here to enter text.

23.0 Withdrawal of Research Participants

Directions: Describe the anticipated circumstances under which research participants will be withdrawn from the research without their consent. Also include the procedures that will be followed when a research participant withdraws or are withdrawn from the research, including partial withdrawal from procedures with continued data collection.

Participants will be removed from the study if the study team believes the participant is fraudulent (e.g., inconsistencies in study information provided), submits surveys that are excessively incomplete (e.g., more than 50% of responses are missing), or is no longer eligible (e.g., care recipient passes away). Participants will be notified by email if they are removed from the study. Participants may continue to participate in the study to complete the second follow up survey, even if the first follow up survey is not complete. The research team will retain study data for participants who are withdrawn or lost to follow up, unless it is specifically requested by the participant that data be removed prior to de-identification.

☐ N/A

24.0 Alternatives to Participation

Directions: List other options to participation. If subjects will be compensated with extra course credit, the course instructor offering extra course credit must provide alternatives to earn extra course credit. The alternative assignment must require equal or less time and effort for the same amount of earned extra credit that you can earn through participation in research. If there are other available clinical treatments, what would be included if a subject continued on standard of care therapy. If there is a viable alternative you must list it in the consent.

Participants may still participate in the CONFIDENCE program, regardless of study participation.

☐ The alternative is for research subjects not to participate.

25.0 Costs to Research Participants

☐ There are **no** costs to research participants or their insurance companies (there are no clinical visits or billable procedures.) – *please leave rest of this section blank*

1. Describe what costs research participants will be responsible for as a result of their participation in the research, including but not limited to: clinical services required by the protocol deemed billable to insurance, transportation to study visits, parking, costs of drugs, cost of therapy, lost broken or stolen devices, etc. Participants, if they choose to receive text messages, will be responsible for costs based on applicable charges from their carrier. Participants may choose to end text messages at any time.

2. Explain who will be responsible for payment of provided services in the event of insurance denials. Not applicable

3. List what procedures, drugs, devices, supplies will be paid by the study sponsor or covered by other funding. List the other funding source. None

26.0 Research Participant Compensation

☐ There is no compensation or reimbursement for research participants – *please leave rest of this section blank*

☒ There is compensation for research participants.
Describe the schedule, payment method, and payment total of any incentives or compensation that research participants will receive for participation in the research (e.g., gift cards or cash with amount, t-shirts, devices, bags, swag, etc.) Amazon gift cards will be sent to participants by email for each study activity (surveys and interviews). We will pay participants for the baseline survey within a week of completion ($50). A second payment will be administered within a week of the first follow up survey being completed ($50), and a third payment 1 week after the third follow up is complete ($60). Payment for interviews will be sent within 1 week of completing the interview ($25). Participants may earn up to $160 for participating, or $185 if they complete the qualitative interview. .

☐ There will be reimbursement for research participants.
Describe the schedule, payment method, and payment total of any reimbursement that research participants will receive for participation in the research (e.g., gift cards or cash with amount, etc.) Click here to enter text.

27.0 Compensation for Research Related Injury

Describe who will pay for the costs of medical treatment and/or compensation in the event of a research related injury:

☐ Funding agency is providing some/all payment for injury
☐ Funding agency is providing no payment for injury
☒ N/A

28.0 Provisions to Monitor the Data to Ensure the Safety of Research Participants

1. Describe how often the data will be monitored for completeness, accuracy and adherence to the protocol. All baseline and follow up surveys will be visually assessed for completeness and unusual responses (e.g., "straight line" responses) within 1 week of completion. In addition, the investigator team will complete a Data Safety Monitoring Report every 6 months of the study. The Data Safety Monitoring Report will include the following core elements: a) Progress towards enrollment and participant retention; 2) Participant characteristics for enrolled and retained participants (e.g., age, race, ethnicity, gender, aspects of the caregiving situation) according to intervention status; and 3) Documentation of adverse events, serious adverse events, and unanticipated problems, as defined below, including resolution of these events and study protocol modifications. Weekly team meetings will also provide a time and space to identify and discuss non-adherence to study protocols. Further, all study incidents will be reported. If there is any observation of harm to a participant, this will be reported to the IRB and study funder by the PI as soon as possible for serious adverse events or within 48 hours, whichever is sooner,

2. Indicate if there will be a Data and Safety Monitoring Board or Committee:
   ☒ There will **not** be a formal Data and Safety Monitoring Board/Committee.

   ☐ There will be a formal Data and Safety Monitoring Board/Committee.

   Provide information about the DSMB/C including the contact information of the committee member(s) (as applicable); whether it is independent from the study sponsor; how often it meets; the type of data that will be used; written reports, etc. Click here to enter text.

29.0 Additional Information

If you have any additional information regarding your study not covered in the template, please include it here. .

30.0 Devices

Does the study include the use of a device that is integral to the study question?

☐ **Yes** – *Answer the questions below.*
☒ **No** – *Leave the rest of this section blank.*

☐ There is an active IDE (Investigational Device Exemption) for the proposed study.
Attach an official letter of support or proof of approval which identifies the IDE holder and IDE number to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device has obtained a 501k clearance.
Attach 501k documentation to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device meets the criteria for an IDE Exemption.
Download the IDE Exemption Form from the SpartaIRB library (HRP-580) and attach to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device (and its use) is a non-significant risk device for the proposed study design.
List devices here and provide the PI's rationale for the non-significant risk device determination. Click here to enter text.

If the research involves device(s), describe your plans to use, store, handle, administer and track those device(s) to ensure that they will be used only on research participants and be used only by authorized investigators. Click here to enter text.

31.0 Community-Based Participatory Research

☒ This is **not** a community-based participatory research project – please leave the rest of this section blank

☐ This is a community-based participatory research project
Describe the involvement of the community in the design and conduct of the research.
Click here to enter text.

Note: Community based research is research that is conducted as an equal partnership between academic investigators and members of a community. In Community Based Participatory Research (CBPR) projects, the community participates fully in all aspects of the research process.

32.0 MULTI-SITE RESEARCH (when CWRU is the IRB of Record)

Does this project have multiple sites?

☐ **Yes**

☒ **No** – please leave the rest of this section blank

Non-Local Site Information for Multi-Site Studies

*If this is a multi-site study where you are the **lead investigator,** list the following information for each relying site:*

1. Name of site: Click here to enter text.
2. PI of relying site: Click here to enter text.
3. Name of IRB contact: Click here to enter text.
4. Phone number of IRB contact: Click here to enter text.
5. Email address of IRB contact: Click here to enter text.

Non-Local Recruitment Methods for Multi-Site Studies

*If this is a multi-site study and research participants will be recruited by methods **not under the control of the local site** (e.g. call centers, national advertisements) describe those methods. Local recruitment methods are described above.*

1. *Describe when, where, and how potential research participants will be recruited.* Click here to enter text.
2. *Describe the methods that will be used to identify potential research participants.* Click here to enter text.
3. *Describe the materials that will be used to recruit research participants.* Click here to enter text.

Multi-Site Research Communication Plan (when you are the lead investigator)

*If this is a multi-site study where you are the **lead investigator**, describe the processes to ensure communication among sites including:*

☐ *All sites will have the most current version of the protocol, consent document, and HIPAA authorization*

☐ *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record)*

☐ *All modifications have been communicated to sites, and approved (including approval of the site's IRB of record) before the modification is implemented*

☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*

☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*

☐ *All local site investigators conduct the study in accordance with applicable federal regulations and local laws*

☐ *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy*

*If this is a multi-site study where you are the **lead investigator,** describe the method for communicating to engaged participant sites the following:*

1. *Problems:* Click here to enter text.

2. *Interim results:* Click here to enter text.
3. *The closure of the study:* Click here to enter text.

33.0 References

Click here to enter text.