Document Coversheet

Study Title: Creating Harmony at HOME: A Pilot Study of a Telehealth Based Program for Rural Caregivers' Ability to Adapt Home Environments for Adults With ADRD

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	Protocol 7/17/23
NCT Number:	NCT05202223
IRB Number	66766
Coversheet created:	10/30/23

NCT05202223: Creating Harmony at HOME: A Pilot Study of a Telehealth Based Program for Rural Caregivers' Ability to Adapt Home Environments for Adults With ADRD

Statistical analysis plan:

Analysis included mean and standard deviation of each endpoint at each visit. A linear mixed model was completed to determine if the mean response varied among the 3 visits (P value listed in the last column). Final analyses used a modified intent to treat (mITT) for a completers analysis which included those participants who completed visit 2.

PROTOCOL TYPE (VERSION 4)

IRB Approval
7/17/2023
IRB # 66767
IRB6
CLOSED

Which IRB

- (•) Medical ( ) NonMedical

Protocol Process Type

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

IMPORTANT NOTE: You will not be able to change your selections for "Which IRB" and "Protocol Process Type" after saving this section. If you select the wrong IRB or Protocol Process Type, you may need to create a new application.

See below for guidance on these options, or refer to ORI's "Getting Started" page. Please contact the Office of Research Integrity (ORI) at 859-257-9428 with any questions prior to saving your selections.

Which IRB

The **Medical IRB** reviews research from the Colleges of:

- Dentistry
- Health Sciences
- Medicine
- Nursing
- Pharmacy and Health Sciences
- and Public Health.

The **Nonmedical IRB** reviews research from the Colleges of:

- Agriculture
- Arts and Sciences
- Business and Economics
- Communication and Information
- Design; Education
- Fine Arts
- Law
- and Social Work

Note: Studies that involve administration of drugs, testing safety or effectiveness of medical devices, or invasive medical procedures must be reviewed by the **Medical IRB** regardless of the college from which the application originates.

Which Protocol Process Type

Under federal regulations, the IRB can process an application to conduct research involving human subjects in one of three ways:

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

The investigator makes the preliminary determination of the type of review for which a study is eligible. Please refer to ORI's "Getting Started" page for more information about which activities are eligible for each type of review.

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.

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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 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 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.
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 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." 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:

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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 qualify for Exempt review. This listing refers only to research that is not exempt.)
(Note: If submission includes materials previously collected for either non-research or research purposes in a protocol for which IRB approval expired, you may check Category 5. However, a separate category must also be selected for prospective collection of data/specimens obtained solely for research purposes)

☑ 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. This listing refers only to research that is not exempt.)

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Modification Request Section

0 unresolved comment(s)

***** If this modification changes the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.*****

Select One:

- (•) This modification does not increase risk to study participants.
- ( ) This modification may or will increase risk to study participants.

Is this modification request due to an Unanticipated Problem/Adverse Event, or Protocol Violation?

( ) Yes (•) No

In your professional opinion, does this modification involve information that might relate to a subject's willingness to continue to take part in the research?

( ) Yes (•) No

If yes, state how the information will be communicated to subjects (i.e., re-consent, send letter, etc.):

For each proposed modification, include a justification.

Example: Jane Doe, MD, is being added as co-investigator because she has expertise with the subjects on this protocol. She has completed human subject protections training, and is authorized to obtain consent.

REDACTED FOR PRIVACY

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PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).
If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title

Creating Harmony at HOME: A pilot study of a telehealth-based program for rural caregivers' ability to adapt home environments for adults with ADRD

Short Title Description
Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.

Harmony at Home

Anticipated Ending Date of Research Project: 7/31/2023

Maximum number of human subjects (or records/specimens to be reviewed) 80

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? (•) Yes ( ) No

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PI CONTACT INFORMATION

0 unresolved comment(s)

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*).

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 listed as PI here.

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.

The Principal Investigator's (PI) contact information is filled in automatically based on who logged in to create the application.

If you are not the Principal Investigator, do NOT add yourself as study personnel.
To change the PI contact information on an application in Researcher edit status:

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

You will automatically be added as study personnel with editing permissions to continue editing the application.

Change Principal Investigator:

First Name:	Elizabeth	Room# & Bldg:	463 Healthy Kentucky Research Bldg
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:	Assistant Professor
PI's Telephone #:	(859) 257-5562	Degree:	PhD
PI's e-mail address:	elizabeth.rhodus@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	10/16/2021
		RCR Trained:	Yes

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

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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.

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

Refer to UK's guidance document on assessing the research risk for additional information.

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SUBJECT DEMOGRAPHICS **0 unresolved comment(s)**

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

Study Population:

Describe the characteristics of the subject population, including age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion.

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;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider these resources:
NIH Diversity Policy
FDA Diversity Guidance

Inclusion and excluded groups: Recruitment and enrollment will be inclusive of all groups living within rural, Appalachia Kentucky who are over the age of 21. We anticipate 40 white females, 26 white males, 6 black males, 8 black females based on population representation in rural Appalachia. There will be no exclusion for race, gender, or ethnic category.

Participants must meet all inclusion criteria in order to participate in the study:

Inclusion Criteria Caregiver of Participant with Dementia:
1. Men or women aged 21-99, inclusive.
2. Willingness and ability to participate in trial and implement recommended intervention strategies throughout duration of study.
3. Access to and ability to use video technology (Zoom) for telehealth visits.
4. English speaking, able to read and write.
5. Ability to retrieve and return mail.
6. Care provider of person with diagnosis of dementia with behavioral disturbance.

Exclusion criteria of caregiver:
1. Unable to provide consent for participation due to cognitive impairment.
2. Severe psychological stress or active state of psychiatric conditions (severe depression, mania, hallucinations/delusions).

Inclusion Criteria 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+) with behavioral disturbance.
4. No change in medical condition for one month prior to screening visit
5. No change in medications for 4 weeks prior to screening visit.
6. If on psychotropic medication, they are at a point where dosage and treatment are stabilized for the duration of the study.
7. Physically acceptable for this study as confirmed by medical history, physical exam, and/or clinical tests completed by medical professional (MD, APRN, PA, RN or OT).
8. Functional sensory abilities with or without aids (hearing, vision, smell, touch, taste)
9. Contact with UKADC or KNI medical provider or patient's primary care physician within 12 months of study recruitment.

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. Skin lesions or skin abnormalities throughout upper extremities.
5. Allergies related to lotion or fragrance.
6. Caregiver report of physically violent behaviors.
7. Initiation of antipsychotic medication within 4 weeks prior to screening or unpredictable use of such medications
8. Diagnosis of profound or total sensory altering disorders including macular degeneration, legal blindness, total deafness, severe peripheral neuropathy, anosmia.
9. 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.
10. Diagnosis or concern of epilepsy.
11. Use of any investigational agents or devices within 30 days prior to screening.
12. Major infection within 4 weeks prior to the Baseline Visit.

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

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):

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Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:	0	0		
Asian:	0	0		
Black/African American:	0	0		
Latinx:	0	0		
Native Hawaiian/Pacific Islander:	0	0		
White:	10	36		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:	1	8		

If unknown, please explain why:

Participants have not completed the demographic survey or chose not to answer questions on race/ethnicity.

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

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

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults
- Economically or Educationally Disadvantaged Persons

Other Resources:

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see also the E-IRB Research Description section on this same topic]
- International Citizens [DoD SOP may apply]
- Military Personnel and/or DoD Civilian Employees

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Assessment of the 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). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

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

◉ Yes ○ No

If Yes and you are not filing for exemption certification, go to "Form T", complete the form, and attach it using the button below.

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_1Ci 6-24.doc

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INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

For creating 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 edit to match your research project.

Additional Resources:

- Informed Consent/Assent Website
- Waiver of Consent vs. Waiver of Signatures
- Sample Repository/Registry/Bank Consent Template

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- If another site is serving as the IRB for the project, attach the form as a "Reliance Consent Form" so the document will not receive a UK IRB approval stamp; the reviewing IRB will need to stamp the consent forms.
- 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
  - "Reliance Consent Form",
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must:

   a) provide a response in the text box below describing how investigators will obtain consent/assent, and
   b) check the box for at least one of the consent items and/or check mark one of the waivers

2. If applicable attach each corresponding document(s) **as a read-only PDF.**
3. 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 select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

Check All That Apply

- [x] Informed Consent Form (and/or Parental Permission Form and/or translated short form)
- [ ] Assent Form
- [ ] Cover Letter (for survey/questionnaire research)
- [ ] Phone Script
- [x] Informed Consent/HIPAA Combined Form
- [ ] Debriefing and/or Permission to Use Data Form
- [ ] Reliance Consent 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 Consent/Parental Permission	Consent Patient 7-28-21 clean.pdf
Informed Consent/Parental Permission	Consent CAREGIVER clean 12-12.pdf

Informed Consent Process:

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Using active voice, describe how investigators will obtain consent/assent. Include:

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)
- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
  If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
  For 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.

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 [redacted] 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 email or smart phone through private dedicated link sent at least 24 hours prior to screening visit. 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 and date (date that informed consent is confirmed) into the designated fields to complete the consenting process. 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. 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.

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 participants.
Participants can address complaints and concerns to either [redacted]. 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 [redacted]

☑ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, 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 a waiver of the requirement for the informed consent process.

☐ I am requesting an 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.

Explain how each condition applies to your research.

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

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

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

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.

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

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.

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

Not applicable.

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.

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 medically-based diagnoses, histories, and testing results. It is required to conduct thorough recruitment for optimal results.

☐ Request for Waiver of Signatures

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **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 (e.g., 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 (e.g., 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, 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.

If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the ***Cover Letter Template*** *as a guide. There is an English and a Spanish version.*

○ **Option 1**

Describe how your study meets these criteria:

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**

Describe how your study meets these criteria:

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**

Describe how your study meets these criteria:

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.

[redacted]

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 click 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 required for a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed below. ***Residents and students who are PI's are encouraged to designate the faculty advisor or at least one other individual 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 personnel;
- Click "select" by the listing for the person you want to add;
- For each person, specify responsibility in the project, whether authorized to obtain informed consent, AND denote who should receive E-IRB notifications (contact status).

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's HSP FAQ page, the RCR Getting Started 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	(RCR)	Removed?	Last Updated	SFI
[redacted]													

[redacted]

RESEARCH DESCRIPTION

0 unresolved comment(s)

You may attach a sponsor's protocol pages in the "Additional Information" section and refer to them where necessary in the Research Description. However, each prompt that applies to your study should contain at least a summary paragraph.

Pro Tips:

- **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 supplemental information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background

Include a brief review of existing literature in the area of your research. You should identify gaps in knowledge that should be addressed and explain how your research will address those gaps or contribute to existing knowledge in this area. For interventional research, search PubMed and ClinicalTrials.gov for duplicative ongoing and completed trials with same condition and intervention(s).

Behavioral disruptions by individuals with Alzheimer's disease and related dementias (ADRD) are reported in nearly 90% of persons living with ADRD. Such behavioral and psychological symptoms of dementia (BPSD) are highly correlated with increased caregiver burden and burnout, decreased quality of life for the person living with dementia and their caregiver, institutionalization, and patient mortality. There is a need for caregiver-initiated and -implemented non-pharmacological interventions directly to and for the person with dementia, including environmental assessment and modification, as first-line treatments for BPSD in persons living with dementia (PLWD).

Delivered via telehealth, Harmony at HOME (H@H) aims to train caregivers of persons with moderate to severe ADRD in the skills of assessing and modifying the home environment to promote "person-environment fit," a concept that posits that the ability to access features within a built environment (e.g. bathroom, stairs,) or that factors within the environment itself (lighting, noise level, temperature), especially when linked with individualized social support, contribute to or even shape behavior. In ideal circumstances, adults adjust or adapt to meet the demands of the environment; likewise, in the ideal, environments are designed in ways that facilitate positive behaviors. ADRD progressively interferes with an individual's capacity to self-optimize person-environment fit; in such cases, caregivers have the opportunity to create a supportive environment that negates some behavioral challenges and encourages functional activity engagement. H@H seeks to help caregivers acquire the skills and sense of mastery that will enable them to create such supportive environments within the homes of people with dementia.

H@H will be tested with caregivers and the person living with dementia in the Appalachian region of rural Kentucky, a region with the poorest healthcare options for older adults in the country and plagued with extremely high rates of co-morbid conditions, including ADRD. Access to quality caregiver training, in-home caregiver support, and respite is significantly limited. This pilot study will enable the investigators not only to establish the feasibility of the program but to demonstrate this capacity with a population of caregivers and persons with dementia that is in particular need and difficult to reach.

Objectives

List your research objectives. Please include a summary of intended research objectives in the box below.

This Stage 1b pilot project aims to establish the feasibility of H@H and to provide a preliminary test for its mechanism of action (instruction, coaching, and performance review) to improve caregiver mastery in decreasing or eliminating BPSD in people living with dementia. It does so by developing and strengthening their caregivers' skills of assessing and modifying the care environment to foster improved person-environment fit for the person living with dementia (patient).
This project will consider the caregiver and the person with dementia (patient) as study participants as both are involved in individualized training for improved behaviors of the person living with dementia.
Objectives include 1) study focus groups with select caregiver participants pre and post intervention to refine intervention to specific needs of persons in rural Appalachia; and 2) assess feasibility of the Harmony at Home intervention over telehealth for persons caring for and living with dementia in rural Appalachia.

Study Design

Describe and explain the study design (e.g., observational, secondary analysis, single/double blind, parallel, crossover, deception, etc.).

- *Clinical Research*: Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *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.
- *Qualitative research*: Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.
- *Research Repositories*: If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository,

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provide scientific justification for establishing an additional repository collecting duplicate material. Describe th
and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK Research Registry Guidance.

This study will utilize a one-arm, pre/post design. Forty people living with dementia with behavioral disturbance and their primary care partner will receive the H@H intervention (total n=80), a 6-week telehealth intervention delivered by an occupational therapist during weekly visits. Focus groups before and after the intervention with caregiver informants, interventionists, and study facilitators will allow opportunity to refine the intervention specific to the needs of caregivers in rural Appalachia. Caregivers of community-residing persons living with dementia with complaints of behavioral disturbance will be recruited for this project. The University of Kentucky Alzheimer's Disease Research Center and the Kentucky Neuroscience Institute have established contacts throughout the rural Appalachian region which provides access to our targeted population.

Attachments

Subject Recruitment Methods & Advertising

Describe how the study team will identify and recruit subjects. Please consider the following items and provide additional information as needed so that the IRB can follow each step of the recruitment process.

- How will the study team identify potential participants?
- Who will first contact the potential subjects, and how?
- Will you use advertisements? If so, how will you distribute those?
- How and where will the research team meet with potential participants?
- If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations.
- How you will minimize undue influence in recruitment?
- Attach copies of all recruiting and advertising materials (emails, verbal scripts, flyers, posts, messages, etc.).

For additional information on recruiting and advertising:

- IRB Application Instructions - Advertisements
- PI Guide to Identification and Recruitment of Human Subjects for Research

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 40 persons living with ADRD and their primary caregiver (total n=80) 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 or medical providers as persons who have potential interest in participation of this study. Recruitment will occur through [redacted] as approved by [redacted] Healthcare IRB (attached). 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. ResearchMatch 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 ([redacted]) is the clinical core director and director of the Telehealth Clinic and neurologist for KNI. Study coordinators [redacted] will be involved via study coordination and community outreach for recruitment using UK IRB approved materials. Researchers are embedded within these networks of patients for recruitment purposes.

Retention plans will include weekly 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. Weekly assessment of participant engagement and needs will be determined to maximize retention to study completion. Reports of research results will also be made available.
At this time, 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
De-identified participant quotes specifically related to the utilization of the intervention may be used for advertising in the form of flyers, emails, and website posts, including social media. Participants will be invited via REDCap link to provide permission to use their deidentified quotes for this purpose. (attached).

Attachments

Attach Type	File Name
Advertising	[redacted]lyer 6-24.docx
Advertising	SB-015 research match.pdf
Advertising	SB-015 social media.pdf

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Advertising	SB-015-flyer.pdf
Advertising	SB-015_MON.pdf
Advertising	quotes mod.docx
Advertising	Harmony at Home flyer v2_STAMPED.pdf
Advertising	SB-015b-flyer.pdf
Advertising	SB-015b_monitor.pdf
Advertising	SB-015b_researchmatch.pdf
Advertising	SB-015b_social media.pdf

Research Procedures

Describe how the research will be conducted.

- What experience will study participants have?
- What will study participants be expected to do?
- How long will the study last?
- Outline the schedule and timing of study procedures.
- Provide visit-by-visit listing of all procedures that will take place.
- Identify all procedures that will be carried out with each group of participants.
- Describe deception and debrief procedures if deception is involved.

Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project. List medications that are explicitly forbidden or permitted during study participation.

Use of protected health information will be used for recruitment purposes only and medical charts will not be accessed following recruitment tasks.

Each caregiver will complete the 6-week Harmony at HOME telehealth intervention:
Select participants will engage in focus groups prior to and following the intervention with caregiver informants, clinicians, and study facilitators. Participants will be selected based on enrollment and willingness to participant The first 10 caregiver participants will be asked to join the focus groups, caregiver participants will be asked in sequential order should any of the initial 10 decline focus group participation. These focus groups will provide feedback needed to refine the intervention to specific needs of caregivers in rural Appalachia. The focus groups will be conducted over Zoom video conferencing and audio recorded using Zoom platform and automatically transcribed through Zoom. One focus group will be held pre intervention and the second will focus group will be held post intervention with the first ten caregiver participants willing to participate. These sessions will last approximately 90 minutes.

The following tasks will be associated with participation in this study and will take place at the person with dementia's home using Zoom video conferencing on the Zoom platform and saved on a UK-created share drive supported by Sanders-Brown Center on Aging. The zoom videos will be recorded and transcribed using Zoom platform. Informed consent will be obtained prior to the following research procedures. Caregiver participants will be asked to use their own personal devices if zoom capable. iPads with cellular service will be provided if the participants do not have a zoom-capable device or if they request to use an UK-issued iPad.

Visit 1: A screening visit will take place and will include review and obtaining informed consent for study participation following review of inclusion/exclusion criteria. Following consent completion, the screener will review demographic information and mail or email you a survey containing the following questions: Adult Sensory Profile; 20-Item Center of Epidemiology Depression Scale; UCLA Loneliness Scale; CHAMPS Social Engagement Scale; and the Zarit Caregiver Burden. Additionally, the screener will ship the behavior journal and iPad (if needed) via Fedex following the screening visit. Upon receipt, written instructions will direct you on how to use Zoom, behavior journals, and iPad (if used). The study coordinator will provide additional direction and confirm understanding of use at the baseline visit.

Visit 2: Baseline data will be collected at Visit 2 consisting of seven surveys/questionnaires completed during the visit with the study coordinator: the Revised Memory and Behavior Problem Checklist, Adult Sensory Profile, Canadian Occupational Performance Measure, 6-Item Revised Caregiver Appraisal Scale; 6-Item Activities of Daily Living; 8-Item Instrumental Activities of Daily Living, Pearlin Mastery assessment, Stait-Trail Anxiety Scale, and Perceived Stress Scale. . The Situational Assessment Activity and Function Profile will be emailed or mailed to you for completion, as well. A focus group will also be held with selected participants. All intervention materials will be mailed to the patient's home following visit 2. Intervention materials will include items which offer environmental modifications to the home, for example: [redacted]

Visit 3: The Occupational Therapist will meet with you for Visit 3. This will initiate week 1 in the behavior workbook. During this visit, the therapist will complete the Canadian Occupational Performance Measure, the Home Occupational Environment Assessment, and the Situational Assessment of the Home Environment.

Visit 4-8: At the end of each week, you and the patient you care for will meet with an occupational therapist to complete intervention training, as well as review the behavior journal and adverse events. These visits will last approximately one hour.

Visit 9: At the final week of intervention, you will engage in a two-hour session which will involve of adverse events, and completion of the Revised Memory and Behavior Problem Checklist, CES Depression scale; 6-Item Revised Caregiver Appraisal Scale; 6-Item Activities of Daily Living; 8-Item Instrumental Activities of Daily Living; Canadian Occupational Performance Measure, Stait-Trait Anxiety Scale; Zarit Caregiver Burden Scale, Pearlin Mastery assessment and Perceived Stress Scale surveys/questionnaires. A focus group will also be held with selected participants. The focus group will consist of the first ten participants willing to participate. The focus group will last approximately 60 minutes and will be conducted over zoom. The focus group will provide feedback needed to refine the intervention to specific needs of caregivers in rural Appalachia.

Visit 10: Four weeks following completion of the intervention, you will complete a follow up session consisting of the same visit 9 assessments.

Lastly, the researcher may contact the caregivers to confirm or clarify interpretation of subjective information gaine
video conferences. The contact may be via phone, email, or a virtual meeting.

It is anticipated that caregivers will spend approximately 11 hours on zoom as part of this study and around 45 hours in at-home intervention and documentation. Screening and baseline will take approximately 1-2 hours, visits on weeks 1-5 will total approximately 5 hours, visit for treatment week will last 2 hours and visit for follow up will task around 2 hours. We anticipate an average of one hour per day over the six week intervention to be used for intervention deliver and documentation in the behavior journal (42 hours) with additional time to complete assessments at home (approx. 3 hours) during baseline and follow up visits.

Throughout the 10 weeks of participant contact, should the participant express significant improvements related to the intervention, a permission request will be provided to assess their interest in allowing quotes related to the intervention to be used as testimonials of the intervention for recruitment and advertising purposes.

Each patient will complete the 6-week Harmony at HOME telehealth intervention:
The following tasks will be associated with participation in this study and will take place at the patient's home using Zoom video conferencing. Informed consent will be obtained prior to the following research procedures.

Visit 1: Review and obtain informed consent from LAR and assess if dissent behaviors are present from patient (approximately 30 minutes)

Visit 2-7: At the end of each week, caregivers and patients will meet with an occupational therapist to complete intervention training, as well as review the behavior journal and adverse events. The patient will engage with the interventionist through discussion and dialog of behaviors, concerns, or feedback regarding intervention training information. These visits will last approximately one hour with the caregiver and patient.

Lastly, the researcher may contact the patients to confirm or clarify interpretation of subjective information gained during the Zoom video conferences. The contact may be via phone, email, or a virtual meeting.

It is anticipated that patients will spend no more than 8 hours on zoom. Approximately 15 minutes for baseline, Treatment weeks 1-6 will last around 1 hour each, and 1 hour for follow up.

This study will utilize a one-arm, pre/post design. Consent will be obtained electronically using REDCap survey distribution. Researchers will assess the feasibility of the primary outcome: increased caregiver competence (Pearlin mastery sub-scale on caregiver competence). Forty persons with dementia and their caregivers will be recruited for participation from the University of Kentucky Alzheimer's Disease Center (UK-ADRC), UK Telehealth Neurology Clinic,and Kentucky Neuroscience Institute. A sample of 40 caregivers has 80% power to show that the compliance (protocol adherence) rate is =60% versus the alternative that the compliance rate is <60% at the 0.05 level of significance. This sample size will allow for assessment of feasibility as the primary outcome based on retention of =75% of study participants completing the study, with =60% protocol adherence, estimated from current clinical trials at UK-ADRC and rehabilitation feasibility trials. All data will be collected remotely and stored electronically on REDCap servers approved by the University of Kentucky IRB. Statistical analyses will be completed using R and SAS programming with assistance from D[redacted] Exploratory analyses 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, comorbidities). 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.

Intervention description:
Harmony at HOME is a 6-week training intervention provided to caregivers with focus on teaching skills for caregiver capacity to assess the environment as antecedent to behavior and modify environmental antecedents. This program will be provided by an occupational therapist who will lead individualized training for caregivers to identify and initiate environmental modification through environment cueing to positively influence behaviors and decrease caregiver burden for the dyad. An environmental cueing approach will tailor antecedents to promote functional behavior and activity engagement for persons with dementia. These studies will be conducted using telehealth, remote technology to target underrepresented and underserved populations throughout rural Appalachia Kentucky. This pilot award will establish feasibility and promise of caregiver mastery related to this important intervention.

The Harmony at HOME (Help Online Modifying the Environment) intervention was developed by study PIs and builds on prior successful foundations of dementia care interventions with a novel approach which combines successful facets of dementia care interventions including remote implementation, antecedent education, and home environment intervention. The intervention will teach caregivers how to 1) [redacted] Determining these specific needs and capacities will enable us to promote environmental setup to address needs-driven care, and sensory stimulation as a cue for behavioral regulation. [redacted]. All participant contact and intervention delivery will be implemented through a telehealth remote platform for persons living within rural

Appalachia Kentucky.

Determination of Tailored Approach of the Intervention:

[redacted]

Attachments

Attach Type	File Name
ResearchProcedures	Caregiver schedule of events 11-12.pdf

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

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

Video recordings of all study sessions and audio recordings of focus groups will be collected using Zoom video conferencing. The automatic transcription feature will be used from Zoom platform.

If caregiver participants do not have a zoom capable device or if they request, a UK owned iPad equipped with vid
plans will be mailed to caregiver participants for use during all study sessions. These devices will be mailed directly to participants homes via fedex and returned via Fedex using home pickup option.

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

Assessments (attached) used for data collection include:
6-Item Activities of Daily Living: Caregiver report of patient abilities for activities of daily living.
Adult Sensory Profile (ASP): A questionnaire to be completed by the caregiver regarding the patients' preferences and behaviors associated with environmental stimulation. Will be mailed or emailed for completion.
Canadian Occupational Performance Measure (COPM): An interview-based assessment with the caregiver regarding the patient's daily functional performance (i.e., bathing, dressing, feeding) and the caregiver's satisfaction with the level of performance.
20-Item Center of Epidemiology Depression Scale: Assessment of caregiver depressive symptoms.
CHAMPS Social Engagement Scale: Assessment of social engagement of caregivers.
Home Occupational Environment Assessment (HOEA): An assessment of home accessibility and safety.
8-Item Instrumental Activities of Daily Living: Caregiver report of patient abilities in instrumental activities of daily living, such as finance management and medication management.
Pearlin Mastery: Assessment on caregiver competence.
Perceived Stress Scale: Scale to assess caregiver stress.
6-Item Revised Caregiver Appraisal Scale: Assessment of caregiver satisfaction related to intervention.
Revised Memory and Behavior Problems Checklist: Caregiver report of behavioral concerns presented by the patient.
Situational Assessment- Activity and Function Profile: Caregiver report of situational elements and patient participation of activities completed within the home.
Situational Assessment of the Home Environment: Therapist led review of home environment accessibility and set up for patient use.
Stait-Trait Anxiety Scale: Assessment of caregiver-reported feelings of anxiety.
UCLA Loneliness Scale: Assessment of caregiver-reported feelings of loneliness.
Zarit Caregiver Burden Scale: A brief assessment of caregiver burden associated with patient care, to be completed by the caregiver. Will be mailed or emailed to the caregiver.

Focus groups of the first ten participants who are willing to participate will engage in an online Zoom focus group pre intervention and post intervention with goals to culturally adapt the intervention for those living in Appalachia, and to gain feedback regarding their experience with the intervention.

Feasibility as measured by caregiver competence will be assessed as the primary outcome of this study. Primary outcome: Caregiver mastery will be assessed using the 4-item Pearlin mastery sub-scale on caregiver competence (a=.74) at pre- and post-test and one-month post-intervention follow up. Exploratory outcomes will examine impact of the intervention on caregiver burden (4 item Zarit Burden Interview; a=.78), stress (10-item Perceived Stress Scale; a=.84-.86), the 6-item caregiver appraisal sub-scale on caregiver satisfaction a=.67-.76), and change in BPSD (24-item Revised Memory and Behavior Problems Checklist; a=.67-.90) at pre- and post-test. These measures are included in the attachment.

Attachments

Attach Type	File Name
DataCollection	Focus Group 1 Interview Guide_rev.docx
DataCollection	Focus Group 1 Interview Guide_v2 clean.docx
DataCollection	Focus Group 2 Post Interview Guide_rev.docx
DataCollection	Focus Group 2 Post Interview Guide_v2 Clean.docx
DataCollection	HARMONY AT HOME PARTICIPANT MANUAL 1-16-22.pdf
DataCollection	SAAF.pdf
DataCollection	HARMONY AT HOME PARTICIPANT WORKBOOK highlighted 1-19-22.docx
DataCollection	HARMONY AT HOME PARTICIPANT MANUAL 1-16-22.docx
DataCollection	SAAF revised highlighted 1-19-22.docx
DataCollection	SAAF revised clean 1-19-22.docx
DataCollection	CHAMPS remote.pdf
DataCollection	UCLA remote.pdf
DataCollection	lawton-iadl.pdf
DataCollection	katz-adl.pdf
DataCollection	RCAS.pdf
DataCollection	State Trait Y1.pdf
DataCollection	Demographic Caregiving History.pdf
DataCollection	Center For Epidemiologic Studies Scale.pdf
DataCollection	SAHE 11-12-21.doc
DataCollection	Focus Group 1 Demographic Survey Questions.docx
DataCollection	Focus Group 2 Demographic Survey Questions.docx
DataCollection	HOEA 2.pdf
DataCollection	Zarit Caregiver Burden Inventory.pdf

DataCollection	Perceived Stress.pdf
DataCollection	COPM.pdf
DataCollection	ASP.pdf
DataCollection	RMBPC.pdf

Resources

Describe the availability of the resources and adequacy of the facilities that you will use to perform the research. Such resources may include:

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;
- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;
- Resources for communication with subjects, such as language translation/interpretation services.

a) Staffing and personnel, in terms of availability, number, expertise, and experience
-[redacted] will provide oversight of the entire study and development and implementation of all policies, procedures and processes. In these roles, [redacted] 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.
-[redacted] will serve as medical supervisor. She is faculty within the Department of Neurology at the University of Kentucky (UK), as well as clinical neurologist for UK Healthcare, which provides ideal qualifications to serve as safety officer for this low-risk study involving participants with ADRD and their caregivers. She will serve as the safety officer for this project. As safety officer, she will review all adverse events (AE) and unanticipated problems (UP) reported to date of review. Scheduled reviews will occur every 6 months for duration of project. She will also review serious SAE within 48 hours of occurrence.
-Interventionists- Occupational therapist(s): [redacted] (non-UK study personnel) will serve as interventionists for this study. [redacted] will provide weekly telehealth interventions as described in the research description.
-[redacted] will serve as study coordinators and conduct community outreach in rural Kentucky. Both are [redacted] and are not covered by the UK IRB. A determination letter from the [redacted] IRB regarding their activities is attached.
b) Equipment
-Personally owned zoom-capable devices of caregiver participants (please note, this is not a requirement. UK-issued iPad devices will be provided if participant do not have or do not wish to use their own personal devices).
-UK-owned iPads, some with cellular Wi-Fi enabled (for duration of study), which was approved in our funding budget but have not yet obtained (as previously described, funding is understandably not released until IRB approval).
-UK Zoom, email, OneDrive, and university-owned computers and software will be used for this study.
-Intervention Toolboxes will be mailed to participants following Visit 2.
[redacted]

Potential Risks & Benefits

Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.
- Which risks may affect a subject's willingness to participate in the study?
- Describe likely adverse effects of drugs, biologics, devices or procedures participants may encounter while in the study.
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

- Describe potential direct benefits to study participants – including diagnostic or therapeutic, physical, psychol
  learning benefits. This cannot include incentives or payments.
- State if there are no direct benefits.
- Describe potential benefits to society and/or general knowledge to be gained.

Describe why potential benefits are reasonable in relation to potential risks. If applicable, justify why risks to vulnerable subjects are reasonable to potential benefits.

Description and justification for the proposed involvement of human subjects: The focus of our study is on investigating the caregiver mastery of a telehealth-based intervention targeting caregivers training to understand and apply person-environment fit to improve functional behavior for older adults, including those from varying backgrounds, race/ethnicity, socioeconomic status, among persons with Alzheimer's disease and related dementia living within their homes in rural communities. The research strategy will specifically target rural Appalachia to educate and increase caregivers' access to and use of behavioral strategies for persons with Alzheimer's disease and related dementias (ADRD).

Due to the nature of the telehealth intervention of conducting video conferencing within the dyad home, both caregiver and care recipient with dementia will be included in study recruitment. In an abundance of caution, we will consent both the caregiver and the person with ADRD through approved IRB processes at UK. This will include consent with the person with ADRD legally authorized representative (if this is not the same as the caregiver), as well as assent procedures for the person with cognitive impairment.

Characteristics of subject population (number, age range, and health status): Inclusion and excluded groups: Recruitment and enrollment will be inclusive of all groups living within rural, Appalachia Kentucky who are over the age of 21.

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.

Potential risks to patient participants:
• Possible discomfort from intervention materials, such as skin irritation, headache, disliking recommendations.
• A risk of sensory overstimulation is present, however, impact of such risks are mild, temporary, and often subside within four hours of intervention.
Potential risks to caregiver participants:
• Possible stress added to you due to the addition of intervention and assessment time.
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. There are minimal risks from participating in this study.

Potential Benefits
It is unknown if this study will present with benefits to participants. However, some individuals have experienced improved relationships with those they care for, and empowered decision making while caregiving. Patients may experience relaxed moods with decreased occurrence of behavioral disruption when participating in activities included in this study.
Importance of Knowledge to be Gained
Knowledge gained from the proposed projects will provide an innovative approach to assessment of key elements to successful aging in place for older adults with cognitive impairment through person-environment fit. Additionally, the clinical trial proposed will offer insights to an innovative approach to improve in home care and the caregiving experience for those with Alzheimer's disease and related dementias within the rural, Appalachian context. Cumulatively, this knowledge will allow for the next phase in intervention development leading toward implementation of the person-environment fit framework to maximize quality of life and wellbeing within the home for this population. Benefits and knowledge gained are reasonable in relation to the low risk of participation in this study.

Available Alternative Opportunities/Treatments

Describe alternative treatments or opportunities that might be available to those who choose not to participate in the study, and which offer the subject equal or greater advantages. If applicable, 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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Records, Privacy, and Confidentiality

Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Specify who will have access to the data/specimens and why they need access.

Describe how data will be managed after the study is complete:

- If data/specimens will be maintained, specify whether identifiers will be removed from the maintained information/material.
- If identifiers will not be removed, provide justification for retaining them and describe how you will protect confidentiality.
- If the data/specimens will be destroyed, verify that this will not violate retention policies and will adhere to applicable facility

requirements.

If this study will use de-identified data from another source, 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 collaborators not affiliated with UK.

For additional considerations:
Return of Research Results or Incidental Research Findings
HIPAA policies
FERPA policies
Procedures for Transfer agreements
Information regarding multi-site studies
NIH Genomic Data Sharing (GDS) Policy
Digital Data

Video recordings will be collected of all intervention sessions, and audio recordings will be collected of focus group sessions. These will be recorded using Zoom platform and saved on a secure share drive maintained by Sanders-Brown Center on Aging. This recordings will be used to validate the fidelity of the study intervention among interventionists (occupational therapists).
Existing records of PHI will be used for recruitment purposes to identify eligible participants from the Kentucky Neuroscience Institute and the Sanders-Brown Center on Aging longitudinal cohorts.
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 [redacted] 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.

NIH Data and Resources Sharing Plan
This pilot project will include data from a community-based sample of 40 informal caregivers of persons living with moderate to severe dementia. In line with the official protocol of the Roybal Translational Research Center to Promote Context-Specific Caregiving Mastery for Informal Caregivers of Community-Dwelling Persons Living with Alzheimer's Disease at Emory University, the dataset will include common measures of caregiver self-efficacy and mastery developed by Perlin and colleagues as well as certain demographic data. These data will be deposited in the Center data repository and stored in PI [redacted] at the University of Kentucky. Data from this pilot study will be available to qualified researchers through a data sharing agreement that is fully consistent with NIH data sharing policies and applicable laws and regulations as well as official policies and practices established by the Roybal Center at Emory. These data will be made available no later than the on-line publication date of the main findings from the final dataset.
Following our IRB protocol, each participant, will be assigned a participant number and pseudonym upon enrollment in the study, 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 Pharmaceutical Complex building at the University of Kentucky. Although these data will be de-identified prior to release for sharing, there remains a possibility of deductive disclosure of participants with unusual characteristics. Therefore, this data sharing agreement will require: 1) a commitment only to use the data for research purposes and not to identify any individual participant; 2) a commitment to securing the data using appropriate computer technology; and 3) a commitment to destroy or return the data after analyses are completed.
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 Pharmaceutical 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 ([redacted]). 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.

Protection regarding possible risks of environmental modifications:
The interventionist (occupational therapist) will continuously monitor for sensory overload or psychosocial stress and burden in the PLWD and/or their caregiver during the training sessions. Caregivers will be trained to assess themselves and their PLWDs for any signs of discomfort, sensory overload, or skin irritation, distress or anxiety. Caregiver response will likewise be monitored during research interviews. If a participant/caregiver shows signs of distress or anxiety, the interventionist will provide the participant/caregiver with a break. If the participant wishes to proceed then another topic may be discussed, if not the interview or observation will be rescheduled for a different date.

UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Do you confirm that you will retain all IRB-related records for a minimum of 6 years after study closure?

◉ Yes ○ No

Payment

Describe the incentives (monetary or other) being offered to subjects for their participation. If monetary compensation is offered, indicate the amount and describe the terms and schedule of payment. Please review this guidance for more information on payments to subjects, including restrictions and expectations.

Participants will not receive any monetary compensation.

Costs to Subjects

Include a list of services and/or tests that will not be paid for by the sponsor and/or the study (e.g., MRI, HIV). Keep in mind that a subject will not know what is "standard" – and thus not covered by the sponsor/study – unless you tell them.

There are no costs associated with taking part in 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, 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, 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.

We have attached our data safety monitoring plan in the attachment section of this application.

1.0 PARTICPANTS SAFETY
1.1 Potential Risks and Benefits for Participants
Potential Risks:
This study poses minimal risk. There is minimal risk associated with potential breach of privacy and confidentiality. There is possible stress linked to carrying out the environmental modifications in addition to regular caregiving activities and possible emotional distress associated with research interviews. Some of the modifications to the sensory environment may include the use of topical lotions. It is minimally possible that these may cause skin irritation, rash, or dermatitis.
Potential Benefits:
It is unknown if this study will create notable benefits. However, some individuals have experienced improved relationships with those they care for, and empowered decision making while caregiving. Patients may experience relaxed moods with decreased occurrence of behavioral disruption when participating in activities included in this study.
1.2 Adverse Event and Serious Adverse Event Collection and Reporting
The only expected possibly deleterious outcomes for informal caregiver participants are minor and transient emotional upset experienced while participating in program modules, research surveys and interviews, as well as possible breach of confidentiality. The other possible deleterious outcomes for the caregiver are those related to minor skin irritation.
1.2.1 Adverse Event (AE):
Any untoward or unfavorable medical occurrence in a human study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participant's involvement in the research, whether or not considered related to participation in the research. As noted above, the only expected AEs with possibly deleterious outcomes for this study are risks of minor and transient emotional upset experienced while participating in program modules, research surveys and interviews, as well as possible breach of confidentiality. The other possible deleterious outcomes for the caregiver are those related to minor skin irritation.
1.2.2 Serious Adverse Event (SAE):
Any adverse event that:
Results in death
Is life threatening, or places the participant at immediate risk of death from the event

as it occurred
Requires or prolongs hospitalization
Causes persistent or significant disability or incapacity
Results in congenital anomalies or birth defects
Is another condition which investigators judge to represent significant hazards
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No Serious Adverse Events are expected. This is a very low risk study, principally involving participants being asked to participate in an online program designed to enhance their caregiving self-efficacy and mastery in assessing and modifying the care environment in ways that promote greater and more satisfying behavior in the person for whom they provide care.
The study also involves caregivers in pre-post intervention surveys and, for some caregivers, qualitative focus group discussions on Zoom platform.
1.2.3 Unanticipated Problem (UP):
Defined by DHHS 45 CFR part 46 as any incident, experience, or outcome that meets all of the following criteria:
Unexpected, in terms of nature, severity, or frequency, given (a) the research
procedures that are described in the protocol-related documents, such as the IRB approved research protocol and informed consent document; and (b) the
characteristics of the study population;
Related or Possibly Related to participation in the research (in this guidance
document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research);
Suggests that the research places participants or others at a greater risk of harm(including physical, psychological, economic, or social harm) than was previously known or recognized.
1.2.4. Reporting Timelines
Any unanticipated Serious Adverse Event (SAE) related to the intervention will be reported to the NIA Program Officer and the Safety Officer within 48 hours of the study team's knowledge of the SAE.
Any Unanticipated Problem (UP) involving risks to study participants or others will be reported to the NIA Program Officer within 48 hours of the study team's knowledge of the UP.
The study will provide the NIA Program Officer and the Safety Officer with quarterly reports of any Adverse Events occurring during the study.
1.3 Protection Against Study Risks
Informed Consent Process. Consent for participation will be obtained by the PI ([redacted] or study coordinator following a University of Kentucky IRB-approved consent process. The purpose, nature, and duration of the study and the parts they will be asked to play in it will be explained to the caregiver. The consent process will provide information about the possible risks and benefits of participation. The process will indicate that participation is voluntary and that the individuals have the right to withdraw from the study at
any time; it will also inform caregiver participants about honoraria associated with participation in the research surveys and interviews. The risks will be explained and opportunity for questions provided throughout the process. Participants will be assured that participation or nonparticipation of this study will have no direct effect on enrollment or participation in any Sanders-Brown Center on Aging (SBCoA) or University of Kentucky program or healthcare
DSMP Template Updated 4 September 2019 3 services. A copy of the consent form will be emailed or mailed to the participants prior to Visit 1.
Protection Against Risks.
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 Pharmaceutical Complex building at the University of Kentucky. The files will be stored for a period of six years 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. 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.
Protection regarding possible risks of environmental modifications. The interventionist will continuously monitor for sensory overload or psychosocial stress and burden in the PLWD and/or their caregiver during the training sessions. Caregivers will be trained to observe themselves and their PLWDs for any signs of discomfort, sensory overload, or skin irritation, distress or anxiety. Caregiver response will likewise be monitored during research interviews. If a participant/caregiver shows signs of distress or anxiety, the researcher will provide the participant/caregiver with a break. If the participant wishes to proceed then another topic may be discussed, if not the interview or observation will be rescheduled for a different date.
INTERIM ANALYSIS
No interim analysis is planned
2.0 Data and Safety monitoring
The project PI [redacted] will be responsible for ensuring participants' safety in this minimal risk, single-site study. Because this study is being conducted at a single site, involves fewer than 200 subjects, and is not a phase III clinical trial, it does not require a Data Safety and Monitoring Board. Instead, [redacted] (a physician) has agreed to serve as the Safety Officer for the project.
3.1 Frequency of Data and Safety Monitoring
The PI will be informed of any deaths as soon as they occur and will notify the NIA Program Officer and the Safety Officer (SO) within 24 hours of notification; the PI will also inform the IRB of any such events within the time frame specified by the IRB. Beginning with the initiation of the intervention study activities, the PI [redacted]) will be responsible for providing quarterly summary reports of SAEs to the NIA Program Officer and the SO. Beginning with the
initiation of intervention study activities, safety reports will be sent to the SO twice a year and will include a detailed analysis of study progress, data and safety issues. Such reports will be developed by the PI and Co-I but reviewed by key study personnel and, as

appropriate, study consultants and advisors.

3.2 Data Analysis and Coordination
All quantitative data will be stored in a REDCap database. Data from individual subjects will be deidentified and stored using ID numbers; the document linking subject names and ID numbers will not be part of that database but will be stored in secure server at Sanders-Brown Center on Aging in a password-protected file. Qualitative data transcripts will be de-identified and also stored on this server in password-protected files. Transmission of de-identified study data will occur over secure emails messages. Data management and analysis will be conducted by [redacted] PhD, project CO-I.
Study participants will receive a 1 to 2 page summary of study results either by mail or email, depending on the preference, prior to destroying participant contact information.

3.3 Content of Data and Safety Monitoring Report
The study PI [redacted]) will provide semi-annual data safety and monitoring reports to the NIA Program Officer and the SO. Each report will update the previous report. Each report will summarize:
Overall study status
Study participant characteristics
Study recruitment and retention statistics
Data completeness
Summary statistics on caregiver and care recipient outcome measures
Deployment of the risk protocol based on observations or scale scores
Unanticipated Serious Adverse Events, including Deaths.

3.4 DSMB Membership and Affiliation
The Safety Officer for this study will be:
[redacted]
College of Medicine
University of Kentucky

[redacted] is a seasoned physician with extensive knowledge of clinical trial, as well as clinical research involving stroke and epilepsy, similar to dementia research. Through the UK College of Medicine, she has at her disposal a variety of methodological and statistical experts, should she need them to fulfill my responsibilities as Safety Officer.

3.5 Conflict of Interest for DSMB/SO
[redacted] has no direct involvement with the current study; her biosketch indicating that she has no conflict of interest is attached.

3.6 Protection of Confidentiality
Data will be presented in a de-identified manner in SO reports. In meetings with the SO, data and discussion are confidential. Participant identities will not be known to the SO.

3.7 DSMB/SO Responsibilities
The SO will:
Review the research protocol, informed consent documents and plans for data safety and monitoring; Recommend subject recruitment be initiated after receipt of a satisfactory
protocol; Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, performance of the trial sites, and other factors that can affect study outcome; Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial; Review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator; Protect the safety of the study participants; Report to NIA on the safety and progress of the trial; Make recommendations to the NIA and the Principal Investigator concerning
continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study; If appropriate, review interim analyses in accordance with stopping rules, which are clearly defined in advance of data analysis and have the approval of the SO; Ensure the confidentiality of the study data and the results of monitoring; and,
Assist the NIA by commenting on any problems with study conduct, enrollment, sample size, and/or data collection.

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Future Use and Sharing of Material (e.g., Data/Specimens/Information)

If the material collected for this study will be used by members of the research team or shared with other researchers for future studies, please address the following:

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research
- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used
- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

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N/A

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

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.
When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

The PI is required to identify someone who is willing to serve as the cultural consultant to the IRB.

- This 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 be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who agrees to be the cultural consultant for your study.
- ORI staff will facilitate the review process with your consultant. Please do not ask them to review your protocol separately.

For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

Local Requirements:

If you will conduct research at an international location, identify and describe:

- relevant local regulations
- data privacy regulations
- applicable laws
- ethics review requirements for human subject protection

Please provide links or sources where possible. If the project has been or will be reviewed by a local ethics review board, attach a copy in the "Additional Information/Materials" section. You may also consult the current edition of the International Compilation of Human Research Standards

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Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis (**
○ 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:

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

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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	WoA Approval Letter - IRB# 66767.pdf
Waiver	Form K 6-24.pdf

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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 Investigational Drug Service (IDS) pharmacies (Oncology or Non-Oncology). 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.

Complete and attach the required Study Drug Form picking "Study Drug Form" for the document type. Any

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applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA co
etc.) should be attached using "Other Drug Documentation" for the document type.

Attachments

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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 SOP.

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Does the intended use of any research device being tested (not clinically observed) in this study meet the regul
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.

Complete and attach the required Study Device Form, picking the "Study Device Form" for the document type. Any applicable device documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.) should be attached using "Other Device Documentation" for the document type.

Attachments

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RESEARCH SITES

0 unresolved comment(s)

To complete this section, ensure the responses are accurate then click "SAVE".

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

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), including:

- 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.
- Supportive documentation, including letters of support, can be attached below.
- NOTE: 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. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK

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sites.
- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

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

Describe the role of any non-UK site(s) or non-UK personnel who will be participating in your research.

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, describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites:

C) If your research involves collaboration with any sites and/or personnel outside the University of Kentucky, then it is considered multisite research and IRB reliance issues will need to be addressed. This may include national multi-center trials as well local studies involving sites/personnel external to UK. If you would like to request that the University of Kentucky IRB (UK IRB) serve as the lead IRB for your study, or if you would like the UK IRB to defer review to another IRB, please contact the IRBReliance@uky.edu.

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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

	For additional requirements and information:
☐ Academic Degree/Required Research	• Cancer Research (MCC PRMC)
☐ Alcohol/Drug/Substance Abuse Research	• Certificate of Confidentiality (look up "Confidentiality/Privacy...")
☐ Biological Specimen Bank Creation (for sharing)	• CCTS (Center for Clinical and Translational Science)
☐ Cancer Research	• Clinical Research (look up "What is the definition of....)
☐ CCTS-Center for Clinical & Translational Science	• Clinical Trial
☐ Certificate of Confidentiality	• Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...")
☑ Clinical Research	• Collection of Biological Specimens (look up "Specimen/Tissue Collection...")
☐ Clinical Trial - Phase 1	• Community-Based Participatory Research (look up "Community-Engaged...")
☑ Clinical Trial	• Data & Safety Monitoring Board (DSMB)
☐ Collection of Biological Specimens for internal banking and use (not sharing)	*For Medical IRB: Service Request Form for CCTS DSMB
☐ Community-Based Participatory Research	• Data & Safety Monitoring Plan
☐ Deception	• Deception*
☐ Educational/Student Records (e.g., GPA, test scores)	*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)	• Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
☐ Gene Transfer	• Genetic Research (look up "Specimen/Tissue Collection...")
☐ Genetic Research	• Gene Transfer
☐ GWAS (Genome-Wide Association Study) or NIH Genomic Data Sharing (GDS)	• HIV/AIDS Research (look up "Reportable Diseases/Conditions")
☐ Human Cells, Tissues, and Cellular and Tissue Based Products	• Screening for Reportable Diseases [E2.0000] (PDF)
☐ Individual Expanded Access or Compassionate Use	• International Research (look up "International & Non-English Speaking")
☐ International Research	• NIH Genomic Data Sharing (GDS) Policy (PDF)
☐ Planned Emergency Research Involving Exception from Informed Consent	• Planned Emergency Research Involving Waiver of Informed Consent*
☐ Recombinant DNA	*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"
☐ Registry or data repository creation	• Use, storage and disposal of radioactive material and radiation producing devices
☐ Stem Cell Research	
☐ Suicide Ideation or Behavior Research	
☑ Survey Research	
☐ Transplants	
☐ Use, storage and disposal of radioactive material and radiation producing devices	
☐ Vaccine Trials	

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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 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
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist
- (EPA) Environmental Protection Agency

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.):

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

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The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other
(See DoD SOP and DoD Summary 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)

Assurance/Certification Attachments

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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 attach form
- Radioactive Drug Research Committee (RDRC)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)** - Attach MCC PRMC materials, if any, per instructions.
- Office of Medical Education (OME)
- Graduate Medical Education Committee (GME)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send 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 PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

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ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

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

Approval Letter Details:

If you wish to have specific language included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type that language in the box below exactly as it should appear in the letter. The text you enter will automatically appear at the top of all approval letters, identical to how you typed it, until you update it. Don't include instructions or questions to ORI staff as those will appear in your approval letter. **If these details need to be changed for any reason, you are responsible for updating the content of this field.**

Additional Materials:

If you have other materials you would like to include for the IRB's consideration, check all that apply and attach the corresponding documents using the Attachments button below.

- ☑ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☑ Other Documents

Protocol/Other Attachments

Attach Type	File Name
Other	UKY IRB 66767_IIA[redacted]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.

To view the materials currently attached to your application, click “All Attachments” on the left menu bar.

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SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

All IRB applications require additional assurances by a Department Chairperson or equivalent (DA), and when applicable, a Faculty Advisor or equivalent (FA). This signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. The person assigned as DA *should not* also be listed in the Study Personnel section, and the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, refer to "What does the Department Chairperson's Assurance Statement on the IRB application mean?"

For a detailed illustration of how to complete this section, please review the short online video tutorial "Signatures (Assurance) Section - How to Complete." Otherwise, follow the steps below.

Required Signatures:

First Name	Last Name	Role	Department	Date Signed	
[redacted]	[redacted]	Department Authorization	Department of Neuroscience	05/21/2021 12:25 PM	View/Sign
[redacted]	[redacted]	Principal Investigator	Sanders-Brown Ctr On Aging	05/21/2021 11:39 AM	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.

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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 cannot be sent to the Office of Research Integrity/IRB.

If applicable, remember to update the Approval Letter Details text box under the Additional Information section

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 you will receive a message 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.

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Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	DeterminationLetter	Letter.pdf		0.126	jchine2	7/17/2023 7:27:23 AM
	ProtocolPdf	Protocol_Approval.pdf		1.954	jchine2	5/22/2023 8:29:49 AM
	Stamped Consent Form	Consent Patient 7-28-21 clean.pdf		0.303	jchine2	5/22/2023 8:28:43 AM
	Stamped Consent Form	Consent CAREGIVER clean 12-12.pdf		0.193	jchine2	5/22/2023 8:28:43 AM
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	AdditionInfoConsiderations	[redacted] Signed_ Exemption Certification Letter.pdf	[redacted] IRB Exemption form	0.268		1:45:12 PM
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Protocol Changes

Protocol Nu[illegible]

No Changes
There are no recorded changes tracked for this protocol.

Study Personnel Changes:

No Changes
There are no recorded changes to study personnel.

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No comments