INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Ceresti Health, Inc. / "Improving health equities for Hispanic/Latino families living with dementia by validating a Spanish-language Caregiver-Enabled Care Program (CECP) in PACE participants"**
Protocol Number:	**CER-2024-111-001**
Principal Investigator:	**Dirk Soenksen, M.S., M.B.A.**
Telephone:	**760-453-0997 (24 Hours)**
Address:	**Ceresti Health** **East Coast Office** **167 Washington St.** **Norwell, MA 02061**

KEY INFORMATION

You are invited to take part in a research study sponsored by us, Ceresti Health. This research study is studying our Spanish-language Caregiver Enabled Care Program (CECP) as a possible intervention to engage and support family caregivers of persons living with dementia.

You are being asked to participate in this study because you meet the following study inclusion criteria:

- You are a Spanish-speaking family caregiver (spouse, adult child, other family member, friend) who provides care/support for a person with dementia who is a participant of a Program of All-Inclusive Care for the Elderly (PACE) or dementia support network or provider.
- You identify as Hispanic/Latino
- You are an adult aged 18 or olde
- Your primary language is Spanish. You are able to speak, read, and write in Spanish.

OR

- You are a participant of a Program of All-Inclusive Care for the Elderly (PACE) or dementia support network or provider.
- You identify as Hispanic/Latino
- You have a Spanish-speaking familial caregiver (spouse, adult child, other family member, or friend) that is willing and able to participate in all aspects of this study

- You have a diagnosis of dementia
- You have no plans to disenroll from your PACE program or dementia support network or provider in the next 6 months

The following is a summary of this study:

- The purpose of this study is to assess potential outcomes of our Caregiver-Enabled Care Program (CECP) with Spanish-speaking caregivers of persons with dementia.
- The CECP is a 6-month program that provides personalized education, proactive coaching, and remote monitoring. The CECP is delivered through a tablet that shipped to the caregiver's home. The tablet is provided at no cost to you and does not require WiFi.
- We predict that that Spanish-speaking caregivers who enroll in our Spanish-language CECP will actively engage in the program each week for the program duration of 6 months.
- You might want to participate in this research study if you seek tailored support through a program offering personalized education, coaching, and access to essential resources aimed at improving your ability to care for your loved one with dementia.
- You might not want to participate in this research study if you have limited time availability, find it challenging to commit to a six-month program or feel that you do not need the type of caregiver resources our program has to offer.
- As with any research study there are certain risks and benefits.
- The risks are expected to be no more than you might encounter in everyday life. These risks include feelings of emotion such as sadness or anxiety over discussing your loved one's condition or challenges of being a caregiver.
- The potential benefits may include access to resources to help you better communicate and care for your loved one and strategies to manage challenging behaviors. You may experience feelings of being emotionally supported and of being more capable in your role as a caregiver or a sense of reduced difficulty in your caregiving role.
- These risks and benefits are not all inclusive. You may or may not experience them. More information of the risks and benefits is given in this form below to help you decide whether you want to participate in this study.
- An investigator on this study has an ownership interest in, the company sponsoring this research study. As a result, the investigator may benefit financially from a successful study. Please speak with your study doctor if you have questions about this.

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given

his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

Please read this form carefully. Take your time to ask the study staff as many questions about the study as you would like. The study staff can explain words or information that you do not understand. Reading this form and talking to the study staff may help you decide whether to take part or not.
If you decide to take part in this study, you must sign your name at the end of this form.

BACKGROUND AND PURPOSE

Our Caregiver-Enabled Care Program (CECP) is a non-medical digital program intended to support the wellness of family caregivers and increase their knowledge, skills and confidence in caring for their loved one. CECP delivers personalized health education, access to resources, coaching, and remote monitoring via a dedicated tablet that is shipped to the caregiver's home.

Our English-language version of our CECP was the first of its kind and is the only large-scale, evidence-based, successfully commercialized nonmedical digital population health intervention for family caregivers of persons with dementia. The goal of our Spanish-language CECP is make our CECP available for Spanish-speaking family caregivers of persons with dementia.

This is the first time that the Spanish language CECP been used in in people. The aim of this study is to help us understand the ways in which caregivers engage in the program and use this knowledge to optimize the program.

About 135 participant dyads will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will last 6 months and will include regular engagement with the CECP each week from the privacy and comfort of your own home or preferred location using your dedicated tablet. You will communicate with your coaches using secure messaging or telephone, with time and frequency of calls established between you and your coach based on your needs and preferences.

Before any study-related procedures are performed, you will be asked to read and sign this consent document.

If you decide to take part in this study and go on to receive the study intervention, you will participate in the CECP. The following will happen:

Study Intervention:

- You will be provided a Ceresti tablet (no Wi-Fi required). This tablet will display only the CECP. The tablet will be sent to you via courier at no cost to you.
- You will be provided with personalized educational content and a daily plan that will be available on the tablet.
- A Spanish-speaking Ceresti coach will be assigned to you and available to you for 1:1 personalized coaching via telephone.
- You will have access to on-demand resources such as information about community-based resources and other materials that you can access at your preference and convenience.
- You will be prompted on your tablet to complete an approximately 45-second set of questions to give observations about changes to your loved one's condition. You will complete this summary twice a week, on average.
    - When appropriate, your coach will alert your PACE care staff or dementia support provider about changes in your loved one's condition that can potentially be addressed before they worsen or become more serious.
    - For example, such changes could include but are not limited to a change in mental status, a change in urination, change in fever, change in emergency department visits, and other changes you observe.
- You will also be prompted on your tablet to complete brief custom questions about your own status and well-being, such loneliness, confidence in your caregiver skills, and other aspects of your well-being. You will complete these brief questions approximately monthly as part of the CECP.

The study intervention, the CECP, will be given to you only during this study and not after the study is over.

EXPECTATIONS

If you participate in this study, you will be expected to engage in the CECP content described above. Your participation is voluntary. You can stop participating in the study at any time with no penalty. If you do decide to withdraw your voluntary participation in the study, you would simply stop engaging in the CECP and would return the tablet to us at no cost to you.

RISKS OF STUDY PROCEDURES

The proposed study involves engaging in a 6-month caregiver education and coaching program delivered via an electronic device. This study is expected to involve no more than minimal risk that would be no greater than would be expected in everyday life.

The foreseeable risks to participating in this research are as follows:

- You could experience mild stress or discomfort when engaging in discussions and activities related to caregiving for a loved one with dementia as these activities may evoke emotional distress or feelings of sadness, anxiety, frustration, or reminders of the challenges associate with dementia caregiving.

- Although the intervention aims to reduce stress and burden among dementia family caregivers, engagement in the CECP for six months may unintentionally cause you to feel pressed for time. This could especially happen at first while you are learning how to engage in the content and if you are already feeling busy with your caregiving tasks.
- It is possible participating in the study could involve some physical discomfort from using the tablet and engaging in the program regularly. Such discomforts could include tiredness, eyestrain, headaches, or musculoskeletal strain from using electronic devices and concentrating on the education material.
- You could encounter technical difficulties with electronic tablet devices, such as software glitches, connectivity issues, or device failures, which could disrupt your participation in the study or lead to feelings of frustration.
- A possible risk for any research study is loss of confidentiality in which persons outside of the study get a hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail below in this form.

There may be other risks that are unknown**.**

We will take measures to help prevent the potential risks.

- The study staff will provide ongoing support and guidance to you throughout the intervention period, addressing any concerns or difficulties you may encounter. This support will include technical assistance with the tablet and emotional support to help you cope with any distressing emotions that may arise.
- To safeguard privacy and confidentiality, all data collected during the study will be stored securely and anonymized, with access restricted to authorized study staff only. Participants' personal information will be kept private, including in publications or presentations resulting from the study.
- Flexibility is built into the personalized CECP to accommodate your needs, preferences, and schedule. You will have the option to reschedule coaching sessions or engage with intervention materials at times that are convenient for you, minimizing disruption to your daily routines.
- You can ask questions or express concerns at any time throughout the study. The study staff is committed to answering your questions and addressing any concerns you have as they arise throughout the study.

BENEFITS

You may benefit as a result of your participation in this study.

- The CECP is intended to provide accessible information to help enhance understanding of caring for a loved one with dementia and improving caregiving skills.
- You may learn practical skills and strategies to better care for your loved ones with dementia. This may include ways to better communication, manage challenging behaviors, and provide emotional support.

- The study intervention may lead to reduced stress and burden associated with caregiving. You may feel more confident and capable in your role as a caregiver, which could positively impact your overall well-being and quality of life.
- Better-informed caregivers may be able to provide more effective support for their loved one with dementia, leading to enhanced well-being and quality of life for the person with dementia.

There is, however, no guarantee that you or your loved one will benefit from your participation in this study. The possible benefits listed here are examples of the types of benefits that caregivers and their loved ones with dementia might experience. However, each individual participant is unique, and the potential benefits of participating in the study may or may not apply to you.
Information learned from the study may help other people in the future. This study is intended to contribute to scientific research aimed at improving the lives of dementia patients and their caregivers. By participating in the study, you may help advancing understanding and knowledge in the field of dementia care.

ALTERNATIVES TO PARTICIPATION

This study is for research purposes. The only alternative is to not participate in this study.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

COMPENSATION FOR PARTICIPATION

You will not receive any monetary compensation for your participation in this study.

COSTS

There will be no cost to you for your participation in this study.

The study-related intervention and procedures will be provided to you at no charge to you or your insurance company.

CONFIDENTIALITY

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This

means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

This study is a Phase 1 clinical study. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research participants.

FUTURE RESEARCH STUDIES

Identifiers might be removed from your identifiable private information and could then be used for future research studies or distributed to another research investigator for future research studies without additional informed consent.

CLINICALLY RELEVANT RESULTS

Research results that are clinically relevant will be disclosed to you under these conditions:

- We intend to publish the results of the proposed in peer-reviewed scientific journals, conference proceedings, and ways to publish scientific findings. The publications resulting from this study will include only general findings and will not be included individual results or data that identifies any individual person.
- We will provide participants with summaries of the general findings resulting from publication through accessible means. These means include summaries or informational brochures made available on our website where we routinely provide such information.
- You have a right to receive a copy of any publications resulting from the study upon request. You can provide feedback and ask questions regarding the study results.
- A dedicated member of the study staff will be available to address any questions or concerns you have about any published findings that result from this study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study if you have questions, concerns or complaints about the study such as:

- Payment of compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00078049.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

However, please note any information collected up to the point of your withdrawal will not be removed.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the Investigator may ask you to have some end-of-study assessments for your well-being.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

If applicable:

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Participant

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study investigator and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Ceresti Health.
- Representatives of your PACE or dementia support provider partner of Ceresti Health.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Governmental agencies of other countries.
- Other research doctors and medical centers participating in this study.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the Spanish-language CECP works as intended.
- For other research activities related to the Spanish-language CECP.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study investigator at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your study health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of the Person Conducting the Authorization Discussion

_____ _____
Signature of the Person Conducting the Authorization Discussion Date

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Participant