Document Coversheet

Study Title: Improving Person-Environment Fit of Community-Residing Older Adults with Dementia

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	10/13/2021
NCT Number:	NCT05722743
IRB Number	72893
Coversheet created:	7/27/2026

Statistical Analysis

The primary outcome analysis is the feasibility of implementation as measured by caregiver satisfaction. Power analyses have been conducted using data from the proof-of-concept trial which demonstrated an effect size of 2.0 for caregiver satisfaction and 1.0 for patient performance. Seventeen dyads per group will have adequate power to show that the intervention group has increased caregiver satisfaction (power 99%). We anticipate a 10% dropout out rate and 38 dyads (76 participants) will be recruited to allow for 19 dyads per arm. Statistical significance will be determined at the 0.05 level and since this is a pilot study, no adjustment will be made for testing significance of multiple endpoints. Exploratory analysis will be conducted to gather feasibility data on the potential efficacy of the intervention on secondary outcomes, including behavior, functional performance, and caregiver burden, with change from baseline to the end of the study and 1-month post-intervention follow up using analysis of covariance (ANCOVA) that will include prespecified covariates (i.e., age, gender, education, disease state). Frequencies of demographic variables (sex, age, cognitive status, education, caregiver relationship, caregiver age), behavior change, and adverse events will be compared among participants within the same group and between groups for differences using either Fisher Exact or chi-square tests. While we would likely not expect to see significant change on our secondary outcome measures following an 8-week intervention, we will utilize exploratory measures to determine the most potential for maximal impact in future stage research.

IRB Approval
10/13/2021
IRB # 72893
IRB2

PROTOCOL TYPE

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Which IRB

(•) Medical ( ) NonMedical

Protocol Process Type

( ) Exemption
(•) Expedited (Must be risk level 1)
( ) Full

IMPORTANT NOTE: Once you have saved your choices under "Which IRB" and "Protocol Process Type", you will not be able to change your selections. If you select the wrong IRB Type and/or your application is deemed eligible for a different Protocol Process Type, it may be necessary to create a new application.

Please see below for guidance on which selections to make, and/or go to ORI's "Getting Started" web page. If you still have questions about which IRB or Protocol Process Type to choose, please contact the Office of Research Integrity (ORI) at 859-257-9428 **prior** to saving your selections.

Which IRB

The **Medical IRB** reviews research emanating from the Colleges of Dentistry; Health Sciences; Medicine; Nursing; Pharmacy and Health Sciences; and Public Health.

The **Nonmedical IRB** reviews research originating from the Colleges of Agriculture; Arts & Sciences; Business & Economics; Communication & Information; Design; Education; Engineering; Fine Arts; Law; and Social Work. The Nonmedical IRB does not review studies that involve administration of drugs, testing safety or effectiveness of medical devices, or studies that involve invasive medical procedures, regardless of from what college the application originates.

Which Protocol Process Type

Under federal regulations, an investigator's application to conduct a research project involving human subjects can be processed by the IRBs in three ways:

- by full review;
- by exemption certification;
- by expedited review.

The preliminary determination that a research project is eligible for exemption certification or expedited review is made by the investigator. For assistance in determining which review process type your IRB application is eligible for, please go to ORI's "Getting Started" web page.

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

EXPEDITED CERTIFICATION

0 unresolved comment(s)

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

A. Research activities that (1) present no more than *minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
B. The categories in this list apply regardless of the age of subjects, except as noted.
C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
D. The expedited review procedure may not be used for classified research involving human subjects.
E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR 46.102(i)*

Check the appropriate categories that apply to your research project:

☐ Study was originally approved by the full IRB at a convened meeting.

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

A. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
B. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

* Study must meet one of the IDE Exempt categories listed on the Device Form Attachment.
** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements- 21 CFR 812.2(c)
NOTE: Select Category 1 for compassionate use medical device applications or individual patient expanded access investigational drug applications for which FDA has waived the requirement for full review.

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP [PDF] for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a) If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☐ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

A. Hair and nail clippings in a nondisfiguring manner;
B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
C. Permanent teeth if routine patient care indicates a need for extraction;
D. Excreta and external secretions (including sweat);
E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
F. placenta removed at delivery;
G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
J. Sputum collected after saline mist nebulization.

☑ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
B. Weighing or testing sensory acuity;
C. Magnetic resonance imaging;
D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 5) Research involving materials (data, documents, records, or specimens) that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis) as well as research involving existing information or specimens that were previously collected for research purposes, provided they were not collected for the currently proposed research. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.104(d)(4). This listing refers only to research that is not exempt.)

☑ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☑ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.104 (d)(2) and (d)(3). This listing refers only to research that is not exempt.)

PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (If applicable, use the exact title listed in the grant/contract application). *** Effective 4/16/2020: If your research involves investigating any aspect of COVID-19, please enter "COVID19" at the start of your Project and Short Titles ***

Improving Person-Environment Fit of Community-Residing Older Adults with Dementia

Short Title Description

Note: "Short Title" should consist of a couple key words to easily identify your study - these key words (rather than the whole title) will be displayed on the Dashboard in the listing for your study.

Person-Environment Fit

Anticipated Ending Date of Research Project: 12/30/2022

Number of human subjects (or records/specimens reviewed): 70

Study is/will be open to new subject enrollment or data/specimen collection: (•) Yes ( ) No

PI CONTACT INFORMATION

0 unresolved comment(s)

The Principal Investigator's (PI) contact information is filled in automatically based on who was logged in when the application was created (with LinkBlue ID). If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be the same person listed below.

If you are not the Principal Investigator, do NOT add yourself as study personnel. You may change the PI contact information on an application that is in Researcher edit mode by:

- clicking the "Change Principal Investigator" link below;
- searching for the PI's name using the search feature;
- clicking "Select" by the name of the Principal Investigator, then "Save Contact Information".

You will automatically be added as study personnel with edit authorization so you can continue editing the application.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to myUK and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a 'Name Change Form' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the HR Benefits Office for additional information.

Note: Principal Investigator (PI) role for E-IRB access
The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*).

Change Principal Investigator:

First Name:	Elizabeth	Room# & Bldg:	1030 S. Broadway
Last Name:	Rhodus	Speed Sort#:	40504
Middle Name	Kelly		
Department:	Sanders-Brown Ctr On Aging …	Dept Code:	7H030
PI's Employee/Student ID#:	12060375	Rank:	Post-Doctoral Fellow
PI's Telephone #:	8592575562	Degree:	PhD, MS, OTR/L
PI's e-mail address:	elizabeth.rhodus@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	Trained:	Yes
		Date Trained	10/24/2018

Do you, the PI, have a significant financial interest related to your responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2)?

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

- (●) (Risk Level 1) Not greater than minimal risk
- ( ) (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ( ) (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ( ) (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests [45 CFR 46.102(i)]

*****For Expedited and Exempt Applications, the research activities must present no more than minimal risk to human subjects (Risk Level 1).*****

Download UK's guidance document on assessing the research risk for additional information on risk [PDF]

SUBJECT DEMOGRAPHICS

0 unresolved comment(s)

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 21 to 99

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):

Enter Numbers Only!

Ethnic Origin	#Male	#Female
American Indian/Alaskan Native:		
Asian:		
Black/African American:	3	3
Hispanic/Latino:		
Native Hawaiian/Pacific Islander:		
White/Caucasian:	30	34
Other or Unknown:		

If unknown, please explain why:

Indicate the categories of subjects and controls to be included in the study. Depending on the subject category applicable to your research you may be required to complete additional forms. [Note, if the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check mark populations which the research does not specifically target. For instance, a large record review of a diverse population may incidentally include a prisoner or an international citizen, but, if the focus or intent of the study has nothing to do with that status, you do not need to check those category(ies).]

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☑ Impaired Consent Capacity

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook under the named topic:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults: Link to required Form

And/Or:

Adults
☐ Pregnant Women/Neonates/Fetal Material
☐ Prisoners
☐ Non-English Speaking
☐ International Citizens
☑ Normal Volunteers
☐ Military Personnel and/or DoD Civilian Employees
☐ Patients
☑ Appalachian Population

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see instructions for recruitment and E-IRB Research Description section on same topic]
- International Citizens [HTML] (DoD SOP may apply [PDF])
- Military Personnel and/or DoD Civilian Employees (DoD SOP may apply [PDF])

The next questions involve assessment of the study relative to potential recruitment of subjects with impaired consent capacity (or likelihood).

☐ Check this box if your study does not involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). (you will not need to answer the impaired consent capacity questions)

Does this study focus on adult subjects with any of the clinical conditions listed below that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

◉ Yes ○ No

If Yes, go to the following link and complete and attach the indicated form unless you are filing for an exemption certification: https://ris.uky.edu/ori/oriforms/formt/Scale.asp

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

Attach Type	File Name
ImpairedConsent	Form_T_1Di.doc

INFORMED CONSENT/ASSENT PROCESS/WAIVER

1 unresolved comment(s)

For your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and revise to be in accord with your research project.

Additional Resources:

- Sample Repository/Registry/Bank Consent (Word)
- Instructions for Proposed Informed Consent Document
- Instructions for Proposed Assent Form

Consent/Assent Tips:

- **If you have multiple consent documents, be sure to upload each individually (not all in a combined file).**
- **Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".**
- **It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.**
- **Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.**
  Document Types that do NOT get an IRB approval stamp are:
  - **"Highlighted Changes",**
  - **"Phone Script", and**
  - **"Sponsor's Sample Consent Form".**

How to Get the Informed Consent Section Check Mark

1. **You must check the box for at least one of the consent items and/or check mark one of the waivers, then if applicable attach the corresponding document(s) as a PDF (if open to enrollment).**
2. **If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only check mark the "Stamped Consent Doc(s) Not Needed".**
3. **After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!**

Check All That Apply

- ☑ Informed Consent Form (and/or Parental Permission Form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☑ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- ☐ Stamped Consent Doc(s) Not Needed

Attachments

Attach Type	File Name
Informed ConsentParental Permission	Consent Patient-clean 9-19.pdf
Informed ConsentParental Permission	Consent CAREGIVER 9-20 clean.pdf
InformedConsent_HighlightedChanges	Consent CAREGIVER 9-20 highlighted.docx
InformedConsent_HighlightedChanges	Consent Patient-highlighted.docx

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for the informed consent process, or alteration of some or all of the elements of informed consent (i.e. medical record review, deception research, or collection of biological

specimens), complete Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting waiver of the requirement for the informed consent process.

☐ I am requesting alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered, and/or omitted, and justify the alteration.

SECTION 2.

The IRB may consider your request provided that **all** of the following conditions apply to your research and are appropriately justified. Explain in the space provided for each condition how it applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

e) If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

- Private information/specimens are “identifiable” if the investigator may ascertain the identity of the subject or if identifiers are associated with the information (e.g., medical records). This could be any of the 18 HIPAA identifiers including dates of service.
- If not using identifiable private information or identifiable biospecimens, insert N/A below.

Request for Waiver of Documentation of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for documentation of informed consent (i.e. telephone survey or mailed survey, internet research, or certain international research), **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk to the subject and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study, and explain in the space provided how your study meets the criteria for the selected regulatory option.

Note: The IRB cannot waive the requirement for documentation or alter the consent form for FDA-regulated research unless it meets Option #2 below. FDA does not accept Option #1.

Note: Even if a waiver of the requirement for documentation is approved by the IRB, participants must still be provided oral or written (e.g., cover letter) information including all required and appropriate elements of consent so they have the knowledge and opportunity to consider whether or not to participate. To help ensure required elements are included in your consent document, please use the **Cover Letter Template** as a guide: *English*- [WORD], Spanish- [WORD] The cover letter template was developed specifically for survey/questionnaire research; however, it may be useful as a guide for developing a consent document for other types of research as well.

Option 1

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

Option 2

a) The research presents no more than minimal risk to the participant:

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

Option 3

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

STUDY PERSONNEL

0 unresolved comment(s)

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must save by hitting the 'Save Study Personnel Information' button.

(•) Yes ( ) No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is being completed to meet the requirements of a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed as such below. ***Residents and students who are PI's are encouraged to designate at least one other individual (e.g., faculty advisor) as a contact with an editor role (DP).***
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR/FR, MR) or 'Other Review", and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature, search for applicable personnel first, then click "select" by the listing for the person you want to add as study personnel to your protocol. For each individual selected, be sure to specify responsibility in the project, whether authorized by the principal investigator to obtain informed consent, AND denote who should regularly receive E-IRB notifications.

NOTE: Study personnel are required to receive human research protection (HSP) training before implementing any research procedures (e.g., CITI). For information about mandatory training requirements for study personnel, visit UK's FAQ's on Mandatory Training web page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (HSPTrainingSupport@uky.edu) for credit.

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	Removed?	Last Updated	SFI
Jicha	Gregory	Co-Investigator	SP	N	N		P	Y	12/11/2019	N	08/30/2021	N
Koehl	Lisa	Co-Investigator	SP	N	N		P	Y	04/15/2021	N	08/30/2021	N
Schoenberg	Nancy	Faculty Advisor	SP	N	N		P	Y	05/29/2021	N	08/30/2021	N
Wilcock	Donna	Faculty Advisor	SP	N	N		P	Y	08/19/2019	N	08/30/2021	N

RESEARCH DESCRIPTION

0 unresolved comment(s)

****!!!PLEASE READ!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.**

Workaround(s):

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

Alzheimer's disease and related dementias (ADRD) are a common and devastating diagnosis among older adults, with one in 10 individuals over the age of 65 having dementia, and as many as one in three over the age of 85 having cognitive impairment or dementia [1]. Individuals with ADRD face numerous changes throughout the course of cognitive decline, including reduction in independence, activity engagement, and safety [2]. Further, behaviors and psychiatric symptoms of dementia (BPSD) are reported in over 80% of those diagnosed with ADRD and contribute to increased mortality [3-6]. Most common BPSD include apathy, depression, agitation, aggression, anxiety, and sleep disorders [7-9]. These behaviors often drive increased caregiver burden, placement in institutional care, and decreased quality of life for caregivers and person with ADRD [10-12]. Safe and effective treatment options are limited [4]. More vulnerable populations, including rural residents, often experience greater negative impacts from ADRD due to limited access to healthcare, [13,14] lack of available caregiver training, [15,16] and elevated rates of comorbid conditions [17]. Innovative and robust assessment and intervention approaches for persons with ADRD specifically targeting rural [18] regions are needed to improve quality of life and well-being for both the person with ADRD and their caregiver. National and international agencies, such as the American Academy of Neurology, recognize a strong need for non-pharmacological intervention, including environmental assessment and modification, as first-line treatment for BPSD in ADRD [4,19]. However, lack of assessments and interventions to guide and apply such mechanisms severely limit real-world implementation [20] According to a recent comprehensive systematic literature review conducted by the Agency for Healthcare Research and Quality (AHRQ), [21] dementia care interventions lack sufficient evidence for widespread utilization. Limitations with research design, reproducibility, dissemination, outcome measures, and inclusion of diverse populations have severely restricted implementation and universal adoption of dementia care practices. These limitations have led AHRQ, as well as NIH, to call for innovative, highly rigorous research in dementia care science to develop effective and reproducible intervention options. The Science of Behavior Change program [22] encourages increased experimental methodology for enhanced scientific rigor in behavior change research. It suggests researchers must identify mechanisms of action, measure appropriate outcomes, and determine the influence on behavior change. The proposed research project answers this call by addressing these areas and catalyzes Dr. Rhodus' research career to develop innovative, rigorous dementia care practices.

Person-Environment Fit in Community-Residing Adults with ADRD

Identification of underlying mechanisms, such as environmental context, related to behavior change/BPSD is needed to improve behavior science and research in this area [22]. The research proposed here is guided by mechanisms established by environmental gerontologists who have long recognized behavior as a product of environmental interaction. In 1936, Lewin defined (B)ehavior as a (f)unction of the (P)erson and (E)nvironment: B = f (P,E) [23]. Lawton and Nahemow [24] developed the Ecological Model of Aging which depicts zones of adaptive behavior when environmental factors/demands are aligned with one's capability and competence. This model predicts zones of maximum comfort and performance when environmental factors are appropriate to individual ability. Despite being a long established concept, the relationship between people and their environment, referred to as the person-environment fit, continues to be applicable [25] and informs pragmatic development of assessment and intervention for community-residing adults with ADRD. However, there is sparse evidence for the combined effects of these environmental factors on behavioral regulation and performance for people with ADRD [26-28]. To fill this gap, this project will integrate existing ADRD measures and interventions to create a holistic approach to behavioral regulation through person-environment fit for people with ADRD. We place interactions affecting person-environment fit within an established model of functional cognition which presents multiple levels of influence, including brain, behavior, and performance [29]. We add environment as a level of influence. This perspective allows for a holistic approach that assesses and intervenes on the combined influences of person and environment.

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Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below.

Integrate personal (functional, behavioral, and physiological) and environmental (physical, social, and sensorial) assessment to measure person-environment fit in community-residing adults with dementia to support performance and participation within the home environment.

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a Research Repository (bank, registry) indicate whether the material you plan to collect would or would not be available from a commercial supplier, clinical lab, or established IRB approved research repository. Provide scientific justification for establishment of an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance [PDF] or the UK Research Registry Guidance [PDF]

Using a cross-sectional approach, 35 dyads (person with ADRD and caregiver) will be enrolled in this observational, quantitative study to assess the relationship between personal and environmental factors for community-dwelling people with ADRD. Measures will be collected over the course of 7 days in participants' homes. Most assessments are completed at one time point; however, prior work has confirmed 7 days is needed to proper psychophysiological data collection.50 Analyses will document relationships among environmental features and personal function, behavior, and physiological functioning. Results will inform development of a measure of person-environment fit specific for people with ADRD living in the community.

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Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners, economically or educationally disadvantaged persons or others who are likely to be vulnerable.

If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of women or minorities requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- The proposed dates of enrollment (beginning and end);
- The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button, however, a summary paragraph must be provided in the text box below.

Thirty-five community-dwelling dyads (person living with ADRD and their primary caregiver) who are living at home will be recruited for this study. Participants recruited will include those with a diagnosis of dementia (moderate to severe) and living in rural Appalachia. Initial recruitment efforts will occur through the UK-ADRC cohort, which currently has 121 participants with ADRD diagnosis who agree to be contacted for recruitment in studies. Additional recruitment will be provided through Dr. Gregory Jicha's rural Appalachia referrals to the UK Telemedicine Neurology Clinic, as well as patients seen within the Kentucky Neuroscience Institute at UK. Recruitment all also occur in partnership with the UK Center for Health Equity Transformation, all of which will use Institutional Review Board approved procedures.

No exclusions will be made based on sex/gender or racial/ethnic groups.

Enrollment is planned to begin January 2022 and end December 2022.

Inclusion Criteria

Participants must meet all inclusion criteria in order to participate in the study:
Participants with Dementia:
1. Men or women aged 65-99, inclusive.
2. Living at home in the community with one primary caregiver.
3. Diagnosis of Alzheimer's disease as primary dementia type of moderate to severe stages (confirmed by Clinical Dementia Rating

Scale score
of 1.0+)
4. If on psychotropic medication, they are at a point where dosage and treatment are stabilized for the duration of the study.
5. Functional sensory abilities with or without aids (hearing, vision, smell, touch, taste)
6. Caregiver report of challenges related to behaviors within 4 weeks of study enrollment.
7. Caregiver willing to participate throughout duration of study.
8. Contact with UKADC or KNI medical provider within 12 months of study recruitment.

Caregiver for Participant with Dementia:
1. Men or women aged 21-99, inclusive.
2. Willingness to participate in study and implement recommended data collection tools.
3. English speaking, able to read and write.
4. Ability to retrieve and send mail.

Exclusion Criteria
Participants with Dementia:
1. Unstable medical conditions within one month prior to screening visit such as poorly controlled blood pressure, diabetes, current cancer diagnosis,
or breathing problems, etc.
2. Wheelchair or bed bound.
3. Residence in skilled nursing facility or facility-based care.
4. Caregiver report of physically violent behaviors.
5. Initiation of antipsychotic medication within 4 weeks prior to screening or unpredictable use of such medications
6. Diagnosis of profound or total sensory altering disorders including macular degeneration, legal blindness, total deafness, severe peripheral
neuropathy, anosmia.
7. Major depression in past 12 months (DSM-IV criteria), major mental illness such as schizophrenia, bipolar disorder, personality disorders, or recent
(in past 12 months) alcohol or substance abuse.
8. Major infection within 4 weeks prior to the Baseline Visit.

Caregiver for Participant with Dementia:
1. Diagnosis of mild cognitive impairment or dementia.

Participants with impaired ability to consent will be sought as the goals of this study involve the dyad of patients with dementia (which causes impaired cognition) and their caregivers. The study would not be able to be conducted without inclusion of persons with impaired cognitive capacity.

Attachments

Subject Recruitment Methods & Privacy: Using active voice, describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information.

Describe the setting in which an individual will be interacting with an investigator or how and where members of the research team will meet potential participants. If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations as participants in clinical research. Describe steps taken to minimize undue influence in recruiting potential participants.

Please note: Based upon both legal and ethical concerns, the UK IRB does not approve finder's fees or "cold call" procedures made by research staff unknown to the potential participant. The ORI/IRB does not control permission to any UK listserv, mass mailing list, etc. Investigators must secure prior approval for access and use from owners/managers.

For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page and the PI Guide to Identification and Recruitment of Human Subjects for Research [PDF].

This project, located at the University of Kentucky (UK) will use established cohorts, networks, and patient-groups for recruitment. UK is a leading healthcare center for neurology care in the state of Kentucky. UK also has well-established community partnerships and networks within rural, Appalachia Kentucky. Recruitment for study objectives will involve 35 persons living with ADRD and their primary caregiver (total n=70) who exhibit behavioral disturbance in conjunction with dementia. Similar to recruitment strategies for Alzheimer's Disease clinical trials at the University of Kentucky Alzheimer's Disease Research Center (UK-ADRC), we will identify individuals through a variety of approaches from those enrolled in the longitudinal cohort of the UK-ADRC (300 participants living within rural Kentucky), the Kentucky Neuroscience Institute at the University of Kentucky (800 patients living within rural Kentucky), patients of the UK Rural Telehealth Neurology Clinic, and community engagement events sponsored by Sanders-Brown Center on Aging (SBCoA). We will contact individuals who are referred by the SBCoA clinical staff including social work, medical providers, or community-based professionals as persons who have potential interest in participation of this study. Recruitment tools will include flyers, email correspondence, community representative outreach, and ads on UK affiliated Center websites/social media accounts. Recruitment from KNI will occur prior to informed consent including a review of medical records to identify additional subjects that are not in the recruitment database. This PHI information will be collected via AEHR UKHC or Epic. Research Match will also be used for email correspondence with support of the Center for Clinical and Translational Science at UK. Study PIs are affiliated with Sanders-Brown Center on Aging, and co-investigators (Jicha) is the clinical core director and director of the Telehealth Clinic and neurologist for KNI. Researchers are embedded within these networks of patients for recruitment purposes.

Additional recruitment efforts will occur in partnership with the UK Center for Health Equity Transformation (CHET). CHET has established numerous collaborations within the rural, Appalachian community which will offer additional recruitment opportunity. For example, CHET Director, Dr. Nancy Schoenberg maintains three study sites in rural Appalachian communities from which she operates her research projects. One of these sites, located in Whitesburg, KY, is a 2000 square foot building that currently houses two community-based interventions involving churches and community centers as recruitment venues. Dr. Schoenberg will welcome Dr. Rhodus to immerse herself in those sites and forge interactions with staff members who could assist her with outreach. The UK Center for Clinical and Translational Science (CCTS) provides support and assistance for community outreach, recruitment, and research activities throughout Kentucky, including multiple points of contact throughout rural Appalachia Kentucky. Recruitment tools will include flyers, email correspondence, community representative outreach, newsletter articles, FAQ sheets, and ads on Center websites.

Retention plans will include contact by a member of the research team to participants throughout the duration of their involvement in the study. Research staff will clearly explain the requirements of the study prior to enrollment, obtain several contact avenues (phone numbers, email), and will be flexible in scheduling appointments.

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Advertising: Specify if any advertising will be performed. If yes, please see "IRB Application Instructions - Advertisements" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page for the *PI Guide to Identification and Recruitment of Human Subjects for Research* [D7.0000] document [PDF]. If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.

Note: Print and media advertisements that will be presented to the public also require review by UK Public Relations (PR) to ensure compliance with UK graphic standards, and equal opportunity language. See Advertising Instructions for PR contacts.

Recruitment tools will include a flyer, email correspondence (attached below), and social media advertising on UK's CCTS and Sanders-Brown Center on Aging accounts. Should we decide to utilize additional recruitment tools, we will pursue IRB modification for each of the additional recruitment tools and advertisements.

Attachments

Attach Type	File Name
Advertising	research match.pdf
Advertising	Rhodus_Flyer 8-30.docx
Advertising	social media.pdf

Informed Consent Process: Using active voice, describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent., steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Describe provisions for obtaining consent/assent among any relevant special populations such as children (see Children in Research Policy [PDF] for guidance), prisoners (see Summary of Prisoner Regulations [PDF] for guidance), and persons with impaired decisional capacity (see Impaired Consent Capacity Policy [PDF] for guidance). Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page.

Informed Consent for Research Involving Emancipated Individuals
If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP [PDF].

Informed Consent for Research Involving Non-English Speaking Subjects
If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.

Research Repositories
If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template [PDF]

Informed consent will be sought from two groups: Caregivers and patients with advanced dementia.
A caregiver responding to the study ad via phone or email to (PI, Rhodus or study personnel to be named) will be contacted via email or phone call to schedule a screening visit. Consent will be sent to participant following initial contact and indication of interest in research study prior to screening visit.
Caregiver:
Following verbal confirmation from participants, the person authorized to obtain consent will create a new redcap record and email the electronic consent form electronically distributed through REDcap to their email or smart phone through private dedicated link at least 24 hours prior to screening visit. All study procedures will be described in detail over the phone or zoom during screening visits prior to initiation of any study procedures. The consent form will be reviewed during the screening visit to clarify any questions the participant may have. If the participant is in agreement, they will be asked to electronically sign the form. Upon receipt in REDCap, the person authorized to obtain consent will then add their name (sign) and date (date that informed consent is confirmed via phone or zoom) into the designated fields to complete the consenting process. This If the person is unable to obtain the electronic copy, a paper copy will be mailed to participant 7 days prior to screening visit. The form will need to be signed during the screening visit with visual confirmation on zoom video and returned via mail, email, or fax prior to data collection at baseline visit. The UK personnel authorized to obtain consent will sign and date the form upon receipt using the date that informed consent was confirmed.

Patient with advanced dementia:
Because of the substantial cognitive impairment associated with a diagnosis of advanced dementia, informed consent for patients will be sought from their legally authorized representative (LAR). The LAR will be identified by UK (SBCoA or KNI) chart review if this person is not the caregiver participant. All research procedures will be thoroughly described over phone or zoom to the legally authorized representative prior to seeking consent for participation. Electronic consent will be sought by the patient's legally authorized representative on the consent form electronically distributed through REDcap to the LARs email or smart phone through private dedicated link sent at least 24 hours prior to screening visit. The consent form will be reviewed with the LAR during the screening visit to clarify any questions the participant may have. If the LAR is in agreement, they will be asked to electronically sign the form. Upon receipt in REDCap, the person authorized to obtain consent will then add their name and date (date that informed consent is confirmed) into the designated fields to complete the consenting process. If the LAR is unable to obtain the electronic copy, a paper copy will be mailed to the LAR 7 days prior to screening visit. The form will need to be signed during the screening visit with visual confirmation on zoom video and returned via mail, email, or fax prior to data collection at baseline visit. The UK personnel authorized to obtain consent will sign and date the form upon receipt using the date that informed consent was confirmed. The study procedures will be described over zoom video conferencing for the person with dementia and signs for dissent (as listed in Form T) will be assessed.
LARs and caregiver participants will keep a copy of the consent (either electronic or paper). If the consent is signed electronically, an automatic email of a copy of the consent will be sent to their email on file. If a paper copy is used, two copies of the form will be mailed, and one copy will be sent back to research team and one copy will be retained by LAR and participants.

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Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

Two groups of participants will be included in this study: persons with dementia and their primary caregiver.

Research procedures for caregivers will include the following for an approximate total time of 5.5 to 6 hours:

Screening: A screening visit will take place over Zoom video conferencing and will include review and obtaining informed consent for study participation following review of inclusion/exclusion criteria with the LAR and caregiver. Following screening, the data collection tools (behavior work book and Empatica E4 device) will be mailed to you. (approx. 15 min.)
Day 1: During a phone conversation with the researcher, you will complete the Canadian Occupational Performance Measure and Clinical Dementia Rating Scale. You will also don the Empatica E4 on the wrist of the person you are caring for and begin daily behavior journaling in the provided book. (45 minutes)
Day 2: The Adult Sensory Profile will be mailed or emailed to you for completion. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes)
Day 3: During a phone conversation with the researcher, you will complete the Neuropsychiatric Inventory and the Revised Memory and Behavior Problem Checklist. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes)
Day 4: The Zarit Caregiver Burden Inventory will be mailed or emailed to you for completion. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes)
Day 5: During a Zoom video conference, you will complete the Home Occupational Environment Assessment. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes)
Day 6: The Functional Behavior Profile will be mailed or emailed to you for completion. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes)
Day 7: You will also monitor wear of the Empatica device and complete daily behavior journal. Following conclusion of day 7, you will return the behavior journal and Empatica E4 via prepaid shipping to the local Fedex drop off (determined with assistance from researcher). (45 minutes)

Research activities for person with dementia (patient):
Total participation time for persons with dementia will including 2 hours. The will wear an activity monitor, called Empatica E4, on their wrist for seven consecutive days. During this time, their caregiver will also complete daily journal entries summarizing observed behaviors.
Day 1: They will don the activity monitor on wrist.
Day 2-6: The caregiver will monitor wear of the activity monitor including taking off during bathing and for charging.
Day 7: Following Day 7 wear, with assistance from the caregiver, they will remove the activity monitor for return to the University of Kentucky.

All sessions occurring over Zoom video conferencing will be video and audio recorded and all phone sessions will be audio recorded. Recordings will be stored on REDCap.

Attachments

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

Note: The IRB approval process does not include a statistical review. Investigators are strongly encouraged to develop data management and analysis plans in consult with a statistician.

Existing PHI records will including: Name, email address, phone number, DOB, address, medical history, diagnoses, medications, primary contact information, University of Kentucky Healthcare medical identification number, tests completed at Sanders-Brown Center on Aging or the Kentucky Neuroscience Institute. Sources of the PHI will come from the Sanders-Brown Center on Aging cohort database and clinical notes in patient files; and PHI from KNI will be collected through AEHR UKHC or Epic for any patients with memory impairment at KNI.

All visits occurring over Zoom will be video and audio recorded and saved on REDCap. All phone calls will be audio recorded and saved to REDCap.

Behavior Workbook/Journals will be used to collect daily records of patient behaviors as observed and reported by caregivers in relation to environmental stressors. These will be printed and mailed to participants, and returned with iPads at conclusion of study.

Multiple measures will assess personal and environmental factors. These assessments were selected based on recommendation from a multidisciplinary expert panel including fields of occupation therapy, social work, engineering, physiology, psychology, and neurology as ideal measurements of targeted areas. In addition to these measures, a daily journal will be completed by caregivers to

document perceived stress level of persons with ADRD and the environmental setting during data collection to better inform data interpretation.
Independent Variables:
Home Environment:
1) Physical: Home Occupational Environment Assessment (HOEA). Caregivers will systematically assess the home environment including accessibility, sanitation, food storage, safety, and sensorial
stimulation.
2) Social: Caregiver demographics; Zarit Caregiver Burden Scale. The social context of the person with ADRD is described through analysis of caregiver demographics and rate of caregiver burden measured by the Zarit Caregiver Burden, a 22-item survey in which the caregiver rates level of burden on 5-point Likert scale.

Neurological:
1) Sensory Response: Caregiver report of patients' functional sensory acuity, Adult Sensory Profile. Caregivers will be interviewed to determine patients' functional sensory acuity (i.e., wears glasses, hearing aids, presence of neuropathy, etc.). The caregiver will complete the Adult Sensory Profile as proxy for the person with ADRD. This is a valid and reliable 60-question assessment to determine sensory simulation preference and neurological ability for processing sensory stimulation.
2) Physiological Response: Assessment of psychophysiological biomarkers (as indicator of stress) will include heart rate variability, electrodermal activity, and blood pressure. These responses will be assessed using innovative wearable technology (Empatica E4 wrist device) which provides real-time record of physiological/inertial signals from multiple sensors in the device including Blood Volume Pulse (BVP), Electrodermal Activity (EDA), Inter Beat Interval (IBI), Skin Temperature (ST), and Tri-Axial Acceleration (TAA). Preliminary work has demonstrated integration of these measurements are a reliable predictor of stress in older adults using machine-based learning science.

Behavior:
1) Behavior: Revised Memory and Behavior Problem Checklist (RMBPC) and Neuropsychiatric Inventory (NPI). The RMBPC is a valid and reliable measure of caregiver-reported behavior problems in people with ADRD and includes subscales of memory, depression, and disruptive behaviors. The NPI is commonly used as an assessment of BPSD in older adults diagnosed with MCI or dementia, internationally, with high reliability and validity. Assessment includes 12 behavioral and psychiatric domains which are rated by caregiver as present or absent (yes/no). Caregivers further rate severity of present behavioral domains. The severity score is summed to yield a total as a measure of BPSD burden.
2) Cognition: Clinical Dementia Rating Scale (CDR). The CDR, a valid and reliable measure, determines severity of cognitive impairment. Six cognitive domains are assessed in CDR (memory, orientation, judgement and problem solving, community affairs, home and hobbies, and personal care) with feedback from patient performance and caregiver results scored by a trained professional.

Dependent Variables:
Performance: 1) Function: Functional Behavior Profile (FBP). The FBP is an established reliable and valid measure of task performance, social interaction, and problem solving with adults with ADRD.
2) Performance: Canadian Occupational Performance Measure (COPM). The COPM is a reliable and validated measure of performance in primary daily activities (self-care, leisure, productivity) with dyad-rated performance and satisfaction.

Attachments

Attach Type	File Name
DataCollection	HOEA 2.pdf
DataCollection	COPM.pdf
DataCollection	ASP.pdf
DataCollection	Zarit Caregiver Burden Inventory.pdf
DataCollection	RMBPC.pdf
DataCollection	final fbp.doc
DataCollection	CDR.pdf
DataCollection	npiq-questionnaire.pdf
DataCollection	Behavior Journal.pdf

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see FDA Guidance). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you

have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

a) Staffing and personnel, in terms of availability, number, expertise, and experience
-Dr. Rhodus will provide oversight of the entire study and development and implementation of all policies, procedures and processes. In these roles, Dr. Rhodus will be responsible for the implementation of the Scientific Agenda, the Leadership Plan, and the objectives ensure that systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including human research, data and facilities.
-We are utilizing an existing UK student worker to further assist with recruitment, consenting, and study coordination. This UK student worker will be named at a later date.
-We will utilize our connections with UK Sanders-Brown Center on Aging.
b) Equipment:
-Printed behavior work books will be mailed to participant and returned upon completion of this study
-Empatica E4 device will be used during this study for biometric data collection and returned to UK upon completion. These devices on UK owned.
-UK owned computers will be used. One UK-owned Desktop with password protection housed at 1030 S. Broadway Ste 5 Lexington KY 40504 and one UK-owned laptop with encryption and password protection will be used. Those listed on this IRB protocol will be only persons able to access protected data. All data will be stored and maintained behind a UK Firewall.
-REDCap will be used for data storage.

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

Potential risks include risk of breach of confidentiality. To minimize this risk, all subject data is de-identified at each visit and kept in a secure database at Sanders-Brown Center on Aging.

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Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

Protections against breach of confidentiality of data:
Upon enrollment in the study, each participant will be assigned a participant number and pseudonym, which will be used to identify the person during data analysis and when managing data. All data will be uploaded and saved to REDCap the day of acquisition from participants. REDCap is a password-protected, secure data management web application in the secure data center run by the Institute for Pharmaceutical Outcomes and Policy (IPOP) physically located in the new Biological and harmaceutical Complex building at the University of Kentucky. The files will be stored for a period of six years and destroyed according to UK Policy A13-050. Confidentiality will be maintained; however, in the case in which abuse or concern of participants' safety, the researcher is required by law to report to authorities.

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc…), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for Protection of Vulnerable Subjects [C3.0100] [PDF].

Information learned in this study may help others, specifically those informally caregiving for dementia. We anticipate participants will have increased knowledge related to caregiving practices for persons with dementia, however, because of the feasibility nature of this study, we do not know if participants will get any benefit from taking part in this study. However, some people have experienced opportunity for social engagement when participating in occupational therapy services, caregiving education, and research in general.

Available Alternative Treatment(s): Describe alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

None. Participants may opt not to participate in this study if they so choose.

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Research Materials, Records and Privacy: Identify the sources of research material obtained from living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):
If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

Existing records of PHI within UK EHR/medical records and EPIC will be used for recruitment purposes to identify eligible participants from the Kentucky Neuroscience Institute and the Sanders-Brown Center on Aging longitudinal cohorts.

Biometric data will be collected to assess physiological response to environmental stressors. The device, Empatica E4 will collect psychophysiological biomarkers (as indicator of stress) including heart rate variability, electrodermal activity, and blood pressure. These responses will be assessed using innovative wearable technology (Empatica E4 wrist device) which provides real-time record of physiological/inertial signals from multiple sensors in the device including Blood Volume Pulse (BVP), Electrodermal Activity (EDA), Inter Beat Interval (IBI), Skin Temperature (ST), and Tri-Axial Acceleration (TAA). Preliminary work has demonstrated integration of these measurements are a reliable predictor of stress in older adults using machine-based learning science.

Confidentiality: Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Please address the following items or indicate if the following has been addressed in a HIPAA or Limited Review form:

- physical security measures (e.g., locked facility, limited access);
- data security (e.g., password-protection, data encryption);
- who will have access to the data/specimens and identifiers;
- safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality);
- procedures employed when sharing material or data, (e.g., honest broker if applicable, written agreement with recipient not to re-identify, measures to ensure that subject identifiers are not shared with recipients).
- management after the study

Describe whether data/specimens will be maintained indefinitely or destroyed. If maintained, specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them. If the data/specimens will be destroyed, describe how and when the data/specimens will be destroyed. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data/specimens with entities not affiliated with UK (If the research is non-sponsored you need a data use agreement to share data/specimens [Transfer Agreements]).

HIPAA/FERPA Minimal Access Standards: The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "Confidentiality and Data Security Guidelines for Electronic Data" [PDF].

Cloud storage: For storage of data on cloud services other than UK OneDrive, please verify security settings are sufficient and in accordance with respective departmental, UK Corporate Compliance, and/or UK Information Technology requirements.

Creation of digital data application/program: If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. For relevant information to include, see Considerations for Protocol Design Concerning Digital Data [PDF]. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriately protected.

NIH-funded genomic research: The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data consistent with the informed consent of study participants from which the data was obtained. If you are submitting genomic data to an NIH data repository, describe your NIH data sharing plan.

Management after study: Describe how the collected data/specimens will be managed after the end of the study. Specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them and specify what steps will be taken to secure the data/specimens (e.g., maintaining a coded list of identifiers separate from the data/specimens).

If the data/specimens will be destroyed, describe how, when, and why this will be done. Note that destruction of primary data may violate NIH and NSF retention and sharing requirements, journal publication guidance, and University Data-Retention policies. Additionally, primary data may be necessary for other purposes (to validate reproducibility, for data sharing, or for evidence in various investigations). PIs should carefully consider whether the destruction of data is justified.

The investigator is responsible for retaining signed consent and assent documents and IRB research records for at least six

years after study closure, as outlined in the Study Closure SOP [PDF]. If the research falls under the authority of the FDA or other regulatory agencies, or a study sponsor is involved, additional requirements may apply.

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All materials, except behavior journals, will be in electronic format. All data will be uploaded and saved to REDCap the day of acquisition from participants. Hard copies of behavior journals will be electronically scanned with 48 hours of receipt and destroyed via shredding following uploading to REDCap. All hard copies (behavior journals and paper copies of consent forms) will be stored at the Sanders-Brown Center on Aging Clinic at 1030 S. Broadway Lexington KY 40504 Ste 5 office 105 in a locked filing cabinet. The building, office, and cabinet will be locked at all times of non-use. REDCap is a password-protected, secure data management web application in the secure data center run by the Institute for Pharmaceutical Outcomes and Policy (IPOP) physically located in the new Biological and Pharmaceutical Complex building at the University of Kentucky. The files will be stored for a period of six years and destroyed per UK Policy A13-050. Digital audio recordings will be obtained. These electronic files will also be stored on REDCap. Upon enrollment in the study, subjects will be given pseudonyms to protect confidentiality and de-identify data. Each participant will be assigned a participant number and pseudonym, which will be used to identify the person during data analysis and when managing data. This de-identified human subject data will be stored on REDCap. Records maintained by SBCoA are not UK medical records, and so PHI and PII will not be used. At the conclusion of the study, all individual data stored on REDCap, a secure location, for a period of 6 years, after which deletion of electronic files will destroy it. All video recording/electronic data will be stored for a period of six years after which files will be destroyed using the University of Kentucky's Policy for Reuse and Disposal of Electronic Media. UK Healthcare Policy and Procedure A13-050 states "all electronic media shall be erased (i.e. purged) using data overwriting software that conforms to the requirements stated in NIST SP800-88." IRB research records (approved IRB protocol,
Form K, signed consent documents etc.) will be maintained for 6 years after study closure per the study closure SOP.
Confidentiality will be maintained, however, in the case in which abuse or concern of participants' safety, the researcher is required by law to report to authorities.

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Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

Following completion of participation in this study (seven days of data collection), Caregiver of dyad will be mailed one $50 gift card per dyad to the local general merchandise store. Person with dementia will not receive any payment.

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

There are no costs associated with completion of this study.

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

If relying on an independent agent or committee for DSMB services, it is the PI's responsibility to establish the services with the agent or committee. Please be reminded that the PI must submit DSMB reports to the IRB via modification or continuing review.

DATA AND SAFETY MONITORING PLAN
The Principle Investigator (PI, Rhodus) will be responsible for monitoring the data and safety of participants along with the co-investigators (Co-I's: Jicha and Koehl)
a. Periodic Review: The PI will hold bi-weekly meetings for the first two months of enrollment with Co-I's, then monthly for until data collection is complete. Co-I (Jicha) will review all minor AE and SAE reported to date of review. The meetings will include evaluation of all research procedures, fidelity to protocol, discussion of newly enrolled participants, and review of status of all formally enrolled participants including all adverse events. Adverse events will be reviewed to determine if changes in the protocol are indicated.
Participant demographics to date, recruitment progress, difficulties encountered during enrollment, an update on data entry, and any other issues or concerns that have arisen since the last research team meeting will also be discussed.
In addition to review of all research procedures and AE/SAE, specific review of risk related to behavioral condition of the patient and data collection will be completed at meetings. Review will assess:
1. Risk to behavioral condition: Daily communication with caregivers of patients with behavior disturbance throughout the duration of data collection per participant-dyad. If substantial behavioral change is noted by caregiver or patient report, this behavior change will

be reviewed with Co-I's.
2. Adverse Events: In compliance with Federal Regulation 21CFR §56.108(b)(1) and 45 CFR 46.103(b)(5), any unanticipated problems, including adverse events that are unexpected and related to the study, will be promptly reported to the University Institutional Review Board (IRB). Events judged as “unexpected” are those not specified in the IRB-approved research protocol or informed consent document.
The Data and Safety Monitoring Plan for the proposed project incorporates the policies on human subject data and safety monitoring specified by the University of Kentucky IRB.
Risk Assessment: Minimal risk. The study procedures and intervention represents minimal risk to study participants as this study involves a one week cross-sectional data collection approach including surveys, behavior journaling, and wearing of digital wrist device (Empatica E4).
The PI and Co-I (Jicha) will assess the severity (intensity) of reported AEs according to the NCI CTC. If a participant experiences an event not detailed by the NCI CTC, the following guidelines will be used to analyze severity:
• Mild: symptoms or signs exist and may require treatment, but are transient and easily tolerated.
• Moderate: treatment is required and continued monitoring of event is prescribed to avert participant discomfort.
• Severe: event requires treatment and continued monitoring is prescribed to prevent incapacitating or life threatening effects to the participant's health.
• Life threatening: when the participant is, in the opinion of the Investigator, at immediate risk of death from the event as it occurs, or if the event requires immediate medical treatment and continued monitoring. Note that this definition does not include an event that, had it occurred in a more serious form, might have caused death.
• Fatal: Death resulted from AE.
All adverse events occurring during the study observed by study personnel or reported by the participant (whether or not attributed to study procedures), will be recorded in the subject electronic record. Medically significant adverse events considered related to the study procedures by the Co-I (Jicha) will be followed until resolved or considered stable. It will be left to the Co-I (Jicha) clinical judgment whether or not an adverse event is of sufficient severity to require the participant's removal from the study. A participant may also voluntarily withdraw from treatment due to what he or she perceives as an intolerable adverse event. If either of these occur, the participant must undergo a Termination (early discontinuation) visit, and be given appropriate care under medical supervision until symptoms cease or the condition becomes stable.
In order to adhere to all applicable laws and regulations for reporting an SAE, the PI will formally notify the UK IRB within 24 hours of the study site staff becoming aware of the SAE. Adverse events will be coded according to body system using MedDRA. A final medical review and sign off on all codes by a designated reviewer within the ADCS will ensure accuracy and consistency. In this study, we do not anticipate moderate, severe, life-threatening or fatal AEs.
c. Plans for Safety Review: A methodical review of all procedures will be an integral part of each research team meeting. This review will include discussion of the protocol to ensure adherence, discussion of procedures to insure confidentiality is maintained and that data are collected with minimal risk for violations of confidentiality. A meeting involving the PI, faculty advisors, co-investigators, and lay coworkers will be called if an unexpected adverse event occurs.
d. Plans for Data Quality: The research design, methods and procedures have been reviewed by all members of the research team, all of whom have indicated their approval of the processes as delineated and believe that this research project will yield quality data that will generate new knowledge. Detailed operationalization of this plan will be done as a team to assure data quality.
e. Reporting Mechanisms: Reporting for this study will include an annual report to the University of Kentucky IRB, with appropriate updates and reports in the event of an adverse event(s). SAEs will be reported to the UK IRB within 24 hours of notification as mandated by this regulatory body. Annual reporting will also be provided to funder: NIH/NIA.
f. Plans for Modification or Termination of Study: If SAE or frequent AE’s beyond mild severity occur in more than 30% of participants, we will review research intervention causes and modify intervention to minimize risk. We will withdrawal patients with AE’s above moderate severity if AE is associated with study intervention, as this will indicate risks may exceed potential benefits of this study.

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Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

Participants can address complaints and concerns to either Elizabeth Rhodus of Sanders-Brown Center on Aging, or Allison Gibson, College of Social Work. If participants have questions or requests for information about the research, they may contact any research team member they have been in contact with. If participants have any questions, suggestions or concerns about their rights as a volunteer in this research, they may contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

Does your research involve **Non-English Speaking Subjects or Subjects from a Foreign Culture**?

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.

Include contact information for someone who can act as a cultural consultant for your study. The person should be familiar

with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted. The consultant should not have any direct involvement with the study. If you do not know someone who would be willing to act as your cultural consultant, the Office of Research Integrity will try to find someone to fill this role (this may delay the approval process for your protocol). Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study. For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

For recruitment of Non-English speaking subjects, the consent document needs to be in the subject's native language. Download the informed consent template available in the E-IRB "Informed Consent/Assent Process" section and use it as a guide for developing the consent document. (Note: Your translated consent document can be attached to your application in the "Informed Consent" section; **be sure to save your responses in this section first**.)

If research is to be conducted at an international location, identify local regulations, laws, or ethics review requirements for human subject protection. If the project has been or will be reviewed by a local Ethics Committee, attach a copy of the review to the UK IRB using the attachment button below. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?

○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

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1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the investigator assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe the experience/knowledge/training (if any) of the investigator serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if any sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?

○ Yes ○ No

If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.

Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ◉ Yes ○ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s):

☐ HIPAA De-identification Certification Form

☑ HIPAA Waiver of Authorization

Attachments

Attach Type	File Name
Waiver	Form K 8-30.doc
Waiver	HIPAA Waiver approval 72893.pdf

STUDY DRUG INFORMATION

0 unresolved comment(s)

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

○ Yes ◉ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize the Investigational Drug Service (IDS). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ○ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the "Expanded Access SOP" [PDF].

Please also complete and attach the Study Drug Form (PDF) (required):

Attachments

STUDY DEVICE INFORMATION

0 unresolved comment(s)

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer “no” above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

○ Yes ○ No

If Yes, complete the following:
IDE or HDE #(s)

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor’s authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the “Medical Device Clinical Investigations, Compassionate Use, and Treatment IDE SOP" [PDF]

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition of Significant Risk (SR) device?

- Yes. Device(s) as used in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- No. All devices, as used in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Please also complete and attach the Study Device Form (PDF) (required):

Attachments

RESEARCH SITES

0 unresolved comment(s)

In order for this section to be considered complete, you must click "SAVE" after ensuring all responses are accurate.

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☐ UK Classroom(s)/Lab(s)
- ☑ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☐ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

List all other non-UK owned/operated locations where the research will be conducted:*

*A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.

Attachments

B) Is this a multi-site study for which you are the lead investigator or UK is the lead site? ○ Yes ◉ No

If **YES**, you must describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites in the E-IRB "Research Description" section under *Resources*.

If the non-UK sites or non-UK personnel are *engaged* in the research, there are additional federal and university requirements which need to be completed for their participation, such as the establishment of a cooperative IRB review agreement with the non-UK site. Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

RESEARCH ATTRIBUTES

0 unresolved comment(s)

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

☐ Academic Degree/Required Research
☑ Aging Research
☐ Alcohol Abuse Research
☐ Cancer Research
☐ Certificate of Confidentiality
☐ CCTS-Center for Clinical & Translational Science
☐ Clinical Research
☑ Clinical Trial
☐ Clinical Trial Multicenter(excluding NIH Cooperative Groups)
☐ Clinical Trial NIH cooperative groups (i.e., SWOG, RTOG)
☐ Clinical Trial Placebo Controlled Trial
☐ Clinical Trial UK Only
☐ Collection of Biological Specimens
☐ Collection of Biological Specimens for Banking
☐ Community-Based Participatory Research
☐ Data & Safety Monitoring Board
☐ Data & Safety Monitoring Plan
☐ Deception
☐ Drug/Substance Abuse Research
☐ Educational/Student Records (e.g., GPA, test scores)
☐ Emergency Use (Single Patient)
☐ Genetic Research
☐ Gene Transfer
☐ GWAS (Genome-Wide Association Study) or NIH-funded study generating large scale genomic data
☐ International Research
☐ Internet Research
☐ Planned Emergency Research Involving Waiver of Informed Consent
☐ Pluripotent Stem Cell Research
☐ Recombinant DNA
☑ Survey Research
☐ Transplants
☐ Use of radioactive material, ionizing radiation, or x-rays [Radiation Safety Committee review required]
☐ Vaccine Trials

Click applicable listing(s) for additional requirements and/or information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial (look up "What is the definition of....)

  Determine if research meets NIH definition of clinical trial;
  *Reminder: Ensure compliance with applicable requirements including:
  - Clinicaltrials.gov registration;
  - Good Clinical Practice (GCP) training; and
  - Consent Posting Requirement [PDF] for federal funded trials.

- Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...")
- Collection of Biological Specimens (look up "Specimen/Tissue Collection...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

  *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "Specimen/Tissue Collection...")
- Gene Transfer
- HIV/AIDS Research (look up "Reportable Diseases/Conditions")
- Screening for Reportable Diseases [E2.0000] (PDF)
- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Waiver of Informed Consent*

  *For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver

of Informed Consent Process"

- Use of radioactive material, ionizing radiation or x-rays for research

FUNDING/SUPPORT

0 unresolved comment(s)

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☐ Not applicable

Check All That Apply

- ☑ Grant application pending
- ☑ (HHS) Dept. of Health & Human Services
  - ☑ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Other:

Click applicable listing(s) for additional requirements and/or information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info]
- National Science Foundation
- (DoEd) U.S. Department of Education [PDF]
- DoJ) Department of Justice or Bureau of Prisons ([PDF]
- (DoE) Department of Energy Summary [PDF] and Department of Energy Identifiable Information Compliance Checklist [PDF]
- (EPA) Environmental Protection Agency [PDF]

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

National Institutes on Health/NIA

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP [PDF] and DoD Summary [PDF] for details)

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC)--Attach required IBC materials
- Radiation Safety Committee (RSC)-- For applicability, see instructions and/or upload form [WORD] [PDF]
- Radioactive Drug Research Committee (RDRC)--information
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)**--Attach MCC PRMC materials, if any, per instructions
- See requirement of Office of Medical Education (OME)
- See requirement of Graduate Medical Education Committee (GME)

Attachments

**** If you are proposing a study involving cancer research, be sure to have "Cancer Research" marked in the E-IRB "Research Attributes" section.** If your study involves cancer research, ORI will provide a copy of your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

Do you want specific information inserted into your approval letter? ○ Yes ◉ No

Approval Letter Details (e.g., serial #):

Submission Description: If you wish to have specific details included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type in the box below exactly what you wish to see on the approval letter. What you type will automatically appear at the top of all approval letters, identical to how you typed it, until it is changed by you (Hint: don't include instructions or questions to ORI staff as those will appear in your approval letter). **If these details need to be changed as a result of revisions, continuation review, or modifications to the application, you are responsible for updating the content of the field below accordingly.**

Protocol/Product Attachments - For each item checked, please attach the corresponding material.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Drug Documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.)
- ☑ Device Documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.)
- ☐ Other Documents

Protocol/Product Attachments

Attach Type	File Name
AddInfoProduct	Establishment Registration & Device Listing.pdf

NOTE: Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

Additional Materials:

If you have other materials you would like to include in your application for the IRB's consideration, please attach using the Attachments button below.

[To view what materials are currently attached to your application, go to "Application Links" in the menu bar on the left and click "All Attachments".]

Attachments

Attach Type	File Name
AdditionInfoConsiderations	Comments addressed 9-17-21.docx
AdditionInfoConsiderations	E-IRB 72893 1st Pen and Ink Comments CF Dementia Subject.pdf
AdditionInfoConsiderations	E-IRB 72893 1st set Caregiver CF Pen and Ink Comments.pdf

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

On all IRB applications there is a requirement for additional assurances by a Department Chairperson (or equivalent) [hereafter referred to as "Department Authorization" (DA)], and when applicable, a Faculty Advisor (FA) (or equivalent), which signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. Note: the individual assigned as DA *should not* also be listed in the Study Personnel section, the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, download the guidance document "What does the Department Chairperson's Assurance Statement on the IRB application mean? [PDF]"

Required Signatures:

First Name	Last Name	Role	Department	Date Signed	
Linda	Van Eldik	Department Authorization	Department of Neuroscience	08/31/2021 03:22 PM	View/Sign
Elizabeth	Rhodus	Principal Investigator	Sanders-Brown Ctr On Aging	08/31/2021 02:13 PM	View/Sign

Department Authorization

☑ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator has been notified of the additional regulatory requirements of the sponsor and by signing the principal investigator Assurance Statement, confirms he/she can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

**IF APPLICABLE FOR RELIANCE: I attest that the principal investigator has been notified of the regulatory requirements of both the Reviewing and Relying IRBs, according to the information provided in the E-IRB application. The attached Reliance Assurance Statement, signed by the principal investigator, confirms that he/she can comply with both sets of IRB requirements.

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☑ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.
- If applying for an Abbreviated Application (AA) to rely on an external IRB, I understand that certain items above (1, 3, 4, 7-8) may not apply, or may be altered due to external institutional/IRB policies. I document my agreement with the Principal Investigator Reliance Assurance Statement by digitally signing this application.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Please notify the personnel required for signing your IRB application after sending for signatures. Once all signatures have been recorded, you will need to return to this section to submit your application to ORI.

SUBMISSION INFORMATION

0 unresolved comment(s)

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed; otherwise your submission for IRB review and approval will not be able to be sent to the Office of Research Integrity/IRB.

Please remember to update, when applicable, the Approval Letter Details text box under the Additional Information section to ensure verbiage you want on your approval letter is accurate.

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and a message will be forthcoming to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Your protocol has been submitted.

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	Stamped Consent Form	Consent Patient-clean 9-19.pdf		0.199	jchine2	10/14/2021 1:26:02 PM
	Stamped Consent Form	Consent CAREGIVER 9-20 clean.pdf		0.176	jchine2	10/14/2021 1:26:02 PM
	ApprovalLetter	ApprovalLetter.pdf		0.102	jchine2	10/14/2021 1:26:02 PM
	Waiver	HIPAA Waiver approval 72893.pdf	Waiver approval	0.223	jchine2	10/14/2021 1:16:23 PM
	InformedConsent_HighlightedChanges	Consent CAREGIVER 9-20 highlighted.docx	Caregiver Consent highlighted	0.069	ekrh223	9/20/2021 10:01:47 AM
	Informed ConsentParental Permission	Consent CAREGIVER 9-20 clean.pdf	Caregiver consent clean	0.188	ekrh223	9/20/2021 10:01:20 AM
	InformedConsent_HighlightedChanges	Consent Patient-highlighted.docx	Patient Consent highlighted	0.067	ekrh223	9/19/2021 4:34:26 PM
	Informed ConsentParental Permission	Consent Patient-clean 9-19.pdf	Patient consent clean	0.201	ekrh223	9/19/2021 4:34:12 PM
	AdditionInfoConsiderations	E-IRB 72893 1st set Caregiver CF Pen and Ink Comments.pdf	1st set Caregiver CF Pen and Ink Comments	2.415	klars2	9/17/2021 3:15:13 PM
	AdditionInfoConsiderations	E-IRB 72893 1st Pen and Ink Comments CF Dementia Subject.pdf	Pen and Ink Comments Dementia Subject CF	2.222	klars2	9/17/2021 2:46:57 PM
	AdditionInfoConsiderations	Comments addressed 9-17-21.docx	Comments addressed	0.015	ekrh223	9/17/2021 8:02:54 AM
	Advertising	social media.pdf	social media	1.246	ekrh223	8/30/2021 5:45:36 PM
	Advertising	Rhodus_Flyer 8-30.docx	Flyer	0.296	ekrh223	8/30/2021 5:45:25 PM
	Advertising	research match.pdf	Research match	0.078	ekrh223	8/30/2021 5:45:16 PM
	AddInfoProduct	Establishment Registration & Device Listing.pdf	FDA of Empatica	0.200	ekrh223	8/30/2021 5:32:49 PM
	DataCollection	Behavior Journal.pdf	Behavior Journal	1.071	ekrh223	8/30/2021 5:29:59 PM
	DataCollection	npiq-questionnaire.pdf	NPI	0.124	ekrh223	8/30/2021 5:25:27 PM
	DataCollection	CDR.pdf	CDR	0.122	ekrh223	8/30/2021 5:24:51 PM
	DataCollection	final fbp.doc	FBP	0.044	ekrh223	8/30/2021 5:24:26 PM
	DataCollection	RMBPC.pdf	RMBPC	2.210	ekrh223	8/30/2021 5:23:24 PM
	DataCollection	Zarit Caregiver Burden Inventory.pdf	Zarit	0.190	ekrh223	8/30/2021 5:23:10 PM
	DataCollection	ASP.pdf	ASP	0.120	ekrh223	8/30/2021 5:22:48 PM
	DataCollection	COPM.pdf	COPM	0.898	ekrh223	8/30/2021 5:22:36 PM
	DataCollection	HOEA 2.pdf	HOEA	0.144	ekrh223	8/30/2021 5:22:22 PM
	Waiver	Form K 8-30.doc	Form K	0.042	ekrh223	8/30/2021 2:53:30 PM
	ImpairedConsent	Form_T_1Di.doc	Form T	0.087	ekrh223	8/30/2021 2:30:37 PM

Protocol Changes

Protocol Number: 72893

Informed Consent RequestWaiverInformedConsent changed by ekrh223 on 9/17/2021 7:46:49 AM

~~Y~~N

Informed Consent WaiveIC changed by ekrh223 on 9/17/2021 7:41:02 AM

~~Y~~N

Informed Consent WaiveICInfoAfterStudy changed by ekrh223 on 9/17/2021 7:41:02 AM

~~not applicable~~

Informed Consent WaiveICMinRisk changed by ekrh223 on 9/17/2021 7:41:02 AM

~~Waiver is for accessing medical records for ¶~~
~~recruitment purposes and the research involves ¶~~
~~no more than minimal risks.~~

Informed Consent WaiveICPracticably changed by ekrh223 on 9/17/2021 7:41:02 AM

~~We would be unable to sufficiently recruit ¶~~
~~participants without access to medical records ¶~~
~~prior to recruitment because characteristics of ¶~~
~~study population is very specific (i.e., diagnosis ¶~~
~~of dementia with behavioral disturbance, living ¶~~
~~within rural region). ¶~~
~~Information included in recruitment directly ¶~~
~~relates to medical records and demographics ¶~~
~~included in PHI. This study cannot be ¶~~
~~conducted without inclusion of PHI information. ¶~~
~~Researchers are looking at medical records to ¶~~
~~identify additional subjects that are not in the ¶~~
~~recruitment database.~~

Informed Consent WaiveICPrivateInformationSpecimens changed by ekrh223 on 9/17/2021 7:41:02 AM

~~We would be unable to recruit for this study ¶~~
~~without access to medical records and ¶~~
~~identifiable private ¶~~
~~information. This information will be used to ¶~~
~~confirm inclusion criteria and enable research ¶~~
~~personnel to contact potential participants for ¶~~
~~recruitment purposes. ¶~~
~~The nature of this study includes medicallybased diagnoses, histories, and testing results. ¶~~
~~It is required to conduct thorough recruitment ¶~~
~~for optimal results~~

Informed Consent WaiveICRights changed by ekrh223 on 9/17/2021 7:41:02 AM

~~All information will be protected following ¶~~
~~HIPAA guidelines including use of University of ¶~~
~~Kentucky issued computers, password ¶~~
~~protected computers and REDCap data base, ¶~~

~~and confidentiality of all identifiable information~~

PI Contact Information Degree changed by ekrh223 on 9/17/2021 7:23:53 AM

PhD, MS, OTR/L

PI Contact Information Rank changed by ekrh223 on 9/17/2021 7:23:53 AM

Post-Doctoral Fellow

Research Attributes ClinicalResearch changed by ekrh223 on 9/17/2021 7:30:59 AM

~~Y~~

Research Attributes ClinicalTrial changed by ekrh223 on 9/17/2021 7:30:59 AM

Y

Research Description Confidentiality changed by ekrh223 on 9/14/2021 5:59:54 PM

All materials, except behavior journals, will be in electronic format. All data will be uploaded and saved to REDCap the day of acquisition from participants. Hard copies of behavior journals will be electronically scanned with 48 hours of receipt and destroyed via shredding following uploading to REDCap. All hard copies (behavior journals and paper copies of consent forms) will be stored at ¶
the Sanders-Brown Center on Aging Clinic at 1030 S. Broadway Lexington KY 40504 Ste 5 office 105 in a locked filing cabinet. The building, office, and cabinet will be locked at all times of non-use. REDCap is a password-protected, secure data management web application in the secure data center run by the Institute for Pharmaceutical Outcomes and Policy (IPOP) physically located in the new Biological and Pharmaceutical Complex building at the University of Kentucky. The files will be stored for a period of six years and destroyed per UK Policy A13-050. Digital audio recordings ~~and electronic transcription of all interviews~~ will be obtained. These electronic files will also be stored on REDCap. Upon enrollment in the study, subjects will be given pseudonyms to protect confidentiality and de-identify data. Each participant will be assigned a participant number and pseudonym, which will be used to identify the person during data analysis and when managing data. This de-identified human subject data will be stored on REDCap. Records maintained by SBCoA are not UK medical records, and so PHI and PII will not be used. At the conclusion of the study, all individual data stored on REDCap, a secure location, for a period of 6 years, after which deletion of electronic files will destroy it. All video recording/electronic data will be stored for a period of six years after which files will be destroyed using the University of Kentucky's Policy for Reuse and Disposal of Electronic Media. UK Healthcare Policy and Procedure A13-050 states "all electronic media shall be erased (i.e. purged) using data overwriting software that conforms to the requirements stated in NIST SP800-88." IRB research records (approved IRB protocol, ¶
Form K, signed consent documents etc.) will be maintained for 6 years after study closure per the study closure SOP. ¶
Confidentiality will be maintained, however, in the case in which abuse or concern of participants' safety, the researcher is required by law to report to authorities.

Research Description DataAndSafetyMonitoring changed by ekrh223 on 9/17/2021 7:21:27 AM

DATA AND SAFETY MONITORING PLAN ¶
The Principle Investigator (PI, Rhodus) will be responsible for monitoring the data and safety of participants along with the co-investigators~~.~~ (Co-I's: Jicha and Koehl) ¶
a. Periodic Review: The PI will hold bi-weekly meetings for the first two months of enrollment with Co-I's, then monthly for ¶
until data collection is complete. ~~The faculty advisor~~Co-I (Jicha) will review all minor AE and SAE reported to date of review. ~~The staff meetings will include the PI, co-investigators, and lay co-workers in charge of assessment.~~ The meetings will include evaluation of all research procedures, fidelity to protocol, discussion of newly enrolled participants, and review of status of all formally enrolled participants including all adverse events. Adverse events will be reviewed to determine if changes in the protocol are indicated. ¶
Participant demographics to date, recruitment progress, difficulties encountered during enrollment, an update on data entry, and any ¶
other issues or concerns that have arisen since the last research team meeting will also be discussed. ¶
In addition to review of all research procedures and AE/SAE, specific review of risk related to behavioral condition of the patient and ¶
~~related to the interven~~ data collection will be completed at meetings. Review will assess: ¶
1. Risk to behavioral condition: ~~Weekly checks via Zoom video conferencing of behavioral tracking will occur with PI and~~Daily

communication with caregivers of patients with behavior disturbance throughout the duration of data collection per participants. ¶
-dyad. If substantial behavioral change is noted by caregiver or patient report, this behavior change will be reviewed with faculty advisor. ¶
2. Risk of Intervention: Weekly checks via Zoom video conferencing with participants will assess adverse events and patient ¶
complaint related to the intervention tools. We anticipate the following potential areas of concern: ¶
a. Lotions-minor dermatological reaction ¶
b. Exercise cards-muscle soreness, fall during exercise ¶
c. Snacks-possible choking hazard ¶
d. Actigraph wear-skin irritation at wear site (wrist) ¶
e. Scents of lotion-headache ¶
f. Gel lap pad-strain from lifting 3 pound lap pad. ¶
bCo-I's. ¶
2. Adverse Events: In compliance with Federal Regulation 21CFR §56.108(b)(1) and 45 CFR 46.103(b)(5), any unanticipated ¶
problems, including adverse events that are unexpected and related to the study, will be promptly reported to the University ¶
Institutional Review Board (IRB). Events judged as “unexpected” are those not specified in the IRB-approved research protocol or ¶
informed consent document. ¶
The Data and Safety Monitoring Plan for the proposed project incorporates the policies on human subject data and safety monitoring ¶
specified by the University of Kentucky IRB. ¶
Risk Assessment: Minimal risk. The study procedures and intervention represents minimal risk to study participants as this study ¶
intervention is a combined environment-based educational/sensory stimulation and standard-of-care intervention to improve ¶
neuropsychiatric behaviors in people with dementia. ¶
The PI and faculty advisor involves a one week cross-sectional data collection approach including surveys, behavior journaling, and wearing of digital wrist device (Empatica E4). ¶
The PI and Co-I (Jicha) will assess the severity (intensity) of reported AEs according to the NCI CTC. If a participant experiences ¶
an event not detailed by the NCI CTC, the following guidelines will be used to analyze severity: ¶
• Mild: symptoms or signs exist and may require treatment, but are transient and easily tolerated. ¶
• Moderate: treatment is required and continued monitoring of event is prescribed to avert participant discomfort. ¶
• Severe: event requires treatment and continued monitoring is prescribed to prevent incapacitating or life threatening effects to the ¶
participant's health. ¶
• Life threatening: when the participant is, in the opinion of the Investigator, at immediate risk of death from the event as it occurs, or if ¶
the event requires immediate medical treatment and continued monitoring. Note that this definition does not include an event that, had ¶
it occurred in a more serious form, might have caused death. ¶
• Fatal: Death resulted from AE. ¶
All adverse events occurring during the study observed by study personnel or reported by the participant (whether or not attributed to ¶
study procedures or interventions), will be recorded in the subject electronic record. Medically significant adverse events considered ¶
related to the study procedures or interventions by the faculty advisorby the Co-I (Jicha) will be followed until resolved or considered stable. It will be left ¶
to the faculty advisor'sCo-I (Jicha) clinical judgment whether or not an adverse event is of sufficient severity to require the participant's removal ¶
from treatmenthe study. A participant may also voluntarily withdraw from treatment due to what he or she perceives as an intolerable adverse ¶
event. If either of these occur, the participant must undergo a Termination (early discontinuation) visit, and be given appropriate care ¶
under medical supervision until symptoms cease or the condition becomes stable. ¶
In order to adhere to all applicable laws and regulations for reporting an SAE, the PI will formally notify the UK IRB within 24 hours of ¶
the study site staff becoming aware of the SAE. Adverse events will be coded according to body system using MedDRA. A final ¶
medical review and sign off on all codes by a designated reviewer within the ADCS will ensure accuracy and consistency. ¶
In this study, we do not anticipate moderate, severe, life-threatening or fatal AEs. ¶
c. Plans for Safety Review: A methodical review of all procedures will be an integral part of each research team meeting. This review ¶
will include discussion of the protocol to ensure adherence, discussion of procedures to insure confidentiality is maintained and that ¶
data are collected with minimal risk for violations of confidentiality. A meeting involving the PI, faculty advisors, co-investigators, and lay ¶
coworkers will be called if an unexpected adverse event occurs. ¶
d. Plans for Data Quality: The research design, methods and procedures have been reviewed by all members of the research team, ¶
all of whom have indicated their approval of the processes as delineated and believe that this research project will yield quality data ¶
that will generate new knowledge. Detailed operationalization of this plan will be done as a team to assure data quality. ¶
e. Reporting Mechanisms: Reporting for this study will include an annual report to the University of Kentucky IRB, with appropriate ¶
updates and reports in the event of an adverse event(s). SAEs will be reported to the UK IRB within 24 hours of notification as ¶
mandated by this regulatory body. Annual reporting will also be provided to funder: NIH/NIA. ¶
f. Plans for Modification or Termination of Study: If SAE or frequent AE’s beyond mild severity occur in more than 30% of participants, ¶
we will review research intervention causes and modify intervention to minimize risk. We will withdrawal patients with AE’s above ¶
moderate severity if AE is associated with study intervention, as this will indicate risks may exceed potential benefits of this study.

Research Description DataAndSafetyMonitoring changed by ekrh223 on 9/17/2021 7:07:58 AM

~~Not applicable~~DATA AND SAFETY MONITORING PLAN ¶
The Principle Investigator (PI, Rhodus) will be responsible for monitoring the data and safety of participants along with the co-investigators. ¶
a. Periodic Review: The PI will hold bi-weekly meetings for the first two months of enrollment with Co-I's, then monthly for ¶
until data collection is complete. The faculty advisor will review all minor AE and SAE reported to date of review. The staff meetings will include the PI, co-investigators, and lay co-workers in charge of assessment. The meetings will include evaluation of all research procedures, fidelity to protocol, discussion of newly enrolled participants, and review of status of all formally enrolled participants including all adverse events. Adverse events will be reviewed to determine if changes in the protocol are indicated. ¶
Participant demographics to date, recruitment progress, difficulties encountered during enrollment, an update on data entry, and any ¶
other issues or concerns that have arisen since the last research team meeting will also be discussed. ¶
In addition to review of all research procedures and AE/SAE, specific review of risk related to behavioral condition of the patient and ¶
related to the intervention will be completed at meetings. Review will assess: ¶
1. Risk to behavioral condition: Weekly checks via Zoom video conferencing of behavioral tracking will occur with PI and participants. ¶
If substantial behavioral change is noted by caregiver or patient report, this behavior change will be reviewed with faculty advisor. ¶
2. Risk of Intervention: Weekly checks via Zoom video conferencing with participants will assess adverse events and patient ¶
complaint related to the intervention tools. We anticipate the following potential areas of concern: ¶
a. Lotions-minor dermatological reaction ¶
b. Exercise cards-muscle soreness, fall during exercise ¶
c. Snacks-possible choking hazard ¶
d. Actigraph wear-skin irritation at wear site (wrist) ¶
e. Scents of lotion-headache ¶
f. Gel lap pad-strain from lifting 3 pound lap pad. ¶
b. Adverse Events: In compliance with Federal Regulation 21CFR §56.108(b)(1) and 45 CFR 46.103(b)(5), any unanticipated ¶
problems, including adverse events that are unexpected and related to the study, will be promptly reported to the University ¶
Institutional Review Board (IRB). Events judged as “unexpected” are those not specified in the IRB-approved research protocol or ¶
informed consent document. ¶
The Data and Safety Monitoring Plan for the proposed project incorporates the policies on human subject data and safety monitoring ¶
specified by the University of Kentucky IRB. ¶
Risk Assessment: Minimal risk. The study procedures and intervention represents minimal risk to study participants as this study ¶
intervention is a combined environment-based educational/sensory stimulation and standard-of-care intervention to improve ¶
neuropsychiatric behaviors in people with dementia. ¶
The PI and faculty advisor will assess the severity (intensity) of reported AEs according to the NCI CTC. If a participant experiences ¶
an event not detailed by the NCI CTC, the following guidelines will be used to analyze severity: ¶
• Mild: symptoms or signs exist and may require treatment, but are transient and easily tolerated. ¶
• Moderate: treatment is required and continued monitoring of event is prescribed to avert participant discomfort. ¶
• Severe: event requires treatment and continued monitoring is prescribed to prevent incapacitating or life threatening effects to the ¶
participant's health. ¶
• Life threatening: when the participant is, in the opinion of the Investigator, at immediate risk of death from the event as it occurs, or if ¶
the event requires immediate medical treatment and continued monitoring. Note that this definition does not include an event that, had ¶
it occurred in a more serious form, might have caused death. ¶
• Fatal: Death resulted from AE. ¶
All adverse events occurring during the study observed by study personnel or reported by the participant (whether or not attributed to ¶
study procedures or interventions), will be recorded in the subject electronic record. Medically significant adverse events considered ¶
related to the study procedures or interventions by the faculty advisor will be followed until resolved or considered stable. It will be left ¶
to the faculty advisor’s clinical judgment whether or not an adverse event is of sufficient severity to require the participant's removal ¶
from treatment. A participant may also voluntarily withdraw from treatment due to what he or she perceives as an intolerable adverse ¶
event. If either of these occur, the participant must undergo a Termination (early discontinuation) visit, and be given appropriate care ¶
under medical supervision until symptoms cease or the condition becomes stable. ¶
In order to adhere to all applicable laws and regulations for reporting an SAE, the PI will formally notify the UK IRB within 24 hours of ¶
the study site staff becoming aware of the SAE. Adverse events will be coded according to body system using MedDRA. A final ¶
medical review and sign off on all codes by a designated reviewer within the ADCS will ensure accuracy and consistency. ¶
In this study, we do not anticipate moderate, severe, life-threatening or fatal AEs. ¶
c. Plans for Safety Review: A methodical review of all procedures will be an integral part of each research team meeting. This review ¶
will include discussion of the protocol to ensure adherence, discussion of procedures to insure confidentiality is maintained and that ¶
data are collected with minimal risk for violations of confidentiality. A meeting involving the PI, faculty advisor, co-investigators, and lay ¶
coworkers will be called if an unexpected adverse event occurs. ¶

d. Plans for Data Quality: The research design, methods and procedures have been reviewed by all members of the research team, ¶ all of whom have indicated their approval of the processes as delineated and believe that this research project will yield quality data ¶ that will generate new knowledge. Detailed operationalization of this plan will be done as a team to assure data quality. ¶
e. Reporting Mechanisms: Reporting for this study will include an annual report to the University of Kentucky IRB, with appropriate ¶ updates and reports in the event of an adverse event(s). SAEs will be reported to the UK IRB within 24 hours of notification as ¶ mandated by this regulatory body. ¶
f. Plans for Modification or Termination of Study: If SAE or frequent AE's beyond mild severity occur in more than 30% of participants, ¶ we will review research intervention causes and modify intervention to minimize risk. We will withdrawal patients with AE's above ¶ moderate severity if AE is associated with study intervention, as this will indicate risks may exceed potential benefits of this study.

Research Description DataCollection changed by ekrh223 on 9/14/2021 5:59:54 PM

Existing PHI records will including: Name, email address, phone number, DOB, address, medical history, diagnoses, medications, primary contact information, University of Kentucky Healthcare medical identification number, tests completed at Sanders-Brown Center on Aging or the Kentucky Neuroscience Institute. Sources of the PHI will come from the Sanders-Brown Center on Aging cohort database and clinical notes in patient files; and PHI from KNI will be collected through AEHR UKHC or Epic for any patients with memory impairment at KNI. ¶
¶
All visits occurring over Zoom will be video and audio recorded and saved on ~~a drive stored by the University of Kentucky Sanders-Brown Center on Aging which contains password protection and requires access granted only by Center IT administrators~~REDCap. All phone calls will be audio recorded and saved to REDCap. ¶
¶
Behavior Workbook/Journals will be used to collect daily records of patient behaviors as observed and reported by caregivers in relation to environmental stressors. These will be printed and mailed to participants, and returned with iPads at conclusion of study. ¶
¶
Multiple measures will assess personal and environmental factors. These assessments were selected based on recommendation from a multidisciplinary expert panel including fields of occupation therapy, social work, engineering, physiology, psychology, and neurology as ideal measurements of targeted areas. In addition to these measures, a daily journal will be completed by caregivers to document perceived stress level of persons with ADRD and the environmental setting during data collection to better inform data interpretation. ¶
Independent Variables: ¶
Home Environment: ¶
1) Physical: Home Occupational Environment Assessment (HOEA). Caregivers will systematically assess the home environment including accessibility, sanitation, food storage, safety, and sensorial ¶
stimulation. ¶
2) Social: Caregiver demographics; Zarit Caregiver Burden Scale. The social context of the person with ADRD is described through analysis of caregiver demographics and rate of caregiver burden measured by the Zarit Caregiver Burden, a 22-item survey in which the caregiver rates level of burden on 5-point Likert scale. ¶
¶
Neurological: ¶
1) Sensory Response: Caregiver report of patients' functional sensory acuity, Adult Sensory Profile. Caregivers will be interviewed to determine patients' functional sensory acuity (i.e., wears glasses, hearing aids, presence of neuropathy, etc.). The caregiver will complete the Adult Sensory Profile as proxy for the person with ADRD. This is a valid and reliable 60-question assessment to determine sensory simulation preference and neurological ability for processing sensory stimulation. ¶
2) Physiological Response: Assessment of psychophysiological biomarkers (as indicator of stress) will include heart rate variability, electrodermal activity, and blood pressure. These responses will be assessed using innovative wearable technology (Empatica E4 wrist device) which provides real-time record of physiological/inertial signals from multiple sensors in the device including Blood Volume Pulse (BVP), Electrodermal Activity (EDA), Inter Beat Interval (IBI), Skin Temperature (ST), and Tri-Axial Acceleration (TAA). Preliminary work has demonstrated integration of these measurements are a reliable predictor of stress in older adults using machine-based learning science. ¶
¶
Behavior: ¶
1) Behavior: Revised Memory and Behavior Problem Checklist (RMBPC) and Neuropsychiatric Inventory (NPI). The RMBPC is a valid and reliable measure of caregiver-reported behavior problems in people with ADRD and includes subscales of memory, depression, and disruptive behaviors. The NPI is commonly used as an assessment of BPSD in older adults diagnosed with MCI or dementia, internationally, with high reliability and validity. Assessment includes 12 behavioral and psychiatric domains which are rated by caregiver as present or absent (yes/no). Caregivers further rate severity of present behavioral domains. The severity score is summed to yield a total as a measure of BPSD burden. ¶
2) Cognition: Clinical Dementia Rating Scale (CDR). The CDR, a valid and reliable measure, determines severity of cognitive impairment. Six cognitive domains are assessed in CDR (memory, orientation, judgement and problem solving, community affairs, home

and hobbies, and personal care) with feedback from patient performance and caregiver results scored by a trained professional. ¶
¶
Dependent Variables: ¶
Performance: 1) Function: Functional Behavior Profile (FBP). The FBP is an established reliable and valid measure of task performance, social interaction, and problem solving with adults with ADRD. ¶
2) Performance: Canadian Occupational Performance Measure (COPM). The COPM is a reliable and validated measure of performance in primary daily activities (self-care, leisure, productivity) with dyad-rated performance and satisfaction.

Research Description DataCollection changed by ekrh223 on 9/14/2021 5:48:08 PM

Existing PHI records will including: Name, email address, phone number, DOB, address, medical history, diagnoses, medications, primary contact information, University of Kentucky Healthcare medical identification number, tests completed at Sanders-Brown Center on Aging or the Kentucky Neuroscience Institute. Sources of the PHI will come from the Sanders-Brown Center on Aging cohort database and clinical notes in patient files; and PHI from KNI will be collected through AEHR UKHC or Epic for any patients with memory impairment at KNI. ¶
¶
All visits occurring over Zoom will be recorded and saved on a drive stored by the University of Kentucky Sanders-Brown Center on Aging which contains password protection and requires access granted only by Center IT administrators. ¶
¶
Behavior Workbook/Journals will be used to collect daily records of patient behaviors as observed and reported by caregivers in relation to environmental stressors. These will be printed and mailed to participants, and returned with iPads at conclusion of study. ¶
¶
Multiple measures will assess personal and environmental factors. These assessments were selected based on recommendation from a multidisciplinary expert panel including fields of occupation therapy, social work, engineering, physiology, psychology, and neurology as ideal measurements of targeted areas. In addition to these measures, a daily journal will be completed by caregivers to document perceived stress level of persons with ADRD and the environmental setting during data collection to better inform data interpretation. ¶
Independent Variables: ¶
Home Environment: ¶
1) Physical: Home Occupational Environment Assessment (HOEA). Caregivers will systematically assess the home environment including accessibility, sanitation, food storage, safety, and sensorial ¶
stimulation. ¶
2) Social: Caregiver demographics; Zarit Caregiver Burden Scale. The social context of the person with ADRD is described through analysis of caregiver demographics and rate of caregiver burden measured by the Zarit Caregiver Burden, a 22-item survey in which the caregiver rates level of burden on 5-point Likert scale. ¶
¶
Neurological: ¶
1) Sensory Response: Caregiver report of patients' functional sensory acuity, Adult Sensory Profile. Caregivers will be interviewed to determine patients' functional sensory acuity (i.e., wears glasses, hearing aids, presence of neuropathy, etc.). The caregiver will complete the Adult Sensory Profile as proxy for the person with ADRD. This is a valid and reliable 60-question assessment to determine sensory simulation preference and neurological ability for processing sensory stimulation. ¶
2) Physiological Response: Assessment of psychophysiological biomarkers (as indicator of stress) will include heart rate variability, electrodermal activity, and blood pressure. These responses will be assessed using innovative wearable technology (Empatica E4 wrist device) which provides real-time record of physiological/inertial signals from multiple sensors in the device including Blood Volume Pulse (BVP), Electrodermal Activity (EDA), Inter Beat Interval (IBI), Skin Temperature (ST), and Tri-Axial Acceleration (TAA). Preliminary work has demonstrated integration of these measurements are a reliable predictor of stress in older adults using machine-based learning science. ¶
¶
Behavior: ¶
1) Behavior: Revised Memory and Behavior Problem Checklist (RMBPC) and Neuropsychiatric Inventory (NPI). The RMBPC is a valid and reliable measure of caregiver-reported behavior problems in people with ADRD and includes subscales of memory, depression, and disruptive behaviors. The NPI is commonly used as an assessment of BPSD in older adults diagnosed with MCI or dementia, internationally, with high reliability and validity. Assessment includes 12 behavioral and psychiatric domains which are rated by caregiver as present or absent (yes/no). Caregivers further rate severity of present behavioral domains. The severity score is summed to yield a total as a measure of BPSD burden. ¶
2) Cognition: Clinical Dementia Rating Scale (CDR). The CDR, a valid and reliable measure, determines severity of cognitive impairment. Six cognitive domains are assessed in CDR (memory, orientation, judgement and problem solving, community affairs, home and hobbies, and personal care) with feedback from patient performance and caregiver results scored by a trained professional. ¶
¶
Dependent Variables: ¶

Performance: 1) Function: Functional Behavior Profile (FBP). The FBP is an established reliable and valid measure of task performance, social interaction, and problem solving with adults with ADRD. ¶
2) Performance: Canadian Occupational Performance Measure (COPM). The COPM is a reliable and validated measure of performance in primary daily activities (self-care, leisure, productivity) with dyad-rated performance and satisfaction.

Research Description InformedConsentProcess changed by ekrh223 on 9/14/2021 6:09:46 PM

Informed consent will be sought from two groups: Caregivers and patients with advanced dementia. ¶
A caregiver responding to the study ad via phone or email to (PI, Rhodus or study personnel to be named) will be contacted via email or phone call to schedule a screening visit. Consent will be sent to participant following initial contact and indication of interest in research study prior to screening visit. ¶
Caregiver: ¶
Following verbal confirmation from participants, the person authorized to obtain consent will create a new redcap record and email the electronic consent form electronically distributed through REDcap to their email or smart phone through private dedicated link at least 24 hours prior to screening visit. All study procedures will be described in detail over the phone or zoom during screening visits prior to initiation of any study procedures. The consent form will be reviewed during the screening visit to clarify any questions the participant may have. If the participant is in agreement, they will be asked to electronically sign the form. Upon receipt in REDCap, the person authorized to obtain consent will then add their name (sign) and date (date that informed consent is confirmed via phone or zoom) into the designated fields to complete the consenting process. This If the person is unable to obtain the electronic copy, a paper copy will be mailed to participant 7 days prior to screening visit. The form will need to be signed during the screening visit with visual confirmation on zoom video and returned via mail, email, or fax prior to data collection at baseline visit. The UK personnel authorized to obtain consent will sign and date the form upon receipt using the date that informed consent was confirmed. ¶
¶
Patient with advanced dementia: ¶
Because of the substantial cognitive impairment associated with a diagnosis of advanced dementia, informed consent for patients will be sought from their legally authorized representative (LAR). The LAR will be identified by UK (SBCoA or KNI) chart review if this person is not the caregiver participant. All research procedures will be thoroughly described over phone or zoom to the legally authorized representative prior to seeking consent for participation. Electronic consent will be sought by the patient's legally authorized representative on the consent form electronically distributed through REDcap to their LARs email or smart phone through private dedicated link sent at least 24 hours prior to screening visit. The consent form will be reviewed with the LAR during the screening visit to clarify any questions the participant may have. If the participantLAR is in agreement, they will be asked to electronically sign the form. Upon receipt in REDCap, the person authorized to obtain consent will then add their name and date (date that informed consent is confirmed) into the designated fields to complete the consenting process. If the personLAR is unable to obtain the electronic copy, a paper copy will be mailed to participantthe LAR 7 days prior to screening visit. The form will need to be signed during the screening visit with visual confirmation on zoom video and returned via mail, email, or fax prior to data collection at baseline visit. The UK personnel authorized to obtain consent will sign and date the form upon receipt using the date that informed consent was confirmed. The study procedures will be described over zoom video conferencing for the person with dementia and signs for dissent (as listed in Form T) will be assessed. ¶
PLARs and caregiver participants will keep a copy of the consent (either electronic or paper). If the consent is signed electronically, an automatic email of a copy of the consent will be sent to their email on file. If a paper copy is used, two copies of the form will be mailed, and one copy will be sent back to research team and one copy will be retained by LAR and participants.

Research Description Payment changed by ekrh223 on 9/14/2021 5:59:54 PM

Following completion of participation in this study (seven days of data collection), pCarticipants will receiveegiver of dyad will be mailed one $50 gift card per dyad to the local general merchandise store. Person with dementia will not receive any payment.

Research Description ResearchMaterialsRecordsPrivacy changed by ekrh223 on 9/14/2021 6:09:46 PM

Existing records of PHI within UK EHR/medical records and EPIC will be used for recruitment purposes to identify eligible participants from the Kentucky Neuroscience Institute and the Sanders-Brown Center on Aging longitudinal cohorts. ¶
¶
Biometric data will be collected to assess physiological response to environmental stressors. The device, Empatica E4 will collect psychophysiological biomarkers (as indicator of stress) including heart rate variability, electrodermal activity, and blood pressure. These responses will be assessed using innovative wearable technology (Empatica E4 wrist device) which provides real-time record of physiological/inertial signals from multiple sensors in the device including Blood Volume Pulse (BVP), Electrodermal Activity (EDA), Inter Beat Interval (IBI), Skin Temperature (ST), and Tri-Axial Acceleration (TAA). Preliminary work has demonstrated integration of these measurements are a reliable predictor of stress in older adults using machine-based learning science.

Research Description ResearchProcedures changed by ekrh223 on 9/19/2021 4:32:47 PM

Two groups of participants will be included in this study: persons with dementia and their primary caregiver. ¶
¶
Research procedures for caregivers will include the following for an approximate total time of 5.5 to 6 hours: ¶
¶
Screening: A screening visit will take place over Zoom video conferencing and will include review and obtaining informed consent for study participation following review of inclusion/exclusion criteria with the LAR and caregiver. Following screening, the data collection tools (behavior work book and Empatica E4 device) will be mailed to you. (approx. 15 min.) ¶
Day 1: During a phone conversation with the researcher, you will complete the Canadian Occupational Performance Measure and Clinical Dementia Rating Scale. You will also don the Empatica E4 on the wrist of the person you are caring for and begin daily behavior journaling in the provided book. (45 minutes) ¶
Day 2: The Adult Sensory Profile will be mailed or emailed to you for completion. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes) ¶
Day 3: During a phone conversation with the researcher, you will complete the Neuropsychiatric Inventory and the Revised Memory and Behavior Problem Checklist. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes) ¶
Day 4: The Zarit Caregiver Burden Inventory will be mailed or emailed to you for completion. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes) ¶
Day 5: During a ~~phone~~Zoom video con~~v~~fer~~sation~~ence, you will complete the Home Occupational Environment Assessment. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes) ¶
Day 6: The Functional Behavior Profile will be mailed or emailed to you for completion. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes) ¶
Day 7: You will also monitor wear of the Empatica device and complete daily behavior journal. Following conclusion of day 7, you will return the behavior journal and Empatica E4 via prepaid shipping to the local Fedex drop off (determined with assistance from researcher). (45 minutes) ¶
¶
Research activities for person with dementia (patient): ¶
Total participation time for persons with dementia will including 2 hours. The will wear an activity monitor, called Empatica E4, on their wrist for seven consecutive days. During this time, their caregiver will also complete daily journal entries summarizing observed behaviors. ¶
Day 1: They will don the activity monitor on wrist. ¶
Day 2-6: The caregiver will monitor wear of the activity monitor including taking off during bathing and for charging. ¶
Day 7: Following Day 7 wear, with assistance from the caregiver, they will remove the activity monitor for return to the University of Kentucky. ¶
¶
All sessions occurring over Zoom video conferencing will be video and audio recorded and all phone sessions will be audio recorded. Recordings will be stored on REDCap.

Research Description ResearchProcedures changed by ekrh223 on 9/14/2021 6:09:46 PM

Two groups of participants will be included in this study: persons with dementia and their primary caregiver. ¶
¶
Research procedures for caregivers will include the following for an approximate total time of 5.5 to 6 hours: ¶
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Screening: A screening visit will take place over Zoom video conferencing and will include review and obtaining informed consent for study participation following review of inclusion/exclusion criteria with the LAR and caregiver. Following screening, the data collection tools (behavior work book and Empatica E4 device) will be mailed to you. (approx. 15 min.) ¶
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Day 5: During a phone conversation, you will complete the Home Occupational Environment Assessment. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes) ¶

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Research activities for person with dementia (patient): ¶
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Day 1: They will don the activity monitor on wrist. ¶
Day 2-6: The caregiver will monitor wear of the activity monitor including taking off during bathing and for charging. ¶
Day 7: Following Day 7 wear, with assistance from the caregiver, they will remove the activity monitor for return to the University of Kentucky. ¶
¶
All sessions occurring over Zoom video conferencing will be video and audio recorded and all phone sessions will be audio recorded. Recordings will be stored on REDCap.

Research Description ResearchProcedures changed by ekrh223 on 9/14/2021 5:48:08 PM

Two groups of participants will be included in this study: persons with dementia and their primary caregiver. ¶
¶
Research procedures for caregivers will include the following for an approximate total time of 5.5 to 6 hours: ¶
¶
Screening: A screening visit will take place over Zoom video conferencing and will include review and obtaining informed consent for study participation following review of inclusion/exclusion criteria with the LAR and caregiver. Following screening, the data collection tools (behavior work book and Empatica E4 device) will be mailed to you. (approx. 15 min.) ¶
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Day 2: The Adult Sensory Profile will be mailed or emailed to you for completion. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes) ¶
Day 3: During a phone conversation with the researcher, you will complete the Neuropsychiatric Inventory and the Revised Memory and Behavior Problem Checklist. You will also monitor wear of the Empatica device and complete daily behavior journal. (45 minutes) ¶
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Day 1: They will don the activity monitor on wrist. ¶
Day 2-6: The caregiver will monitor wear of the activity monitor including taking off during bathing and for charging. ¶
Day 7: Following Day 7 wear, with assistance from the caregiver, they will remove the activity monitor for return to the University of Kentucky.

Research Description Resources changed by ekrh223 on 9/14/2021 5:59:54 PM

a) Staffing and personnel, in terms of availability, number, expertise, and experience ¶
-Dr. Rhodus will provide oversight of the entire study and development and implementation of all policies, procedures and processes. In these roles, Dr. Rhodus will be responsible for the implementation of the Scientific Agenda, the Leadership Plan, and the objectives ensure that systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including human research, data and facilities. ¶

-We are utilizing an existing UK student worker to further assist with recruitment, consenting, and study coordination. This UK student worker will be named at a later date. ¶
-We will utilize our connections with UK Sanders-Brown Center on Aging. ¶
b) Equipment: ¶
-Printed behavior work books will be mailed to participant and returned upon completion of this study ¶
-Empatica E4 device will be used during this study for biometric data collection and returned to UK upon completion. These devices on UK owned. ¶
-UK owned computers will be used. One UK-owned Desktop with password protection housed at 1030 S. Broadway Ste 5 Lexington KY 40504 and one UK-owned laptop with encryption and password protection will be used. Those listed on this IRB protocol will be only persons able to access protected data. All data will be stored and maintained behind a UK Firewall. ¶
-REDCap will be used for data storage.

Research Description SafetyPrecautions changed by ekrh223 on 9/14/2021 5:59:54 PM

Protections against breach of confidentiality of data: ¶
Upon enrollment in the study, each participant will be assigned a participant number and pseudonym, which will be used to identify the person during data analysis and when managing data. All data will be uploaded and saved to REDCap the day of acquisition from participants. REDCap is a password-protected, secure data management web application in the secure data center run by the Institute for Pharmaceutical Outcomes and Policy (IPOP) physically located in the new Biological and harmaceutical Complex building at the University of Kentucky. The files will be stored for a period of six years and destroyed according to UK Policy A13-050. ~~Digital video/audio recordings and electronic transcription of all study sessions and audio recording of focus groups will be obtained using Zoom platform. These electronic files will also be stored on on a secure share drive developed and maintained by the UK Sanders-Brown Center on Aging (Mr. Tim Shannon).~~ Confidentiality will be maintained; however, in the case in which abuse or concern of participants' safety, the researcher is required by law to report to authorities.

Study Personnel Changes:

No Changes

There are no recorded changes to study personnel.

Expedited Categories Comment by Karen Larson - ORI to PI on 9/14/2021 11:34:57 AM

Please explain/comment why Expedited Category 6 is marked?

PI Contact Information Comment by Karen Larson - ORI to PI on 9/14/2021 10:19:41 AM

Please complete rank and degree fields.

Subject Demographics Comment by Karen Larson - ORI to IRB/PI on 9/14/2021 11:15:16 AM

An Appalachian Consultant will review application and provide recommendations to the IRB.

Research Description Comment by Karen Larson - ORI to PI on 9/17/2021 3:03:57 PM

Procedures- Dementia Subject- Need to include how long (minutes or hours) their participation will take. CF says 2 hrs. Caregiver- Day 5 need to include use of Zoom.

Research Description Comment by Karen Larson - ORI to PI on 9/17/2021 2:12:21 PM

Removed.

Research Description Comment by Karen Larson - ORI to PI on 9/14/2021 11:45:38 AM

Data and Safety Monitoring: Need to complete as per the instructions "The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, or NIH-funded/FDA-regulated clinical investigations." Your study is NIH funded. It is not "N/A."

Research Description Comment by Karen Larson - ORI to PI on 9/14/2021 11:43:49 AM

Payment- Need to clarify Caregiver of dyad is being mailed the $50 gift card. Dementia patient will not receive any payment.

Research Description Comment by Karen Larson - ORI to PI on 9/14/2021 11:41:05 AM

Confidentiality- See comments under Safety Precautions section-Where in Procedures is it discussed about " Digital audio recordings and electronic transcription of all interviews will be obtained. These electronic files will also be stored on REDCap" and "All video recording/electronic data"?

Research Description Comment by Karen Larson - ORI to PI on 9/14/2021 11:38:40 AM

Resources- Will a UK computer be used? If a desktop data must be password protected. If a laptop data must be encrypted. Where will computer be physically kept (room number and building name)? How will it be secured and who will have access to data on it? Please verify data will be stored and maintained behind UK firewall. Or will you use UK VPN with your personal computer or One Drive to access and store data on? Please be reminded that all local servers must be approved by UKHC IT. Suggest include REDCap and Empatica E4- clarify who owns the devices.

Research Description Comment by Karen Larson - ORI to PI on 9/14/2021 11:37:08 AM

Research Materials, Records and Privacy: Suggest include EHR/medical records and EPIC.

Research Description Comment by Karen Larson - ORI to PI on 9/14/2021 11:35:42 AM

Safety Precautions- Please clarify "Digital video/audio recordings and electronic transcription of all study sessions and audio recording of focus groups will be obtained using Zoom platform. These electronic files will also be stored on on a secure share drive developed and maintained by the UK Sanders-Brown Center on Aging (Mr. Tim Shannon)."- as no discussion of any Focus Groups nor recording of any phone calls nor via Zoom are described in the Procedures section.

Research Description Comment by Karen Larson - ORI to PI on 9/14/2021 11:07:40 AM

Procedures- 1. As study will involve seeing subjects inside their home, please contact UK Legal at (859) 323-1161 or email Steven Clifton at steve.clifton@uky.edu to determine if a Kentucky notice requirement applies to the study. 2. Please clarify where screening visit will take place? Will it be in potential subjects' home (dementia patient and their caregiver) or over phone or via Zoom? For the screening visit will dementia patients' LAR be required to be present?

Research Description Comment by Karen Larson - ORI to PI on 9/14/2021 10:59:36 AM

Informed Consent Process- For Patient with advanced dementia, please discuss in terms of LAR with use of REDCap Consent Form and a mailed Consent Form.

Research Description Comment by Karen Larson - ORI to PI on 9/14/2021 10:52:18 AM

Advertising- 1. Please check with UK Public Relations is they need to review and approve ads that contain UK Logo before use with subjects. 2. Have email ads and/or correspondence been attached?

Informed Consent Comment by Karen Larson - ORI to PI on 9/20/2021 9:12:23 AM

Caregiver CF- Under "What are the possible risks and discomforts"- Why was "There are no known risks involved in this study" removed and yet left on Dementia Subject CF?

Informed Consent Comment by Karen Larson - ORI to PI on 9/17/2021 2:51:08 PM

Consent Forms- See "Pen and Ink" comments for both types of CFs uploaded under "Additional Information/Materials" section. You may need to refer to current Consent Form template found under Application Links, All Templates. Delete current high-lighted and clean CFs. Go to All Attachments, click on red "x" by each document. Re-upload new high-lighted and clean CF versions. Call Karen at (859) 257-3038 if you have any questions.

Informed Consent Comment by Karen Larson - ORI to PI on 9/14/2021 11:48:00 AM

Consent Forms will not be pre-screened until Procedures are clarified see comments under Safety Precautions and Confidentiality.

Informed Consent Comment by Karen Larson - ORI to PI on 9/14/2021 10:43:55 AM

Consent Forms- Clinical Trial is marked as an Attribute. See if study will need to be registered on clinicalTrials.gov. or not. Look at https://clinicaltrials.gov/ct2/manage-recs/how-register. Please contact OSPA if you have questions on this topic. If yes, you will need to revise any Consent Forms (see template CF language under What else do you need to know section).

Informed Consent Comment by Karen Larson - ORI to IRB/PI on 9/14/2021 10:38:03 AM

Waiver of Informed Consent is not needed for pre-screening to identify subjects according to 2019 New Common Rule. Remove checkmark and all written content below. Note- A Waiver of Authorization (WOA) is needed for pre-screening to identify subjects in

medical records.

Signatures (Assurances) Comment by Karen Larson - ORI to PI on 9/14/2021 10:21:57 AM

Please clarify if Dr. Van Eldik is your Department Chair?