Document Coversheet

Study Title: Development of a User Centered Design Approach for Screening, Referral, and Enrollment in Food as Medicine Among Adults

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	2/6/2025
NCT Number:	NCT07011251
IRB Number	93234
Coversheet created:	6/10/2025

PROTOCOL TYPE (VERSION 5)

IRB Approval
2/6/2025
IRB # 93234
Exempt

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.

EXEMPTION CATEGORIES

0 unresolved comment(s)

LIMITATIONS: Certain research activities **cannot** be exempt because additional protection has been granted by federal regulations for vulnerable populations. The categories of research that cannot be exempt are as follows:

- Research involving the surveying or interviewing of children (exempt category 2);
- Research involving educational test or the observation of public behavior of children if the investigators participate in the activities being observed (exempt category 2);
- Research involving benign behavioral intervention with children (exempt category 3);
- Research involving prisoners (unless the research is aimed at involving a broader subject population and the involvement of the prisoner(s) is only incidental).

Please note: *The revised common rule regulations now allow for the application of all exempt categories to research involving the use of pregnant women, human fetuses, and neonates, assuming* ***all*** *the research activities fall within one or more categories of exempt research as determined by the IRB.*

Research activities are exempt from the human research protection regulations when the only involvement of human subjects falls within one or more of below categories. **Research categories 1-5 do not apply to Food and Drug Administration (FDA) regulated research.** For additional guidance, see the UK ORI Exemption Categories Tool or the Issues to be Addressed with Exempt Review document.

Check the appropriate category(ies) that apply(ies) to your research project:

☐ (1) Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instruction strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

☑ (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures with adults, or observation of public behavior including visual or auditory recording (with minors as long a study personnel do not interact when observing), if at least **one** of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

If retaining identifiers, complete and attach the Limited Review Form under the Additional Information section using the Additional Materials attachment button.

☑ (3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or
B. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

If retaining identifiers, complete and attach the Limited Review Form [PDF] under the Additional Information section using the Additional Materials attachment button.

☐ (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens that have been or will be collected for some other 'primary' or 'initial' activity, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;
ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 20B(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

☐ (5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

- Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

☐ (6) Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed; or
ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exemption Category 7 and Category 8 both require "Broad consent" provisions and involve storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research (7) OR research involving the use of identifiable private information or identifiable biospecimens for secondary research use (8). These categories are not an option at the University of Kentucky at this time, as the provisions require institution-wide tracking of individuals who do not agree to secondary use of their identifiable private information or identifiable biospecimens.

☐ This protocol is approved by a Non-UK IRB. This category should be chosen only after you have contacted the ORI Reliance Team and submitted the Reliance Registration Form [PDF]. If you have not submitted the Reliance Registration Form to ORI Reliance staff, please contact us at irbreliance@uky.edu.

MODIFICATION REQUEST SECTION

0 unresolved comment(s)

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

Select One:

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

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

( ) Yes (•) No

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

( ) Yes (•) No

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

For each proposed modification, include a justification.

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

Nathan Eapen is being added as a student data collector and will help with data analysis. He has completed the human subjects protections and responsible conduct of research trainings.
Jacob Stone is being added as a medical supervisor for one of the clinics. He will assist with entering patient PHI post intervention.
Shorus Minella is being removed from the project as she are no longer involved in this work.

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

Development of a user centered design approach for screening, referral, and enrollment in Food as Medicine among adults

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.

food insecurity, food as medicine, hypertension

Anticipated Ending Date of Research Project: 6/30/2025

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

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

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:	Alison	Room# & Bldg:	308 Funkhouser Building
Last Name:	Gustafson	Speed Sort#:	405060054
Middle Name			
Department:	Dietetics and Human Nutrition…	Dept Code:	81500
PI's Employee/Student ID#:	10846342	Rank:	
PI's Telephone #:	8592571309	Degree:	
PI's e-mail address:	alison.gustafson@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	11/30/2024
		RCR Trained:	Yes

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

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

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

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

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

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

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

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 to 64

Study Population:

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

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider these resources:
NIH Diversity Policy
FDA Diversity Guidance

Inclusion Criteria - Diagnosis of hypertension, experiencing
food insecurity as indicated by 2-item Hunger Vital Sign, English or Spanish speaking, no plans to move from the area for at least 1 year, willing and able to accept text
messages, free living to the extent that participant has control over dietary intake, and willing and able to provide written informed consent and participate in all study activities.
Exclusion criteria - Participant in weight research intervention in last 12 months; only one member of each household may take part in this
study; considering bariatric surgery in the next year or prior bariatric surgery; lack of safe, stable residence and ability to store meals;

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:	30	30		
Latinx:	20	20		
Native Hawaiian/Pacific Islander:				
White:	50	50		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:				

If unknown, please explain why:

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

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

- ☐ 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!

☐ Not applicable

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

Attach Type	File Name
Survey Consent	Survey_consent_not_enrolled_08.30.24.pdf
Survey Consent	Survey_consent_staff_08.30.24.pdf
Survey Consent	Survey_consent_refused_assistance_06.27.24.pdf
Survey Consent	provider_qualitative_clean.pdf

Survey Consent	patient_qualitative_clean.pdf
Informed Consent/HIPAA Combined Form	informed_consent_FIM_CLEAN.pdf

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.

Informed consent will be sought from individuals who meet basic eligibility criteria and who have been screened for food insecurity and meet clinical definition of having hypertension based on a healthcare provider.
Informed consent will be provided right after eligibility criteria questions are complete.
The trained data collector (Christa Mayfield) will obtain informed consent from all participants via a text link
send to phone for econsent. A RedCap link will be sent to participants.
The consent form will be copied and pasted within the REDCap eConsent feature where all collected data for the project will be housed. Through this mode, participants that consent to participate will be prompted to sign through the mouse drawn feature. The consent form may be completed via mobile device as well as desktop by using your finger to directly sign and submit the consent form. The eConsent is compatible across desktop, tablet, and mobile devices to allow as many points of electronic access as possible. Prospective study participants reached through any mode of recruitment effort, will be sent the unique web link via email to review and complete the consent form. The method of signing the consent document has the sign/date stamp option. All safety and personally identifiable information will be protected by storing all information within the REDCap system. Prospective subjects may accept or decline participation in the study after reviewing the consent form and included information. If
consent is obtained, individuals will receive a phone call from study coordinator to provide instruction for participation, to set up the Food as Medicine package based on their individual needs. All participants will receive a
copy of the consent form upon signing to refer to throughout their participation in the study and will be included in the Project Booklet that will be mailed to each participant. Initial survey collection will occur in week one, followed by the 12-week intervention process,and will conclude with a final survey.
Consent will be obtained and reviewed only by study personnel to minimize any possibility of coercion or undue influence. This study target population is adults 18-64 not deemed as a special population, therefore, no consent will be collected on behalf of another participating study individual.

Comparator group - We are requesting waiver of signatures for comparator group of 10 patients who did not want food assistance. We would like to see if they would agree to take a 20-30 minute survey. Patients who agree to participate will be sent a redcap link to complete the survey. Prior to the survey, participants will be able to read the cover letter or will be read the cover letter aloud if completing the survey by phone with a trained data collector. Participants will be able to select that they agree to participate in Redcap, or verbal consent will be obtained if by phone. If a participant does not agree, they will be thanked for their time and the survey will end.
Not enrolled group - We are requesting waiver of signatures for the group of up to 10 patients who originally wanted assistance in the clinic office, were referred, but did not complete enrollment. These participants initially agreed to the clinic provider to wanting to

receive the food is medicine program. However, they didn't respond to text messages. We want to understand what were the barriers for not answering the message from the study team and completing enrollment. Patients will be sent a link a redcap link inviting them to complete the survey. Prior to the survey, participants will be able to read the cover letter or read the cover letter aloud if they contact the data collector to complete the survey by phone. Participants will be able to select that they agree to participate in Redcap, or verbal consent will be obtained if by phone. If a participant does not agree, they will be thanked for their time and the survey will end. Staff survey - We are requesting waiver of signatures for the user experience survey with staff. Staff will be sent a redcap link to complete the survey and will be able to read the cover letter before participating. Participants will be able to select that they agree to participate in Redcap. If a staff member does not agree, they will be thanked for their time and the survey will end.

☐ 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:

The survey for the 10 patients who did not want assistance, the 10 patients who did not enroll, and the staff present no more than minimal risk. There are three distinct groups for this part: 1) those who answered "no" for food assistance but have food insecurity; 2) those who answered yes to food assistance but didn't complete enrollment; and 3) clinic staff. For all groups, breach of confidentiality would be the primary risk. All data will be kept confidential and de-identified prior to sharing with other researchers. A record linking the study id and name will be kept by the Alison Gustafson and Christa Mayfield in order to send participants their gift card and as required by the loadable card program.

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):

Procedures for the comparator group include a 20-30 minute survey. Patients that answer 'no' to wanting assistance but agree to a survey will be sent a direct link to the survey in Redcap. The survey will collect descriptive data, such as demographics, food security status, and experience with food resources and being asked if they want assistance by their healthcare provider. Patients are asked the Hunger Vital Signs screener as part of standard of care in all UK Healthcare ambulatory clinics. Procedures for the group who did not enroll include a 15-20 minute survey. They will receive a direct link to the survey in Redcap. The survey will ask about barriers and facilitators for enrolling, food resources available, and race, ethnicity, and income. Procedures for staff include a 15-20 minute survey in Redcap. The survey will ask for feedback on the screening and referral process, language in the initial texts, patient experience.

○ **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
Arlinghaus	Carlie	Data Collection	SP	Y	N		P	Y	08/24/2023	Y	N	08/07/2024	N	Y
Batey	Lauren	Data Collection	SP	Y	N		P	Y	01/22/2025	Y	N	08/07/2024	N	Y
Bush	Joshua	Co-Investigator	SP	N	N		P	Y	02/22/2022	Y	N	12/22/2023	N	Y
Causey	Kylee	Recruitment	SP	N	N		P	Y	08/05/2024	Y	N	08/15/2024	N	Y
Cosson	Ethan	Data Collection	SP	Y	N		P	Y	08/25/2023	Y	N	08/07/2024	N	Y
Eapen	Nathan	Data Collection	SP	Y	N		S	Y	01/08/2025	Y	N	01/30/2025	N	Y
Frick	Marissa	Study Coordinator	SP	Y	N		P	Y	02/07/2023	Y	N	10/09/2024	N	Y
Lauckner	Carolyn	Co-Investigator	SP	N	N		P	Y	04/13/2023	Y	N	12/22/2023	N	Y
Mayfield	Christa	Study Coordinator	DP	Y	N		P	Y	07/14/2022	Y	N	12/22/2023	N	Y
Poe	Brooke	Data Collection	SP	Y	N		P	Y	01/17/2024	Y	N	02/16/2024	N	Y
Sass	Jessica	Medical Supervisor	SP	Y	N		P	Y	04/19/2022	Y	N	12/22/2023	N	Y
Stone	Jacob	Medical Supervisor	SP	N	N		P	Y	08/26/2024	Y	N	01/30/2025	N	Y
Winter	Lydia	Data Collection	SP	Y	N		P	Y	05/13/2024	Y	N	08/07/2024	N	Y
Black	Karen	Recruitment	SP	N	N		P				Y	02/16/2024	N	Y
Grise	Christian	Data Collection	SP	Y	N		S	Y	07/30/2024	Y	Y	10/09/2024	N	N
Minella	Shorus	Recruitment	SP	N	N			Y	08/04/2023	Y	Y	01/30/2025	N	N

RESEARCH DESCRIPTION

0 unresolved comment(s)

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

Pro Tips:

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

Background

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

Food insecurity is a major public health concern - Among adults, food insecurity is linked to decreased nutrient intakes, increased rates of mental health problems and depression, increased rates of diabetes, complications from diabetes1-4, and increased risk for cardiovascular disease5. These negative health outcomes have elevated food insecurity into a leading healthcare issue. Food Insecurity, Hypertension, and health equity – Rural residents overall experience higher rates of cardiovascular disease relative to urban counterparts. The Appalachia region, where one hospital in our study is located, has particularly low life expectancy and high chronic disease burden6. In addition, these residents experience higher rates of food insecurity than urban residents 7,8, with 22% of adults in Eastern Appalachian Kentucky reporting food insecurity. Food insecurity is consistently more prevalent among households with a person living with cardiovascular disease, and similarly, cardiovascular disease is also more prevalent in food-insecure households3,9. The confluence of higher rates of cardiovascular disease coupled with higher rates of food insecurity creates an urgent need to identify implementation processes for screening and referral among patients most in need. Policy changes in screening for Social Determinants of Health (SDoH) and implications for practice– Starting in 2024, Centers for Medicare and Medicaid have mandated screening for SDoH including food insecurity among hospitals receiving this type of federal and state funding10. However, there remains no cohesive approach or approved protocol for how this screening process should occur. Moreover, there is wide variability in the actual process with which hospitals, clinics, managed care organizations will screen patients for food insecurity and then refer to an appropriate FIM package for uptake11,12. Thus, our study can provide key evidence for the most effective ways to ensure all eligible patients are being screened in an efficient but also culturally appropriate and sensitive manner. Screening and referral mode may impact uptake of food as medicine programs - There is suggestive evidence that affirmative responses may be more readily given when questions can be answered privately, in a manner removed from interpersonal interactions. Furthermore, there may be less stigma associated with answering these questions when conducted in private and in an easily accessible manner, such as via a text message 13. One recent study found success with online screening mechanisms for food insecurity and other related social determinants of health14. In addition, automated screening may provide less burden for providers reducing time constraints and disruption to intake processes and clinic flow and increasing the likelihood of consistent implementation of screening protocols15. Our study is leveraging these early findings to now test our automation approach across diverse rural and urban communities to be able to answer these layered implementation science questions of how best to screen, refer, and enroll to address food insecurity and improve utilization in the short-term.

Objectives

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

AIM 1a: Compare screening rates and food insecurity identification between: 1) automated screening and 2) standard face-to-face patient screening in a provider office. Hypothesis: There will be a higher screening percentage rate and identification of food insecurity among automation relative to face-to-face screening conducted in provider offices.
AIM 1b: Compare FIM enrollment rates between: 1) automated referral and 2) face-to-face referral into a centralized hub. Hypothesis: There will be a higher percentage of individuals answering "yes" to wanting assistance with FIM programs among automation relative to face-to-face.
AIM 2: Explore how enrollment into a tailored FIM package is associated with user engagement in the program, short-term health outcomes, and cost-efficiencies among participants in diverse communities.
AIM 3: Obtain patient and provider feedback during multiple time points of the design and implementation process related to screening, referral, enrollment, and engagement, to allow for user-acceptance to be tested, iterated upon, and improved in order to understand the lived experience for all users of the FIM referral program.

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.

Quasi experimental study design with all participants receiving a food as medicine program based on their individual needs. In addition, for AIM 3 we will be conducting qualitative research to understand from the user perspective barriers and facilitators related to screening and referral.

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

AIM 1 - Medicaid adults age, 18-64, who have have been diagnosed with HTN will be recruited from UKHealthcare ambulatory clinics. UKHealthcare sends all patients via MyChart the Hunger Vital Signs screener. Adults who answered yes to one of two questions on the Hunger Vital Signs screener, and who click on "wanting assistance" with food, and who have a diagnosis
of HTN will be contacted by Brooke Poe if they would like to participate in a food as medicine program. If they respond yes, their contact information is then sent forward to Dr. Gustafson and study team for enrollment into an appropriate food as medicine package based on their individual needs.
Brook Poe with supervision from Jessica Sass, Director of Population Health at UKHealthcare has HIPAA clearance to contact patients and is part of her current roles and responsibilities. The list of eligible participants will be captured from the Epic system by an approved Epic trained clinical provider, Brook Poe. Epic will allow
the list to be generated based on the criteria of food insecurity and a diagnosis of HTN and wanting assistance with food. Adults will be called or sent a text message to determine eligibility and interest in participation from Brooke Poe. If the adults answer "yes" to wanting to participate
after initial contact their contact information is uploaded into RedCap to follow-up for enrollment and informed
consent. Jessica Sass, as Director of Population Health, will serve as the medical director of this project and for HIPAA compliance and agreement.
Face to face screener - adults who are patients at Gill Heart clinic will receive the face to face Hunger Vital Signs screener. Shorus will ask patients the screener questions at check-in and will ask the follow-up questions related to wanting assistance. If they then also agree to participate in the food as medicine program their contact information is uploaded into the RedCap system. Clinic staff may give patients who screened positive for food insecurity the recruitment flyer when asking if they want assistance.

Comparator group - among 10 individuals who answered affirmative to being food insecure based on the Hunger Vital Signs screener but indicated "no" for wanting assistance will be contacted by Brittany Poe to gauge interest in participating in a 20-30 minute survey related to reasons for not wanting assistance. If they agree their name and contact information will be uploaded into RedCap to then be sent a link to a brief survey. If they don't complete the survey within one day Christa Mayfield will call up to 2 times. This process will take place until 10 individuals complete the survey.

Aim 3 data will be collected from both patients and providers. Nurse case managers involved in screening and referral will be contacted via text and e-mail if they would like to participate in the Aim 3 qualitative data collection. Those who are on the IRB protocol will be the individuals involved in the post intervention interview. Patients will also be recruited to participate in Aim 3 data collection through texts and e-mails during the various stages of screening, enrollment, referral, and engagement to provide user-feedback throughout the implementation process and for post-intervention interviews. Patients who are enrolled in the food as medicine program will be contacted to participate in the brief user-feedback interviews during the 3-month food as medicine program. Patients who were referred but chose not to enroll will be contacted via text and email one time if they would like to complete a brief user-experience survey via a Redcap survey link. If they don't complete the survey, they will not be contacted again.

Attachments

Attach Type	File Name
Advertising	shortsurvey_notwantingassistance_CLEAN.pdf

Advertising	shortsurvey_notwantingassistance_HIGHLIGHTED.pdf
Advertising	Flyer_STAMPED.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.

Patients who complete the screening and informed consent will then participate in either the 1) Grocery Prescription – participants will receive a card loaded with $100 per month to be used on the Instacart Fresh Funds program website/app or a SodaHealth grocery prescription card to be used inside a Kroger or Food City stores. Patients who select grocery delivery where Instacart is not available will receive Food City meals for the same value. Both programs provide access to approved healthy foods based on the Dietary Approaches to Stop Hypertension (DASH) diet or 2) Medically Tailored Meals (MTM) – participants receive approximately 5 frozen meals per week from Mom's Meals that follow an approved diet for those with hypertension. Participants will complete screening questions (screening decision tree attached) after informed consent to determine which food package the participant will receive. The screening decision tree is a tool that asks about kitchen availability for preparing foods, skills, and access to transportation. Depending on how the patient answers they will receive either grocery prescription or MTM for 3-months or 12-weeks. (see screening decision tree questions to determine which FIM package they will receive).

Participants are first screened for food insecurity as part of standard of care across all UKHealthcare ambulatory clinics. Once they have agreed to wanting food assistance and complete the above mentioned details for enrollment they are then contacted to participate in one of the two described FIM programs. From screening to enrollment takes approximately 7 days. After that point they are then receiving either FIM package for 12-weeks. After they complete the 12-week FIM program they receive a follow-up survey asking the same questions related to food insecurity. However, in the follow-up survey there are additional questions related to acceptability of the program, ease of signing up, ease of participating, and feedback in general (See post intervention survey).

The procedures carried out include: 1) two surveys baseline and post intervention; 2) short surveys to understand the user-experience during the 3-month FIM package program; 3) participating in either the grocery prescription or the MTM program; 4) attending their clinical visits as part of standard of care.

Comparator Group - for those that answer "no" but agree to the 20-30 minute survey. They will receive a direct link to the survey to answer questions at one time point.

AIM 3
qualitative survey will be administered to nurses involved in screening and referral (N=2 nurses from UKHealthcare) and 2 clinic staff who are involved in the day to day operations of patients which may encounter questions from patients with the screener or who may need to help patients complete the screener if they did not at patient check-in. In addition, 14 will be recruited from those who participated in the FIM to participate. Patients who are enrolled in the food as medicine program will be contacted to participate in the brief user-feedback interviews during the 3-month food as medicine program. Up to 10 patients who were referred but chose not to enroll will be recruited to complete a brief user experience survey via Redcap.

Attachments

Attach Type	File Name
ResearchProcedures	DecisionTree_CLEAN.pdf
ResearchProcedures	DecisionTree_HIGHLIGHTED.pdf

Data Collection & Research Materials

In this section, please provide the following:

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

Participants will participate either the grocery prescription program or the MTM each week for 12-weeks. They are expected to shop for food each week and use their
grocery prescription card or will have the MTM delivered to their home. They will also participate in a survey at the beginning of the study and at the
end of the study. They will also, a select few, will participate in surveys that are delivered every 3 weeks to gauge user-centered design feedback about the entire screening, referral, enrollment process.
Participants will be recruited through any UKHealthcare ambulatory clinic since all of UKHealthcare will screen for food insecurity when patients make an appointment at a UKhealthcare clinic. Over 3 months a total of 200 adults diagnosed with HTN will be recruited to

participate in the study. They will fill out a link connected to RedCap for informed consent and enrollment into the study, as described above. The link will be provided via text and e-mail to those who meet eligibility criteria listed above. Once enrolled they will receive instructions for how to use their grocery prescription card at participating stores or how meal delivery via Mom's Meals will take place over the next 3-months or 12-weeks. They will be mailed a welcome packet, and will be sent via a text message with a link for instructions via the Food as Health Alliance webpage. The program coordinator (Christa Mayfield) will also follow-up after enrollment to make sure their initial account information is accurate. At first and last visit Via a RedCap link participants will fill out a baseline and post intervention survey with questions related to age, height, weight, USDA short-item food insecurity, meal planning, meal preparation questions.
Patients are allocated to one of two programs based on further screening with the screening decision tool and thus all patients will receive a FIM package. This is not a clinical trial. There is no randomization of subjects.
There are two methods of research materials. The first one (Patient Health Information PHI) is Blood pressure captured from the medical records. As part of epic reports, Blood pressure measurements are obtained as part of standard of care measurements. For those that are screened at Gill Heart clinic from face-to-face screening, Shorus will upload patient medical record data. This data will be provided from the Epic records “my chart” from Shorus, Brooke Poe and sent to Dr. Gustafson linked by participant name. Data will then entered into RedCap for each participant with their ID for two time points; baseline and post intervention. The chart review will take place approximately June 2024 - August 2024 for baseline and then time point two for post program PHI data collection after completing the food as medicine package September - November 2024. This data is necessary as change in blood pressure is the primary outcome of interest of the study. The implementation science questions aims to answer “ can a food as medicine program improve blood pressure over 12-weeks”. This data point is needed to answer the research question.

Secondary data points that will be captured are not patient data but is related to capturing how many patients that screen for food insecurity answer wanting assistance with food insecurity. During June 2024 - August 2024 Jessica Sass and Brooke Poe will run the Epic reports capture the following metrics.
"Percent screened" is derived by all those who answered the screener/ all those who received the screener over three months between June 2024 - August 2024. To quantify “all who received screener” Brooke Poe will run “slicer/dicer” in Epic each month to capture the # of patients that completed an appointment at the respective clinic with HTN ages 18+. To quantify those who answered the screener, the same process is conducted in Epic each month. Since all facilities must screen for FI in 2024 all patients should have received this screener. Screening success identification derived as: # of patients that screened positive for food insecurity/ # of patients that answered the screener. AIM 1b – rate of enrollment - To determine rates of enrollment in a FIM package we will assess # of patients who report “yes” for assistance/# of patients that screened positive for food insecurity. We will also assess # who received an FIM package/# who asked for assistance.

Survey – The survey will be sent via a text message which will contain a link to fill it out via RedCap. If participants do not want to or are not able to fill this out a data collector will set up a time to conduct the survey via the phone. They will also be able to fill out the survey via a welcome packet which contains a paper copy and a self-addressed stamped returned envelope with participant ID at the top right corner. The survey contains secondary data measures of food insecurity, meal planning, that are key to understanding the mediating effects of the intervention on the pathway to blood pressure control. These data points also allow investigators to understand what was effective in the intervention delivery from a process view point relative to what was cumbersome. We hope to gain understanding of process measures to conduct a larger scale study to be replicated across other sites. (see attachment for baseline and post intervention surveys and user-centered design surveys).

AIM 3 - Structured in a user-centered design approach, we will iteratively seek feedback from a subsample of patients (n=14) and providers (n=4, ideally 2 nurse manager/clinic) at critical decisions points in the development process of the new automated system. Feedback will be captured through brief 15-minute structured interviews where elements of the system design are presented to users (such as the language used in initial texts), feedback is obtained, and design elements are revised based upon that feedback. These interviews will occur starting at the beginning of the project, with approximately 2 interviews per person in the first 6 months of the grant, then as needed for the remainder of the study. We will collect in-depth qualitative data from a larger sample of users at the end of the implementation period. This will include a broader sample of patients who participated in face-to-face (n=15) and automation (n=15) screening and referral processes, all available nurse case managers or clinic managers from UK Healthcare. Qualitative interview guides developed by the research team using the CFIR framework for the staff members who are implementing the program, the participant interview guides will be developed based on user-centered design principles. In interviews, patients will be asked about their receipt of, comfort with, ease of use, and preference for the automated and face-to-face systems. Providers will be asked about the implementation process for their system, the burden of and their comfort with each system, as well as their perceptions of patient satisfaction. Each interview will last between 30-60 minutes and will be conducted over the phone or Zoom. All interviews will be audio recorded and transcribed verbatim by a professional transcription service. To collect key perspectives from eligible but unenrolled patients, we will recruit up to 10 patients who did not want assistance in the clinic office and 10 patients who were referred for assistance but did not enroll to complete brief user experience surveys via Redcap. Surveys will ask about food resources available and key barriers in the screening, referral, and enrollment process.

Attachments

Attach Type	File Name
DataCollection	POST Interview guide for healthcare partners CFIR.pdf
DataCollection	Baseline_survey_CLEAN.pdf
DataCollection	Baseline_survey_HIGHLIGHTED.pdf

DataCollection	post_survey_additionalquestions_CLEAN.pdf
DataCollection	post_survey_additionalquestions_HIGHLIGHTED.pdf
DataCollection	User_experience_surveyquestions_CLEAN.pdf
DataCollection	User_experience_surveyquestions_HIGHLIGHTED.pdf
DataCollection	User_experience_survey_not enrolled_08.30.24.pdf
DataCollection	POST intervention interview guide for patients_1.6.25_CLEAN.pdf
DataCollection	POST intervention interview guide for patients_1.6.25_HIGHLIGHTED.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.

The study team is utilizing staff and personnel from Public Health, College of Medicine, College of Ag, food, and environment and UKHealthcare for
recruitment, enrollment, and implementation of the study. Medical services are provided to participants as part of standard of care and thus our study is not requiring anything outside of normal procedures. Personnel at UKHealthcare will not conduct anything outside of normal operating procedures. Brooke Poe and Shorus will conduct the screening and list generating of patients as part of their MJR's and will assist with Epic capture of
eligible participants.

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?
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

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

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

Potential Benefits include improving understanding of how to prepare healthy meals, improvements in financial resources since food cost is being supplemented. There are no known potential risks. However, with any study there is always the possibility of some adverse outcome associated with participation in the survey process.

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).

Current standard of care treatment for Medicaid adults with hypertension is consultation with a registered dietitian and
ability to receive food supplements through Supplemental Nutrition Assistance Program and/or nearby food pantries. These individuals will be given referral to these services for those who choose not to participate will be provided with the same resources to help combat food insecurity.

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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

Medical records of only height, weight, blood pressure will be shared between UKHealthcare clinical personnel (Brooke Poe and Jessica Sass) on this study and the PI of the study. These data points will be uploaded into RedCap by the PI for merging with survey data for each study participant. Full datasets will be de-identified for use among Dr. Lauckner and Dr. Bush for data analyses, reporting of results, and
dissemination. All data will be stored on a password protected computer and only the Co-I's will have access to the data set. Data is stored on an encrypted computer. There are no physical files being retained.
For those who complete the survey by paper copy, the surveys will be kept in a locked file cabinet for a minimum of 6 years after study closure.
Transcripts from interviews will be stored in a password protected computer and will be stored for a minimum of 6 years after study closure.

☑ **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 payment with a Western Union MasterCard. The Mastercard will be sent to their homes and linked to their ID. They will have an empty Western Union Card at the start of the study. All participants will receive $50 uploaded to their card after completing the baseline survey and $25 uploaded to their card after completing the post intervention survey. A total of $25 will be uploaded
onto their card over the course of the intervention. If a card is lost or stolen, the account is canceled and a new
card will be sent to the participant. Christa Mayfield and Dr. Gustafson will share responsibility for this process and for checking all amounts.

For those who selected not wanting food assistance but agree to participate in a short survey they will receive $50 loaded onto a Western Union gift card.
For those who participate in AIM 3 the participant will receive $50 for their one hour interview. The Western Union card process will be used for those who participate in AIM 3.
For those who were referred but did not enroll and agree to the short survey, they will receive $25 onto a Western Union gift card.

Costs to Subjects

Describe any research costs which participants may be responsible for if they participate in the study (e.g., urine, HIV test).

There are no direct costs for participants to participate. They will be responsible for any costs of their food bill for items that are not eligible for the grocery prescription program, such as chips, candy.

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.

This program is not greater than minimal risk

Back to Top

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

Data may be saved to scientific databases and shared in the future. Data will be aggregated and no individual identifiers will be used for future use. Data may be used for up to six (6) years.

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

Attach Type	File Name
Waiver	MR 93234 HIPAA Waiver.pdf

STUDY DRUG INFORMATION

0 unresolved comment(s)

The term drug may include:

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

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

○ Yes ◉ No

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

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize 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:

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

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

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:

American Heart Association

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.):

American Heart Association

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.**

24FIM1255467 - American Heart Association Reference Number
Development of user-centered design screening, referral, enrollment, and engagement in Food as Medicine package

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

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 Status" 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	
Tammy	Stephenson	Department Authorization	Dietetics and Human Nutrition		01/18/2024 02:50 PM	View/Sign
Alison	Gustafson	Principal Investigator	Dietetics and Human Nutrition		01/18/2024 11:16 AM	View/Sign

Department Authorization

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

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

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

Principal Investigator's Assurance Statement

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

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

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

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

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Once all Assurance Statement signatures have been acquired, return to this section to submit your application to ORI.

SUBMISSION INFORMATION

0 unresolved comment(s)

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

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

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

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

Your protocol has been submitted.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.081	kjwi262	2/6/2025 1:21:02 PM
	Stamped Consent Form	Survey_consent_refused_assistance_06.27.24.pdf		0.132	kjwi262	2/6/2025 1:21:02 PM
	Stamped Consent Form	provider_qualitative_clean.pdf		0.219	kjwi262	2/6/2025 1:21:02 PM
	Stamped Consent Form	patient_qualitative_clean.pdf		0.250	kjwi262	2/6/2025 1:21:02 PM
	Stamped Consent Form	informed_consent_FIM_CLEAN.pdf		0.171	kjwi262	2/6/2025 1:21:02 PM
	Stamped Consent Form	Survey_consent_not_enrolled_08.30.24.pdf		0.132	kjwi262	2/6/2025 1:21:01 PM
	Stamped Consent Form	Survey_consent_staff_08.30.24.pdf		0.132	kjwi262	2/6/2025 1:21:01 PM
	DataCollection	POST intervention interview guide for patients_1.6.25_HIGHLIGHTED.pdf		0.189	clma291	1/7/2025 10:31:11 AM
	DataCollection	POST intervention interview guide for patients_1.6.25_CLEAN.pdf		0.188	clma291	1/7/2025 10:30:50 AM
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	CoverLetter	Survey_consent_not_enrolled_08.30.24.pdf		0.133	clma291	8/30/2024 1:43:42 PM
	DataCollection	User_experience_survey_not enrolled_08.30.24.pdf		0.114	clma291	8/30/2024 1:42:31 PM
	CoverLetter	Survey_consent_refused_assistance_06.27.24.pdf		0.133	clma291	6/27/2024 3:18:38 PM
	Advertising	Flyer_STAMPED.pdf		2.800	clma291	6/27/2024 3:15:22 PM
	Informed ConsentHIPAA Combined Form	informed_consent_FIM_CLEAN.pdf		0.172	clma291	5/31/2024 4:28:32 PM
	Advertising	shortsurvey_notwantingassistance_HIGHLIGHTED.pdf		0.068	clma291	5/30/2024 10:26:59 AM
	Advertising	shortsurvey_notwantingassistance_CLEAN.pdf		0.068	clma291	5/30/2024 10:26:51 AM
	DataCollection	User_experience_surveyquestions_HIGHLIGHTED.pdf		0.275	clma291	5/30/2024 9:14:29 AM
	DataCollection	User_experience_surveyquestions_CLEAN.pdf		0.273	clma291	5/30/2024 9:14:19 AM
	DataCollection	post_survey_additionalquestions_HIGHLIGHTED.pdf		0.171	clma291	5/29/2024 3:25:08 PM
	DataCollection	post_survey_additionalquestions_CLEAN.pdf		0.171	clma291	5/29/2024 3:24:57 PM
	DataCollection	Baseline_survey_HIGHLIGHTED.pdf		0.347	clma291	5/29/2024 3:24:47 PM
	DataCollection	Baseline_survey_CLEAN.pdf		0.345	clma291	5/29/2024 3:24:36 PM
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	ResearchProcedures	DecisionTree_CLEAN.pdf		0.100	clma291	5/13/2024 10:56:26 AM
	Waiver	MR 93234 HIPAA Waiver.pdf	HIPAA Waiver	0.200	kjwi262	3/12/2024 10:58:12 AM
	CoverLetter	patient_qualitative_clean.pdf		0.229	agu227	1/31/2024 4:00:49 PM
	CoverLetter	provider_qualitative_clean.pdf		0.198	agu227	1/31/2024 4:00:12 PM
	DataCollection	POST Interview guide for healthcare partners CFIR.pdf		0.135	agu227	1/18/2024 11:13:17 AM

Protocol Changes

Protocol Number: 93234

No Changes

There are no recorded changes tracked for this protocol.

Study Personnel Changes:

Status	PPIdentity	ProtocolID	PersonID	RoleInProtocol	IsContact	LastName	FirstName	Email	DeptCode	RoomBuilding	SpeedSort	PhoneNum	DeptDesc	AuthorizedConsent	ResponsibilityInProject	Degree	Rank	StatusFlag	IsRemoved	ModBy	ModDate	SFI	IsPIRN	MiddleName
Deleted	993361	102592	12402624	SP	N	Minella	Shorus	Shorus.Minella@uky.edu						N	Recruitment				Y	clma291	1/30/2025 2:09:16 PM	N		
Inserted	993368	102592	12143333	SP	N	Eapen	Nathan	Nathan.Eapen@uky.edu						Y	Data Collection			S	N	clma291	1/30/2025 2:07:09 PM	N		
Inserted	993369	102592	10036194	SP	N	Stone	Jacob	jlston2@uky.edu						N	Medical Supervisor			P	N	clma291	1/30/2025 2:08:21 PM	N		

No comments

Statistical Analysis Plan NCT07011251

Descriptive statistics with mean, SE, and percentage are reported for demographic variables. T-test and chi-square tests were used to look at changes pre- and post-intervention. Linear regression adjusted for sex, age, medication use, household size, household income, and race/ethnicity to examine the effect of participation in the FIM on primary and secondary outcomes. GLM was used to assess mean changes in dietary intake for men and women baseline to post intervention. Dietary intake is analyzed separately for men and women since they have different dietary needs and national guidelines. Chi square analyses were used to measure changes for categories in general health, financial strain, and food security status.