Our Care Wishes – Dementia Protocol

Protocol Title: Adaptation of the OurCareWishes.org advanced care platform for persons with dementia in nursing homes and their caregivers

IRB Protocol #: 834878

Principal Investigator: Nancy A Hodgson

Latest IRB Approval Date: August 16, 2021

Institutional Review Board
3600 Civic Center Blvd., 9th Floor
Philadelphia, PA 19104
Phone: 215-573-2540
(Federalwide Assurance # 00004028)

DATE: 16-Aug-2021
TO: Nancy A Hodgson
CC: Talwar, Sonia
Summerhayes, Emily P

RE:
IRB PROTOCOL#: 834878
PROTOCOL TITLE: Adaptation of the OurCareWishes.org advanced care platform for persons with dementia in nursing homes and their caregivers

SPONSOR: NO SPONSOR NUMBER
REVIEW BOARD: IRB #8

IRB AMENDMENT: NOTICE OF ACKNOWLEDGMENT

Dear Dr. Hodgson,

The documents noted below, for the above-referenced protocol, were reviewed by the Institutional Review Board and acknowledged on 13-Aug-2021.

The documents included with the application noted below are acknowledged:
-HSERA modification submission (confirmation # deeeecdf) submitted 8/11/2021

ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.
- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and

maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: http://www.irb.upenn.edu

***This letter constitutes official University of Pennsylvania IRB correspondence. ***

Modification

Basic Info

Confirmation Number:	**deeeecdf**
Protocol Number:	**834878**
Created By:	**CAFFEE, LAUREL**
Principal Investigator:	**HODGSON, NANCY A**
Protocol Title:	**Adaptation of the OurCareWishes.org advanced care platform for persons with dementia in nursing homes and caregivers**
Short Title:	**Our Care Wishes - Dementia**
Protocol Description:	**The research study is being conducted to develop an Our Care Wishes Dementia website. This website will help persons with dementia and their surrogate decision-makers document personal and medical care wishes.**
Application Type:	**EXEMPT Category 2**

PennERA Protocol Status

Acknowledged

Resubmission*
No

Are you submitting a Modification to this protocol?*

Yes

Current Status of Study

Study Status

Closed to subject enrollment (remains active)

If study is currently in progress, please enter the following

Number of subjects enrolled at Penn since the study was initiated

15

Actual enrollment at participating centers

7

If study is closed to further enrollment, please enter the following

Number of subjects in therapy or intervention

4

Number of subjects in long-term follow-up only

0

IRB Determination
If the change represents more than minimal risk to subjects, it must be reviewed and approved by the IRB at a convened meeting. For a modification to be considered more than minimal risk, the proposed change would increase the risk of discomfort or decrease benefit. The IRB must review and approve the proposed change at a convened meeting before the change can be implemented unless the change is necessary to eliminate an immediate hazard to the research participants. In the case of a change implemented to eliminate an immediate hazard to participants, the IRB will review the change to determine that it is consistent with ensuring the participant′s continued welfare. Examples: Convened Board Increase in target enrollment for investigator initiated research or potential Phase I research Expanding inclusion or removing exclusion criteria where the new population may be at increased risk Revised risk information with active participants Minor risk revisions that may affect a subject′s willingness to continue to participate Expedited Review Increase in target enrollment at Penn where overall enrollment target is not exceeded or potentially sponsored research Expanding inclusion or removing exclusion where the new population has the same expected risk as the previous, based on similarities of condition Revised risk information with subjects in long-term follow-up Minor risk revisions with no subjects enrolled to date
Expedited Review

Modification Summary
Please describe any required modification to the protocol. If you are using this form to submit an exception or report a deviation, enter 'N/A' in the box below.
Dear IRB Administrator, We have outlined the changes below. Thank you for your attention. Personnel Changes Remove Sarah Bujno as Study Contact Remove Anjali Rajpara as Study Contact Thank you!

Risk / Benefit
Does this amendment alter the Risk/Benefit profile of the study?
No

Change in Consent
Has there been a change in the consent documents?
No

If YES, please choose from the options below regarding re-consenting

Deviations

Are you reporting a deviation to this protocol?*

No

Exceptions

Are you reporting an exception to this protocol?*

No

Protocol Details

Resubmission*
Yes

Hospital Sites
Will any research activities and/or services be conducted at a Penn Medicine affiliated hospital site?
No

Study Personnel

Principal Investigator

Name:	**HODGSON, NANCY A**
Dept / School / Div:	**602 - Biobehavioral and Health Sciences**
Campus Address Mail Code	
Address:	**418 Curie Blvd.**
City State Zip:	**Philadelphia PA 19104-4217**
Phone:	**215-898-8413**
Fax:	**-**
Pager:	
Email:	**hodgsonn@nursing.upenn.edu**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Study Contacts

Name:	**TALWAR, SONIA**
Dept / School / Div:	**602 - Biobehavioral and Health Sciences**
Campus Address Mail Code	
Address:	
City State Zip:	
Phone:	
Fax:	
Pager:	
Email:	**talwars@nursing.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**SUMMERHAYES, EMILY P**
Dept / School / Div:	**602 - Biobehavioral and Health Sciences**
Campus Address Mail Code	
Address:	
City State Zip:	
Phone:	
Fax:	
Pager:	
Email:	**esummer@nursing.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Other Investigator

Name:	**ERSEK, MARY T**
Dept / School / Div:	**602 - Biobehavioral and Health Sciences**
Campus Address Mail Code	**6096**
Address:	**CLAIRE M. FAGIN HALL** **418 CURIE BLVD**
City State Zip:	**PHILADELPHIA PA 19104-6096**
Phone:	**215-746-3563**
Fax:	**215-898-3056**
Pager:	
Email:	**ersekm@nursing.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**01/11/2021**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Responsible Org (Department/School/Division):

602 - Biobehavioral and Health Sciences

Key Study Personnel

Name:	**MORGAN, BRIANNA**
Department/School/Division:	**Health System**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**VAN DER TUYN, MATTHEW**
Department/School/Division:	**Research Services**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**BEHRENS, LIZA**
Department/School/Division:	**Biobehavioral and Health Sciences**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**CARPENTER, JOAN G**
Department/School/Division:	**Biobehavioral and Health Sciences**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

HRPP

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
No

If the answer is YES, indicate which items is is provided with this submission:

CTRC Resources*
Does the research involve CTRC resources?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
N/A

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Sociobehavioral (i.e. observational or interventional)

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
x	**Survey instrument**
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

Name:	**LIU, CHIU-FANG**
Dept / School / Div:	**631 - Office of Nursing Research**
Phone:	**215-898-8413**
Fax:	**-**
Pager:	
Email:	**chiufang@nursing.upenn.edu**

Department budget code

000 - 000 - 0 - 000000 - 0000 - 0000 - 0000

Funding Sponsors

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

Funding sponsors gift
Is this research being funded by a philanthropic gift?

Project Funding*
Is this project funded by or associated with a grant or contract?
No

Sponsor Funding
Is this study funded by an industry sponsor?

Status of contract

The following documents are currently attached to this item:

There are no documents attached for this item.

Protocol

Objectives

Overall objectives
One approach to decrease burdensome end-of-life transitions and treatments for PWD is to engage family decision-makers and, when possible, PWD, in advance care planning (ACP) conversations. These discussions should be documented and summarize the persons values, preferences for care, and treatment decisions in ways that facilitate communication with care providers. ACP is particularly important in dementia given the progressive nature of the disease that leads to gradual and irreversible loss of decision-making capacity. As a result, family caregivers are often called upon to make a variety of decisions related to care. Many PWD want to share in healthcare decision-making, but are often excluded from these conversations. Thus, resources to assist PWD and their family caregivers engage in ACP must use a shared decision-making approach that balances patient autonomy with declining capacity. Support for family caregivers also requires attention to the complexities of surrogate decision-making including: 1) ensuring that surrogate decision-makers (SDMs) decisions are informed by the

incapacitated persons values and preferences; 2) supporting SDMs in the common situation in which they did not have conversations about end-of-life care when the PWD was cognitively intact; and 3) attending to the uncertain legal status of formal advance directives completed by SDMs. Given that most PWD receive either short- or long-term care in a nursing home (NH) as their disease advances (described more fully in the Overall Research Plan), NH admission represents a critical opportunity for goals of care conversations and documentation of care preferences. Indeed, when these discussions occur, and PWD and SDMs are supported in articulating goals, most choose less aggressive approaches to care. Despite the opportunity for discussing treatment preferences, the NH admission process typically focuses only on decisions about cardiopulmonary resuscitation, although families of NH residents with advance dementia report that the most common care decisions they face involve feeding problems, infections and pain. Web-based ACP platforms facilitate completion of advance care plans, improve decision-making quality, and enhance shared decision making. However there are few studies that examine ACP in PWD, especially in the NH setting. Of the existing ACP platforms, most were developed for use with all older adults or those with advanced cancer or heart disease. Two recent randomized clinical trials examined the effects of dementia-specific ACP video decision aids; they showed increased rates of goals of care discussions and ACP completion. Although these results are promising, both investigative groups recommended integrating the decision aid into NH practice and more robust ACP programs. This pilot takes the first step in addressing these recommendations by adapting an existing successful online ACP platform to the specific needs of PWD and their SDMs. Moreover, the platform enables the development of written care plans that can be incorporated into the NHs electronic health record (EHR) and easily shared with caregivers and clinicians.

Background

The Our Care Wishes (OCW) platform has undergone extensive mixed-methods testing and is already in use by health systems and in RCTs. OCW was rigorously developed and refined to optimize ACP completion rates. It has been tested among more than 3,000 patients. More than 70% of patients who have engaged with the platform have completed an ACP, and the sites Net Promotor Score, a standard measure that assesses the users likelihood to recommend a product or service, is 80%. The platform also has a back-end interface that enables care plans to be automatically uploaded into EHRs. It is being studied in an ongoing RCT of ACP for bone-marrow transplantation patients. These findings support the feasibility of having PWD and their caregivers complete OCW, as well as the need for further refinement of the content to meet the needs of PWD.

Study Design

Design

Our application is grounded in the Ecological Model of Patient Centered Communication. There is a growing body of research demonstrating that aligned and documented ACP communication is associated with better outcomes for PWD. Aim 1: Tailor the OCW platform. Several adaptations are needed to ensure that OCW: 1) specifically addresses end-of-life issues for PWD and their SDMs; 2) aligns with the legal requirements and ethical principles involved in surrogate decision-making; 3) addresses the needs of diverse users; and 4) integrates seamlessly with the PointClickCare EHR used by all Genesis facilities and most NHs nationwide. To meet these goals, we will convene a stakeholder group of clinicians with expertise in NH and dementia care, PWD and their family caregivers, an ethicist, and an eldercare attorney. This group will advise us on content and the interface. The group will meet 7-8 times over 4 months using Blue Jeans videoconferencing software. All meetings will be audiotaped to capture the full group discussion and decisions. The goal of the web-based meetings is to reach consensus on the content and interface of the adapted website. We expect that the elements suggested for revision will include content regarding: 1) principles of shared decision-making; 2) the role of caregivers as SDMs; 3) the natural progression of dementia; 4) common end-of-life decisions; and 5) the benefits and burdens of interventions for PWD. Aim 2: Examine the user interface and acceptability of the OCW-Dementia platform. To evaluate the acceptability and usefulness of the platform, we will recruit up to 10 Genesis staff members (based on suggestion from Genesis management), and they will assent to comment on the platform and accompanying Qualtrics surveys. Study team members will interview Genesis staff on their reactions to the platform and surveys and take notes on the reactions. These interviews will take place virtually via BlueJeans and will not be recorded. Staff will not submit or discuss any identifiable information and will be instructed to not discuss any identifiable information of patients/residents of Genesis. The website and survey links will be emailed to Genesis staff and they will review the website and surveys prior to the interviews. At the beginning of the interview, study team members will confirm Genesis staff assent to participation and remind them

that their participation is completely voluntary and can be ended at any time. Each session will last up to half an hour. To evaluate the acceptability and usefulness of the platform, we will also recruit up to 15 Healthy Patterns Sleep Study participants (IRB protocol # 825000) for virtual beta testing of the website. Participants will be selected if they have previously agreed to being contacted for research and if they have a computer or smartphone on which to view the website and surveys. Participants will be recruited as dyads (caregiver and person with dementia). Dyads will consent to the study staff contacting them via phone or BlueJeans and guiding them through the website and accompanying Qualtrics surveys. Qualtrics surveys will be administered before and after the viewing of the website; surveys will ask dyads for their feedback on the website and their confidence making decisions about future care. Virtual beta testing platforms will depend on the participants' ability and resources, and may include telephone, Skype, FaceTime, or BlueJeans and any internet browsers. Study staff will take notes on the reactions of dyads in order to improve the website and user experience after beta testing. When filling out the surveys, no identifiable information will be collected. The calls and/or video chats will not be recorded. Each Healthy Patterns participant within each dyad will receive $15 via Greenphire gift cards at the end of study participation.Gift cards will be mailed to dyads. Each session will last up to an hour. Some identifiable information (name, DOB, email address, phone number, address) will be entered in the website but will not be used or recorded in the study. The website is hosted by Pantheon, which is a Penn approved hosting platform. The site is encrypted with SSL (Secure Sockets Layer) to protect participant information. Aim 3: Randomized Pilot. Setting/sample. We will conduct the pilot study in up to four Genesis facilities with diverse locations (urban, suburban, rural). We will also include at least one facility that serves mostly minority populations to test the effectiveness of the OCW-Dementia module among racially and ethnically diverse PWD. We will recruit up to 50 patients/residents and their SDMs. Eligible PWD will be receiving short-or long-term care at a participating NH, have documented moderate to severe cognitive impairment and have an identified SDM. We will exclude residents clearly exhibiting terminal decline, thereby reducing the likelihood of attrition. Study team members will work with Genesis staff to recruit dyads (Genesis residents and their family members or supportive decision-makers (SDMs) who are interested in participating in the study. Study team will read an assent script to interested SDMs, gain verbal assent and then send SDMs the study summary and copy of the assent script. After verbal assent is acquired, dyads will be assigned to the intervention group or usual care arm. At each site, up to 10 dyads will be recruited. Half of the dyads recruited at each site will receive their usual care and complete the demographics survey, COVID-19 survey and pre and post confidence in decision making surveys. The second half of dyads recruited at each site will receive the intervention as well as complete the demographics survey, COVID-19 survey and pre and post confidence in decision making surveys.

Study duration
Participation will last up 1 hour per session. There will be two sessions total. Study recruitment will begin in August of 2020 and end by November of 2020. All study activities will end December 2020.

Characteristics of the Study Population

Target population
Persons with dementia and their surrogate decision makers.

Subjects enrolled by Penn Researchers
50

Subjects enrolled by Collaborating Researchers
0

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject recruitment
For Aim 2, Genesis staff members recruited will be those recommended by Genesis management. Additional participants will be recruited from the Healthy Patterns Sleep Study (IRB Protocol 825000) who have agreed to be contacted for future research. These participants (dyads) are persons with dementia with caregivers in the greater Philadelphia area who will have access to a smartphone or computer. We will conduct the pilot study in up to four Genesis facilities with diverse locations (urban, suburban, rural). We will also include at least one facility that serves mostly minority populations to test the effectiveness of the OCW-Dementia module among racially and ethnically diverse PWD. We will recruit up to 50 patients/residents and their SDMs. Eligible PWD will be receiving short-or long-term care at a participating NH, have documented moderate to severe cognitive impairment and have an identified SDM. We will exclude residents clearly exhibiting terminal decline, thereby reducing the likelihood of attrition. Strategies to address potential study limitations. If we are unable to rapidly recruit sufficient numbers of PWD and SDMs at up to four facilities for Aim 3, we will work with Genesis leaders to expand recruitment to additional facilities. There are 25 Genesis facilities within a 25-mile radius of the Penns campus. For Aim 3, Study team members will work with Genesis staff to recruit dyads, ie. Genesis residents and their supportive decision-makers (SDMs) who are interested in participating in the study. Study team will read an assent script to interested SDMs, gain verbal assent and then send SDMs the study summary and copy of the assent script. After verbal assent is acquired, dyads will be randomized to the intervention group or usual care arm. At each site, up to 10 dyads will be recruited. Half of the dyads recruited at each site will receive their usual care and complete the demographics survey, COVID-19 survey and pre and post confidence in decision making surveys. The second half of dyads recruited at each site will receive the intervention as well as complete the demographics survey, COVID-19 survey and pre and post confidence in decision making surveys.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

Participants recruited from the Healthy Patterns Sleep Study (IRB Protocol 825000) for virtual beta testing will be compensated $15 each via Greenphire gift cards at the end of study participation. Participants who are residents of Genesis Healthcare and recruited by Genesis Healthcare staff will not receive financial incentive or compensation at the request of the Clinical Project Outcomes Coordinator at Genesis Healthcare.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
Aim 2: For participants recruited in the beta testing trial, study personnel will convene PWDs and their caregivers via video chart to administer the pre-survey and facilitate completion of OCW-Dementia. One week later, study personnel will call PWDs and caregivers to administer the post survey. Participants will be paid after completion of post survey. Aim 3: In the usual care arm, Genesis staff will follow their facilities standard admission policies, which include asking about the presence of advance directives, and offering assistance in completing an AD in accordance with state laws. Staff or study personnel will administer the pre-survey at the time of usual care and then administer the post survey and COVID-19 survey one week later to participants randomized to the usual care arm. In the intervention arm, Genesis staff will convene SDMs and PWDs via phone, video chat or in person, provide tablet computers to PWD and facilitate conversation about the website so that SDMs and PWDs can complete OCW-Dementia. An infection control policy will be implemented for tablet computer usage. Genesis staff or study personnel will administer the pre-survey prior to website completion and administer the post survey and COVID-19 survey one week after website completion

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
We will use Z-tests to test our hypothesis that a significantly higher percentage of participants in the intervention group will complete an ACP compared with those in the usual care group. We adjust for participant characteristics due to the small sample size, but only the most important characteristics using likelihood ratio testing to avoid an overfit model. To generate new hypotheses, we will examine differences between groups with regard to demographic and clinical variables using parametric t-tests or nonparametric Wilcoxon tests (for continuous variables) and Fishers Exact tests for binary variables. To explore differences in Decisional Conflict scale scores, we will conduct a two-group independent T-test. Based on estimates derived from the Genesis EHR, we expect that 30% of PWD/SDM in the usual care arm will have a completed ACP within several weeks following admission to participating NHs. In the intervention arm, we estimate that 70% of SDMs/PWD will complete an ACP, as has been found among other OCW users (see Preliminary Studies). Enrolling 25 participants in each arm would yield 91.5% power to detect this difference of 70% vs. 30% ACP completion rate between the intervention and control groups. This calculation is based on a 1-sided Z-test with pooled variance and a significance level of 0.05.

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject Confidentiality
All research information will be kept in locked cabinets, in secure locked offices at the School of Nursing. Access to identifying information will be limited to research staff assigned to the project. Subjects will be advised of the precautions we will take to preserve confidentiality during the consent process. Data with identifiers will not be permitted outside of the PI office space. All discussions between the research staff members will be held in a private area. Pre-coded data collection instruments will be prepared for use with study participants at each testing occasion. Identification numbers to assure participant confidentiality will be used. Only one master log of subject name, address and telephone number and study identification assignment will be maintained. This log, in both hard copy and disk, will be stored in a locked filing cabinet separate from other identifying information. All de-identified data abstracted from study tools will be entered into a password protected and encrypted internet-based data management system known as REDCap (Research Electronic Data Capture). We will store all paper-based records in the PI's secure office space for 7 years, per requirements, and only de-identified data (without names or medical record numbers of patients enrolled) will be entered into REDCap system.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
N/A

*Data Protection**

- x **Name**
- x **Street address, city, county, precinct, zip code, and equivalent geocodes**
- x **All elements of dates (except year) for dates directly related to an individual and all ages over 89**
- x **Telephone and fax number**
- x **Electronic mail addresses**
- **Social security numbers**
- **Medical record numbers**
- **Health plan ID numbers**
- **Account numbers**
- **Certificate/license numbers**
- **Vehicle identifiers and serial numbers, including license plate numbers**
- **Device identifiers/serial numbers**
- **Web addresses (URLs)**
- **Internet IP addresses**
- **Biometric identifiers, incl. finger and voice prints**
- **Full face photographic images and any comparable images**
- **Any other unique identifying number, characteristic, or code**
- **None**

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Consent

1. Consent Process

Overview
Two groups of individuals will be participants in this research study, i.e. primary participants - Persons with Dementia (PWD) and their surrogate decision-maker (SDM) or caregivers. For Aim 2, Genesis staff will verbally assent to participating in a discussion with the study team and providing feedback on the platform and surveys. Healthy Patterns Sleep Study dyads will verbally agree to take the surveys and tell the study team about their experience with the website. Dyads will also document consent by clicking a box on each survey that states that by clicking the box, they demonstrate their full consent to participation. For Aim 3, With help from Genesis staff, study team members will recruit dyads, ie Genesis residents and their supportive decision-makers (SDMs) who are interested in participating in the study. After expressing interest, study team members will call SDMs of residents to read a Penn approved assent script and answer questions about the details of the study. After verbal assent is confirmed, SDMs will receive a copy of the assent script and study summary. Consent will be documented at the time of survey administration. Prior to answering survey questions in Qualtrics, dyads will check a box next to language that states, by clicking this box, you demonstrate your full consent to participation. Consent will be documented at administration of both pre and post surveys.

Risk / Benefit

Potential Study Risks
You may become uneasy or tired during the assessment process. You may become slightly agitated with a stranger. While this rarely occurs, the study staff is trained to handle these minor discomforts. The study staff members are also trained to detect impending frustration or agitation before it becomes a problem. They will know when to stop the assessment or activity before a person becomes upset. There is the possibility that taking part in the study will not affect agitation or that agitated behaviors may become worse. You may get tired or bored when we are asking you questions, or you are completing questionnaires. You do not have to answer any question you do not want to answer. Information obtained about you for this study will be kept confidential as much as possible.

Potential Study Benefits
There is no benefit to you. However, your participation could help us understand participant reactions to the Our Care Wishes Dementia website, which can benefit you indirectly. In the future, this may help other people capture their medical care preferences. Will I receive the results of research testing? Most tests done in research studies are only for research and have no clear meaning for participants. Research results will not be returned to you because they will only be used for Our Care Wishes Dementia website development. What other choices do I have? Your alternative to being in the study is to not be in the study. What happens if I do not choose to join the research study? You may choose to join the study, or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your therapist, social worker, nurse, or doctor will not be upset with your decision. If you are currently receiving services and you choose not to volunteer in the research study, your services will continue. When is the study over? Can I leave the study before it ends? The study is expected to end after all the information has been collected. The study may be stopped without your consent for the following reasons: o The PI feels it is best for your safety and/or health-you will be informed of the reasons why. o You have not followed the study instructions o The PI, the sponsor or the Institutional Review Board (IRB) at the University of Pennsylvania can stop the study anytime You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care. If you no longer wish to be in the research study, please contact Dr. Hodgson, at 215-573-7387. Leaving this study early will not stop you from getting regular medical care. How will my personal information be protected during the study? We will

do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. Confidentiality will be maintained by de-identifying all participant data and assigning unique participant identification codes. An exception to confidentiality is if you report child or elder abuse or neglect, or if you report suicidal or homicidal ideation or intent to the research team. Any information about child or elder abuse or intent to harm yourself or others will be reported to the authorities, as required by law.

Risk / Benefit Assessment
This is a minimal risk study with potential benefits to participants and society.

General Attachments

The following documents are currently attached to this item:

Cover Letter (summaryofchangesocw.pdf)