

Document Coversheet

Study Title: Social Network Analysis to Identify Community Health Workers

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	10/26/2022
NCT Number:	NCT04210024
IRB Number	45657
Coversheet created:	7/11/2024

Which IRB

 Medical NonMedical

Protocol Process Type

 Exemption
 Expedited (Must be risk level 1)
 Full

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

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

Which IRB

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

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

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

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

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

Which Protocol Process Type

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

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

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

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

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



STUDY 1: Social network Analysis and Social Support Intervention for Rural Dwelling Older 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 1: Rural Dwelling Older Adults with T2DM

Anticipated Ending Date of Research Project: 10/1/2023

Maximum number of human subjects (or records/specimens to be reviewed) 200

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? 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.) to

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](#)

Participants (CHWs) must be over the age of 18.

Since this is a community-based participatory study, participants must be residents of Appalachia Kentucky to ensure they are knowledgeable of the community and will be able to provide names of other members in the community through snowball sampling.

Participants must have the ability to speak and understand English as the training they will be receiving will be in English, and the sessions they will be conducting should be in English as well.

Since participants will be conveying self-care information to others, they should be able to provide consent for himself/herself.

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
American Indian/Alaskan Native:	0	1	
Asian:	0	0	
Black/African American:	0	2	
Latinx:	0	0	
Native Hawaiian/Pacific Islander:	0	1	
White:	96	100	
American Arab/Middle Eastern/North African:			
Indigenous People Around the World:			
More than One Race:			
Unknown or Not Reported:			

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)

ADDITIONAL INFORMATION:

- 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

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

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 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**

Informed Consent Form (and/or Parental Permission Form and/or translated short form)

Assent Form

Cover Letter (for survey/questionnaire research)

Phone Script

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**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](#).

Each potential participant will be given a summary of the study and its purpose, and will be asked to provide their consent as a signature at the end of the informed consent document attached. Participants will not be asked to undergo training or provide sessions without first giving their consent to partake in the study.

If subjects should have complaints, they will be encouraged to contact Dr. Brittany Smalls at 859-323-4619 or Brittany.Smalls@uky.edu. Should they feel unsafe contacting Dr. Smalls, they are encouraged to contact the UK ORI at 859-257-9428

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.

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.

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

Workaround(s):

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

Background

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).

The World Health Organization along with the National Institutes of Health and the Institute of Medicine (IOM) have recognized the importance of addressing social determinants to reduce health disparities and improve health outcomes. Management of T2DM in older adults requires strategies that are individualized to address competing health needs, specifically geriatric syndromes. Because of the high rates of T2DM and devastating consequences, some segments of the population experience greater vulnerability to this disease. The prevalence of T2DM is 17% higher in rural-dwellers compared to their urban counterparts. The prevalence of T2DM in Kentucky's rural Appalachian counties is 13.6%, compared to the overall state prevalence of 10.6%. Appropriate self-care behaviors are necessary for optimal clinical outcomes in T2DM and account for 90% of the variance in glycemic control. Specifically, rural dwellers are exposed to challenging social environment factors, including high rates of poverty, limited access to needed healthcare services, and healthy foods, and social support that may not promote beneficial decision-making, which are barriers to self-care and optimal clinical outcomes. Older adults living with T2DM have more difficulty adhering to self-care regimens and social environment factors account for up to 85% of their self-care non-adherence compared to their younger counterparts. Notable social environment factors include self-efficacy, distress, and lack of social support. Specifically, social support plays a significant role in older adults with T2DM. The extent and type of social support that may be available in rural communities can positively or negatively impact self-care in older rural-dwelling adults. Social support is an important social environment factor to target in T2DM due to its well-established relationship with self-care. Yet, the mechanism by which social support and social networks influence T2DM self-care is unresolved.

Objectives

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

Our objective of this study is to recruit influential community members using Snowball Sampling Methods. We will train community members identified through social network analysis as influential and well-connected as community health workers using the Diabetes Empowerment Education Program (DEEP).

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.](#)

Community-based participatory research: We will include community members in the implementation and dissemination of this study. Community members will be recruited through snowball sampling, and will be trained to conduct Type 2 Diabetes self-managements sessions with older adults in their community.

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](#)

The proposed research employs the Integrated Behavior Model (IBM) to address fundamental drivers of behavior for older rural-dwelling adults with T2DM in the context of their social network. 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. We will use a snowball recruitment method to recruit participants in this study. In Aim 1, we will identify individuals who are connected to several individuals within their community and have the capacity to influence norms that hinder T2DM self-care. We will recruit 10 individuals who have received medical care from the Center of Excellence in Rural Health (CERH) within the past 12 months. Initial recruitment will be conducted by a community liaison in Appalachia Kentucky. This core group of 10 "seeds" will be used to conduct the first wave of interviews. Since the aim of social network analysis is to understand a community by mapping the relationships that connect them as a network, each seed will be asked to identify 3 persons believed to be influential in their community. Those who are identified in wave 1 will also be asked to identify 3 people each from their community who are also respected as leaders and can be trusted to provide health related information to community members. This process will continue for 4 waves of recruitment (N~200). Participants will receive \$15 for participating in an interview. To reduce risks in snowball recruitment in Aim 1, we will gently ask each seed and subsequent participants whether they would be willing to pass a recruitment/referral card to the 3 persons they identified as potential participants so these participants can contact the study principal investigator (PI) if they are interested in taking part in the study. We will let participants know that they will be asked to provide only the first name, last initial and occupation (or job title) of those 3 potential recruits, but that they have the right to decline to provide this information. We will also assure participants that no names will be used for recruitment, cold calls or included in any published materials.

Study participants and subsequent participants will be asked to pass a recruitment/referral card to the 3 persons they identified as potential participants so these participants can contact the study principal investigator (PI) if they are interested in taking part in the study.

Attachments

Attach Type	File Name
Advertising	Study 1 recruitment-referral card3 APPROVED.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.

Patients will be asked to identify 3 people from their community that they believe to be respected as leaders, seen as influential, and can be trusted to provide health-related information to community members. Participants identified as influential and interconnected through social network analysis will then be invited to partake in a 2.5-day training session (diabetes education), which will take place at designated community organizations. Participants will then be asked to conduct sessions with older adults living with Type 2 Diabetes in their community. Participants will be interviewed twice by a member of the research team to determine their progress and fidelity to the diabetes education curriculum and overall study protocol and objectives.

Attachments

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.

Participants will be asked to provide demographic information including age, sex, race/ethnicity, education, employment status, contact information (address, telephone number, email). An interview guide will be adapted from a previously published intervention assessing social networks and health behavior informed by preliminary data and the expert opinion of my team of mentors and collaborators. The interviews will begin with two broad general questions asking "who" is included in their social network 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 following domains: size and structure of social network; resources available through social network; beliefs of those in social network regarding general healthy behavior; knowledge of available healthy lifestyle choices; and perceived acceptable healthy behaviors (social norms). The first 5 participant interviews will be pilot interviews to ensure questions are acceptable, understandable and comprehensive.

Data will be collected from CHWs pre- and post-training to assess the following: T2DM knowledge: Diabetes Knowledge Questionnaire (DKQ) a 24-item survey that has a reliability coefficient of 0.78 and showed sensitivity to a T2DM knowledge intervention. Health literacy: Newest Vital Sign (NVS) is a 6-item survey to assess health literacy comprehension and numeracy. Means and paired t-tests will be conducted to determine if health literacy and T2DM knowledge improved in each CHW during the DEEP training.

Attachments

Attach Type	File Name
DataCollection	Community Networks Interview Guide draft Final updated 1.6.20.docx

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.

We will conduct the snowball sampling interviews at community organizations, including the Center of Excellence in Rural Health and Barren River Area Development District. Dr. Feltner has offered Dr. Smalls her assistance and access to the Center of Excellence on Rural Health and executive leadership of BRAADD have committed to providing support for this study. The diabetes education self-care program was selected due to its flexibility in choosing the order of modules presented to meet the needs of the community residents, it has been used in low-resourced populations and was shown to have positive behavior change, and includes a module that specifically highlights how to support family and friends with T2DM.

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.

There are no potential risks aside from potential breach of confidentiality to the community health workers. No health information will be collected, therefore a breach of confidentiality will not put health information at risk. Another potential risk is that participants will become tired or uninterested in delivering sessions to older adults with Type 2 Diabetes.

Benefits to the participants include a high level of satisfaction gained from providing their community members with self-care management education. Another benefit to the participant is improved employment opportunities relating to the training and experience they will receive as part of the study.

Available Alternative Opportunities/Treatments

Describe alternative treatments or opportunities that might be available to those who choose not to participate in the study, and which offer the subject equal or greater advantages. If applicable, this should include a discussion of the current standard of care treatment(s).

There are no alternative treatments available to the participants if they choose not to participate in the study.

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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](#)

Data will be collected from CHWs pre- and post-training to assess the following: T2DM knowledge: Diabetes Knowledge Questionnaire (DKQ) a 24-item survey that has a reliability coefficient of 0.78 and showed sensitivity to a T2DM knowledge intervention. Health literacy: Newest Vital Sign (NVS) is a 6-item survey to assess health literacy comprehension and numeracy. Means and paired t-tests will be conducted to determine if health literacy and T2DM knowledge improved in each CHW during the DEEP training.

Interviews with participants will be recorded.

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.

All precautions will be taken to keep participants safe. To secure against a potential breach of confidentiality, all audio and/or text files will be de-identified and kept on a password-protected secure server at the Department of Family and Community Medicine. No health information will be collected from community health workers. To keep community health workers engaged and to safeguard against them becoming uninterested in delivering sessions, community health workers will be compensated \$50 for each session they complete.

[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

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Payment

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

Participants (CHWs) will be compensated \$200 for completing the 20-hour (2.5-days) diabetes education training sessions. Participants will also be compensated \$50 per session they conduct with an older adult.

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 is no cost to subjects associated with the research other than their time.

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.



All members of the research team will be CITI trained for conducting human subjects research. The principal investigator and primary mentor will monitor the study to ensure that all potential risks remain minimal. All research team personnel will be provided a standard operating procedure manual that outline recruitment strategies, the informed consent process, and contact information for the University of Kentucky ORI. The study will not collect health information or health data, and the principal investigator will welcome any mock audits by the UK ORI to ensure study fidelity and ethical conduct.

Future Use and Sharing of Research Data

If the results of 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 de-identified data will be 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 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 will act as the cultural consultant for your study.

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

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:

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

Yes No

PI-Sponsored FDA-Regulated Research

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

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

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

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

Yes No

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

[Attachments](#)

HIPAA**0 unresolved
comment(s)**

Is HIPAA applicable? Yes No

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

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

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

[Attachments](#)

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

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



Attachments

RESEARCH SITES

0 unresolved
comment(s)

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

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

UK Sites

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

Schools/Education Institutions

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

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

Other Medical Facilities

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

- Correctional Facilities
- Home Health Agencies
- International Sites

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see [IRB Application Instructions - Off-Site Research](#) web page), including:

- A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the [IRB Application Instructions - Off-Site Research](#) web page for more information.
- Supportive documentation, including letters of support, can be attached below.
- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK

sites.

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

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

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

Attachments

Attach Type	File Name
-Individual Investigator Agreement	IIA blank.doc
-Individual Investigator Agreement	Eddens_57243_Individual Investigator Agreement_247238.pdf
-Individual Investigator Agreement	45657 Eddens IIA.pdf
-Letter of Support & Local Context	diabetes partnership letter.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

- Academic Degree/Required Research
- Alcohol/Drug/Substance Abuse Research
- Biological Specimen Bank Creation (for sharing)
- Cancer Research
- CCTS-Center for Clinical & Translational Science
- Certificate of Confidentiality
- Clinical Research
- Clinical Trial - Phase 1
- Clinical Trial
- Collection of Biological Specimens for internal banking and use (not sharing)
- Community-Based Participatory Research
- Deception
- Educational/Student Records (e.g., GPA, test scores)
- Emergency Use (Single Patient)
- Gene Transfer
- Genetic Research
- GWAS (Genome-Wide Association Study) or NIH Genomic Data Sharing (GDS)
- Human Cells, Tissues, and Cellular and Tissue Based Products
- 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
- Vaccine Trials

For additional requirements and information:

- [Cancer Research \(MCC PRMC\)](#)
- [Certificate of Confidentiality](#) (look up "Confidentiality/Privacy...")
- [CCTS \(Center for Clinical and Translational Science\)](#)
- [Clinical Research](#) (look up "What is the definition of....")
- [Clinical Trial](#)
- [Collection of Biological Specimens for Banking](#) (look up "Specimen/Tissue Collection...")
- [Collection of Biological Specimens](#) (look up "Specimen/Tissue Collection...")
- [Community-Based Participatory Research](#) (look up "Community-Engaged...")
- [Data & Safety Monitoring Board \(DSMB\)](#)

*For Medical IRB: [Service Request Form](#) for CCTS DSMB

- [Data & Safety Monitoring Plan](#)
- [Deception*](#)

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

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

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

- [Use, storage and disposal of radioactive material and radiation producing devices](#)

FUNDING/SUPPORT

0 unresolved
comment(s)

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

Not applicable

Check All That Apply

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

Other:

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

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

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

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.

Attach Type	File Name
GrantContract	PAR-18-418_NIDDK Mentored Research Scientist Development Award (K01-Clinical Trial Required).pdf