TITLE: Translating Data Science to Palliative Care Practice for Persons Living with Dementia

Oral Informed Consent Guide - 09/19/2023

Waiver of Authorization for Member Consent – 06/20/2023

Retrieved - 10/02/2025

NCT NUMBER: NCT05942040

Note: Consent was performed differently based on participant role. Oral Informed Consent was used for "CBPC Team Member" participants (pg. 2-3). Electronic health records of "MA Plan Members" were accessed via Waiver of Consent (pg. 4-6).

Oral Consent Guide: Aim 3

Greet person politely.

Introduce yourself and organization.

Ask to speak with person of interest.

Emphasis the purpose of the study and briefly describe procedures, where they will take place, and how long the interaction will last.

> Improve the way we use health records to connect people with additional support services such as palliative care.
>
> And/or
>
> To better understand what seriously ill adults and their family members think about palliative care, develop an intervention to improve understanding of palliative care and pilot test the intervention.
>
> *Let them know that their decision whether or not to participate will not affect their relationship {or employment} with VNS Health or Rutgers*
>
> *Ask if they would like to hear more about the second part of the study?*
>
> *If YES, continue.*
>
> *If NO, thank the person for their time.*

- Three 5-10-minute surveys to answer questions about
  - Their experience using information materials to tell eligible individuals and their families about palliative care.
- The surveys should take a total of 15-30 minutes.
- Interviews and focus groups will be conducted in person, by telephone, or zoom a recorded with your permission.
- Participants will also be asked to complete a brief questionnaire with demographic information and about your knowledge of palliative care.
- The questionnaire can be completed online via a unique link sent to their email or by telephone with study personnel.

Mention any risk and benefits associated with participating in the study.

> The risks from being in this study are minimal. You may become uncomfortable when answering questions. If this happens, please let the study team members know.

You can choose to stop participating at any time. There is also a risk information we collect may be stolen or breached.

Mention compensation and any information that you will need to collect in order to make payment (mailing address, email address, etc.)

- Compensation: $25 for each of the three rounds of feedback you provide during interviews or focus groups, up to $75.

Describe how their information will be protected.

We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you. We will protect the confidentiality of your research records by storing them in locked file cabinets or on secure servers that only study team members can access. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

It is possible that other people may need to see the information we collect about you. These people work for Rutgers University, VNS Health (formerly Visiting Nurse Service of New York), the National Institutes of Health, and government offices that are responsible for making sure the research is done safely and properly.

A description of this study will be posted on a public website, http://ClinicalTrials.gov, and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. No information that can identify you will be posted.

What will happen to the information they provide after the study is over?

We will keep your research data (answers that you provide to the question we ask) to use for future research. Your name and other information that can identify you will be kept secure and stored in a separately from research data collected as part of the project. We may share your research data with other investigators without asking your consent again.

Provide contact information for the researcher and/or the IRB.

If you have questions about this research, you may contact ***Dr. Elizabeth Luth, PhD at eal133@ifh.rutgers.edu*** *or VNS Health IRB at (212) 609 5766.*

Ask if the participant has any questions that you can answer.

Ask explicitly- **do you agree to participate in this research?** And record the response.

DATE:	June 20, 2023
TO:	Elizabeth Luth, PhD
FROM:	VNS Health Institutional Review Board (IRB)
STUDY TITLE:	[2041096-3] Translating Data Science to Palliative Care Practice for Persons Living with Dementia
IRB REFERENCE #:	E23-02
SUBMISSION TYPE:	New Study - Response/Follow-Up
ACTION:	APPROVED
APPROVAL DATE:	June 20, 2023
EXPIRATION DATE:	June 19, 2024
REVIEW TYPE:	Expedited Review
PROJECT RISK LEVEL:	MINIMAL RISK

Thank you for your submission of Response/Follow-Up materials for this research study. VNS Health Institutional Review Board (IRB) has APPROVED your submission.

The following items are approved in this submission:

- Amendment/Modification - 00. IRB Response follow-up Memo.docx (UPDATED: 06/13/2023)
- Consent Form - 08b. Aim 1-2 Oral Consent Guide TC 20230612_11.docx (UPDATED: 06/13/2023)
- Consent Form - 08c. Aim 3 Oral Consent Guide TC 20230612_II.docx (UPDATED: 06/13/2023)
- Consent Form - 08c. Aim 3 Oral Consent Guide 20230612.docx (UPDATED: 06/13/2023)
- Consent Form - 08b. Aim 1-2 Oral Consent Guide.20230612.docx (UPDATED: 06/13/2023)
- Protocol - 08a. IRB Protocol Translating Data Science TC 20230612_II.docx (UPDATED: 06/13/2023)
- Protocol - 08a. IRB Protocol Translating Data Science.20230612_II.docx (UPDATED: 06/13/2023)
- Abstract/Summary - 07. IRB Protocol SummaryTranslating Data Science.20230425.docx (UPDATED: 04/27/2023)
- Conflict of Interest - Declaration - 03e. McDonald IRB Conflict of Interest.pdf (UPDATED: 04/28/2023)
- Conflict of Interest - Declaration - 03d. Brickner IRB Conflict of Interest v2.0.pdf (UPDATED: 04/28/2023)
- Conflict of Interest - Declaration - 03a. Bowles IRB Conflict of Interest v2.0.pdf (UPDATED: 04/27/2023)
- Conflict of Interest - Declaration - 03b. Luth IRB Conflict of Interest v2.072_signed.pdf (UPDATED:04/27/2023)
- Conflict of Interest - Declaration - 03c. Amposnah IRB Conflict of Interest v2.0.pdf (UPDATED:04/27/2023)
- Cover Sheet - 06. IRB Protocol Cover sheet 20230426.pdf (UPDATED: 04/27/2023)

- CV/Resume - 02c.Biosketch_Bowles PAIR Dec 2022.pdf (UPDATED: 04/27/2023)
- CV/Resume - 02b..Biosketch_Brickner_PAIR Luth.pdf (UPDATED: 04/27/2023)
- CV/Resume - 02a..Biosketch-Luth.20221222.pdf (UPDATED: 04/27/2023)
- Data Collection - 10. Study Instruments 20230425.docx (UPDATED: 04/27/2023)
- HIPAA Waiver - 09. Waiver of Authorization Form 20230419.docx (UPDATED: 04/27/2023)
- Investigator Agreement - 11a. IRB Authorization Agreement_Relying on VNS Health IRB_Rutgers_VNS RU SIGNED.pdf (UPDATED: 04/27/2023)
- Letter - 04.LoS VNS for PennRoybal 20230105 - signed.pdf (UPDATED: 04/27/2023)
- Other - 11b. VNS Health Local Context Form v1.0.pdf (UPDATED: 04/27/2023)
- Other - 12. DSMP_Luth 20230324.docx (UPDATED: 04/27/2023)
- Other - 05.VNS Health - Template DUA for LDS (External Researchers)_20230411.docx (UPDATED: 04/27/2023)
- Training/Certification - 01b.Amponsah.Citi.CGP.EXPpdf.pdf (UPDATED: 04/27/2023)
- Training/Certification - 01b.Amponsah.citi. Human SubjectsCertificate.pdf (UPDATED: 04/27/2023)

This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and the research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Continuation applications will be due no later than 30 days from the approval expiration date. Please use the appropriate renewal forms for this procedure.

The submission of a study closure report is due within 60 days of the end of primary data collection or within 60 days of end of primary analysis if not a primary data collection effort. Closure report forms may be obtained from the IRB administrator.

If you have any questions, please contact Lori King at (212) 609-5766 or lori.king@vnshealth.org. Please include your study title and reference number in all correspondence with this office.

For the Institutional Review Board,

Susan Regan, IRB Chair

HIPAA Waiver of Patient Authorization

DATE: June 20, 2023

TO: Elizabeth Luth, PhD
FROM: VNS Health Institutional Review Board (IRB)

STUDY TITLE: [2041096-3] Translating Data Science to Palliative Care Practice for Persons Living with Dementia
IRB REFERENCE #: E23-02
SUBMISSION TYPE: New Study - Response/Follow-Up

ACTION: APPROVED

Documentation of HIPAA Waiver Approval		
YES	**NO**	***Does the research proposal listed above meet the following criteria?***
X		The research could not practicably be conducted without the waiver
X		The research could not practicably be conducted without access to and use of the protected health information described within the research project proposal
X		The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: 1. An adequate plan to protect the identifiers from improper use and disclosure; 2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is health or research justification for retaining the identifiers, or such retention is otherwise required by law; and 3. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart

A brief description of the protected health information being requested for use or access in the research project listed above has been reviewed and has been determined to be necessary for conducting the research. **The VNS Health approved Protected Health Information (PHI), for this study, is the following:** diagnoses, triggering events, discharge status, race, ethnicity, age, palliative care eligibility determination dates, and palliative care refusal dates. **Protected identifiers that would be accessed or collected:** Patient name, address including zip code, electronic health record identifier, dates of admission and discharge; Caregiver name, phone number, email address (when available), relationship to patient

All of the necessary criteria required under the Privacy Rule (45 CFR §164.512) have been satisfied for approval of waiver of authorization. The Institutional Review Board of VNS Health has reviewed and approved the waiver of authorization under normal or expedited review procedures as outlined in the Common Rule.

For the Institutional Review Board,

Susan Regan, IRB Chair

***Protected health information** refers to individually identifiable health information maintained or transmitted electronically or in any other form or medium, including written and oral methods