IMPORTANT NOTE:

If you accidentally select the wrong IRB type or "Protocol Process Type" while your Initial Review (IR) application is in draft form (unsubmitted), you may change your selections. Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions regarding your selections *prior* to submitting your Initial Review application.

If your **submitted IR application has been returned to you for requested revisions or additional information,** to streamline the review process **do not make changes** to your selections here **unless instructed to do so by the ORI/IRB.**

Changes to this section cannot be made after initial approval has been issued (the option is not available for MR or CR).

For guidance, see:

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

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.)

CONTINUATION REVIEW/FINAL REVIEW

0 unresolved comment(s)

In accordance with federal regulations and/or local policies, the IRB conducts periodic review of all currently approved projects. If you need your IRB approval to continue and you do not complete and submit the required materials in a timely manner, IRB approval will expire at the end of your current approval period.

If you have any questions, please contact the Office of Research Integrity at 859-257-9428 or email IRBsubmission@uky.edu.

To initiate your continuation review (CR)/annual administrative review (AAR), or properly close your study, complete this section and update/correct all other sections of your IRB application as applicable.
*****IMPORTANT*** Before leaving this page to update other sections of your application, be sure to SAVE this section first.**

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1. Status of the Research

Check the statement(s) that best describe(s) the current status of your research:

- ☐ No subjects have enrolled to date.
- ☐ Recruitment and/or enrollment of new subjects or review of records/specimens continue.
- ☐ Study is closed to enrollment, but subjects still receive research-related interventions (e.g., treatment, blood draws).
- ☐ Study enrollment is permanently closed; subjects have completed all research-related interventions; and the study remains active only for long-term follow-up of subjects (see Tool Tip above for info on long-term follow-up of subjects).*
- ☑ Research has progressed to the point that it involves 1) Data analysis, including analysis of identifiable private information or identifiable biospecimens; and/or 2) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.*
- ☐ The remaining research activities are limited only to data analysis. There is access to records or specimens either directly or through codes or links to the data.*
- ☐ The remaining research activities are limited only to data analysis. There is no subject/record/specimen identifying codes or links to the data; the researcher or research team cannot readily ascertain the subject's identity.*
- ☐ All study activities are complete. IRB approval can be inactivated.

*Possibility that review will move from Full to Expedited.

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2. If subjects have been enrolled within the last year, and the IRB approved a consent/assent form for your study:

Please attach a complete, signed copy for the last two subjects enrolled with **each** consent/assent form/HIPAA form since the last annual review.
(Example: If 3 different approved consent forms were used since the last annual review, please provide the two most recent signed copies of each version for a total of six.)

Attachments

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3. Informed Consent

If the study is **open to subject enrollment, please go to the Informed Consent section of the E-IRB Application and verify attachment(s) include:**

- One clean copy in PDF (without the IRB Approval stamp) of the currently approved consent/assent document(s), or,
- If requesting changes to the consent/assent document(s), submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted).

If the study is **open to subject enrollment and the IRB has waived the requirement to document informed consent, please go to the Informed Consent section of the E-IRB Application and verify attachment(s) include:**

- One clean copy in PDF of the currently approved document used for the informed consent process (e.g., cover letter, phone script), or,
- If requesting changes to the consent/assent document(s), submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted).

If the study is **closed to subject enrollment, please go to the Informed Consent section of the E-IRB Application and remove Informed Consent Documents designated to get an IRB approval stamp to avoid having them appear valid for enrollment.**

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4. Unanticipated Problems Involving Risk to Subjects or Others/Adverse Events Summary & Assessment

Did any **problems/adverse events** occur during the last 12 months?

○ Yes ◉ No

In the space below, provide a written summary of both unanticipated problems* and available information regarding adverse events since the last review (e.g., initial review or annual/continuing review). The amount of detail provided in such a summary will vary depending on the type of research being conducted; in many cases, such a summary could be a brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and investigator's brochure (if applicable). **The summary must include the PI's assessment whether the problems/adverse events warrant changes to the protocol, consent process, or risk/benefit ratio.**

Note: It is the IRB's expectation that all unanticipated problems involving risk to subjects or others or related deaths requiring prompt reporting are submitted in the appropriate time frame (See Policy [PDF]). Your response to this Annual/Continuing Review is considered assurance that all prompt reportable problems/adverse events have been submitted for IRB review.

*For multisite studies, the written summary should describe external events determined to be unanticipated problems involving risk to subjects or others.

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

Using Practice Facilitation and Operationalizing Referral Information Technology (UP FOR IT) to Increase DSMES Utilization

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.

UP FOR IT

Anticipated Ending Date of Research Project: 4/1/2026

Maximum number of human subjects (or records/specimens to be reviewed) 22

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:	Mary	Room# & Bldg:	111 Washington Avenue
Last Name:	Lacy Leigh	Speed Sort#:	40536
Middle Name	Elizabeth		
Department:	Dept Of Epidemiology - 7P170	Dept Code:	7P170
PI's Employee/Student ID#:	12466319	Rank:	Assistant Professor
PI's Telephone #:	8595621126	Degree:	PhD
PI's e-mail address:	mary.lacy@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	7/7/2023
		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..) 0 years to 100 years

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

The primary study population for this project is clinic staff and DSMES providers. Clinic staff and DSMES providers from the healthcare systems/geographic areas where our team implemented the first Diabetes Learning Collaborative will be the target population for Objective 1. Clinic staff and DSMES providers from healthcare systems/geographic areas where we are implementing UP FOR IT will be the target population for Objectives 2 and 3.

Patients with diabetes who receive care at clinics that are participating in the intervention are not considered human subjects because patient identifiers are not collected.

Objective 1: We will recruit key informants from two stakeholder groups: 1) clinic staff and clinicians who participated in the first Diabetes Learning Collaborative and 2) KDPH DSMES providers whose DSMES service catchment area included those clinical practices participating in the first Diabetes Learning Collaborative. Kentucky Regional Extension Cooperative staff who supported the first Diabetes Learning Collaborative will recruit two stakeholders from each of the five participating clinical practices (N=10) for surveys/key informant interviews. KDPH will aid in recruiting three DSMES providers from the regions where the first Diabetes Learning Collaborative took place. This will yield a total sample size for Objective 1 of 13 (n=10 clinic staff and n=3 DSMES providers). Kentucky Regional Extension Cooperative (KREC) staff who supported the first Diabetes Learning Collaborative and are study personnel will also be invited to participate in the key informant interviews including Vance Drakeford, Jessica Elliott, Michelle Hibbard, Brent McKune, and Kathryn Sabitus. There are no additional inclusion/exclusion criteria beyond prior participation in the Diabetes Learning Collaborative. The proposed start date for enrolling these participants is July 1, 2022 and the proposed end date is September 1, 2022.

Objective 2: The study population for Objective 2 is clinic staff from all clinics participating in UP FOR IT. Our partners at the Kentucky Regional Extension Cooperative have identified partner clinics in two healthcare systems in Kentucky (Big Sandy and Penny Royal, see LOS). We anticipate having between 5-6 participants at each of the 11 clinics that are participating in the intervention. This will yield a total sample size for Objective 2 of n=65 clinic staff. There are no additional inclusion/exclusion criteria beyond employment at a participating clinic. The proposed start date for enrolling these participants is October 1, 2022 and the proposed end date is November 30, 2022.

Objective 3: We will recruit key informants from two stakeholder groups: 1) clinic staff and clinicians who participated in the UP FOR IT intervention and 2) KDPH DSMES providers whose DSMES service catchment area included those clinical practices participating in UP FOR IT. Kentucky Regional Extension Cooperative staff will recruit two stakeholders from each of the 11 participating clinical practices from two healthcare systems (N=22) for surveys/key informant interviews. KDPH will aid in recruiting two DSMES providers from the regions where UP FOR IT took place. This will yield a total sample size for Objective 3 of 13 (n=22 clinic staff and n=2 DSMES providers). There are no additional inclusion/exclusion criteria beyond participation in UP FOR IT. The proposed start date for enrolling these participants is October 1, 2024 and the proposed end date is December 1, 2024.

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:				
Asian:				
Black/African American:				
Latinx:				
Native Hawaiian/Pacific Islander:				
White:				
American Arab/Middle Eastern/North				

African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:	39	39		

If unknown, please explain why:

We will be enrolling clinic staff/DSMES providers as our primary study population and patients as a secondary population (not human subjects). In Objective 1, we will enroll n=13 participants who are clinic staff/ DSMES providers. In Objective 2, we will enroll n=65 clinic staff/DSMES providers. Based on feedback from IRB/ORI and the fact that we will not collected any patient identifiers, patients are not considered human subjects.

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

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

- ☐ 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, in the text box below, 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

Will electronic consent form/process be utilized on-site or remotely for this study?

○ Yes ◉ No

If yes, in addition to addressing the above bullet points, describe the e-consent method and platform, including any hyperlinks, videos, or enhancements used to convey information, if applicable. Attach a representation of the e-consent with signature fields. For guidance, see the ORI E-Consent web page.

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.

Objective 1: We request a Waiver of Documentation of Informed Consent from clinic staff and DSMES providers that are recruited to participate in the surveys/interviews for Objective 1. The study team will conduct interviews via phone and will record the audio for purposes of later qualitative analysis.

Objective 2: We request a Waiver of Documentation of Informed Consent from clinic staff that are recruited to participate in the learning collaborative for Objective 2. The collaboratives will be conducted virtually. Patients are not considered human subjects as we are not collecting any patient identifiers.

Objective 3: We request a Waiver of Documentation of Informed Consent from clinic staff and DSMES providers that are recruited to participate in the surveys/interviews for Objective 3. The study team will conduct interviews via phone and will record the audio for purposes of later qualitative analysis.
Contact information for the PI and contact information for the UK Office of Research Integrity will be provided on the cover letters (for interview and survey) and the consent form. If participants wish to withdraw, their reasons will be reported to the PI, co-PI and study staff. If they have complaints or requests for information about the research, they will be directed to the contact information for the PI provided on their consent form. The consent form also contains contact information for the UK Office of Research Integrity, to which they might also offer their complaints and/or ask for more information in a safe, confidential, and reliable channel.

☐ 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.

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

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

☑ Request for Waiver of 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:

We are requesting a Waiver of Documentation of the Informed Consent Process for Objectives #1, #2 and #3 - REDCap surveys, phone interviews, and the learning collaborative. These activities present no more than minimal risk to the subjects.

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):

Cover letters and phone scripts are involved, no in-person contact. In the research section, the data safety and monitoring section indicates the primary study population will be consented in person; however, these individuals will now be consented over the phone using the attached phone script. The learning collaborative activities will be offered to these individuals virtually or in-person. The data safety and monitoring section is updated to reflect this change.

○ **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	Data Analysis/Processing	SP	N	N		P	Y	08/30/2023	Y	N	11/13/2024	N	Y
Drakeford	Vance	Recruitment	SP	Y	N		P	Y	06/09/2022	Y	N	07/11/2022	N	Y
Elliott	Jessica	Data Analysis/Processing	SP	Y	N	BA	P	Y	03/18/2022	Y	N	03/14/2022	N	Y
Hibbard	Karen	Data Collection	SP	Y	N	BS	P	Y	03/21/2022	Y	N	02/08/2022	N	Y
Keck	James	Co-Investigator	SP	N	N	MD	N	Y	03/03/3000		N	07/26/2023	N	Y
Kopelen	Victoria	Data Analysis/Processing	SP	N	N		P	Y	12/03/2023	Y	N	11/13/2024	N	Y
Kruse-Diehr	Aaron	Co-Investigator	DP	Y	N	PhD	P	Y	02/21/2022	Y	N	01/18/2022	N	Y
McKune	Brent	Co-Investigator	DP	Y	N	MBA	P	Y	03/10/2022	Y	N	02/08/2022	N	Y
Rabin	Adrienn	Consultant/Advisor	SP	N	N	PhD	N	Y	03/03/3000		N	11/02/2022	N	Y
White	Carol	Study Coordinator	DP	N	Y		P	Y	10/29/2024	Y	N	10/10/2022	N	Y
Wright	Laura	Project Assistance/Support	SP	Y	N		P	Y	03/30/2023	Y	N	03/30/2023	N	Y
Keck	James	Co-Investigator	DP	Y	N	MD	P	N	07/28/2020		Y	07/25/2023	N	Y
Luvisi	Mary	Data Collection	SP	Y	N	BS	P	Y	04/10/2022	Y	Y	03/25/2022	N	Y
Sabitus	Kathryn	Data Analysis/Processing	SP	Y	N		P	Y	06/21/2022		Y	03/30/2023	N	Y

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).

Rates of diabetes in Kentucky are among the highest in the United States (US) and rural areas of Kentucky experience even higher rates of diabetes and diabetes-related complications. From 2000 to 2020, the prevalence of diabetes in Kentucky more than doubled from 6.5% to 13.3%. Kentucky has the 7th highest prevalence of diabetes and the 4th highest rate of diabetes mortality in the US. Within Kentucky, rural areas face an even higher burden of diabetes and its related complications. While the statewide prevalence of diabetes is already among the highest in the nation, in Appalachia, the prevalence of diabetes exceeds 20% of the adult population.

Diabetes self-management education and support (DSMES) is an integral part of diabetes management. It is associated with a range of improvements in diabetes-related outcomes and reduction in diabetes-related healthcare costs, yet it is vastly underutilized. DSMES is an evidence-based service delivered by a credentialed diabetes educator that teaches people with diabetes how to effectively self-manage their disease. DSMES effectively provides individuals necessary skills to manage their diabetes; it is linked to better glycemic control, a reduction in mortality, and improved quality of life. In addition to its clinical effectiveness, DSMES is cost-effective and reduces the overall cost of care for people with diabetes. Driving its cost-effectiveness, DSMES is associated with better alignment with best practice diabetes treatment, lower claims costs, increased medication adherence, and decreased spending on inpatient care. However, despite strong evidence supporting DSMES and clear guidelines from the American Diabetes Association (ADA) recommending its use and specifying times when DSMES should be offered,12 DSMES is significantly underutilized. Recent estimates suggest that <10% of individuals with diagnosed diabetes have used DSMES. Further, studies suggest that rates of DSMES participation are even lower in rural populations.

Studies examining barriers to DSMES have identified a variety of reasons for DSMES underutilization including barriers at the heath system level, provider level and patient level. One of the fundamental barriers identified by the American Association of Diabetes Educators was lack of a DSMES referral from a provider. Referring a patient to DSMES necessitates clinician awareness and engagement, patient identification, a referral mechanism, and an available DSMES supplier, and barriers can and do occur throughout this process. The ongoing expansion of electronic health records (EHR) creates opportunities to more efficiently and comprehensively identify patients who could benefit from DSMES and supports electronic referral processes. A recent quality improvement study implemented an electronic DSMES referral process to identify and refer patients for DSMES at the four key time points recommended by the ADA, which, in combination with protocol training, increased DSMES referrals from 0% to 31%. The proposed study leverages unique statewide partnerships to implement and expand health information technology to automate patient identification and facilitate referrals to DSMES services. We hypothesize, however, that health information technology is necessary, but not sufficient, to drive DSMES utilization.

Availability of DSMES in Kentucky has increased but utilization remains low. As of 2019, there were 90 nationally recognized and accredited DSMES programs in Kentucky, which provided in-person classes in 80 of Kentucky's 120 counties. Healthy Living with Diabetes, an umbrella DSMES program administered by the Kentucky Department of Public Health (KDPH), is the largest DSMES program in the state. KDPH partners with 17 local health districts across Kentucky to provide free DSMES services in-person in 66 counties and via telehealth to residents in all 120 counties. The number of counties with DSMES services in Kentucky increased from 27 counties in 2012 to 80 counties in 2019. However, during this same period, annual DSMES participation decreased from a high of 14,545 participants in 2013 to 10,278 participants in 2019.

The KDPH DSMES program ameliorates several of the potential barriers, namely geographic access (all counties covered), cost to patient (free), and limited provider reimbursement (diabetes educators are government employees), suggesting that DSMES supply is not the limiting factor in DSMES utilization. Low DSMES demand is likely a larger driver of low DSMES utilization in Kentucky. Prior research found clinician referral to be a significant driver of DSMES uptake, such that strategies that target patient identification, bolster referral mechanisms, and increase clinician engagement and awareness should increase DSMES utilization in Kentucky.

Kentucky suffers from a high prevalence of diabetes and its associated complications. DSMES improves diabetes outcomes and is now widely available to Kentuckians but is vastly underutilized. Clinic and provider-level factors contribute to low DSMES utilization, and the Chronic Care Model provides a blueprint for clinics to identify and address DSMES barriers. Our study team has successfully used the Chronic Care Model to improve diabetes care in rural Kentucky clinics and will use this previous experience to plan, implement, and evaluate an intervention that utilizes health information technology and collaborative practice facilitation to increase DSMES utilization.

This project will yield an evidence-based implementation strategy that is scalable and sustainable and has the potential to reduce diabetes-related morbidity and mortality through efficient, systematic identification and referral of patients with diabetes to accredited and recognized DSMES providers.

Objectives

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

In this study, we propose implementing health information technology, including automated patient identification and bidirectional secure messaging between clinicians and DSMES providers, and using practice facilitation to address referral barriers and increase clinician awareness and motivation. We have partnered with KDPH (statewide DSMES provider), Kentucky Regional Extension Cooperative (KY-REC, practice facilitation partner), Kentucky Health Information Exchange (health information technology (HIT) partner) and two healthcare systems in rural Kentucky. Our proposal builds on a diabetes quality improvement collaborative facilitated by KY-REC and KDPH that demonstrated increased DSMES utilization. We will use a rigorous study design to evaluate implementation processes and effectiveness by testing the hypothesis that patient identification and referral strategies, bidirectional linkages between clinics and DSMES providers, and primary care clinician engagement will increase DSMES utilization through the following objectives:

Objective 1 – Planning: To use an established implementation science framework (PRISM) to identify determinants of DSMES uptake in Kentucky by interviewing previous DSMES quality improvement collaborative stakeholders, and to adapt the previous intervention using implementation mapping to connect stakeholder determinants to intervention strategies and outcomes.

Objective 2 – Implementation: To implement an intervention comprised of health information technology and a practice facilitation collaborative with two healthcare systems in rural Kentucky to increase DSMES referral rates and gather preliminary data for the planned R01 study.

Objective 3 – Evaluation: To evaluate the pragmatic implementability of the intervention by assessing the feasibility, acceptability, and sustainability of the intervention via stakeholder and participant survey, administrative and interview data.

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.

Objective 1 involves interviews with key stakeholder and implementation mapping to adapt the previously implemented Diabetes Quality Improvement Learning Collaborative (DLC) for maximal impact on DSMES utilization. We will engage clinical practices that participated in the initial collaborative (conducted by our partners at the Kentucky Regional Extension Cooperative) to learn what worked and where there are opportunities to improve the design and delivery of the DLC. Stakeholder input will inform the implementation mapping process. Key stakeholders we plan to interview include clinicians, clinic staff, and DSMES providers. Interviews will be conducted via phone and audio will be recorded. Guided by the PRISM framework, we will ask questions about the previous DLC implementation as well as hypothetical questions to guide necessary contextual adaptations for future administration. Specifically, we will explore organizational perspectives related to the DLC, characteristics of organizations that impacted/might impact the success of the DLC, ways in which the external environment impacted/might impact intervention success, and infrastructure needs to ensure implementation success. After collecting stakeholder input, we will use implementation mapping to identify objectives, barriers, and implementation determinants. These will then inform the adaptation of the DLC implementation strategies and lead to implementation protocols and evaluation plans. Data collected and synthesized in Objective 1 will refine and adapt this preliminary model for use in Objective 2.

Objective 2 is a pragmatic cluster randomized trial. We have partnered with two rural healthcare systems (one in eastern Kentucky and one in Western Kentucky) for this study. Two clinics from each system will be randomized to participate in the intervention (4 total intervention sites) and the remaining clinics will serve as the control sites. The intervention consists of health information technology (including an automated patient identification system and bidirectional e-referral system connecting clinics to the DSMES providers) and a practice facilitation collaborative. The collaborative is a structured, facilitated process that brings together teams from different organizations to learn from one another. The collaborative utilizes the Model for Improvement, a quality improvement approach designed by the Institute for Healthcare Improvement that uses rapid cycle quality improvement – repeated PDSA (plan do study act) cycles meant to identify care quality barriers and rapidly implement and measure change. Teams from intervention clinics will apply this quality improvement strategy to identify and address quality gaps in diabetes care and DSMES utilization at their clinics. Practice facilitators on the study team will provide individualized coaching (practice facilitation) to clinics in the intervention arm of the study. We will assess the effect of the interventions on DSMES referrals (primary outcome), by comparing rates of referrals between intervention and control clinics (clinics within the healthcare system not randomized to the intervention). Secondary outcomes include DSMES attendance, patient satisfaction and diabetes knowledge, A1c control, and intervention feasibility and acceptability.

Objective 3 involves surveys and interviews with clinic staff that participated in the intervention and DSMES providers from the geographic areas where the intervention took place. Interviews will be conducted via phone and audio will be recorded. The goal of Objective 3 is to understand how the various implementation strategies embedded within the practice facilitation collaborative and clinical context influenced DSMES uptake to inform future refinement for program replication and scale-up.

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

Objective 1: Kentucky Regional Extension Cooperative staff who supported the first Diabetes Learning Collaborative will recruit two stakeholders from each of the five participating clinical practices to participate in surveys and a key informant interview. KDPH will aid in recruiting three DSMES providers from the regions where the first Diabetes Learning Collaborative took place. Recruitment phone and email scripts are attached.

Objective 2: We have partnered with two healthcare organizations in Kentucky for this pilot study: Mercy Health (Mercy Health Marcum & Wallace and Mercy Health Primary Care Clinics (see LOS) and Pikeville Medical Center (see LOS). Both healthcare organizations are non-profit health centers that provide primary and preventive health care to underserved patients. Pikeville includes one participating clinic that is a federally qualified health center. Recruitment for the proposed study targets healthcare organizations in rural settings with multiple clinical sites to allow control and intervention clusters to be randomized at the clinic level within a healthcare organization. This strategy enables us to pilot our intervention in two distinct rural Kentucky settings where the population is disproportionately burdened with diabetes. We will use as control sites other clinics within the healthcare organization with similar patient populations and are of a similar size, location, and financial structure as the intervention site.

Objective 3: Kentucky Regional Extension Cooperative staff will recruit two stakeholders from each of the 11 participating clinical practices from two healthcare systems to participate in surveys and a key informant interview. KDPH will aid in recruiting two DSMES providers from the regions where UP FOR IT took place.
n/a

Attachments

Attach Type	File Name
Advertising	DSMES AIM 1 Recruitment Email_11.1.22.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.

Objective 1: A study team member not involved in the first DLC in will conduct the key informant interviews to minimize stakeholder and interviewer bias. Interview guides are attached. Interviews will happen via telephone and will be recorded; we will transcribe interviews for analysis. Based on these findings, key stakeholders and members of the research team will utilize the PRISM Assessment Tool (attached) a group-based action planning approach, to assess and address contextual domains for the implementation of an evidence-based intervention (DSMES) and select or adapt strategies that address key areas identified as being important and showing low alignment with the local context.

Objective 2: Baseline measures include patient demographics (sex, race/ethnicity, insurance coverage, rural/urban distribution), A1c control (mean A1c, % of patients with A1c >9%) and blood pressure. Clinics will also report number of DSMES referrals and DSMES attendance from the 9-month baseline period. In addition to baseline data, control and intervention clinics will generate monthly reports from their electronic health record system to track DSMES referrals and A1c control. DSMES attendance will also be reported by the clinics based on feedback data from the bidirectional referral system linking clinics with DSMES providers. All data will be examined at the clinic level and will be de-identified/aggregated to the clinic level prior to being shared with our study team. The following data is being extracted from patient electronic health records by clinic staff: DSMES referrals (% referred/% eligible at the clinic level), DSMES attendance (% attended/% referred at the clinic level), A1c Data (mean A1c levels and % with A1c >9% at the following time points will be extracted from electronic health record data and de-identified/aggregated into intervention vs control clinics as well as for the subset of patients within intervention vs control clinics that attended DSMES: baseline, monthly during the intervention and for the 6 months following intervention. In addition to the data being extracted from patients' electronic health records, we will also be receiving data from the DSMES providers on patient satisfaction with the class and diabetes knowledge. This outcome will be reported to the study team monthly for all patients from study clinics who attended DSMES classes during the 9-month study + 6 month follow-up period. Patient satisfaction and diabetes knowledge will be evaluated using de-identified data from patient surveys that are routinely collected by DSMES providers for all individuals immediately following DSMES attendance. KDPH will provide the study team with de-identified data for all patients from the two participating healthcare systems who attend DSMES (aggregated to the clinic level). All data used in Objective 2 is data that is routinely collected; no additional data will be collected as a part of the study.

Objective 3: We will use the same qualitative methods described in Objective 1 to analyze PRISM concepts, such as fidelity to the core components of the PFC and any necessary adaptations to either the PFC or to the selected implementation strategies (using the PRISM Assessment Tool, attached). To do so, we will conduct midpoint evaluations with program staff and other key stakeholders six months after initial program rollout as well as immediately upon conclusion. We will again use the PRISM survey and interview guide (see attachments: PRISM Assessment Tool and PRISM Interview Guide) to assess PRISM domains and provide context to understand the reasoning for any differences that exist between pre-implementation (i.e., anticipated) and midstream (i.e., unanticipated) adaptations. Two implementation scientists (Drs. Diehr and Keck) with significant qualitative research experience will independently code the data and map responses to PRISM domains. To better understand the context and reasoning for implementation strategies, we will collect monthly reports from the learning collaborative teams; following the recommendations of Proctor and colleagues, we will ask the teams to (1) name, (2) define, and (3) operationalize (actor, action, target, temporality, dose, intended implementation outcome affected, and justification) each implementation strategy using a simple template document. These reports will help contextualize qualitative findings with respect to program adaptations. Finally, upon program conclusion, we will assess the implementation outcomes of feasibility, acceptability, and appropriateness on each implementation strategy as well as the intervention itself. To do so, we will ask program staff and other key stakeholders to complete a brief, 12-item psychometrically validated survey consisting of three scales measuring feasibility, acceptability, and appropriateness; for each scale, scores are summed and averaged for each individual scale, with higher scores indicating more favorable implementation outcomes (Attached: Triple P System Implementation Outcomes). These data will provide summative information about which strategies were effective at increasing DSMES utilization within the specific program setting. Taken together, these data will help refine any additional necessary adaptations and selection/refinement of implementation strategies for future scale-up activities.

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.

Please see attached file 'Data Collection Summary_UP FOR IT.pdf' for a complete list of data to be collected and surveys/tools for the full list of questions.

Attachments

Attach Type	File Name
DataCollection	PRISM assessment tool.pdf
DataCollection	PRISM Interview Guide.pdf
DataCollection	AIM_IAM_FIM_Implementation Outcomes.pdf
DataCollection	Data Collection Summary _UP FOR IT (Clean).pdf
DataCollection	Data Collection Summary _UP FOR IT (Highlighted).pdf
DataCollection	Interview Guide for Clinic Participants_080922.pdf
DataCollection	Interview Guide for KY REC_080922.pdf
DataCollection	Interview Guide for HLWD_081822_AKD.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.

UK Resource Staff designated to the project and their primary responsibilities include: Mary E Lacy Leigh, PhD (MPI) will have oversight of the entire project along with James Keck, MD (MPI). Each will ensure all functions and objectives for the study are met. They will both be active in all aspects of the project in terms of survey/interviews, intervention development and implementation, and all data measures. They also will lead all scholarly activities that result from the project. In addition to these joint responsibilities, Dr. Lacy will be responsible for leading the study team, study design, data analysis, knowledge dissemination and budgetary oversight. Additionally, Dr. Lacy will collaborate with the Kentucky Department of Public Health to obtain and analyze DSMES programmatic data. Dr. Keck's responsibilities include engaging and communicating with participant clinics and clinicians, implementation science study design and evaluation, communicating findings with stakeholders, and providing ethics oversight. Dr. Kruse-Diehr, PhD (co-I) He will provide subject matter expertise to the implementation design and lead the implementation evaluation. Brent McKune (Co-I) will provide oversight & direction to the Kentucky Regional Extension Cooperative team who will interview participants in Objective 1 and interface with clinic staff in Objective 2. Mary Luvisi (Health Information Technology Advisor, Kentucky Regional Extension Cooperative) will complete health IT gap analyses, support data workflows, collection, and reporting, and conduct onsite data validation audits. She will also assist with practice quality improvement work via monthly calls and quarterly onsite visits to provide technical assistance. Karen 'Michelle' Hibbard (Quality Improvement Advisor, Kentucky Regional Extension Cooperative) will work directly with practices to support their quality improve activities via staff education, ongoing training and site visits and data reporting. She will host monthly learning collaborative meetings in addition to frequent webinars and onsite learning sessions focused on using data to improve diabetes care. Jessica Elliott (Data Research Analyst, Kentucky Regional Extension Cooperative) will create reports, dashboards, and other analytical tools to measure performance metrics and demonstrate improved outcomes. The study will have the support of the departments and centers that support each of the individual investigators, including: the College of Public Health, College of Medicine, Kentucky Regional Extension Cooperative, Barnstable Brown Diabetes and Obesity Center, Center for Clinical and Translational Science, and the Translational and Implementation Science Alliance. Borsika Rabin, PhD, PharmD, MPH, will serve as a Consultant. Dr. Rabin has extensive expertise in the selection and operationalization of implementation science models and is a national expert in the use of RE-AIM and PRISM frameworks. She will provide expertise in the planning, implementation, and evaluation phases of the project.

All team members will have access to computers, printers, video- and audio-conferencing capability and appropriate software to carry out the study. Study data will be stored in a password protected, cloud-based database accessible to study team members.

Survey data (Objective #3) will be obtained via REDCap (Research Electronic Data Capture). REDCap is a secure web based application tool used for building and managing surveys and databases used for research, created by Vanderbilt University. Vanderbilt developed a Consortium of institutions to share this research and data capture tool. The Consortium was launched in 2006 and has Consortium partners including the University of Kentucky. The security of the application is largely dependent on the IT infrastructure and environment in which REDCap is hosted, not the software itself. Vanderbilt has a list of best practices that were utilized when installing and hosting the REDCap instance locally. For more information on Consortium Partners, please view http://www.project-redcap.org/consortium.php.

The University of Kentucky REDCap instance was installed in the Institute for Pharmaceutical Outcomes & Policy in 2008 and is located in 180 BioPharm Complex (BPC). The web server and the database server are located on separate servers behind a firewall with in-house control with UK's campus network. In addition, in order to maintain secure communications, the web server has a secured security license (SSL) and is located on https://redcap.rdmc.org/redcap/. Research data is stored locally and is backed up daily using MySQL Administrator software using the Windows Server 2008 R2 edition.

REDCap implements authentication of users that log into the system. All accounts are set up using the LinkBlue ID and are password protected. Furthermore, the software has an auto logout feature included. Once a REDCap user creates a project, they are the owner and have full rights to the project. Once study personnel/users are added by the owner, user rights or privileges are established. User rights can be for view only, edit only, or view and edit. User rights or access, can be further limited to individual case forms within the project. Custom locking of case report forms or digital signatures are another feature that can be assigned in the user rights section of the project. REDCap maintains a built-in audit trail that logs all user activity and pages viewed. The logging record can be viewed by those with proper user rights.

Data exportation is defined within the user rights section, and can be limited by user as a full data set or as a deidentified data set. Data is exported into comma delimited (CSV) files which can be uploaded into Excel, SAS, SPSS, STATA, or R for analysis. Advanced features of deidentification include removal of free form text, removal of dates, date shifting that keeps the integrity of the date interval, and/or removal of fields tagged as identifiers. REDCap also has an internal email function for large data sets or sensitive data. This feature can be used to send emails to non-REDCap users as well. The file is stored on REDCap and allows non users to log in using a secure password to download the files (password to access email is sent in a separate email to the user).

REDCap stores its system data and project information in various relational database tables within a single MySQL database. All data submitted via the web server by the researcher is encrypted while transmitted. The portable devices do not download the data, it is directly stored into the secure web based connection (https) behind the firewall. This reduces the liability and possibility of researchers losing protected health information. All files are password protected once entered into the system. All project data is stored and hosted locally. No data is ever shared with Vanderbilt or the consortium partners.

REDCap software uses various methods to protect against malicious users that attempt to identify or exploit any security vulnerabilities in the system. In REDCap, all data is intentionally filtered, sanitized, and escaped for every query string data found in the URL while accessing REDCap. Server environment variables that are vulnerable to forgery by users are checked and sanitized. All user submitted data is filtered for any possible harmful mark-up tags (scripts) and then escaped prior to ever being displayed on a web page within the application. SQL queries sent to the database server from REDCap are properly escaped prior to being sent. User defined data used within the SQL query has the data type checked to prevent any mismatching of data types (makes sure a number is really a number). The processes of filtering, sanitation, data type checking, and escaping all help to protect against methods of attacks.

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.

Primary population (clinic staff and DSMES providers): In the course of this study, there are minimal risks related to the project. Primary participants of the study are clinic staff at the 11 participating clinics and clinic staff and DSMES providers that will participate in surveys/interviews. No identifying information will be used in any report or publication that is produced as part of this study; data will be presented only in the aggregate. No identifying variables for providers or clinic staff will be in the data sets other than a Unique Identifiable Number (UIN).
There is no direct benefit of the proposed research to the study subjects. However, if the intervention results in increased patient referrals to DSMES services, DSMES is associated with better diabetes-related outcomes which would benefit patients (secondary study population). Additionally, the knowledge gained from this study would lead to a larger-scale intervention and other patients with diabetes may benefit from intervention that optimize utilization of DSMES services.

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).

This protocol involves activities for professionals to encourage referrals of eligible patients to DSMES. The alternative is to not participate, and hence continue in the clinician's current treatment protocol for these patients.

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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

Objectives 1 and 3: The data will consist of the survey (objective 3 only) and interview responses of participants. All surveys will be de-identified. Each provider participant will be randomly assigned a unique identifying number (UIN) upon entrance to the study. Interviews will be audio-recorded for purposes of later qualitative analysis of the sessions that may influence interpretations of the best implementation approaches. Permission will be requested of participants to collect the audio tape of the interview during the consent process. The purpose of the taping is for research transcription only, and only CITI-certified research staff/investigators will have access to the audio and be permitted to listen - and then only for transcription purposes. The tapes will be stored as digital files on a secure computer. Everyone with access to the data will participate in all relevant trainings and will adhere to UKY's high standards for ensuring confidentially of all data. All study data will be stored in a password protected, cloud-based database only accessible to study team members. In Objective #1, interview data will be used to inform the adaptation of the implementation strategies and lead to implementation protocols and evaluation plans. Data collected and synthesized in Objective 1 will refine and adapt this preliminary model for use in Objective 2. Data from Objective #3 (survey and interview data), will be used to understand how the various implementation strategies embedded within the learning collaborative and clinical context influenced DSMES uptake to inform future refinement for program replication and scale-up.

Objective 2: Data for Objective 2 consists of only data that is routinely collected either via existing surveys (DSMES providers) or electronic health records. All data for this objective will be de-identified (including the full list of HIPAA identifiers) and aggregated to the clinic level prior to being provided to study staff. The study team will not have access to any patient-level identifiable information. The study team will be relying on routinely collected data that is de-identified and aggregated by clinic staff to evaluate outcomes. No identifying information will be used in any report or publication that is produced as part of this study; data will be presented only in the aggregate. Everyone with access to the data will participate in all relevant trainings and will adhere to UKY's high standards for ensuring confidentially of all data. All study data will be stored in a password protected, cloud-based database only accessible to study team members. Data for Objective #2 will be used to assess the effect of the interventions on DSMES referrals (primary outcome), by comparing rates of referrals between intervention and control clinics (clinics within the healthcare system not randomized to the intervention). Secondary outcomes include DSMES attendance, patient satisfaction and diabetes knowledge, A1c control, and intervention feasibility and acceptability.
Objective #1 and #3: The only information/data gathered on an individual, non-de-identified level are from key informant interviews. All transcriptions and all further thematic analysis and subsequent description for publication or other purposes will be completed without the use of participant names. Any other created paper files will be kept in a locked cabinet and the digital information (e.g., transcripts) will be stored on a secured network. Study files will be maintained for at least five years after final publication of study findings, and then will be shredded/securely discarded.

Objective #2: All consent forms will be maintained in a confidential locked cabinet located in a locked office of Mary Lacy (office 212F of the College of Public Health, Research Facility #1 Building) for at least six years after study closure, and then will be shredded and securely discarded. All study files files will be maintained for at least five years after final publication of study findings, and then will be shredded/securely discarded. In all cases, no individual level results will be shown and only summative data will be reported.
Primary population (clinic staff and DSMES providers): Primary participants in the intervention will be informed that participation is not anonymous due to the collaborative nature of the intervention; however, any data collected from the primary participants, e.g., demographic descriptors or qualitative feedback about the process will be de-identified and/or disseminated in aggregate with other primary participant data. No identifying information will be used in any report or publication that is produced as part of this study; data will be presented only in the aggregate. Everyone with access to the data will participate in all relevant trainings and will adhere to UKY's high standards for ensuring confidentially of all data. All study data will be stored in a password protected, cloud-based database only accessible to study team members. Primary participants in the study will not be prospectively evaluated for adverse events; however, they will be encouraged to contact the study PI if they feel they have experienced an adverse event.

☑ **UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Check this item to confirm that you will retain all IRB-related records for a minimum of 6 years after study closure.**

Payment

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

Participants will receive a $50 gift card for their participant in key informant interviews (Objective 1).

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.

Objectives 1 and 3: There are no costs associated with participation in the surveys (Objective 3 only) or interviews other than that of the time involved. Providers and other staff will not be given any monetary reimbursement for participating in the study. Their only direct expense associated with the study is that of their time.

Objective 2: The only costs associated with participation in the intervention are that of the time involved and travel costs to the Practice Facilitation Collaboratives.

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.

Data and Safety Monitoring Plan
Title: Using Practice Facilitation and Operationalizing Referral Information Technology (UP FOR IT) to Increase DSMES Utilization
Principal Investigators: Mary Lacy PhD and James Keck MD MPH

I. Overview
A. The purpose of this study is to pilot test the implementation of health information technology and a practice facilitation collaborative in two healthcare systems in rural Kentucky to increase referrals to and utilization of Diabetes Self-Management Education and Support (DSMES) for patients living with diabetes.
B. The Data and Safety Monitoring Plan (DSMP) outlined below will adhere to the protocol approved by the University of Kentucky IRB.

II. Adverse Events
A. Adverse event assessment
1. Expected risks: This study presents minimum risk to participants; that is the risk is not greater than what is experienced in everyday life. The study participants are employees of healthcare clinics who will participate in intervention. There is the potential for primary participants to experience frustration due to team dynamics and/or lack of improvement in clinical diabetes care goals. The risk of frustration is described in the consent form. To minimize this risk, participant teams receive training on positive team interactions.
2. Primary participants in the study will not be prospectively evaluated for adverse events; however, they will be encouraged to contact the study PI if they feel they have experienced an adverse event.
B. Adverse event reporting
1. Every adverse event that is reported to the principal investigator by a participant will be documented.
2. An adverse event report will be generated for each event that will include a description of the event, when and how it was reported, and a determination of attribution.
3. Recipients of the report will include the study Safety Officer (healthcare research professional not part of the study), an institutional IRB official, and the NIDDK program official.
4. Adverse events will be reported quarterly.
5. Any action resulting in a temporary or permanent suspension of this study will be immediately reported to the appropriate NIDDK program official.

III. Safety Review Plan and Monitoring
A. Sample size justification: This pragmatic cluster randomized pilot study seeks to measure the feasibility, acceptability and approximate magnitude of effectiveness of the DSMES utilization interventions; thus, four clinics will be randomized to receive the intervention and the remaining seven clinics in the two participating rural healthcare systems will serve as controls.

B. Safety and study progress reviews
1. The two principal investigators will review adverse events with the study Safety Officer quarterly given the unmasked, low risk nature of the study.
2. The two principal investigators will review study progress (e.g., recruitment, retention, protocol adherence) quarterly.
3. The annual report will include: 1) list and summary of adverse events; 2) summary of recruitment and retention and reason for dropouts; 3) whether the study is on track to be completed and accomplish the stated aims.
C. There are no Stopping Rules.

IV. Informed Consent
For the primary study population (clinic staff and DSMES providers), informed consent will be obtained virtually from each primary participant at entry into the study by a trained study team member. Clinic staff and DSMES providers may participate in the learning collaborative either virtually or in-person. We are requesting a waiver of informed consent for our primary and secondary study population (patients).

V. Data Quality and Management
A. Data completeness and accuracy: The study team will work with intervention clinics to validate reporting of study data from their electronic health record systems. The validation process will occur during study months 6 to 9. Thereafter, intervention clinics will report data monthly to the study team who will assess the data for completeness and accuracy.
B. Data integrity and protection of databases: Study data obtained from secure clinic electronic health record systems and through surveys/interviews with providers and staff will be stored in a password protected, cloud-based database only accessible to study team members.

VI. Confidentiality
Primary participants in the intervention will be informed that participation is not anonymous due to the collaborative nature of the intervention; however, any data collected from the primary participants, e.g., demographic descriptors or qualitative feedback about the QI process, will be de-identified and/or disseminated in aggregate with other primary participant data. Secondary participants are patients. The study team will not have access to any patient-level identifiable information. The study team will be relying on routinely collected data that is de-identified and aggregated by clinic staff to evaluate outcomes. No identifying information will be used in any report or publication that is produced as part of this study; data will be presented only in the aggregate.

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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

The results of this study may be used by the research team for future studies. Only de-identified data will be kept. No identifiers will be retained. Transcriptions and analyses from the group interviews may be used to inform development of future interventions. The main risk associated with additional use would be the loss of privacy, but to address this we will de-identify all data that is retained. Data will only be shared with other researchers if a member of the study team is involved in the research.

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 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.)

I have attached a HIPAA Waiver of Authorization. ○ Yes ◉ No

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:

Mercy Health (Mercy Health Marcum & Wallace and Mercy Health Primary Care Clinics)
Pikeville Medical Center
Kentucky Department of Public Health (KDPH) Healthy Living with Diabetes network

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

Consultant Borsika Rabin, PhD, PharmD, MPH will assist with the key informant interviews (Aim 1). Dr. Rabin's role as a Consultant: Dr. Rabin has extensive expertise in the selection and operationalization of implementation science models and is a national expert in the use of RE-AIM and PRISM frameworks. She will provide expertise in the planning, implementation, and evaluation phases of the project. Dr. Lacy Leigh (MPI) will have oversight of the entire project along with James Keck, MD (MPI). Dr. Keck's responsibilities include engaging and communicating with participant clinics and clinicians, implementation science study design and evaluation, communicating findings with stakeholders, and providing ethics oversight.

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

Attachments

Attach Type	File Name
-Individual Investigator Agreement	UKY IRB 75928_IIA_Rabin.pdf
-IRB Authorization Agreement	IAA _University of Alaska.pdf
-Letter of Support & Local Context	LOS_ClinicalPractice_BigSandy.pdf
-Letter of Support & Local Context	LOS_ClinicalPractice_Pennyroyal.pdf
-Letter of Support & Local Context	LOS_KDPH.pdf
-Letter of Support & Local Context	MercyHealth_LOS_April 2023.pdf
-Letter of Support & Local Context	Pikeville_LOS_April 2023.pdf

B) 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)

Instructions: For various reasons, it is necessary to determine whether your research activities meet the definition of clinical research and/or a clinical trial. Your responses to the next series of questions will make that determination. For more details on the definitions, go to ORI's clinical research vs. clinical trial web page or visit NIH's decision tree for the NIH Clinical Trial definition.

My research activities include one or more of the following:

Patient-oriented research regarding mechanisms of human disease, therapeutic interventions, clinical studies, or development of new technologies
◉ Yes ○ No

Material of human origin (such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects
○ Yes ◉ No

Epidemiologic or Behavioral Studies
○ Yes ◉ No

Outcomes Research or Health Services Research
◉ Yes ○ No

Does your research involve one or more human subjects prospectively assigned into one or more health-related biomedical or behavioral interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes?
◉ Yes ○ No

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
☐ Collection of Biological Specimens for banking and use
☐ Community-Based Participatory Research
☐ Deception
☐ Educational/Student Records (e.g., GPA, test scores)
☐ Emergency Use (Single Patient)
☐ Gene Transfer
☐ Genetic Research
☐ NIH Genomic Data Sharing (GDS) (databases such as GWAS, dbGaP, GenBank)
☐ Treatment with Human Cells, Tissues, and Cellular and Tissue Based Products
☐ Individual Expanded Access or Compassionate Use
☐ International Research
☐ Planned Emergency Research Involving Exception from

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

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

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

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.):

NIH 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	Human Research Completion Certificate - Laura Wright.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:

Individuals chosen as signees may remove the application from their Inbox without signing the Assurance Statement by clicking "Return to PI" with a comment about why it is being returned (e.g., specific edits are deemed necessary).

The PI, and personnel chosen as a contact, will receive an email notification that edits are needed, and can find the draft application in both the "Draft" folder and the "Signatures Needed" folder located in the menu in the left margin of the default Inbox page. The researcher does not have a 'reply' option to the signee's comments and must make the requested edits directly in the application, or communicate outside the E-IRB system as to why not. Once the response is finalized, the researcher must re-visit the "Assurances Required" section to click the "Return to Signee" button for their re-consideration; the signee will receive an email notification at that time.

Hover your mouse cursor here for additional instructions.

First Name	Last Name	Role	Department	Signee Return Comment	Date Signed	
Erin	Haynes	Department Authorization	Dept Of Epidemiology		01/25/2022 12:37 PM	View/Sign
Mary	Lacy Leigh	Principal Investigator	Dept Of Epidemiology		01/24/2022 04:51 PM	View/Sign

Department Authorization

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

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

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

Principal Investigator's Assurance Statement

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

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

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

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

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

SUBMISSION INFORMATION

0 unresolved comment(s)

***** If this Continuation Review entails a change in the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.*****

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.

Principal Investigator's Assurance Statement

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

1. Having reviewed all the investigational data from this study, including a compilation of all internal and external unanticipated problems.
2. Having reviewed, if applicable, information from the sponsor including updated investigator brochures and data and safety monitoring board reports.

I also attest that I have reviewed pertinent materials concerning the research and concluded either:

A. The human subject risk/benefit relationship is NOT altered, and that it is not necessary to modify the protocol or the informed consent process,
OR,
B. The human subject risk/benefit relationship has been altered, and have previously submitted or am including with this continuation review submission, a modification of the research protocol and informed consent process.

☑ By checking this box, I am providing assurances for the applicable items listed above.

Your protocol has been submitted.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.084	klars2	1/2/2025 10:29:10 AM
	-IRB Authorization Agreement	IAA _University of Alaska.pdf	ORI uploaded IAA to "Research Sites"	0.311	jchine2	7/26/2023 3:06:20 PM
	-Letter of Support & Local Context	Pikeville_LOS_April 2023.pdf	LOS Pikeville Medical Center	0.198	crwhit3	4/12/2023 2:09:39 PM
	-Letter of Support & Local Context	MercyHealth_LOS_April 2023.pdf	LOS Mercy Health	1.375	crwhit3	4/12/2023 2:09:07 PM
	AddInfoProduct	Human Research Completion Certificate - Laura Wright.pdf	HSP Laura Wright	0.074	mla347	4/4/2023 9:36:31 AM
	-Individual Investigator Agreement	UKY IRB 75928_IIA_Rabin.pdf	ORI attached on PI/SP behalf	0.210	jchine2	11/15/2022 1:01:55 PM
	DataCollection	Interview Guide for HLWD_081822_AKD.pdf	Interview Guide - DSMES Educators	0.147	crwhit3	11/8/2022 12:42:25 PM
	DataCollection	Interview Guide for KY REC_080922.pdf	Interview Guide - KREC Staff	0.204	crwhit3	11/8/2022 12:11:48 PM
	DataCollection	Interview Guide for Clinic Participants_080922.pdf	Interview Guide - Clinic Participants	0.206	crwhit3	11/8/2022 12:11:01 PM
	DataCollection	Data Collection Summary _UP FOR IT (Highlighted).pdf	Data Collection Summary - Highlighted	0.096	crwhit3	11/8/2022 12:09:12 PM
	DataCollection	Data Collection Summary _UP FOR IT (Clean).pdf	Data Collection Summary - Clean	0.094	crwhit3	11/8/2022 12:08:45 PM
	Advertising	DSMES AIM 1 Recruitment Email_11.1.22.pdf	DSMES AIM 1 Recruitment Email	0.072	crwhit3	11/2/2022 10:12:22 AM
	DataCollection	AIM_IAM_FIM_Implementation Outcomes.pdf	ImplementationOutcomes_Triple P_headers removed	0.417	mla347	3/11/2022 4:17:22 PM
	DataCollection	PRISM Interview Guide.pdf	PRISM Interview Guide	0.510	mla347	1/24/2022 12:48:43 PM
	DataCollection	PRISM assessment tool.pdf	PRISM Assessment Tool	0.447	mla347	1/24/2022 12:48:31 PM
	-Letter of Support & Local Context	LOS_KDPH.pdf	LOS_KDPH	0.373	mla347	1/19/2022 10:45:48 AM
	-Letter of Support & Local Context	LOS_ClinicalPractice_Pennyroyal.pdf	LOS PennyRoyal	0.123	mla347	1/19/2022 10:45:27 AM
	-Letter of Support & Local Context	LOS_ClinicalPractice_BigSandy.pdf	LOS Big Sandy	0.100	mla347	1/19/2022 10:45:08 AM

Protocol Changes

Protocol Number: 75928

Click link to sort Changed Date

Informed Consent CoverLetterSurvey changed by crwhit3 on 12/17/2024 5:30:14 PM

~~Y~~N

Informed Consent PhoneScriptAssent changed by crwhit3 on 12/17/2024 5:30:14 PM

~~Y~~N

Informed Consent StampedConsent changed by jchine2 on 12/18/2024 8:33:12 AM

~~N~~Y

Project Information IsSubEnrollDataSpecimen changed by crwhit3 on 12/18/2024 9:29:29 AM

~~Y~~N

Project Information SubjectCount changed by crwhit3 on 12/18/2024 9:29:29 AM

~~5065~~22

Study Personnel Changes:

Project Information Comment by Joanne Hines - ORI to PI on 12/18/2024 8:36:22 AM
Due to the status of the research project - please update the total number of research participants enrolled and change "Yes" to "No" for open to enrollment question.

Informed Consent Comment by Joanne Hines - ORI to IRB/PI on 12/18/2024 8:34:25 AM
ORI updated "Check All That Apply" box to "Stamped Consent Doc(s) Not Needed".

PI/study team removed the cover letter and phone script (thank you). Note to PI/study staff/IRB only