Document Coversheet

Study Title: Seed-alter Dyad Social Support Intervention for Rural Dwelling Older Adults With T2DM

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	6/12/2024
NCT Number:	NCT04568486
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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.

For guidance, see:

- Which IRB?
- Which Protocol Process Type?
- "Getting Started"

Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions prior to saving your selections.

Which IRB

(•) Medical ( ) NonMedical

Protocol Process Type

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

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

EXPEDITED CERTIFICATION

0 unresolved comment(s)

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

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

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

Check the appropriate categories that apply to your research project:

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

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

A. Research on drugs for which an investigational new drug application 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:

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.)

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.

Change in study personnel.

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

Social Network Analysis and Social Support Intervention for Older Rural Dwelling Adults with T2DM

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.

STUDY 2: Rural Dwelling Older Adults with T2DM

Anticipated Ending Date of Research Project: 3/31/2024

Maximum number of human subjects (or records/specimens to be reviewed) 262

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

Are you requesting that the UK IRB serve as the lead IRB for a multi-site study, **OR** that the UK IRB defer review to another IRB? [Click here for "IRB Reliance" help]
○ Yes ◉ No
If "Yes," before completing your IRB application, fill out the Reliance Request Form and submit it to irbreliance@uky.edu.

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:	Brittany	Room# & Bldg:	2195 Harrodsburg Rd Suite 125
Last Name:	Smalls	Speed Sort#:	40504
Middle Name	L		
Department:	Family and Community Medici…	Dept Code:	7H460
PI's Employee/Student ID#:	12224507	Rank:	Assistant Professor
PI's Telephone #:	859-323-4619	Degree:	PhD, MHSA, MSHPsych
PI's e-mail address:	Brittany.Smalls@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	1/1/2023
		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

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.

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

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 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

"Seeds", Older adult population: Type 2 diabetes patients in Kentucky, recruited from the Barren River Area Development District (BRADD), Community Action Southern, and Barnstable Brown Diabetes Center. Study eligibility includes: (1) confirmed diagnosis of T2DM via electronic medical record; (2) age =55 years; (3) able to provide consent; and (4) have had at least one clinic visit in the past year. These individuals will participate in the semi-structured interviews of Aim 2 to evaluate and understand current social support.

"Alters", Community Health Workers population: As a result of social network analysis of individual older adults (seeds) in Aim 1, a member of the social network (alter) will be identified to participate in the intervention as a seed-alter dyad (N=262) social support intervention. Alter eligibility includes: =18 years of age, able to provide informed consent, has at least weekly contact with the seed.

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):

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:	1	1		
Asian:	0	1		
Black/African American:	1	2		
Latinx:	0	0		
Native Hawaiian/Pacific Islander:	0	0		
White:	125	131		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:	0	0		

If unknown, please explain why:

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

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_1Ai STUDY 2 Rural Dwelling Older Adults with T2DM.doc

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/HIPAA Combined Form	2.23.23_SeedConsent_Clean.pdf
Informed Consent/Parental Permission	2.22.23_AlterConsent_Clean.pdf

Informed Consent Process:

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.

All study personnel will be CITI/HSP certified and able to obtain consent. Both the seed and alter must give his/her own consent before participating in the intervention. Individuals will be consented prior to the start of the intervention, and will be able to participate immediately after giving consent. Consent will be documented using either REDcap electronic consent, or a physical consent form. Study personnel will read the informed consent to participants if they are unable to read, and will check for comprehension by asking knowledge check questions such as "Do you understand what you will be asked to do?" "After learning about the study, do you still want to participate?"
Should any subjects (Seeds, Alters) have complaints, they will be encouraged to contact the Principal Investigator, Brittany Smalls, PhD at 859-323-4619 or brittany.smalls@uky.edu. They can also send a letter to Dr. Smalls at 740 South Limestone, J530 Kentucky Clinic, Lexington KY 40536. They will also be provided the contact information for the University of Kentucky's ORI.

☐ 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.

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

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

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

☐ 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.

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	Active
Akwari	Kindness	Project Assistance/Support	SP	N	N		P	Y	08/30/2023	Y	N	01/24/2024	N	Y
Borgatti	Stephen	Data Analysis/Processing	SP	N	N		P	N	04/01/2021	Y	N	06/14/2019	N	Y
Douthitt	Key	Recruitment	SP	Y	N		P	Y	11/01/2023	Y	N	06/25/2020	N	Y
Feltner	Frances	Faculty Advisor	SP	Y	N		P	Y	07/13/2023	Y	N	07/09/2018	N	Y
Grissom	Zachary	Project Assistance/Support	SP	N	N		S	Y	08/06/2022	Y	N	03/20/2023	N	Y
Jackson	Ellis	Data Collection	SP	N	N		N	Y	03/03/3000		N	06/27/2023	N	Y
Khanal	Suraksha	Data Analysis/Processing	SP	N	N		P	Y	04/10/2023	Y	N	04/15/2024	N	Y
Kopelen	Victoria	Project Assistance/Support	SP	N	N		S	Y	12/03/2023	Y	N	01/24/2024	N	Y
Kruse-Diehr	Aaron	Data Analysis/Processing	SP	N	N		P	Y	02/21/2022	Y	N	02/10/2024	N	Y
Leshi	Oluwatosin	Project Assistance/Support	SP	N	N	PhD	N	Y	03/03/3000		N	01/18/2023	N	Y
Moser	Debra	Faculty Advisor	SP	Y	N		P	Y	04/05/2023	Y	N	07/09/2018	N	Y
Schaefer	Jill	Study Coordinator	DP	Y	Y		P	Y	04/05/2023	Y	N	01/24/2024	N	Y
Schoenberg	Nancy	Co-Investigator	SP	Y	N		P	Y	03/04/2024	Y	N	07/09/2018	N	Y
Adu	Akosua	Project Assistance/Support	DP	Y	Y		P	Y	08/22/2023	Y	Y	01/27/2020	N	Y
Bacha	Nicole	Study Coordinator	DP	Y	N		P	N	05/10/2021		Y	05/13/2022	N	N
Bateman	Emma	Project Assistance/Support	SP	N	N	Bachelors in Science Biology	S	N	01/03/2021	Y	Y	02/07/2024	N	Y
Coffey	Nicholas	Project Assistance/Support	SP	Y	N		P	Y	07/11/2022	Y	Y	01/13/2022	N	N
Combs	Ellen	Project Assistance/Support	SP	Y	N		P	N	05/29/2021		Y	01/13/2022	N	N
Cowley	Amy	Study Coordinator	DP	Y	Y		P	Y	07/31/2023	Y	Y	01/27/2020	N	Y
Gonzabato	Nelson	Data Analysis/Processing	SP	N	N		P	Y	08/25/2023	Y	Y	02/10/2024	N	N
Haney	Kimberly	Study Coordinator	DP	Y	Y		P	Y	04/25/2024	Y	Y	01/13/2022	N	Y
Martin	Nicole	Project Assistance/Support	SP	Y	N		S	N	03/30/2021		Y	01/13/2022	N	N
Mays	Alisha	Project Assistance/Support	SP	Y	N		P	Y	01/13/2023	N	Y	01/27/2020	N	Y
Nathoo	Tayla	Project Assistance/Support	SP	Y	N		P	N	10/06/2020	N	Y	01/13/2022	N	Y
Pearce	Kevin	Faculty Advisor	SP	N	N		P	Y	09/19/2022	Y	Y	06/14/2019	N	Y

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Smith	India	Project Assistance/Support	SP	Y	N		P	Y	04/08/2024		Y	04/27/2020	N	N
Taylor	Zoe	Study Coordinator	DP	Y	N	MSPH	P	Y	05/12/2022	Y	Y	06/10/2024	N	Y
Vundi	Nikita	Project Assistance/Support	SP	Y	N		P	N	11/25/2019		Y	01/27/2020	N	N

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).

Social support is well documented as having a significant, independent relationship with T2DM self-care. In rural environments social networks and social support may play a different role than in urban environments. In older rural-dwelling adults diagnosed with chronic disease have worse social function and emotional well-being than older adults living in urban areas. The proposed research will provide insight into the impact of social support within community- and individual-level social networks. Historically, social support has been defined by relational characteristics such as marital status and perceived social support. Yet, these characteristics do not adequately explain how relationships influence social support, health behaviors, and health outcomes. Social network analysis (SNA) is characterized as the examination and interpretation of relational connections. This approach can be used to map social networks and understand relationships between individuals as it pertains to social support. The preliminary data used for this K01 application was collected from the BRFSS where data is self-reported and its accuracy cannot be confirmed, and a dataset where social support was not the primary objective of the study and there was a small sample size all older adults. Yet, there remains a body of literature that substantiates the influence of social support on T2DM self-care and the disproportionate burden of T2DM in older adults. The proposed research will provide a comprehensive overview of the role of social support and how to leverage this support in a rural community.

Objectives

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

Describe and evaluate the impact of social support on self-care and clinical outcomes in rural-dwelling older adults with T2DM through semi-structured interviews (Aim 2). Test the feasibility and preliminary effectiveness of a 6-week intervention administered by the research coordinator targeting rural-dwelling older adults with T2DM (seed) and an individual within their social support network (alter) (Aim 3).

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

The study consists of two aims: For Aim 2, A mixed-methods approach will be used to map social networks of older adults and assess their perceived social support from members of their social network and determine its influence on self-care and clinical outcomes. In addition, through Aim 3, social networks will also be assessed to identify an individual within each older adult's network who can best facilitate optimal self-care. This person will form a dyad with the older adult to participate in a multilevel intervention which includes: gauging the feasibility of using community health workers identified via social network analysis, to conduct self-care sessions in rural communities and feasibility of seed-alter dyads to provide social support that improves self-care in older adults.

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

Seeds: Older adults will be primarily recruited from the University of Kentucky (UK) Center of Excellence in Rural Health clinic. Additional recruitment locations will include UK's Community and Family Medicine, Internal Medicine, Endocrinology, and Geriatric outpatient clinics as well as with community organizations associated with the Barren River Area Development District (BRADD). Dr. Key Douthitt, MD will identify eligible participants based on age (=55 years) and diagnosis of diabetes and send out recruitment letters to these participants providing an overview of the study and contact information. Additionally, our providers Dr. Ginny Gottschalk and Dr. Kelly Burgess have agreed to allow mailers to be sent to their eligible patients. Recruitment flyers will also be posted at all clinics involved in recruitment efforts and study information will be available via UK Center for Clinical and Translational Science website that is designed to assist investigators recruit eligible study participants.

Alters: As a result of social network analysis of individual older adults (seeds) in Aim 1, a member of the social network (alter) will be identified to participate in as a seed-alter dyad (N=262) social support intervention. Contact information for alters will be provided by the seed during Aim 1. Eligible alters will be mailed a recruitment letter from the principal investigator that provides an overview of the study and contact information. The seed and alter must be consented to participate in the intervention.
Seed: Recruitment letters signed by a primary care physician will be sent to eligible participants providing an overview of the study and contact information. Recruitment flyers will also be posted at the Center of Excellence in Rural Health and study information will be available via UK Center for Clinical and Translational Science website that is designed to assist investigators recruit eligible study participants.

Alter: Eligible alters will be mailed a recruitment letter from the principal investigator that provides an overview of the study and contact information.

Attachments

Attach Type	File Name
Advertising	University of Kentucky Research-3.pdf
Advertising	Social Network Analysis and Social Support Intervention.pdf
Advertising	University of Kentucky Research-2.pdf
Advertising	SNA_CMRecruitment.pdf
Advertising	SNA.EmailRecruitment.pdf
Advertising	SNA.GENFlyer.pdf
Advertising	Flyer (1).pdf
Advertising	Flyer_Highlighted.pdf
Advertising	Social Networks UPDATED Provider Letter_Gottschalk.pdf
Advertising	Recruitment Letter_UPDATED.BURGESS-1.pdf
Advertising	Recruitment Letter_UPDATED.highlighted.BURGESS-1.pdf
Advertising	Social Networks UPDATED.highlighted.Provider Letter_Gottschalk.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.

The PI will train research staff to administer the education sessions and the research staff will also be provided with a script to ensure fidelity. The research coordinator will provide 6, 1.5 hour self-care sessions using the Diabetes Reversal Outcomes Programs (DROP). Seed-alter dyads will participate in 6 weekly sessions will include modules the following modules: (1) Getting Started-Diabetes and Insulin Resistance, (2) Carbohydrates and Fats, (3) Physical Activity, (4) Proteins and Metabolism Hormones, (5) Oxidative Stress and Inflammation, (6) Epigenetic's, Weight Loss, and Reversal Strategy Wrap Up. The seed will complete the same validated questionnaires from Aim 2 and their clinical outcomes will be abstracted from their electronic medical records for each study visit and the member of the alter will complete validate surveys on social support and T2DM knowledge. Geriatric syndrome information and resources will be provided to seed-alter dyads based on identified risks as a result of validated questionnaires focused on geriatric syndromes.

Attachments

Attach Type	File Name
ResearchProcedures	Agenda- DEEPTraining.pdf
ResearchProcedures	79045_ResearchProcedures_581712 (1).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.

Data collection will be semi-structured interviews that will be audio-recorded, de-identified and transcribed verbatim. A semi-structured interview guide will be adapted from a previously published intervention assessing social networks and health behavior as well as informed by preliminary data and expert opinion of my team of mentors and advisors. Interviews will include two broad general questions asking “who” to map the social network of older rural-dwelling adults diagnosed with T2DM and “how” members of the social network provide social support; using open-ended questions to elicit maximal information with minimal bias. Interview questions will explore the follow domains (although additional domains may be identified during interview development): size and structure of social network; resources available through social network; and beliefs of those in social network regarding T2DM knowledge and self-care. A three question survey will be discharged post intervention to further assess community members perception of community leaders and the tentative role they could play in diabetes education.

For Aim 3, consent will be collected one of two ways. Using a phone script to initiate the informed consent process, potential participants have the option to complete consent using (1) a physical consent form (2) an electronic consent form using REDCap. After consent has been obtained, a research assistant (RA) will collect demographics, T2DM and geriatric risk assessment data, and baseline clinical outcomes (weight, height, pulse, systolic blood pressure, diastolic blood pressure, LDL, and Hemoglobin A1C levels) will be abstracted from electronic medical records of all seeds. The RA will administer the education sessions, which will ideally occur weekly. Once participants have completed the six education sessions, a summer SPARKS student will mail out an optional survey assessing social needs, as well as a self addressed return envelope should the participant choose to complete the survey. At the 6- and 12-month study visits the RA will obtain clinical outcomes and T2DM and geriatric assessments from all seeds. Alters will complete assessments on T2DM knowledge and social support at baseline, 6 and 12 months. These time points have been chosen because this provides enough time for participants to implement behavior changes that can result in meaningful changes in geriatric- and T2DM- specific assessments. Additionally, relevant clinical measures, specifically blood pressure, HbA1c, and lipid panel are clinically relevant for 6 months. Dyads will be given a booster session provided by RA at 6 months. These modules have been chosen because they reinforce understanding of what T2DM looks like on an individual level, practical ways to manage T2DM, and how to support those with T2DM. All self-care sessions and study visits will be held at designated community organizations—churches, senior centers, schools, and community centers. In the event that any of these assessments reflect a risk for a geriatric syndrome, the seed-alter dyad will be asked to contact the seed’s primary care provider (PCP), the PCP will be notified via research note the seed’s electronic medical record, and Dr. Stiles will follow up with all PCPs that are notified. At the 6-month study visit older adults will be asked to participate in a semi-structured interview as a follow up to the interview provided in Aim 2. The purpose of this interview to it

examine if the participants social network, social support, and information provided via social networks changed over time and if there is a relationship with their self-care adherence since baseline.

Attachments

Attach Type	File Name
DataCollection	E.J_Social Needs Questionnaire.docx
DataCollection	Study 2 Aim 3 PATIENT Assessment Tool.pdf
DataCollection	Evaluation survey questions.pdf
DataCollection	Evaluation survey questions_Clean.docx
DataCollection	Study 2 Aim 3 PATIENT Assessment Tool_Clean.pdf
DataCollection	75339_DataCollection_237366.pdf
DataCollection	75339_DataCollection_237366.pdf
DataCollection	Study 2 Aim 2_Community Networks Interview Guide_10 28 20.pdf
DataCollection	Charlson Comorbidity.pdf
DataCollection	Study 2 Aim 3 PATIENT Assessment Tool.pdf
DataCollection	Study 2 Aim 3 ALTER Assessment Tool.pdf
DataCollection	Orsmond and Cohn Feasibility interview packet.pdf
DataCollection	Study 2 Aim 3 PATIENT Assessment Tool.pdf
DataCollection	Study 2 Post-Intervention Questions.pdf
DataCollection	Study 2 Aim 3 PATIENT Assessment Tool.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.

All self-care sessions and study visits will be held at designated community organizations-- churches, senior centers, schools and community centers.

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, psychological or emotional, 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.

Potential Risk to participants are minimal as data collection involves: (1) confirmation of type 2 diabetes diagnosis using billing data and electronic medical records, (2) semi-structured interviews, (3) completion of questionnaires, and (4) electronic chart review (seeds) and collection of data in the form of validated questionnaires for both seeds and alters. Risks include potential loss of confidentiality. Efforts to reduce loss of confidentiality are outlined in the Confidentiality section.
No direct benefits are expected for the seeds and alters who participate in the semi-structured interviews. There is the potential benefit that may be experienced as the result of the intervention such as feelings of increased social support, improved clinical outcomes associated with T2DM diagnosis, and self-management education gained by both seeds and alters. Furthermore, recognition by study staff of significant stress or emotional strain in a seed or alter during an interview may prompt referral to a primary care physician or other health care provider who may provide clinical care to these subjects. The risks posed to the subjects in this study are minimal and are outweighed by the knowledge to be gained. Taken together, findings from this work will directly inform community-based research; help clinicians, policy-makers and members of social networks facilitate adherence to T2DM self-care in rural dwelling older

adults; and reveal targets to improve care for rural dwelling older adults living with complex chronic disease.

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).

Should subjects choose not to participate in the study, there is no alternative treatment offered. Subjects will be encouraged to seek standard treatment of care from their provider.

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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

Sources of research material include Electronic Health Records and medical billing information.

Information to be recorded includes: age, sex, race/ethnicity, marital status. Identity verification: prior to consent, all participants will be asked to complete a verification survey through RedCap detailing their name, birthday, best contact number, and best email address. If potential participants complete the verification survey but do not end up enrolling in the study, their verification survey data will be promptly removed from the studies RedCap. Health status: comorbidities (quantified using Charlson Comorbidity Index). Social support: The Medical Outcomes Study (MOS) Social Support Survey uses a 5-point Likert scale response to their perceived social support with a corresponding value to assess perceived social support. Primary outcome variables. Clinical outcomes: Hemoglobin A1c. Secondary outcome variables. Self-care: The Diabetes Self-Management Questionnaire is a 16-item questionnaire to assess self-care activities activity associated with glycemic control and has an internal consistency of 0.84. Medication adherence: Brooks Medication Adherence Scale is a 6-item scale with a reliability coefficient >0.69 and is sensitive to changes in adherence due to intervention. Quality of life—EuroQol-5D (EQ-5D) is validated measure of 5 dimensions of health-related quality of life including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

Seed characteristics: age, gender, race/ethnicity, education, employment status. Alter characteristics: age, gender, race/ethnicity, education, relationship to the participant. Social support: The Medical Outcomes Study (MOS) Social Support Survey uses a 5-point Likert scale response to their perceived social support with a corresponding value to assess perceived social support. Health status: comorbidities will be quantified using Charlson Comorbidity Index. Geriatric syndrome risk assessments: Cognitive impairment: Montreal Cognitive Assessment-Basic (MoCA-B) was developed to screen for mild cognitive impairment in elderly adults with low education and varying literacy and has a reliability coefficient of 0.91. Nutritional status: Mini-Nutritional Assessment (MNA) was designed and validated to provide a nutritional status in older adults patients in outpatient clinics, in hospitals, and nursing homes. The MNA measures adequate nutritional status, protein-calorie malnutrition, and risk of malnutrition. Frailty: Fried Frailty Index measures five domains of frailty based the definition provided by Fried et al. (2001): exhaustion, unintentional weight loss, low activity, slow walk, and grip strength in the elderly. Physical function: Lawton's Instrumental Activities for Daily Living Scale which evaluates the ability to independently use the toilet, feed, dress, groom, bath and perform physical ambulation. Fall risk: Get Up and Go Test89 requires rising from the chair and walking a short distance and walking back to the chair. The observer is asked to score the performance from 1 (normal—no evidence of fall risk) to 5 (severely abnormal—participant appeared at risk for fall during the assessment). Depression: Geriatric Depression Scale is sensitive to those suffering from mild cognitive impairment and physical illness. Quality of life: EuroQol-5D (EQ-5D) is validated measure of 5 dimensions of health-related quality of life including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D also includes a Visual Analogue Scale by which respondents can report their perceived health status ranging from 0 (the worst possible health) to 100 (the best possible health).
Data collected from validated questionnaires and clinical outcomes (abstracted from the electronic medical records) will be stored in

RedCap. All original data collection forms will only include assigned participant study IDs that were assigned at enrollment and stored in a locked cabinet, in a locked office in the UK Center for Health Services Research. Study participants who are older adults (seeds) will be asked to complete validated geriatric syndrome risk assessments at baseline, 6 and 12 months. During those assessments if it is determined that a seed is at-risk for a geriatric syndrome, a letter will be sent to their primary care provider alerting them of our finding. In that event, we will also recommend the seed to contact their primary care provider for further assessment. Additionally, a board-certified geriatrician (Dr. Stiles) included as an advisor on this grant, will follow-up with primary care providers who have been contacted as a result of our study findings to ensure that study participants receive appropriate standard of care for any identified geriatric syndromes. Additionally, to maintain fidelity among CHWs a structured manual will be created to carefully track fidelity to the protocol. The principal investigator along with the advisor in community health worker training (Dr. Feltner) will conduct random audits of CHW activities by visiting with them or calling participants to check on interaction and advice given.
This study will collect qualitative and quantitative data with minimal risk of requiring medical attention to the research participant. The semi-structured interviews will not inquire about personal health information of research participants. Research participants' audio files will be saved on an encrypted device and the information provided will be de-identified and transcribed by a member of the research team. All audio files will also be saved on the UK Center for Health Services Research password protected server. We do not anticipate that semi-structured interviews will be distressing, however in order to minimize risks to seeds and alters, the research assistant will be carefully trained by both Drs. Smalls and Schoenberg in interview techniques. In the unlikely event that a participant becomes overwhelmed or prefers not to continue the interview for any reason, the research assistant will be instructed to end the interview.

All staff involved in this proposal will have completed requisite training in the protection of human subjects as delineated by the Institutional Review Board of the University of Kentucky (UK). All study documentation will be stored in a locked area, accessible only to the PI, RA and other designated study staff. All interviews will be audio-recorded with the permission of the participant. The audio files will be transcribed using a trained transcriptionist within UK's Center for Health Services Research. Additionally, all desktop, laptop, and handheld devices are encrypted according to UK policies. Participants will be assigned a numerical code for identification in the files. Names and other identifiers will be kept in separate encrypted files accessible only to the investigators.

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.

Initial interview with Seeds and Alters: Participants will receive $20 for completing the interview and validated surveys.
Both the seed and alter will receive $15 for each study visit completed at baseline, 6 and 12 months.

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 cost to subjects other than the time required to attend the sessions.

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.

n/a, risk level 1

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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

No biological specimens will be obtained. All data will be de-identified and stored on a password-protected computer in the Department of Family and Community Medicine, suite 125 at Turfland Clinic (2195 Harrodsburg Road, Lexington, KY 40504). All audio recordings of interviews with potential CHWs will be stored on an encrypted and password-protected recording device, and de-identified during transcription by the research team. Data will be kept for 6 years after study closure and deleted per UK Policy A13-050 and A05-055. Per NIH requirements, all data will be made available upon request.

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

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?
○ Yes ◉ No

HIV/AIDS Research

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

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

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

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?
○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

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

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

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

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?
○ Yes ○ No

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

Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ◉ Yes ○ No

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

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

☐ HIPAA De-identification Certification Form
☐ HIPAA Waiver of Authorization

Attachments

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

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

Attachments

STUDY DEVICE INFORMATION

0 unresolved comment(s)

A DEVICE may be a:

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

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

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

○ Yes ◉ No

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

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

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

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

○ Yes ○ No

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

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

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

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

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

For guidance and reporting requirements at the conclusion of treatment see the Medical Device SOP.

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

- Yes. Device(s) being tested 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 being tested 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

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 (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 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:

Community centers, senior citizen centers, and churches.

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

When able, Dr. Leshi will observe study activities to include both baseline data collection and education sessions. Dr. Leshi is officially UK personnel. Ellis Jackson's role includes data collection and analysis using a social needs survey that will be sent to participants by mail.

Attachments

Attach Type	File Name
-Individual Investigator Agreement	UKY IRB 45777_IIA Leshi.pdf

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.

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

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

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

Other:

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.):

NIDDK

Add Related Grants

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

Add Related Grants

Grant/Contract Attachments

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

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.

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 45777_IIA Leshi.pdf
Other	Verification survey .docx
Other	20230203-09_PFFS_Smalls_UKentuckyCollegeMed.pdf
Other	UKY IRB 4577_IIA_Jackson.pdf
Other	Ellis.Certificate.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.

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	
Roberto	Cardarelli	Department Authorization	Family and Community Medicine	03/02/2020 10:56 AM	View/Sign
Brittany	Smalls	Principal Investigator	Family and Community Medicine	07/11/2018 11:42 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.

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.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.081	jchine2	6/12/2024 10:40:41 AM
	Stamped Consent Form	2.22.23_AlterConsent_Clean.pdf		0.145	jchine2	6/12/2024 10:40:41 AM
	Stamped Consent Form	2.23.23_SeedConsent_Clean.pdf		0.192	jchine2	6/12/2024 10:40:40 AM
	Advertising	Social Networks UPDATED.highlighted.Provider Letter_Gottschalk.pdf	Highlighted version	0.143	jlsc246	7/27/2023 8:21:03 AM
	Advertising	Recruitment Letter_UPDATED.highlighted.BURGESS-1.pdf	Highlighted version	0.206	jlsc246	7/27/2023 8:20:38 AM
	Advertising	Recruitment Letter_UPDATED.BURGESS-1.pdf	Updated provider Letter_Burgess	0.198	jlsc246	7/26/2023 3:19:12 PM
	Advertising	Social Networks UPDATED Provider Letter_Gottschalk.pdf	Updated provider Letter_Gottschalk	0.135	jlsc246	7/26/2023 3:16:09 PM
	DataCollection	E.J_Social Needs Questionnaire.docx	Social Needs Survey	0.019	jlsc246	6/29/2023 1:41:03 PM
	AddInfoProduct	Ellis.Certificate.pdf	Ellis.Jackson.Certificate of Completion	0.162	jlsc246	6/26/2023 2:49:11 PM
	AddInfoProduct	UKY IRB 4577_IIA_Jackson.pdf	Ellis Jackson IIA	0.223	jlsc246	6/26/2023 2:47:00 PM
	Advertising	Flyer_Highlighted.pdf	Updated recruitment flyer with changes highlighted.	0.570	jlsc246	5/17/2023 3:43:28 PM
	Advertising	Flyer (1).pdf	Updated recruitment flyer	0.566	jlsc246	5/17/2023 3:43:01 PM
	Informed ConsentHIPAA Combined Form	2.23.23_SeedConsent_Clean.pdf	Seed Consent Clean	0.183	zmta225	2/23/2023 3:55:41 PM
	Informed ConsentParental Permission	2.22.23_AlterConsent_Clean.pdf	Alter Consent Clean	0.137	zmta225	2/22/2023 12:38:45 PM
	DataCollection	Study 2 Aim 3 PATIENT Assessment Tool_Clean.pdf	Seed data collection tool clean	1.878	zmta225	2/22/2023 12:30:33 PM
	DataCollection	Evaluation survey questions_Clean.docx	Seed 2 post-intervention questions updated non highlighted	0.015	zmta225	2/22/2023 12:29:05 PM
	AddInfoProduct	20230203-09_PFFS_Smalls_UKentuckyCollegeMed.pdf	Permission to use recently updated frailty scale	0.630	zmta225	2/15/2023 10:32:29 AM
	DataCollection	Evaluation survey questions.pdf	Study 2 Post-Intervention Questions Updated	0.032	zmta225	2/15/2023 10:31:04 AM
	DataCollection	Study 2 Aim 3 PATIENT Assessment Tool.pdf	Seed Data Collection Tool	2.775	zmta225	2/15/2023 10:29:19 AM
	-Individual Investigator Agreement	UKY IRB 45777_IIA Leshi.pdf	Individual Investigator Agreement for Dr. Oluwatosin Leshi	0.296	zmta225	1/30/2023 8:15:24 AM
	AddInfoProduct	UKY IRB 45777_IIA Leshi.pdf	Documentation needed for addition of Dr. Leshi to IRB protocol.	0.296	zmta225	1/27/2023 3:11:39 PM
	Advertising	Social Network Analysis and Social Support Intervention.pdf	Case Worker Flyer for Recruitment	0.109	zmta225	11/3/2022 12:10:51 PM
	Advertising	University of Kentucky Research-3.pdf	Flyer and Email Recruitment	0.583	zmta225	11/3/2022 12:10:31

						PM
	AddInfoProduct	Verification survey .docx	This document will serve as a template for the RedCap verification survey.	0.013	zmta225	10/26/2022 8:57:08 AM
	Advertising	SNA.GENFlyer.pdf		0.568	zmta225	8/8/2022 11:07:39 AM
	Advertising	SNA.EmailRecruitment.pdf		0.394	zmta225	8/8/2022 11:06:14 AM
	Advertising	SNA_CMRecruitment.pdf		0.109	zmta225	8/8/2022 11:06:03 AM
	Advertising	University of Kentucky Research-2.pdf		0.567	zmta225	7/28/2022 10:31:16 AM
	DataCollection	75339_DataCollection_237366.pdf		0.157	zmta225	7/18/2022 2:03:08 PM
	DataCollection	75339_DataCollection_237366.pdf		0.157	zmta225	7/18/2022 1:00:19 PM
	ResearchProcedures	79045_ResearchProcedures_581712 (1).pdf		10.005	zmta225	7/14/2022 11:31:22 AM
	DataCollection	Study 2 Aim 3 PATIENT Assessment Tool.pdf		0.707	zmta225	7/13/2022 12:19:32 PM
	DataCollection	Study 2 Post-Intervention Questions.pdf		0.029	zmta225	7/12/2022 2:36:10 PM
	DataCollection	Study 2 Aim 3 PATIENT Assessment Tool.pdf		1.704	zmta225	7/12/2022 2:36:00 PM
	DataCollection	Study 2 Aim 2_Community Networks Interview Guide_10 28 20.pdf	Study 2 Aim 2 Interview Guide	0.164	klha226	10/28/2020 10:09:59 AM
	DataCollection	Orsmond and Cohn Feasibility interview packet.pdf	Feasibility follow-up interview packet	0.086	acmi238	8/14/2018 2:53:08 PM
	DataCollection	Study 2 Aim 3 ALTER Assessment Tool.pdf	Atler data collection packet	0.092	acmi238	8/14/2018 2:52:00 PM
	DataCollection	Study 2 Aim 3 PATIENT Assessment Tool.pdf	Patient data collection packet	0.660	acmi238	8/14/2018 2:51:24 PM
	DataCollection	Charlson Comorbidity.pdf	Charlson Comorbidity Index	0.157	acmi238	7/17/2018 11:11:14 AM
	ResearchProcedures	Agenda- DEEPTraining.pdf	DEEP Training Modules Agenda	0.591	acmi238	7/17/2018 11:09:28 AM
	ImpairedConsent	Form_T_1Ai STUDY 2 Rural Dwelling Older Adults with T2DM.doc	Form T Study 2	0.085	acmi238	7/9/2018 9:16:20 AM

Protocol Changes

Protocol Number: 45777

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

Study Personnel Changes:

Status	PPIdentity	ProtocolID	PersonID	RoleInProtocol	IsContact	LastName	FirstName	Email	DeptCode	RoomBuilding	SpeedSort	PhoneNum	DeptDesc	AuthorizedConsent	ResponsibilityInProject	Degree	Rank	StatusFlag	IsRemoved	ModBy	ModDate	SFI	IsPIRN	MiddleName
Deleted	874804	97093	12645778	DP	N	Taylor	Zoe	Zoe.Taylor@uky.edu						Y	Study Coordinator	MSPH		P	Y	blsm233	6/10/2024 11:18:47 AM	N		

No comments

Statistical Analysis Plan 45777

Study Overview: Data was collected at three-time points baseline, 6 months, and 12 months to assess the effect of intervention on primary and secondary outcome variables.

Descriptive statistics, change in mean score and correlation analysis was done. Sample characteristics were calculated for overall sample. Continuous variables were reported as mean and standard deviation while categorical variables were reported as frequency and percent for each time points. Pearson correlation analysis was done to assess the strength of relationship across difference time points between primary and secondary outcomes variables. Linear mixed effect model was done to analyze the change in primary outcome variable and secondary outcome variables mean score over time. Missing values were excluded from the analysis. Statistical Analysis was done in SAS v 9.4. A p-values of <0.05 was statistically significant.