Document Coversheet

Study Title: Pilot Test of an mHealth Intervention for Reducing Alcohol Use Among Rural Adolescent and Young Adult Cancer Survivors

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	6/2/2025
NCT Number:	NCT05087875
IRB Number	67410
Coversheet created:	7/1/25

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 should review my research?
- 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.

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

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

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

Check the appropriate categories that apply to your research project:

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

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

A. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
B. Research on medical devices for which (i) an investigational device exemption application is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

* Study must meet one of the IDE Exempt categories listed on the Device Form Attachment.
** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements.
NOTE: Select Category 1 for compassionate use medical device applications or individual patient expanded access investigational drug applications for which FDA has waived the requirement for full review.

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☐ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

A. Hair and nail clippings in a nondisfiguring manner;
B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
C. Permanent teeth if routine patient care indicates a need for extraction;
D. Excreta and external secretions (including sweat);
E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
F. placenta removed at delivery;
G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
J. Sputum collected after saline mist nebulization.

☐ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
B. Weighing or testing sensory acuity;
C. Magnetic resonance imaging;
D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 5) Research involving materials (data, documents, records, or specimens) that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis) as well as research involving existing information or specimens that were previously collected for research purposes, provided they were not collected for the currently proposed research. (Note: Some research in this category may qualify for Exempt review. This listing refers only to research that is not exempt.)
(Note: If submission includes materials previously collected for either non-research or research purposes in a protocol for which IRB approval expired, you may check Category 5. However, a separate category must also be selected for prospective collection of data/specimens obtained solely for research purposes)

☐ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

***** 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.

Principal Investigator has been changed to Dr. McLouth.

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

Tracking and Reducing Alcohol Consumption for Adolescent and Young Adult Survivors of Cancer

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.

TRAC-AYA

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

Maximum number of human subjects (or records/specimens to be reviewed) 94

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:	Laurie	Room# & Bldg:	800 Rose St
Last Name:	McLouth	Speed Sort#:	40536
Middle Name	Elizabeth		
Department:	Behavioral Science - 7H150	Dept Code:	7H150
PI's Employee/Student ID#:	12462101	Rank:	
PI's Telephone #:	8595622526	Degree:	PhD
PI's e-mail address:	laurie.mclouth@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	11/7/2022
		RCR Trained:	Yes

Do you, the PI/researcher, 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 this FDA Guidance on Enrollment of Participants from Underrepresented Populations in Clinical Studies

Key Informant Interviews: Participants (n=14) will consist of AYA cancer survivors (n=6), Oncology providers (n=3) including physicians, nurses, nurse practitioners, or physician's assistants, psycho-oncology providers (n=3) (i.e. mental health professionals treating AYA cancer patients), and community advocates (n=2) (i.e. partners from the KY Cancer Consortium and the KY American Cancer Society). Survivors must be between the ages of 18-39 who were diagnosed with cancer between the ages of 15-39. Oncology providers must have been in practice for at least 6 months and spend at least 25% of their practice with AYA cancer patients. Psycho-Oncology providers must have been in practice for at least 6 months and see AYA cancer patients. All participants must speak English.

Open Pilot: Participants (n=4) will consist of AYA cancer survivors. To be eligible to participate in the open pilot, survivors must meet the following criteria:
1) diagnosed with cancer between age 15-39;
2) currently age 18-39;
3) 1-10 years posttreatment (hormonal therapy allowed);
4) report unhealthy alcohol use in the previous 3 months, defined as:
a. exceeding moderate daily drinking levels (more than 1 drink/day for women, more than 2 drinks/day for men) at least 3 times in the past 3 months OR
b. engaging in heavy weekly drinking (more than 7 drinks/week for women, more than 14 drinks/week for men) at least once in the past 3 months OR
c. engaging in binge drinking (more than 3 drinks/sitting for women, more than 4 drinks/sitting for men) at least once in the past 3 months;
5) meeting hazardous drinking criteria on the AUDIT-C questionnaire, defined as a score of 3 or higher for women/4 or higher for men (The AUDIT-C consists of items 1, 2, and 3 from the full AUDIT questionnaire);

Participants with severe psychopathology (psychosis, suicidal behavior, substance dependence) will be excluded from the study. The AUDIT questionnaire will be administered as part of screening to determine alcohol dependence; if survivors have a score of 20 or higher, they will be referred to UKMCC Social Work.

RCT: n=50, Intervention group (TRAC) n=25, and Control group (education and monitoring) n= 25. To be eligible to participate in the RCT, survivors must meet the following criteria:
1) diagnosed with cancer between age 15-39;
2) currently age 18-39;
3) 3 months - 15 years posttreatment (hormonal therapy allowed);
4) report unhealthy alcohol use in the previous 3 months, defined as:
a. exceeding moderate daily drinking levels (more than 1 drink/day for women, more than 2 drinks/day for men) at least 3 times in the past 3 months OR
b. engaging in heavy weekly drinking (more than 7 drinks/week for women, more than 14 drinks/week for men) at least once in the past 3 months OR
c. engaging in binge drinking (more than 3 drinks/sitting for women, more than 4 drinks/sitting for men) at least once in the past 3 months; OR
d. meeting hazardous drinking criteria on the AUDIT-C questionnaire, defined as a score of 3 or higher for women/4 or higher for men (The AUDIT-C consists of items 1, 2, and 3 from the full AUDIT questionnaire)
5) Reside in the United States

Just as with the Open Pilot, participants with severe psychopathology will be excluded from the study. The AUDIT questionnaire will be administered as part of screening to determine alcohol dependence; if survivors have a score of 20 or higher, they will be referred to UKMCC Social Work (if a patient at UK HealthCare). Non-UK patients will be provided with information for SAMHSA's treatment finder, national helpline, and local resources based on the zip code provided at the time of screening. Survivors who score a 20 or higher on the AUDIT questionnaire will not be eligible for the study, as this study is not designed to manage alcohol dependence and its immediate health risks.

Enrollment will begin February 2022 and continue through May 2023 or until the proposed participant pool is reached.

This project will be protected by a Certificate of Confidentiality, which will allow the researchers to refuse to disclose information about the participants or their behaviors unless in cases of child or elder abuse, neglect, or harm to the participants or others. Thus, we will not be required to report any drinking under the legal age of 21 to authorities or information about any other illegal activities.

Added June 2023: We will conduct Key Informant Interviews with cancer survivors aged 40 or older. Detailed eligibility criteria for these interviews are listed below.
1) currently aged 40 years or older;
2) 3 months - 15 years post-treatment (hormone therapy allowed);
3) engage in hazardous alcohol use, defined as:
a. screening positively for alcohol use on the AUDIT-C14 (3 or higher for women, 4 or higher for men) OR
b. reporting an instance of binge drinking (more than 4/5 drinks on one occasion for women/men) in the previous 3 months OR
c. reporting an instance of heavy drinking (more than 7/14 drinks in one week for women/men) in the previous 3 months OR
d. reporting exceeding moderate drinking limits (more than 1/2 drinks on one day for women/men on more than 3 occasions in the previous 3 months.
4) must be able to speak English.
The AUDIT questionnaire will be administered as part of screening to determine alcohol dependence; if survivors have a score of 20 or higher, they will be referred to UKMCC Social Work (if a patient at UK HealthCare). Non-UK patients will be provided with information for SAMHSA's treatment finder, national helpline, and local resources based on the zip code provided at the time of screening. Survivors who score a 20 or higher on the AUDIT questionnaire will not be eligible to participant in the key informant interviews.

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Kentucky State Census, 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:	0	0		
Asian:	4	2		
Black/African American:	6	8		
Latinx:	5	4		
Native Hawaiian/Pacific Islander:				
White:	25	49		
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!

Check All That Apply

- ☐ Informed Consent Form (and/or Parental Permission Form and/or translated short form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☐ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Reliance Consent Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- ☑ Stamped Consent Doc(s) Not Needed

Attachments

Informed Consent Process:

Using active voice, in the text box below, describe how investigators will obtain consent/assent. Include:

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)

- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

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

◉ Yes ○ No

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

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

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
  If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
  For information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.
- *Research Repositories*
  If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template.

Study is closed to enrollment. Stamped consent documents are not needed, and there are no active consenting procedures.

Previous informed consent procedures:
Key Informant Interview Consent:
Participants will be provided a copy of the consent form either in-person or electronically prior to the interview. At the beginning of the interview, the study coordinator will review the consent form and instruct the participant to sign the REDCap consent form (or paper consent form if done in person) if they have not already.

Open Pilot:
Participants will be provided a copy of the consent form either in-person or electronically, depending on their recruitment location (in clinic or remote). Either in person or during a phone call, the coordinator will go through the consent form with the participant, discussing:
a. The overall purpose of the study
b. The time commitment of the study
c. Their expectations as a participant
d. The randomization procedure and intervention/control conditions
e. The compensation they will receive in exchange for their time
f. Any questions the participant has
Once the participant has demonstrated sufficient understanding of the consent document, the coordinator will obtain signed consent, either on a paper form in person, or electronically via the REDCap eConsent framework.

RCT:
Eligible participants for the RCT will be provided a consent form either in person or electronically, depending on their recruitment location (in clinic or remote). The Study Coordinator will address any questions or concerns the participants have about the study; for remote recruitment, participants will be provided with contact information for the PIs, Study Coordinator, and UK ORI in case of questions or concerns. After participants complete the screener, indicate interest in participating, and meet all eligibility criteria, they will complete informed consent either 1) after being contacted by the study coordinator via their preferred method, or 2) being automatically directed to the eConsent in REDCap. Participants who have been pre-screened in the EHR and screen eligible and indicate interest will be automatically directed to the Informed Consent form. If the participant completes the screener, is eligible, and indicates interest in participating in the study but does not complete informed consent, the study coordinator will contact the participant to make sure there are no questions or concerns about the study. If the participant chooses to participate, they will complete consent by providing an electronic signature using the REDCap eConsent framework, or can sign a paper copy if consenting takes place in person.
A copy of the consent form will be sent with the patient on paper or electronically and retained via paper or electronically for study records.

Added June 2023: Interview participants will be provided with a copy of the consent form, either in-person or electronically prior to completing the demographic questionnaire or the interview. Participants will be provided with contact information for the PIs, Study Coordinator, and UK ORI in case of questions or concerns. After participants complete the screener, indicate interest in participating in the interview, and meet all eligibility criteria, they will complete informed consent.

Should participants have questions or complaints, they will be directed to contact the Principal Investigators, the Research Coordinator, or the ORI at 859-257-8428 or toll-free at 1-866-400-9424 (depending on the reason for the complaint or the question at hand). Contact information for these individuals will be provided during the informed consent process.

☐ 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:

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

○ **Option 3**

Describe how your study meets these criteria:

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

STUDY PERSONNEL **0 unresolved comment(s)**

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button.

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is required for a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed below. ***Residents and students who are PI's are encouraged to designate the faculty advisor or at least one other individual as a contact with an editor role (DP).***
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR/FR, MR) or 'Other Review", and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature:

- Search for personnel;
- Click "select" by the listing for the person you want to add;
- For each person, specify responsibility in the project, whether authorized to obtain informed consent, AND denote who should receive E-IRB notifications (contact status).

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's HSP FAQ page, the RCR Home 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
Borger	Tia	Data Analysis/Processing	SP	N	N		P	Y	09/04/2024	Y	N	02/21/2023	N	Y
Brown	Jaime	Project Assistance/Support	SP	N	N		P	Y	11/09/2023	Y	N	01/05/2023	N	Y
Burris	Jessica	Data Analysis/Processing	SP	N	N	PhD	P	Y	06/03/2024	Y	N	02/27/2023	N	Y
Burrows	William	Data Analysis/Processing	SP	N	N		P	Y	09/06/2024	Y	N	11/03/2023	N	Y
Bursac	Vilma	Study Coordinator	DP	Y	Y		P	Y	11/21/2022	Y	N	09/23/2021	N	Y
Carter	Sherry	Project Assistance/Support	SP	N	N		P	Y	02/21/2023	Y	N	01/24/2022	N	Y
Edward	Jean	Co-Investigator	SP	N	N	PhD, RN, CHPE	P	Y	12/19/2022	Y	N	04/11/2022	N	Y
Feather	Abigayle	Data Analysis/Processing	SP	N	N		P	Y	08/25/2022	Y	N	05/15/2024	N	Y
Haddix	Sandra	Data Analysis/Processing	SP	N	N		P	Y	09/01/2022	Y	N	12/17/2024	N	Y
Hands	Isaac	Project Assistance/Support	SP	N	N		P	Y	11/12/2024	Y	N	01/24/2022	N	Y
Haney	Kimberly	Study Coordinator	DP	Y	Y		P	Y	04/25/2024	Y	N	10/07/2021	N	Y
Izgarjan	Emily	Data Analysis/Processing	SP	Y	N		P	Y	09/04/2023	N	N	01/19/2024	N	Y
Kirklewski	Sally	Project Assistance/Support	SP	N	N		N	Y	03/03/3000		N	01/19/2024	N	Y
Lauckner	Carolyn	Co-Investigator	DP	N	Y	PhD	P	Y	04/13/2023	Y	N	05/21/2025	N	Y
Levens	Justin	Project Assistance/Support	SP	N	N		P	Y	01/26/2023	Y	N	10/04/2022	N	Y
Roberts	Monica	Study Coordinator	SP	Y	N	MA, LPCC	P	Y	01/17/2024	Y	N	04/08/2022	N	Y
Shelton	Brent	Data Analysis/Processing	DP	N	N		P	Y	06/14/2023	Y	N	03/30/2021	N	Y
Sorge	Caryn	Co-Investigator	SP	Y	N	MD	P	Y	10/28/2024	Y	N	04/22/2021	N	Y
Garton	Jackson	Study Coordinator	DP	Y	N		P	N	09/24/2021	Y	Y	03/08/2022	N	Y
Kieckbusch	Chaney	Project Assistance/Support	SP	N	N		P	Y	02/21/2024	Y	Y	12/18/2023	N	Y
Shearer	Andrew	Data Analysis/Processing	SP	N	N	MS	P	Y	04/15/2025	Y	Y	10/25/2024	N	Y
Shepherd	Haley	Data Collection	SP	Y	N		S	Y	07/11/2024	Y	Y	11/10/2022	N	Y
Stuck	Jennifer	Study Coordinator	DP	N	Y	MS	S	N	08/31/2021		Y	02/04/2022	N	N

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).

Each year in the U.S., nearly 90,000 people aged 15-39 (adolescents and young adults; AYAs) are diagnosed with cancer. Five-year survival for AYAs is over 80%. Most will live an additional 36-59 years after diagnosis. However, AYAs report poorer psychological and physical health compared to their unaffected peers and have greater than 2-fold risk of dying from non-cancer-related causes. Compared to older cancer survivors and their unaffected peers, AYAs are at elevated risk of cardiovascular disease, cancer recurrence or second primaries, and depression and anxiety. AYAs have high rates of underinsurance and limited access to health care. These disparities are especially salient in rural areas, where over 20% of survivors live. Rural cancer survivors are at increased risk for poorer survival, subsequent cancers, psychological distress, and report higher posttreatment health information needs, particularly in health promotion. Together, these findings suggest rural AYAs are a vulnerable population in need of interventions to improve physical and mental health during survivorship.

Post-treatment health interventions to reduce risk behaviors are critical to improving these outcomes. Interventions have been developed to address physical activity, nutrition, sleep, and mood in AYA cancer survivors. However, alcohol interventions are largely lacking, despite the high prevalence of alcohol use among AYA cancer survivors and the fact that alcohol consumption is associated with increased likelihood of cancer recurrence, development of other physical and mental health comorbidities, and poorer survival. Over 50% of AYA cancer survivors exceed moderate drinking recommendations, with studies finding that between 36-45% report binge drinking. Among survivors, alcohol use is associated with increased likelihood of recurrent cancer and reduced likelihood of survival. These effects are more pronounced among those who drink heavier amounts of alcohol. Alcohol use is also associated with increased risk of heart disease, stroke, liver damage, and increased susceptibility to infections—suggesting that reducing alcohol use would positively impact a variety of health outcomes among AYA cancer survivors. Alcohol use among AYA cancer survivors may be even higher in rural areas, where AYA drinking is higher and access to both health and psychological care is severely limited. Rural residents are also less likely to be screened for substance use during primary care visits and to receive follow-up substance use monitoring, demonstrating the need for supplementing substance use services and implementing evidence-based interventions for rural survivors. No known interventions have addressed rural AYA survivor alcohol use.

One strategy that has been proposed for addressing alcohol use in rural areas is mobile health (mHealth) interventions, especially given growing rates of smartphone ownership. mHealth and similar technology-based interventions have yielded high acceptability and positive effects on health (e.g., fruit/vegetable intake, physical activity) and psychosocial (e.g. anxiety, depression) outcomes among AYAs. However, despite the high prevalence of alcohol use among AYA survivors, few interventions have addressed it. A recent meta-analysis of mhealth substance use interventions among cancer survivors of all age groups found only eight studies that addressed alcohol use, with no clinical trials focused on rural AYA cancer survivors. Rural residents, particularly in Kentucky, have limited access to mental health and health care professionals and report multiple barriers to accessing care, including stigma, distance, and time constraints. An mHealth intervention removes these barriers by allowing participants to receive care without the added time and travel burden of attending an in-person appointment and takes advantage of the growing rates of smartphone ownership in rural areas. It is especially suited for the AYA population, as 96% of individuals aged 18-29 own a smartphone and almost half (48%) report being online "almost constantly."

mHealth approaches are ideal for AYAs given their high technological literacy, smartphone usage, and desire for mHealth tools. mHealth interventions overcome barriers to care experienced by rural survivors, such as transportation issues or stigma related to substance use counseling. A recent meta-analysis of technology-based substance use interventions among survivors found only one trial targeting AYAs and none targeting alcohol use in rural AYAs. The proposed study will address this gap in the literature by adapting and testing an 8-week motivational interviewing mHealth intervention, Tracking and Reducing Alcohol Consumption (TRAC), to reduce alcohol use among rural AYA cancer survivors during post-treatment survivorship. TRAC includes weekly phone sessions with an interventionist and incorporates smartphones for daily self-monitoring of alcohol use. We are currently testing TRAC with veterans living with HIV/AIDS (K01AA02530; PI: Lauckner), and it has shown promising preliminary results, with high feasibility, acceptability, and encouraging preliminary outcomes. However, TRAC has not been tested in AYAs. We therefore propose to adapt TRAC for rural AYAs and conduct a pilot randomized controlled trial (RCT) of the adapted intervention. The study will take place in Kentucky, which leads the nation in cancer incidence and mortality, is 40% rural, and has a higher incidence of AYA cancers compared to other states.

Added June 2023: Over 18 million people in the United States are cancer survivors. By 2032, this number is expected to increase to

over 22 million. Roughly 30% of cancer survivors in the U.S. report engaging in hazardous drinking (i.e., exceeding moderate drinking limits or engaging in binge drinking). Among survivors, alcohol use is associated with increased likelihood of cancer recurrence and reduced likelihood of survival. These effects are more pronounced among those who drink heavier amounts of alcohol. Beyond its effects on cancer incidence and mortality, alcohol is also a known risk factor for heart disease, stroke, liver disease, and immune dysfunction. Thus, decreasing alcohol use, particularly among those who engage in hazardous drinking, would significantly reduce morbidity and mortality among cancer survivors. We recently developed and are piloting a brief motivational interviewing mHealth intervention to reduce hazardous drinking among adolescent and young adult cancer survivors (i.e., survivors aged 18-39; R21CA261844-01; MPI: Lauckner, McLouth; IRB Protocol #67410), who frequently engage in binge and heavy drinking. Our formative research identified that adolescent and young adult cancer survivors (AYAs) had unique stressors that impacted their alcohol use, including fertility concerns, financial stress, and fear of cancer recurrence. Our intervention, called "TRAC-AYA," is tailored to address these potential triggers for alcohol use in this population. However, as AYAs comprise only 4% of the cancer survivor population, survivors over the age of 40 are also at heightened risk for cancer recurrence and second cancers, and hazardous alcohol use continues to be prevalent among individuals aged 40 or older, we now seek to expand the intervention to address the needs of these older survivors by conducting key informant interviews to identify additional content for modules on alcohol triggers relevant to this population. Given the different stages of life of AYAs vs. older survivors, as well as their unique risk profiles, we expect they will have different stressors that contribute to alcohol use.

Objectives

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

Posttreatment rural AYAs are an underserved group at risk for increased alcohol use and poor access to interventions, ultimately leading to poorer physical and mental health. mHealth interventions are recommended for AYAs and have shown high acceptability and positive health effects. To address the lack of mhealth interventions for alcohol use among rural AYAs, we will adapt and pilot an existing mHealth intervention (TRAC) to reduce alcohol use. We will conduct the study in Kentucky, which leads the nation in cancer incidence and mortality, has a higher incidence of AYA cancers compared to other states, is 40% rural, and encompasses over 100 medically underserved areas. The study team has expertise in mHealth interventions, cancer survivorship, clinical trials, and AYA oncology. Thus, we are well-equipped to complete the following Aims:

1. Adapt and refine TRAC for rural posttreatment AYAs. We will conduct semi-structured interviews with key informants (N=14; 6 AYAs, 8 AYA oncology clinicians and community advocates), and conduct an open pilot study (i.e., fully implement the intervention) with a small number of patients (N=4; 2 TRAC, 2 control comparison) to adapt the content and delivery procedures of TRAC for rural AYA cancer survivors, resulting in TRAC-AYA.

2. Test the feasibility and acceptability of conducting an RCT of TRAC-AYA with AYAs (N=50; 25 TRAC, 25 control comparison). Comparison group will receive alcohol monitoring and educational materials. The primary feasibility outcome will be enrollment (=60% of eligible AYAs approached enroll). Secondary feasibility outcomes include retention (=60% complete follow-up) and intervention adherence (=70% complete =60% of intervention sessions; alcohol monitoring =70%). Acceptability will be assessed with mean ratings (scores =7 out of 10) of intervention relevance, helpfulness, and convenience. We will also obtain preliminary data on alcohol use frequency, quantity, binge drinking, and health (PROMIS-29).
Impact: This study proposes an innovative intervention to address a prevalent, but unaddressed health problem in rural AYA survivors. The intervention is informed by preliminary data, leverages the high digital health literacy of AYAs, and will overcome access barriers to increase reach. At the end of this study, we will have feasibility data to inform a definitive RCT of TRAC-AYA to test efficacy, which we will test in the Markey Cancer Center Affiliate Network, a network of rural cancer clinics in Kentucky. If successful, TRAC-AYA could address alcohol use in the over 2 million AYAs living in the US and be generalized to other survivor populations, thus having a high impact on survivorship health outcomes and post-treatment care.

Added June 2023: We will further adapt and refine the TRAC intervention to suit an older population of cancer survivors through semi-structured interviews with key informants (N=35 cancer survivors aged 40 or older).

Study Design

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

- *Clinical Research*: Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *Community-Based Participatory Research*: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.
- *Qualitative research*: Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.
- *Research Repositories*: If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository, provide scientific justification for establishing an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK Research Registry Guidance.

The first part of this study is key informant interviews, which will be done using convenience sampling and conducted through videoconferencing, phone, or in person. The first part of this study will also include an open pilot, with participants randomized to receive either 1) a 4-week intervention with 6 weeks of daily monitoring, or 2) brief education with 6 weeks of daily monitoring. The open pilot will fully implement all study procedures associated with Aim 2, with feedback from participants used to further adapt the intervention as needed prior to implementing it during Aim 2.

This second part of this study is a pilot randomized trial using a parallel design. Individuals are randomized to receive 1) a 4-week intervention with 6 weeks of daily monitoring or 2) brief education with 6 weeks of daily monitoring. The intervention itself is an alcohol reduction intervention based on motivational interviewing and cognitive behavioral skills training for alcohol reduction. Such interventions have been found to successfully reduce alcohol consumption among multiple populations, so the design of the proposed intervention balances participant effort and potential for positive outcomes very well. A design using a brief education and daily monitoring comparison group was chosen for the pilot randomized trial because daily monitoring will provide a rich source of data by which to compare the two groups and examine change over time. Monitoring in and of itself may impact behaviors, thus control group participants may benefit as well, though the magnitude in the intervention group is expected to be larger.

Added June 2023: We will complete key informant interviews, conducted through videoconferencing, phone, or in person according to participant preference.

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

Key Informant Interviews: Oncology providers and psycho-oncology providers will be recruited from MCC and the MCC Affiliate Network, a network of 18 community cancer clinics in KY, as well as national networks of AYA researchers/providers (e.g. ECOG-ACRIN). Community advocates will be recruited through the network of the KY Cancer Consortium and the KY American Cancer Society and relevant contacts from the Markey Cancer Center Community Impact Office. These participants will be recruited through convenience and snowball sampling procedures. We will not use the KY Cancer Consortium, KY American Cancer Society, or Markey Community Impact Office networks to recruit participants; rather we will email known contacts at these organizations directly. We will contact potential participants via email to explain the study and ask if they are interested in participating. Individuals who are interested can call the study coordinator or respond to the email. They will answer brief screening questions via phone (if calling the study coordinator), or online via a REDCap survey (if responding the email) to make sure they meet eligibility criteria. If eligible, the coordinator will schedule a time to complete the interview. AYA survivor participants will be recruited from the UK Markey Cancer Center (MCC) Patient Advisory Group, MCC, and Dr. Sorge's AYA Clinic. We will accept direct referrals from AYA oncologists and providers at Markey Cancer Center. We will also examine clinic schedules and confirm initial eligibility through the medical record. We will obtain provider permission to contact eligible survivors through their preferred method of contact listed in their medical record or at an in-person clinic appointment. Additional recruitment attempts will be made through email, phone, texting (if patient's medical record indicates a preference for it), and mailed letters. Survivors will complete a brief eligibility screener to confirm eligibility and, if eligible, the coordinator will schedule a time to complete their interview.

Open Pilot: AYA cancer survivors will be recruited primarily through clinic schedule review with eligibility confirmed through medical record review. We will pre-screen AYA cancer survivors who have been seen at UK Markey Cancer Center in the past 6 months or have an upcoming appointment in the next month through the electronic health record. To identify potentially eligible survivors to screen, we will build an EPIC® report filtering survivors by relevant ICD-10 codes, oncology provider/relevant clinics, and age (current age 18-39). In addition to this, a Research Nurse working in the AYA clinic will create lists of potentially eligible patients who have an upcoming clinic appointment, and will facilitate communication with the patients and providers during recruitment. We will meet survivors who are potentially eligible in clinic at upcoming survivorship appointments. Survivors will be asked if they are willing to be screened for eligibility. Those who refuse to be screened will be asked to complete a brief refusal survey to indicate why and to collect basic demographic information to inform generalizability of the obtained sample. Those who are willing to be screened will complete a brief screener survey. In addition to in-person recruitment, we will also contact potentially eligible survivors through their preferred method of contact listed in their medical record (phone call, email, text message, MyChart message, or mailed letter), after receiving provider permission to do so. They will receive information describing the study, study coordinator and PI contact information for if they are interested in the study, as well as a refusal survey if they do not want to be screened for the study. If their email address is not provided in the medical record, they will be mailed a letter. This letter will be sent with a paper copy of the refusal survey, a form indicating interest in the study (participants provide their contact info), and a pre-paid envelope for them to return the materials to the research team. If we do not receive a response from this initial contact, we will follow up 3 times over a 3-week period. If we do not reach them after 3 attempts we will remove them from our recruitment list.

TRAC-AYA RCT: For the RCT, recruitment procedures will follow the same as the Open Pilot (see above), however we will do up to 3 recruitment attempts across a 3-month period--either in-person or remote. Time periods between attempts will vary due to clinic schedules (i.e., when potentially eligible patients have clinic appointments). If non-responsive, we will approach the patient again after a

3-month waiting period. In addition to the pre-screening and recruitment activities described above, at the time of check-in all AYA patients arriving for appointments at UK DanceBlue Hematology/Oncology Clinic will be given the opportunity to complete the screening questionnaire using a pre-programmed tablet to determine if they are eligible to participate. Patients would not normally complete questionnaires on a tablet when arriving for their appointments, thus this is not standard-of-care. The PIs, clinic physician (Dr. Caryn Sorge), and Research Nurse (Sherry Carter) will provide instruction to clinic staff regarding screening patients and distribute quick-reference study information sheets to keep in offices. The study coordinator will be available during business hours to provide assistance to clinic staff as needed. Clinic staff will not obtain informed consent or provide any further study information, and will be instructed to provide contact information for the research team should patients have questions about the study. We will also use online recruitment methods--posting approved recruitment language to relevant and appropriate online AYA survivor support groups and websites (including social media groups, e.g., Facebook). Advertisements for online recruitment have been reviewed and approved by UK Public Relations. Stamped versions are attached to this protocol.

In addition to these recruitment procedures, we will utilize the Markey Cancer Center Community Impact Office and their established connections with appropriate list-servs and organizations, as well as resources from UK Center for Clinical and Translational Science recruitment services. We will recruit subjects through flyers, brochures, and digital monitor screen ads (that can be used as a poster, postcard, or Featured Research Study on ukclinicalresearch.com). Study flyers created by the PRS team will be placed on Center for Clinical and Translational Science, Participant Recruitment Services (CCTS PRS) wall mounts located in UK Medical Center, KY Clinic, Good Samaritan Hospital, Turfland Clinic, Shriners, University Health Services, and Shriners. With requested permission, ads may be placed and removed on campus and area facilities by the PRS team. With permission, ads may be placed in businesses in the surrounding community and region by individual study teams. The flyer has been approved by UK Public Relations. The stamped flyer is attached to this protocol.

This study may be advertised on recruitment internet webpages in digital or video form (e.g., UKclinicalresearch.com, ResearchMatch.org, Wellnesshealthandyou.org, UK HealthCare monitor screens and UKclinicalresearch YouTube). The study will be promoted via social media, including UK_CCTS Facebook, UK_CCTS Twitter, UK_CCTS Instagram, UK and UKHC social media, and may be placed by study team on departmental/lab pages. If advertised on UKClinicalresearch.com, the online study flyer will include an option for interested individuals to enter and submit their contact information, they will be asked whether study team can contact them (Yes or No) via study-related text messages, and they will be asked, ‘How did you learn about the study? Internet and social media recruitment will follow the terms of use for each site utilized. The study will also be promoted through UK HealthCare monitor screens at the discretion of UK Healthcare.

Potential participants may be identified from registry databases, including but not limited to ResearchMatch.org*, WellnessHealthandYou.org, Sanders Brown Center on Aging, Infectious Disease, Dentistry, and the Markey Cancer Center. *ResearchMatch.org/uky will be utilized as a recruitment tool for this protocol. ResearchMatch.org/uky is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository (Vanderbilt University IRB #090207)." Once UK IRB approval is obtained the researcher or proxy will upload a flyer with no contact information via ResearchMatch email to selected de-identified participants in the ResearchMatch registry. If the de-identified participant selects “Yes, I’m interested!” the researcher or proxy will receive information about participant, including their contact information and health information they have provided to ResearchMatch. The study coordinator will review this information for inconsistencies in their profile (e.g., listing every health condition, listing health conditions that correspond to two different biological sexes, etc.). We will not contact volunteers who do not appear to be representing themselves honestly in ResearchMatch. The study coordinator will contact volunteers who express interest in the study and pass this initial review with more information about the research study. If the participant selects “No, thanks”, researcher or proxy will not receive any information from de-identified participant. The recruitment message to be used for ResearchMatch has also been approved by UK PR. The stamped document is attached to this protocol.

In addition, the CCTS attends several outreach activities to promote research participation in general (e.g., Roots & Heritage Festival, Latino Festival, Eastern Kentucky University Health fair, etc.) and brings all study flyers that are enrolling participants and using PRS services.

The study will also be advertised through regional AYA clinics (e.g., flyers placed in waiting areas, social media posts, etc.), and participants who are interested in the study may complete the eligibility screener. Participants will not be consented or enrolled at these clinics, and will be directed to contact the study team with any questions or concerns about the study.

RCT participants will also have the opportunity to earn additional money for successful referrals (i.e., the referred individual is eligible and enrolls in the study). If an individual is not a participant in the study but is willing to refer others, they can also receive this referral incentive. They will be given a set of materials including a unique numeric referral code to share with others they think may be interested in the study. Referrals will be confirmed with the referral code and the referred individual must be successfully enrolled (i.e., is eligible, completes informed consent, and completes the baseline survey). Individuals may earn $10 for each successful referral, with a maximum of 10 successful referrals (earning up to $100.00).

Participants who complete the screener through remote means (i.e., participant has not been identified and pre-screened in the EHR) will complete a post-screening follow-up interview (via phone call or Zoom, according to participant preference) to confirm eligibility. The study coordinator will review information about the study and, if interested in the study and determined to be eligible, will complete informed consent with the participant. The script for this interview is attached to this protocol.

Participants who complete the screener but do not meet eligibility criteria at the time of screening will be re-screened after 45 days, and, if eligible, have the opportunity to learn more about the study and choose whether they want to participate.

As in previous work, the PIs will monitor accrual weekly through reports of the number of patients screened, approached, and enrolled.

The Markey Cancer Center Protocol Review Monitoring Committee and Hematology-Oncology Translational Group will also monitor accrual. If accruals fall below projections, the Protocol Review Monitoring Committee will contact the PI to inquire about delays and solicit a plan for increasing accrual.

Participants identified as potentially eligible based on the medical record review who have upcoming appointments will be recruited in clinic using a recruitment script. Participants identified as potentially eligible based on the medical record review but who do not have an upcoming clinic appointment will be contacted through their preferred method of contact listed in their medical record, after receiving provider permission to do so. They will receive information describing the study, study coordinator and PI contact information for if they are interested in the study, as well as a refusal survey if they do not want to be screened for the study. If their email address is not provided in the medical record, they will be mailed a letter. This letter will be sent with a paper copy of the refusal survey, a form indicating interest in the study (participants provide their contact info) and a pre-paid envelope for them to return the materials to the research team.

Added June 2023: Recruitment methods for the Key Informant Interviews involving cancer survivors aged 40 or older will follow the same procedures for the TRAC-AYA RCT, as outlined above. Participants in these key informant interviews will not be approached without first getting approval to do so by their provider.

Attachments

Attach Type	File Name
Advertising	KII (40-64) MyChart recruitment 060923.docx
Advertising	KII (40-64) Phone recruitment 060923.docx
Advertising	KII (40-64) Text Recruitment 060923.docx
Advertising	CIO_email recruitment 020323.docx
Advertising	RCT_social media advertisement.pdf
Advertising	RCT_website advertisement.pdf
Advertising	BEHAV-134_MON with more info-STAMPED.pdf
Advertising	trac-aya flyer_mcc_final-STAMPED.pdf
Advertising	trac-aya_flyer_STAMPED.pdf
Advertising	trac-aya_researchmatch_STAMPED.pdf
Advertising	RCT_recruitment text message_111722_tracked.docx
Advertising	RCT_recruitment text message_111722_clean.docx
Advertising	op_recruitment letter_053122 - tracked changes.docx
Advertising	op_recruitment letter_053122.docx
Advertising	op_recruitment email_053122.docx
Advertising	RecruitmentContactInfoForm.docx
Advertising	RecruitmentScript.OpenPilot.docx
Advertising	Phone_script_Advocates_0811.docx
Advertising	Phone_script_Psych_0811.docx
Advertising	follow-up_email_Advocates_final.docx
Advertising	follow-up_email_Providers_0811.docx
Advertising	follow-up_email_Psych_0811.docx
Advertising	follow-up_email_Survivors_0811.docx
Advertising	follow-up_email_Survivors_UKMCC.docx
Advertising	Recruitment_Providers_10.06Clean.docx
Advertising	Recruitment_Advocates_10.06Clean.docx
Advertising	Recruitment_Psych_10.06Clean.docx
Advertising	Recruitment_Survivors_10.06Clean.docx
Advertising	Recruitment_Survivors_UKMCC_10.06Clean.docx
Advertising	Phone Script - Provider.docx
Advertising	Phone Script - Survivor UKMCC.docx
Advertising	Phone Script - Survivor.docx
Advertising	TRACAYA provider card_103122_trackedchanges.docx
Advertising	TRACAYA provider card_103122_clean.docx
Advertising	RCT_Email recruitment 010523_tracked.docx
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Advertising	MyChart Recruitment_010523_tracked.docx
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Advertising	RCT_Phone recruitment_010523_tracked.docx
Advertising	RCT_Phone recruitment_010523_clean.docx
Advertising	RCT_recruitment script 010523_tracked.docx
Advertising	RCT_recruitment script 010523_clean.docx
Advertising	Lauckner Image-STAMPED.pdf

Advertising	trac-bsc flyer_092023[30]_STAMPED.pdf
Advertising	KII 40-64 Email Recruitment_103123.docx
Advertising	KII 40-64 Letter Recruitment_103123.docx

Research Procedures

Describe how the research will be conducted.

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

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

Study Procedures: Key Informant Interviews
To achieve Aim 1, we will conduct key informant interviews with 14 individuals, including AYA cancer survivors (n = 6), multidisciplinary AYA oncology providers (n = 3), psycho-oncology providers (n = 3), and community cancer survivor advocates (n = 2). These interviews will be conducted in person, via phone, or videoconference, with no follow-ups or re-contacts. We will collect phone numbers or emails to provide $40 Amazon e-gift card as compensation.

Recruitment: Oncology providers and psycho-oncology providers will be recruited from MCC and the MCC Affiliate Network, a network of 18 community cancer clinics in KY, as well as from national networks of AYA researchers/providers (e.g. ECOG-ACRIN). Community advocates will be recruited through the network of the KY Cancer Consortium and the KY American Cancer Society. These participants will be recruited through convenience and snowball sampling procedures. We will not use the KY Cancer Consortium or KY American Cancer Society networks to recruit participants, but will just email known contacts at these organizations directly. We will contact potential participants via email to explain the study and ask if they are interested in participating. Individuals who are interested can call the study coordinator or respond to the email. They will answer brief screening questions via phone to make sure they meet eligibility criteria. If eligible, the coordinator will schedule a time to complete the interview. AYA survivor participants will be recruited from the UK Markey Cancer Center (MCC) Patient Advisory Group, MCC, and Dr. Sorge's AYA Clinic. We will examine clinic schedules and confirm initial eligibility through the medical record. Survivors who are potentially eligible will be sent an email or letter (if no email is included in the medical record) providing information about the study and giving them a chance to opt-out of being contacted. For those who do not opt-out, we will contact them via phone, email, or at clinic appointments and ask them to complete a brief screener. If eligible and interested, the coordinator will schedule a time to complete their interview.

Prior to the interview, all participants will be e-mailed a copy of the consent form (PDF) and a link to an online REDCap consent form. If they are recruited or are conducting their interview in person, we will provide a paper copy. The interviewer will discuss this consent form with the participants, answer any questions that they have, and ensure that the participant signs the consent form electronically prior to beginning the interview.

Interview Protocol: All interviews, which will be 45-60 minutes long, will be conducted through videoconferencing, phone, or in-person. The interviewer will have obtained signed informed consent and permission for the interview to be recorded before beginning the interview. If the interview is conducted via phone or in-person, only the audio will be recorded. If the interview is conducted via Zoom, both the audio and video will be recorded, however, video files will be immediately deleted after the interview is completed and only the audio files will be stored. Participants may turn off their video during the Zoom call if they choose to do so. The interview protocol will solicit feedback on intervention relevance, appropriateness, acceptability, and feasibility of TRAC content and delivery. Questions regarding the intervention content and components will focus on the overall concept of the proposed intervention for the population of rural AYA cancer survivors, the necessity of adding information about survivorship as it relates to alcohol use, stressors faced by rural AYAs that may impact alcohol use, the use of breathalyzers and frequency of monitoring, and the incorporation of breathing or stress reduction techniques. We will also inquire about the delivery of the intervention, asking about the planned number of sessions, the length of sessions, the use of smartphones, and strategies for retention and adherence, among other topics. The interviewer will provide reference materials to the participants via e-mail ahead of the interview, including a diagram of the study steps and components and an example participant manual (these materials are still in development). Participants will be invited to share any final thoughts, and then the interviews will be concluded. Individuals will receive a $40 Amazon e-gift card in exchange for their participation.

Study Procedures: Open Pilot
To achieve Aim 1, we will conduct an open pilot of the TRAC intervention, with a total of 4 participants (2 per condition). Participants in the open pilot will be enrolled in the study for a total of 4 weeks, whether they are in the intervention or control group. If participants are unable to complete study tasks within the 4-week period, they will be given up to 8 weeks to complete the study before being considered noncompleters.

Intervention (Group A) participants will complete 4 intervention sessions on a weekly basis, conducted via phone or videoconference (HIPAA-compliant Zoom), according to participant preference. These sessions will be audio recorded. Participants will also complete daily self-monitoring of alcohol use using mobile surveys and breathalyzers. Control (Group B) participants will receive educational materials regarding alcohol use and will complete mobile monitoring of alcohol use in the same manner as Group A for 4 weeks. All open pilot participants will complete a baseline assessment survey upon enrollment, and a follow-up survey once all intervention/monitoring tasks are completed. All participants will complete a qualitative exit interview which will be audio recorded. Data collected from participants' medical records as part of the recruitment and enrollment process (e.g., cancer type and treatment history,

date of diagnosis, hospitalization history) will be integrated with participants' survey responses and become part of their study record.

The total estimated maximum time commitment for Open Pilot Group A (Intervention) participants is 10 hours, 40 minutes. The total estimated maximum time commitment for Open Pilot Group B (Control) participants is 7 hours, 40 minutes.

All Open Pilot participants will receive up to $220.00 in Amazon e-gift cards for their participation.

Study Procedures: Randomized Controlled Trial
To achieve Aim 2, we will conduct a pilot RCT of the TRAC-AYA intervention with a total of 50 participants (25 per condition). Participants in the RCT will be enrolled in the study for a total of 10 weeks, whether they are in the intervention or control group. If participants are unable to complete monitoring or intervention tasks within the initial 4-week period, they will be given up to 6 weeks to complete the tasks before being considered noncompleters. The delayed post-test is delivered 4 weeks after completion of all monitoring/intervention tasks at 10 weeks.

Intervention (Group A) participants will complete 4 intervention sessions on a weekly basis, conducted via phone or videoconference (HIPAA-compliant Zoom), according to participant preference. These sessions will be audio recorded. Participants will also complete daily self-monitoring of alcohol use using mobile surveys and breathalyzers for 6 weeks. Control (Group B) participants will receive educational materials regarding alcohol use and will complete mobile monitoring of alcohol use in the same manner as Group A for 6 weeks. All RCT participants will complete a baseline assessment survey upon enrollment, a follow-up survey once all intervention/monitoring tasks are completed at 6 weeks, and a qualitative exit interview which will be audio recorded. All RCT participants will also complete a delayed post-test assessment at 10 weeks, 4 weeks after they complete the follow-up survey.

The total estimated maximum time commitment for RCT Group A (Intervention) participants is 13 hours, 45 minutes. The total estimated maximum time commitment for RCT Group B (Control) participants is 10 hours, 45 minutes.

All RCT participants will receive up to $315 in Amazon e-gift cards for their participation.

Added June 2023: Study Procedures: Key Informant Interviews
We will conduct key informant interviews with 35 adult cancer survivors. These interviews will be conducted in person, via phone, or video conference, with no follow-ups or re-contacts. We will collect phone numbers or emails to provide $40 Amazon e-gift card as compensation. Prior to the interview, all participants will be emailed a copy of the consent form (PDF) and a link to an online REDCap consent form. If they are recruited or are conducting their interview in person, we will provide a paper copy. The interviewer will discuss this consent form with the participants, answer any questions that they have, and ensure that the participant signs the consent form electronically prior to beginning the interview. Participants will also complete a brief demographics survey, either before or directly after the interview.

Interview Protocol: All interviews, which will be 45-60 minutes long, will be conducted through videoconferencing, phone, or in-person. The interviewer will have obtained signed informed consent and permission for the interview to be recorded before beginning the interview. If the interview is conducted via phone or in-person, only the audio will be recorded. If the interview is conducted via Zoom, both the audio and video will be recorded, however, video files will be immediately deleted after the interview is completed and only the audio files will be stored. Participants may turn off their video during the Zoom call if they choose to do so. The interview protocol for Round 1 of interviews will solicit feedback on intervention relevance, appropriateness, acceptability, and feasibility of TRAC content and delivery. Questions regarding the intervention content and components will focus on the overall concept of the proposed intervention for the population of adult cancer survivors, the necessity of adding information about survivorship as it relates to alcohol use, stressors faced by adult survivors that may impact alcohol use, the use of breathalyzers and frequency of monitoring, and the incorporation of breathing or stress reduction techniques. We will also inquire about the delivery of the intervention, asking about the planned number of sessions, the length of sessions, the use of smartphones, and strategies for retention and adherence, among other topics. The interviewer will provide reference materials to the participants via email ahead of the interview, including a diagram of the study steps and components and an example participant manual. Round 2 of interviews will solicit feedback from participants about TRAC intervention content, adapted based on feedback provided during Round 1. Participants will be invited to share any final thoughts, and then the interviews will be concluded. Individuals will receive a $40 Amazon e-gift card in exchange for their participation.

The interview protocol and reference materials for Round 1 of interviews is attached to this protocol. Materials for Round 2 will be developed once Round 1 of interviews has concluded, and will be added to this protocol for review and approval prior to implementing them with participants.

Any audio recordings will be transcribed using a transcription service. This service will sign an agreement promising accuracy and confidentiality. Drs. McLouth and Lauckner and the study coordinator will annotate transcripts to identify which aspects of TRAC were the focus of comments. Annotated transcripts will be reviewed to refine proposed coding categories and create a coding categories dictionary. Coders (student research assistants) will meet to compare results and resolve any discrepancies through consensus. Proposed initial coding categories are: Usability of delivery (e.g., perceived efficiency, ease), Length (appropriateness, acceptability), Content (appropriateness, helpfulness, relevance), and AYA specific education (e.g., AYA survivorship and risks of alcohol use for AYAs). If needed, data will be managed in NVivo software and we will engage the Markey Shared Resource Facility for additional coding support.

No study results from Aims 1 or 2, or the additional key informant interviews (added June 2023) will be placed into participants' medical records.

Attachments

Data Collection & Research Materials

In this section, please provide the following:

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

Key Informant Interviews: We will conduct key informant interviews with 14 individuals, including AYA cancer survivors (n = 6), multidisciplinary AYA oncology providers (n = 3), psycho-oncology providers (n = 3), and community cancer survivor advocates (n = 2). These interviews will be conducted in person or via phone or videoconference, with no follow-ups or re-contacts. The interviews will be conducted by the study coordinator, use a semi-structured interview guide developed by Drs. Lauckner and McLouth, and audio recorder if conducted via phone or in-person. Interviews will be supplemented by interview notes. Interviewees will complete a brief demographic survey prior to beginning the interview. The interview protocol will solicit feedback on intervention relevance, appropriateness, acceptability, and feasibility of TRAC content and delivery. Questions regarding the intervention content and components will focus on the overall concept of the proposed intervention for the population of rural AYA cancer survivors, the necessity of adding information about survivorship as it relates to alcohol use, stressors faced by rural AYAs that may impact alcohol use, the use of breathalyzers and frequency of monitoring, and the incorporation of breathing or stress reduction techniques. We will also inquire about the delivery of the intervention, asking about the planned number of sessions, the length of sessions, the use of smartphones, and strategies for retention and adherence, among other topics. The interviewer will provide reference materials to the participants, including a diagram of the study steps and components and an example participant manual. Participants will be invited to share any final thoughts, and then the interviews will be concluded.

Open Pilot and RCT Recruitment Tracking: Potentially eligible participants will be entered into the REDCap database using the Masterlist form. This is the only form that links participants' names and MRNs with their unique study identification number. The potential participant's upcoming clinic appointment will be entered into the Recruitment Tracking Log form in REDCap. Data collected from participants' medical records as part of the recruitment and enrollment process (e.g., cancer type and treatment history, date of diagnosis, hospitalization history) will be stored in forms in REDCap, separate from participants' names and MRNs. These data will be integrated with participants' survey responses.

Open Pilot Enrollment: The open pilot will enroll 4 participants, 2 per condition. First, we will administer a screener to verify participants meet all inclusion criteria. If patients do not wish to be screened and are not interested in participating in the study, we will ask that they complete a brief Refusal to Screen Questionnaire to indicate why and collect basic demographic information to inform generalizability of the obtained sample. If participants agree to be screened and are determined to be eligible for the study, we will also collect information for at least 1 emergency contact (participants have the option to provide a backup emergency contact). We will contact these individuals only in cases of extreme distress, adverse events, or threats of self-harm. We will make clear to participants that we will not specify the nature of the research study to these individuals. If the participant is a patient at UK HealthCare, researchers will also contact their medical care team should any of these cases arise. Once participants have been enrolled in the study they will complete a baseline questionnaire, which may be done in-person, online via REDCap, via phone, or via mail per participant preference. It will ask about 1) Alcohol use, consequences, and attitudes, 2) Tobacco and other substance use, 3) Cancer history, 4) Overall physical/mental health , 5) Healthcare usage and history, 6) Financial toxicity, 7) Health literacy, 8) Coping Self-efficacy, 9) Social support, and 10) Drinking refusal self-efficacy.

Open Pilot Data Collection: For Group A (Intervention) participants only, a brief treatment expectations questionnaire assessing their attitudes toward the intervention will be administered. Additionally, after each counseling session, Group A participants will complete a short intervention session rating questionnaire. All counseling sessions will be audio recorded in order to provide supervision and fidelity checks for the interventionist. Both Group A and Group B (Control) will complete surveys assessing daily alcohol intake each morning and report blood alcohol content (via breathalyzer readings uploaded to REDCap) each evening until they have completed 28 total days of monitoring. In the unlikely event that participants are not able to upload their breathalyzer reading to REDCap, they will text a screenshot of their reading to the study coordinator on a study cell phone who will upload the reading to REDCap on the participant's behalf. Readings will be deleted from the study cell phone immediately after they are uploaded into REDCap. After all intervention/monitoring tasks are completed, both groups will complete a follow-up questionnaire, which may be done in-person, online via REDCap, via phone, or via mail per participant preference. The follow-up questionnaire matches the initial baseline questionnaire, with additional questions about satisfaction with the intervention being shown to Group A (Intervention). All Open Pilot participants will also complete a 20-30 minute semi-structured exit interview at the end of their enrollment period (between 4-8 weeks, depending on how long it takes for them to complete intervention/monitoring tasks). This interview will ask about perceptions of monitoring technology, perceived effects of monitoring, need for additional support, and suggestions for improvement. In addition to these, Group A (Intervention) participants will be asked questions regarding overall satisfaction with the TRAC program, reactions to session content, length, and components. The study coordinator will conduct the interviews. Interviews will be audio recorded and transcribed using a transcription service.

RCT Enrollment: The RCT will enroll 50 participants, 25 per condition. First, we will administer a screener to verify participants meet all inclusion criteria. If patients do not wish to be screened and are not interested in participating in the study, we will ask that they complete a brief Refusal to Screen Questionnaire to indicate why and collect basic demographic information to inform generalizability of the obtained sample. If participants complete the screener and indicate that they are interested in learning more about the study, we will collect their contact information and a member of the study team will follow-up with the participant to obtain informed consent and complete enrollment if they meet all eligibility criteria. Pre-screened participants who screen eligible and indicate interest in the study will be automatically directed to the approved eConsent in REDCap. If participants are determined to be eligible for the study and

consent to enroll, we will also collect information for at least 1 emergency contact (participants have the option to provide a backup emergency contact). We will contact these individuals only in cases of extreme distress, adverse events, or threats of self-harm. We will make clear to participants that we will not specify the nature of the research study to these individuals. If the participant is a patient at UK HealthCare, researchers will also contact their medical care team should any of these cases arise. Once participants have been enrolled in the study they will complete a baseline questionnaire, which may be done in-person, online via REDCap, via phone, or via mail per participant preference. It will ask about 1) Alcohol use, consequences, and attitudes, 2) Tobacco and other substance use, 3) Cancer history, 4) Overall physical/mental health , 5) Healthcare usage and history, 6) Financial toxicity, 7) Health literacy, 8) Coping Self-efficacy, 9) Social support, and 10) Drinking refusal self-efficacy.

RCT Data Collection:For Group A (Intervention) participants only, a brief treatment expectations questionnaire assessing their attitudes toward the intervention will be administered. Additionally, after each counseling session, Group A participants will complete a short intervention session rating questionnaire. All counseling sessions will be audio recorded in order to provide supervision and fidelity checks for the interventionist. Both Group A and Group B (Control) will complete surveys assessing daily alcohol intake each morning and report blood alcohol content (via breathalyzer readings uploaded to REDCap) each evening until they have completed 42 total days of monitoring. In the unlikely event that participants are not able to upload their breathalyzer reading to REDCap, they will text a screenshot of their reading to the study coordinator on a study cell phone who will upload the reading to REDCap on the participant's behalf. Readings will be deleted from the study cell phone immediately after they are uploaded into REDCap. After all intervention/monitoring tasks are completed at 6 weeks, both groups will complete a follow-up questionnaire, which may be done in-person, online via REDCap, via phone, or via mail per participant preference. The follow-up questionnaire matches the initial baseline questionnaire, with additional questions about satisfaction with the intervention being shown to Group A (Intervention). All RCT participants will also complete a 20-30 minute semi-structured exit interview after completing the follow-up questionnaire. This interview will ask about perceptions of monitoring technology, perceived effects of monitoring, need for additional support, and suggestions for improvement. In addition to these, Group A (Intervention) participants will be asked questions regarding overall satisfaction with the TRAC program, reactions to session content, length, and components. The study coordinator will conduct the interviews. Interviews will be audio recorded and transcribed using a transcription service. Finally, 4 weeks after participants complete the follow-up survey, RCT participants will complete the delayed post-test survey at 10 weeks. This final data collection instrument matches the follow-up survey, but will not contain questions relating to satisfaction with the TRAC program. Participants may complete the delayed post-test in-person, online via REDCap, via phone, or via mail per participant preference.

Added June 2023: Key Informant Interviews: We will conduct key informant interviews with 35 adult cancer survivors. These interviews will be conducted in person or via phone or video conference, with no follow-ups or re-contacts. The interviews will be conducted by the study coordinator, use a semi-structured interview guide developed by Drs. Lauckner and McLouth, and audio recorder if conducted via phone or in-person. Interviews will be supplemented by interview notes. Interviewees will complete a brief demographic survey prior to beginning the interview. The interview protocol will solicit feedback on intervention relevance, appropriateness, acceptability, and feasibility of TRAC content and delivery. Questions regarding the intervention content and components will focus on the overall concept of the proposed intervention for the population of adult cancer survivors, the necessity of adding information about survivorship as it relates to alcohol use, stressors faced by adult survivors that may impact alcohol use, the use of breathalyzers and frequency of monitoring, and the incorporation of breathing or stress reduction techniques. We will also inquire about the delivery of the intervention, asking about the planned number of sessions, the length of sessions, the use of smartphones, and strategies for retention and adherence, among other topics. The interviewer will provide reference materials to the participants, including a diagram of the study steps and components and an example participant manual. Participants will be invited to share any final thoughts, and then the interviews will be concluded.

No data collected will be entered into any UK HealthCare medical record.

Attachments

Attach Type	File Name
DataCollection	Round 2 Interview Protocol_0227.docx
DataCollection	TRAC Interview Reference Materials_Round2_0227.docx
DataCollection	KII (40-64) Round 1 Interview Protocol 110923 - tracked changes.docx
DataCollection	KII (40-64) Round 1 Interview Protocol 110923 - clean.docx
DataCollection	RCT Intervention Group Exit Interview Protocol 110923 - tracked changes.docx
DataCollection	RCT Intervention Group Exit Interview Protocol 110923 - clean.docx
DataCollection	RCT Control Group Exit Interview Protocol 110923 - tracked changes.docx
DataCollection	RCT Control Group Exit Interview Protocol 110923 - clean.docx
DataCollection	40-64_Demographic Survey.pdf
DataCollection	40-64_Screener.pdf
DataCollection	KII 40-64 Reference Materials_final.docx
DataCollection	BACtrack Mobile Breathalyzer Troubleshooting Tips.docx
DataCollection	RCT - Screener 051223.pdf
DataCollection	Post-Screening Interview Script 040323.docx
DataCollection	ContactInfo_TRACAYARCTScreenin.pdf
DataCollection	ScreeningRefusalQuestionnaire_(1).pdf
DataCollection	RecruitmentTrackingLog_TRACAYA.pdf
DataCollection	Masterlist_TRACAYAOpenPilotScr(1).pdf
DataCollection	OP_Intervention_iPhone - tracked changes.docx
DataCollection	OP_Intervention_iPhone.docx
DataCollection	OP_Intervention_Android - tracked changes.docx

DataCollection	OP_Intervention_Android.docx
DataCollection	OP_Control Orientation_iPhone - tracked changes.docx
DataCollection	OP_Control Orientation_iPhone.docx
DataCollection	OP_Control Orientation_Android - tracked changes.docx
DataCollection	OP_Control Orientation_Android.docx
DataCollection	PreScreening_TRACAYAOpenPilotS.pdf
DataCollection	ContactInfoForRecruitment_TRAC.pdf
DataCollection	Open Pilot - Screener.pdf
DataCollection	Open Pilot and RCT_Breathalyzer data submission.pdf
DataCollection	Open Pilot and RCT_Refusal form.pdf
DataCollection	Adovcate - Interview Script.pdf
DataCollection	Providers - Interview Script.pdf
DataCollection	Psych - Interview Script.pdf
DataCollection	Survivor - Interview Script.pdf
DataCollection	SurvivorScreener_TRACAYAAim1.pdf
DataCollection	ProviderScreener_TRACAYAAim1.pdf
DataCollection	AdvocateDemographicSurvey_TRAC.pdf
DataCollection	PsychoOncDemographicSurvey_TRAC.pdf
DataCollection	ProviderDemographicSurvey_TRAC.pdf
DataCollection	SurvivorDemographicSurvey_TRAC.pdf
DataCollection	KIIAdvocateScreener_TRACAYA.pdf
DataCollection	KIIPsychScreener_TRACAYA.pdf
DataCollection	KII_InterviewMaterials_final.pdf
DataCollection	KII_protocol.docx
DataCollection	AUDIT_scoring.pdf
DataCollection	TRACAYA Study Text Message Prompts.docx
DataCollection	orientation manual for coordinator_111822_tracked.docx
DataCollection	orientation manual for coordinator_111822_clean.docx
DataCollection	RCT_Survey Option - Baseline_111722.pdf
DataCollection	BaselineSurvey_TRACAYARCTScree.pdf
DataCollection	BaselineSurvey_paper copy_111022.pdf
DataCollection	PostSurvey_Intervention.pdf
DataCollection	PostSurvey_Control.pdf
DataCollection	DelayedPostSurvey_Intervention.pdf
DataCollection	DelayedPostSurvey_Control.pdf
DataCollection	Post-Survey_Intervention_paper copy_111022.pdf
DataCollection	Post-Survey_Control_paper copy.pdf
DataCollection	Delayed Post-Survey_Intervention_paper copy.pdf
DataCollection	Delayed Post-Survey_Control_paper copy.pdf
DataCollection	rct_control_android_110422_tracked.docx
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DataCollection	rct_control_iphone_110422_clean.docx
DataCollection	rct_intervention_android 110822_tracked.docx
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DataCollection	rct_intervention_android 110822_clean.docx
DataCollection	trac interventionist manual_110822_tracked.docx
DataCollection	trac interventionist manual_110822_clean.docx
DataCollection	DailySelfReportSurvey_TRACAYAR.pdf
DataCollection	DailyProAdditionalTrackingPref.pdf
DataCollection	ContactInfoForRecruitment_TRAC.pdf
DataCollection	PreScreening_TRACAYARCTScreeni.pdf
DataCollection	T1TreatmentExpectancy_TRACAYAR.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.

Resources include the PIs and study personnel, UK provided office space, UK provided desktop computers, UK-provided laptops, a UK provided study email address, smartphones for the study coordinator and to give to participants as needed, the breathalyzer mobile app, and Markey Cancer Center medical records, and Markey's OnCore system.

Study personnel will use UK provided computers. Desktops will be located in Dr. Lauckner and Dr. McLouth's offices in the Healthy Kentucky Research Building, Dr. Sorge's office at 800 Rose St., and Dr. Shelton's office at the Markey Cancer Center. Laptops will be kept in a locked office when not in use. All computers will be password protected. Only study personnel will have access to the computers. All data will be stored on a UK hosted, HIPAA compliant OneDive, under multiple layers of password protection. In the event that we need to access study information away from on-campus offices, UK's VPN will be used. No data will be stored on personal devices. Data on laptops will be encrypted.

Potential Risks & Benefits

Risks

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

Benefits

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

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

For key informant interview participants, there is the potential risk of anxiety or discomfort when reporting opinions, but these are expected to be minimal.

For all Open Pilot and RCT participants, there is the potential risk of anxiety or discomfort when reporting opinions or receiving intervention content. The intervention asks participants to reflect on their drinking, including reasons for drinking and its consequences, as well as to monitor their alcohol use. For some participants, thinking about their alcohol use may cause distress. However, in Dr. Lauckner's pilot research to date with veterans with HIV/AIDS, the TRAC intervention has not increased psychological distress or problematic alcohol use. Additionally, there is also the risk of loss of confidentiality, as identifying information will be collected in order to monitor participants' data throughout the course of the planned research. There are also inherent risks in using mobile phones for delivering a health intervention. Participants and study personnel will receive thorough training on how to secure their mobile phones to prevent any unauthorized access to data, and each study phone will have the potential to be remotely wiped in case of theft or loss.

In the event that identifying information is released to an unauthorized party, the substance use behaviors of participants could be revealed to unwanted individuals. This could potentially cause harm, but is unlikely considering the careful plans in place regarding data management and protection. All possible measures will be taken to protect information provided through surveys and intervention participation. Following completion of data collection, responses will become anonymous as identifying information is permanently deleted. For these reasons, we estimate that this project poses minimal risk.
Potential Benefits of the Proposed Research to Human Subjects: Participants in the intervention groups of the Open Pilot and RCT will benefit primarily by receiving free alcohol reduction counseling, which has potential to not only reduce their alcohol use, but improve their overall health. The self-monitoring aspect, which control group participants will also receive, will increase their own awareness of their behaviors and potentially improve their ability to recognize contextual predictors that encourage alcohol use. All participants will receive these benefits with minimal effort, as the intervention can be entirely delivered via mobile phone. By demonstrating feasibility of the intervention through this pilot research, the study will set the stage for a large-scale randomized controlled trial and the opportunity to extend this intervention to a much wider population. Thus, as a whole, these benefits far outweigh the potential risks associated with participation in this research.

Importance of Knowledge to be Gained: The research literature related to alcohol consumption among rural AYA cancer survivors is scarce, with no known interventions specifically targeting this population. The planned study will test an intervention delivered using smartphones, extending reach into areas of rural Kentucky where specialty services and mental health care are scarce. If this intervention is shown to be feasible and acceptable, it will demonstrate that alcohol reduction interventions have potential to be delivered successfully using technology that greatly improves accessibility and that is familiar to the population of AYA cancer survivors. It is the hope that the pilot research proposed here will pave the way for larger randomized controlled trials and intervention extensions, perhaps through the development of a mobile app or targeting other cancer survivor populations.

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).

Those who choose not to participate can receive standard psychosocial care available through the UK Markey Cancer Center Psycho-Oncology program.

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Records, Privacy, and Confidentiality

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

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

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

If this study will use de-identified data from another source, describe what measures will be taken to ensure that subject identifiers are not given to the investigator.

If applicable, describe procedures for sharing data/specimens with collaborators not affiliated with UK.

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

Data consists of pre-screening eligibility criteria from the EHR, participant survey responses (refusal survey, eligibility screener, pre- and post-assessments), breathalyzer readings (collected via a smartphone app and results uploaded to REDCap), exit interviews, audiorecordings of orientation and intervention sessions, and administrative tracking forms (e.g., intervention session completions, fidelity ratings). In the unlikely event that participants are not able to upload their breathalyzer reading to REDCap, they will text a screenshot of their reading to the study coordinator on a study cell phone who will upload the reading to REDCap on the participant's behalf. Readings will be deleted from the study cell phone immediately after they are uploaded into REDCap. These data are necessary for recruitment, study conduct, and intervention evaluation. A masterlist, consisting of participants' name, contact information, and random study identifier, is needed in order to reimburse participants and track recruitment efforts.
Audio files of interviews will be transcribed using a confidential transcription service. The transcription service will provide a signed certification that the transcription is accurate and confidential. Once transcription is complete, the audio files will be deleted. Transcripts from the interviews will be coded using a unique pseudonym. All transcripts will be kept as a password protected file on study personnel UK-hosted Onedrive and shared only with the Principal Investigators and members of the study team listed on this application. No paper transcripts will be used.

All electronic study data, with the exception of audiofiles, will be stored and managed in REDCap, UK's secure electronic data capture system. Any paper documents (e.g., surveys completed on paper, consent forms completed on paper) will be stored in the PI's locked research space in the Healthy Kentucky Research Building (Suite 460), with consent forms stored in separate locked filing cabinet from data collection forms. All downloaded datasets from REDCap will be stored in the PI's UK's HIPAA-compliant OneDrive folder. To protect confidentiality, participants will be assigned a unique study identification number and any identifying information will not be stored alongside survey responses. The masterlist, which will be the only document connecting participant personal information and study identifiers, will be stored in REDCap. Only approved study personnel will have access to the data. Protocol compliance will be monitored and discussed at weekly team meetings. Prior to implementing the intervention, all study personnel will undergo extensive training. Data and electronic records will be kept for a minimum of six years post-study closure then destroyed according to UK Policies A05-055 and A13-050.
We have made every attempt to minimize risks to participants throughout the study protocol, including loss of privacy or confidentiality and psychological discomfort. All study protocols and consent procedures will be approved by the University of Kentucky IRB.

The two largest risks associated with participating in this research are emotional distress and potential loss of confidentiality. To protect against distress as a result of the intervention, respondents will be notified in the consent form of the potential for emotional discomfort. They will be reminded that they have the freedom to skip any questions in assessments that make them uncomfortable, and that they are free to conclude any ongoing intervention session without penalty. In cases of extreme distress, adverse events, of threats of self-harm, an emergency protocol has been developed that provides explicit direction for handling these situations. We will inform the University of Kentucky's IRB, the participant's medical team, and the NIH program officer of any such events.

To protect against loss of confidentiality, we will follow strict data management procedures. Access to data will be permitted only to the

researchers and the interventionist, who will be trained in HIPAA procedures and will sign confidentiality agreements. Any contact information will be stored separately from responses and permanently deleted following the completion of data collection. To protect confidentiality, participants will be assigned a unique study identification number and any identifying information will not be stored alongside survey responses. The mPIs will keep a masterlist, consisting of participants' name, contact information, and study identifier, in order to reimburse participants and track recruitment efforts. This form is stored in UK's secure electronic data capture system, REDCap. Moreover, members of the research team (e.g., research assistants) will be required to participate in training in the areas of ethics, clinical trials, confidentiality protection, and human subjects protection. To secure data on mobile phones, respondents will be taught how to delete messages if they are worried about their information being compromised. Both respondents and the interventionist will be trained and required to secure their phone using a password. A secure web-based service that allows complete control over data will be chosen to deliver the self-monitoring reminders, and any data collected during this process will be downloaded to a secure computer and deleted from the website following the completion of data collection. Finally, all study phones will be capable of being remotely wiped in the case of loss or theft to protect participants' information. After each participant concludes with the intervention, the phone will undergo a factory reset to remove any traces of data or identifying information. Together, these steps are more than adequate to minimize and protect against risk.

Documenting/Reporting Adverse Events: This protocol presents minimal risks to the subjects and adverse events are not anticipated. In the unlikely event that such events occur, serious and unanticipated and related adverse events will be reported in writing within 48 hours to the IRB and any appropriate funding and regulatory agencies. For the current study, the following individuals and agencies will be notified by the PI via e-mail within 5 days of the event occurring: the University of Kentucky IRB, the funding agency, and relevant collaborating organizations. Dr. McLouth and Dr. Lauckner will review any adverse events that occur and evaluate their severity. Based on this review, we will determine if any changes to the protocol are required and will speak with the IRB if necessary.

☑ **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.

Interview subjects will receive a $40 Amazon e-gift card upon completion of the interview.

Throughout the Open Pilot, participants will receive Amazon e-gift cards on the following schedule. On the rare occurrence that a study visit is delayed, the participant may receive additional compensation equivalent to the monitoring tasks completed, but no more than $30:
• After baseline questionnaire: $30
• At the end of the intervention (4 weeks time point): Up to $140 for completing daily monitoring tasks (i.e., morning survey and evening breathalyzer reading)
• After follow-up questionnaire (4 weeks time point): $40
• After exit interview: $10
Total possible: $220.00

Throughout the RCT, participants will receive Amazon e-gift cards on the following schedule. On the rare occurrence that a study visit is delayed, the participant may receive additional compensation equivalent to the monitoring tasks completed, but no more than $30:
• After baseline questionnaire: $20
• At the end of the intervention (6 weeks time point): Up to $230 for completing daily monitoring tasks (i.e., morning survey and evening breathalyzer reading)
• After follow-up questionnaire (6 weeks time point): $25
• After exit interview: $10
• After delayed post-test (8 weeks time point): $30
Total possible: $315.00

Added June 2023: Interview subjects will receive a $40 Amazon e-gift card upon completion of the interview.

All incentives will be paid via Amazon e-gift card. The link to redeem e-gift cards will be emailed or texted directly to participants. Money on the e-gift card will be available as soon as it is redeemed. All gift card procedures will comply with University requirements for purchasing and documentation in collaboration with the PI's business manager.

Costs to Subjects

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

Participants in the interviews will need access to the internet or phone, unless they are completing the interview in person. No other cost is associated with participation.

Open Pilot and RCT participants will be provided with a study smartphone if they do not have reliable access to a phone. Thus, there are no costs associated with participation.

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.

Several mechanisms for monitoring the occurrence of adverse events will be employed. The study coordinator will oversee day-to-day monitoring of the study activities and will have daily contact with the principal investigator. There will be ongoing communication among the research team. This will be facilitated by: 1) weekly meetings with project staff and investigators to discuss study progress, reactions to the intervention, and any adverse events; 2) supervision of the study interventionist and study coordinator; and 3) the principal investigators will monitor the audiotaped intervention sessions. For medical adverse events, survivors will contact their oncology care team, primary care team, or emergency medical services as they would in routine care.

The study interventionist will receive training from Dr. McLouth (MPI), a clinical psychologist, on how to effectively communicate via telephone and assess for actual or potential adverse psychological reactions. For patients who exhibit excessive or worrisome emotional reactions, the interventionist or MPI will follow-up with the patient by telephone within 24 hours and 1 week of the session to ensure that these survivors get adequate mental health care.

To protect privacy, all study databases will be password-protected and accessed only by study personnel.

Plans for Assuring Data Accuracy and Protocol Compliance: Survey data will be collected via mail, in-person, and online through REDCap. All patient-reported and medical record extracted data will be stored in REDCap, a secure electronic data capture system offered by the University of Kentucky Center for Clinical and Translation Science (CCTS). REDCap provides a real-time record of any changes made to data, including which study team member made the change. REDCap can export data into SPSS and SAS for data analysis and run basic descriptive statistic reports. Dr. Shelton will download the REDCap data and examine it for errors after the first 5 survivors have enrolled to check for errors and data problems. We will perform logic and range checks. Patient-reported data and medical record data entered by the study coordinator in REDCap will be examined for accuracy. To protect confidentiality, participants will be assigned a unique study identification number. All identifying information will be stored in separate electronic files. Protocol compliance will be monitored and discussed at weekly team meetings. Prior to implementing the intervention, all study personnel will undergo extensive training by the MPIs. To ensure standardized protocol delivery, both exit interviews and intervention sessions will be audiorecorded. These will be reviewed and corrective feedback will be provided.
In addition to these procedures, the UK Markey Cancer Center Protocol Review Monitoring Committee will monitor the study for accrual, scientific progress, data quality, and ethical conduct.
Potential Adverse Events: Potential adverse events include negative emotional responses following intervention sessions or assessments, or increased substance use. Dr. Lauckner's current pilot study with veterans living with HIV/AIDS has not shown adverse psychological reactions to this intervention.

Plans for Assuring Compliance with Adverse Event Reporting: All survivors will be provided with a study telephone number to call. The call line will be staffed during normal business hours (8:00 am to 5:00 pm) and have voicemail for after business hours. The study coordinator or other designated study staff will contact the survivor within 24 hours of a voicemail. All study staff will be trained and provided with a written protocol that instructs them to complete an electronic adverse event report and immediately send it to the MPIs for follow-up. All severe adverse events will be reported to the Institutional Review Board by the MPIs within 24 hours. The MPIs will also report all adverse events to the Institutional Review Board on an annual basis. In addition, all adverse events are reported to the NIH as part of the annual progress reports. The MPIs are responsible for contacting the National Cancer Institute grant program director in the event that any action resulting in temporary or permanent suspension of the trial occurs.

Data Safety Monitoring Board: In accordance with Markey Cancer Center's Institutional Data and Safety Monitoring Plan, the trial will be reviewed and monitored at least annually by the Markey Cancer Center Data and Safety Monitoring Committee (MCC DSMC), a key component of the Quality Assurance process for protocols being conducted at the University of Kentucky Markey Cancer Center. The MCC DSMC conducts real-time data monitoring and safety review of all trials. Through this process, the MCC DSMC also assesses the continuing validity and scientific merit of the trial. The MCC DSMC will review the trial as determined by the MCC Protocol Review and Monitoring Committee (PRMC). The MCC DSMC will monitor: Adverse Event Analysis, Serious Adverse Events, Protocol Deviations, Accrual, and when applicable, MCC Audit Committee Reports, previous reviews by the DSMC, suggested actions by other committees (e.g., IRB), and other parameters and outcomes as determined by the DSMC. The MCC DSMC can amend, temporarily suspend, or terminate the trial based upon patient safety or compliance concerns. Given the level of risk, as well as oversight by the UK Markey Cancer Center and study consultant review and role (Dr. Salsman), we will not be forming an outside Data Safety Monitoring Board.

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

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

please address the following:

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

Data obtained as part of this study (survey data, recordings from interviews) will be stored, used, and shared for future research. All identifiable information (e.g., name, medical record number, or date of birth) will be removed from the information or samples collected in this study. This means that no link or code to the participant's identity will be kept. After all identifiers have been removed, the information may be used for future research or shared with other researchers without additional informed consent. Once participants give their permission to have their de-identified information stored, they will be available indefinitely and cannot be removed due to the inability to identify them. These data will be stored for up to 6 years following study closure.

Researchers can use the stored information to learn more about alcohol use in survivors of adolescent and young adult cancer, or research additional scientific questions.

There are no risks of additional use, however there is a risk of a breach of confidentiality. The research team will take all precautions to protect against this. Please see the 'Records, Privacy, and Confidentiality' section of this protocol for details of how we will keep participant information private and secure.

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	formk_hipaa waiver_052125_signed.pdf
Waiver	HIPAA Waiver approval.67410.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 [FDA's PDF] 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. When attaching reliance documents, please ensure that you select the correct 'Document Type' from the drop-down menu. See below for the "**Document Types**" in bold, followed by examples of reliance documents for each type:
  - **- Individual Investigator Agreement (IIA)**
    - A completed Individual Investigator Agreement

- IRB Approval (Non-UK)
- A Letter of Approval from a Non-UK IRB

- IRB Authorization Agreement (IAA)
- A SMART IRB Agreement
- An OHRP Agreement
- A DoD Agreement
- An IREx Reliance Notification
- Any Reliance Agreement

- Letter of Support & Local Context
- A Letter of Support from an organization at which some research activities are occurring
- Communications Plan
- Local Context Form

Please reach out to IRBReliance@uky.edu if you have any questions or concerns.

- 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.

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 study involve one or more human subjects prospectively assigned into one or more 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

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 "Banks, Repositories, Registries...")
- Collection of Biological Specimens (look up "Repositories, Registries, Specimen/Tissue Banks...")
- 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

- ☐ International Research
- ☐ Planned Emergency Research Involving Exception from Informed Consent
- ☐ Recombinant DNA
- ☐ Registry or data repository creation
- ☐ Stem Cell Research
- ☐ Suicide Ideation or Behavior Research
- ☑ Survey Research
- ☐ Transplants
- ☐ Use, storage and disposal of radioactive material and radiation producing devices
- ☐ Vaccine Trials

Emergency Use Checklist] (PDF)

- Genetic Research (look up "Banks, Repositories, ...Genetic/Genomic Data Sharing...")
- Gene Transfer

  *For gene transfer research, also go to the E-IRB Application Other Review Committees section, and checkmark Institutional Biosafety Committee

- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Exception to 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-look up "Does the IRB Charge a Fee..."]
- National Science Foundation
- (DoEd) U.S. Department of Education
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist
- (EPA) Environmental Protection Agency

Other:

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

National Cancer Institute

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

☐ 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)

Additional Information

- Institutional Biosafety Committee (IBC) - Attach required IBC materials
- Radiation Safety Committee (RSC) - For applicability, see instructions
- Radioactive Drug Research Committee (RDRC)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)** - Attach MCC PRMC materials, if any, per instructions.
- Office of Medical Education (OME)
- Graduate Medical Education Committee (GME)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

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

Approval Letter Details:

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

Additional Materials:

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

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

Protocol/Other Attachments

Attach Type	File Name
Other	Kirklewski_HSP training certificate.pdf
Protocol	Detailed Protocol_062123_tracked changes.docx
Protocol	Detailed Protocol_062123_clean.docx

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.

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	
Thomas	Kelly	Department Authorization	Behavioral Science		05/21/2025 11:39 AM	View/Sign
Laurie	McLouth	Principal Investigator	Behavioral Science		05/21/2025 01:16 PM	View/Sign

Department Authorization

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

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

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

Principal Investigator's Assurance Statement

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

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

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

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

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). 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		0.075	jchine2	6/3/2025 8:11:00 AM
	Waiver	HIPAA Waiver approval.67410.pdf	HIPAA approval	0.204	jchine2	6/3/2025 8:09:10 AM
	Waiver	formk_hipaa waiver_052125_signed.pdf	Form K - HIPAA Waiver	0.083	klha226	6/2/2025 3:27:56 PM
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Advertising	RecruitmentScript.OpenPilot.docx	Open Pilot- Recruitment Script	0.023	ckla227	5/31/2022 11:07:25 AM
DataCollection	ContactInfoForRecruitment_TRAC.pdf	Open Pilot - Contact Info for Recruitment Form	0.031	klha226	5/31/2022 9:09:26 AM
DataCollection	PreScreening_TRACAYAOpenPilotS.pdf	Open Pilot - Pre-Screening form	0.032	klha226	5/31/2022 9:09:02 AM
DataCollection	OP_Control Orientation_Android.docx	Open Pilot - Control Group Orientation Manual (Android)	2.542	klha226	5/31/2022 8:52:32 AM
DataCollection	OP_Control Orientation_Android - tracked changes.docx	Open Pilot - Control Group Orientation Manual (Android) - tracked changes	2.542	klha226	5/31/2022 8:52:09 AM

	DataCollection	OP_Control Orientation_iPhone.docx	Open Pilot - Control Group Orientation Manual (iPhone)	2.394	klha226	5/31/2022 8:51:41 AM
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	DataCollection	OP_Intervention_Android.docx	Open Pilot - Participant Intervention Manual (Android)	4.483	klha226	5/31/2022 8:49:25 AM
	DataCollection	OP_Intervention_Android - tracked changes.docx	Open Pilot - Participant Intervention Manual (Android) - tracked changes	4.484	klha226	5/31/2022 8:49:01 AM
	DataCollection	OP_Intervention_iPhone.docx	Open Pilot - Participant Intervention Manual (iPhone)	4.417	klha226	5/31/2022 8:48:10 AM
	DataCollection	OP_Intervention_iPhone - tracked changes.docx	Open Pilot - Participant Intervention Manual (iPhone) - tracked changes	4.418	klha226	5/31/2022 8:47:50 AM
	Advertising	RecruitmentContactInfoForm.docx	Recruitment Contact Info Sheet - Open Pilot and RCT	0.023	klha226	5/26/2022 2:53:01 PM
	DataCollection	RecruitmentTrackingLog_TRACAYA.pdf	Open Pilot and RCT - Recruitment Tracking Log	0.051	klha226	5/20/2022 1:54:18 PM
	DataCollection	ScreeningRefusalQuestionnaire_(1).pdf	Open Pilot and RCT - Refusal to Screen Form	0.035	klha226	5/20/2022 8:30:35 AM
	DataCollection	Open Pilot and RCT_Refusal form.pdf	Open Pilot and RCT - Refusal Form	0.035	klha226	4/13/2022 1:51:54 PM
	DataCollection	Open Pilot and RCT_Breathalyzer data submission.pdf	Open Pilot and RCT - Breathalyzer Reading Submission Form	0.031	klha226	4/13/2022 1:51:01 PM
	DataCollection	Open Pilot - Screener.pdf	TRAC Open Pilot - Screener	0.161	klha226	4/13/2022 12:50:22 PM
	DataCollection	Survivor - Interview Script.pdf	Survivor - Interview Script	0.203	klha226	10/18/2021 2:30:11 PM
	DataCollection	Psych - Interview Script.pdf	Psych - Interview Script	0.200	klha226	10/18/2021 2:29:20 PM
	DataCollection	Providers - Interview Script.pdf	Provider - Interview Script	0.203	klha226	10/18/2021 2:28:36 PM
	DataCollection	Adovcate - Interview Script.pdf	Advocate - Interview Script	0.198	klha226	10/18/2021 2:27:53 PM
	DataCollection	SurvivorDemographicSurvey_TRAC.pdf	Survivor - Demographic Survey	0.042	klha226	10/11/2021 11:18:09 AM
	DataCollection	ProviderDemographicSurvey_TRAC.pdf	Provider - Demographic Survey	0.041	klha226	10/11/2021 11:17:57 AM
	DataCollection	PsychoOncDemographicSurvey_TRAC.pdf	Psych - Demographic Survey	0.041	klha226	10/11/2021 11:17:44 AM
	DataCollection	AdvocateDemographicSurvey_TRAC.pdf	Advocate - Demographic Survey	0.038	klha226	10/11/2021 11:17:31 AM
	DataCollection	ProviderScreener_TRACAYAAim1.pdf	Provider Screener	0.036	klha226	10/6/2021 1:24:10 PM
	Advertising	Phone Script - Survivor.docx	Recruitment Phone Script	0.032	klha226	10/6/2021 1:12:50 PM
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						10/6/2021

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DataCollection	KII_InterviewMaterials_final.pdf	Interview reference materials	2.452	jmst268	8/16/2021 12:21:32 PM
DataCollection	KIIPsychScreener_TRACAYA.pdf	Psych screener	0.034	jmst268	8/16/2021 12:20:42 PM
DataCollection	KIIAdvocateScreener_TRACAYA.pdf	Advocate screener	0.034	jmst268	8/16/2021 12:20:28 PM
Advertising	follow-up_email_Survivors_UKMCC.docx	follow up email	0.029	jmst268	8/16/2021 12:17:23 PM
Advertising	follow-up_email_Survivors_0811.docx	follow up email	0.029	jmst268	8/16/2021 12:17:10 PM
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Advertising	Phone_script_Advocates_0811.docx	Recruitment Phone Script	0.023	jmst268	8/16/2021 12:14:57 PM
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DataCollection	AUDIT_scoring.pdf	Instructions for Scoring AUDIT (located in screener)	0.012	ckla227	4/20/2021 3:28:33 PM
DataCollection	KII_protocol.docx	Key Informant Interview Protocol	0.024	ckla227	4/12/2021 3:20:35 PM

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
Updated	1043835	105117	12462101	PI	Y	McLouth	Laurie	laurie.mclouth@uky.edu	7H150	800 Rose St	40536	8595622526	Behavioral Science		Principal Investigator	PhD		P	N	klha226	5/21/2025 11:14:46 AM	N	N	Elizabeth
Updated	1043837	105117	12536754	DP	Y	Lauckner	Carolyn	carolyn.lauckner@uky.edu	7H150	800 Rose St	40536	9899282359	Behavioral Science	N	Co-Investigator	PhD	Assistant Professor	P	N	klha226	5/21/2025 11:13:28 AM	N	N	Kay

HIPAA Comment by Kimberly Haney - PI to PI on 6/2/2025 3:28:26 PM
New HIPAA waiver signed by Dr. McLouth is attached.

HIPAA Comment by Joanne Hines - ORI to IRB/PI on 6/2/2025 2:29:27 PM
2nd request - "New" PI needs to sign the HIPAA waiver - please ensure "where" data is stored is consistent with previous PI/Laukner

HIPAA Comment by Joanne Hines - ORI to IRB/PI on 5/21/2025 2:30:39 PM
"New" PI needs to sign the HIPAA waiver - please ensure "where" data is stored is consistent with previous PI/Laukner (e.g. no changes needed on Form K or research description)?

1 STATISTICAL CONSIDERATIONS

1.1 STATISTICAL HYPOTHESES

Primary Endpoint: We hypothesize that at least 60% of eligible patients approached will enroll in the TRAC-AYA study.

1.2 SAMPLE SIZE DETERMINATION

The sample size of 40 is based on the goal of estimating the probabilities and means for 3 feasibility outcome measures (enrollment ≥ 60% [primary], retention ≥ 60%, adherence [defined as >=70% completing at least 60% of sessions]. Assuming a negative binomial distribution and true probability of enrollment of 60%, the probability that we would have to approach 55 or more people to recruit 40 is <0.05. If we approach ≥55 AYAs to enroll 40, it is unlikely the true probability of enrollment is 60% or greater, concluding a future efficacy study may not be feasible. Out of 40 AYAs, if the true probability of retention is 60% we expect at least 19 AYAs will be retained (i.e., probability of n≤19 retained given true retention probability of 60% is <0.05), so if more than 21 AYAs are not retained, an efficacy study may not be feasible. We have 80% power (using a 2-tailed alpha of 0.05) to detect an adherence proportion of 0.72 if we assume a null hypothesis adherence proportion of 0.50.

1.3 POPULATIONS FOR ANALYSES

The sample from Aim 1 (n = 18) will be used to refine procedures and the intervention protocol. The sample from Aim 2 (n = 40) will be used to analyze feasibility and acceptability data and describe pre-post changes in patient-reported outcomes.

1.4 STATISTICAL ANALYSES

1.4.1 AIM 1 ANALYSES

For Aim 1, all interviews will be audio recorded and transcribed using a transcription service. Study staff will annotate transcripts to identify which aspects of TRAC were the focus of comments. Annotated transcripts will be reviewed to refine proposed coding categories and create a coding categories dictionary. Coders will meet to compare results and resolve any discrepancies through consensus. Proposed initial coding categories are: Usability of delivery (e.g., perceived efficiency, ease), Length (appropriateness, acceptability), Content (appropriateness, helpfulness, relevance), and AYA specific education (e.g., AYA survivorship and risks of alcohol use for AYAs). If needed, data will be managed in NVivo software and we will engage the Markey Shared Resource Facility for additional coding support.

1.4.2 AIM 2 ANALYSES

1.4.2.1 FEASIBILITY

Enrollment: the number of AYAs enrolled divided by the number of eligible AYAs approached (hypothesized value = 60%).
Retention the percentage of AYAs who complete baseline and follow-up questionnaires (T0, T1; hypothesized value = 60%).
Adherence: the percentage of AYAs who complete at least 75% of sessions in 8 weeks (hypothesized value = 70%); alcohol monitoring hypothesized value = 70%).

We will calculate 95% CIs for feasibility measures to determine the range of estimates that are consistent with our data. We will use one-sample negative binomial probabilities and tests of binomial proportions to compare to hypothesized values. We will summarize reasons for ineligibility and refusal and compare AYAs who drop out or do not adhere by demographic and clinical characteristics, and baseline scores of the measures (e.g., PROMIS-29, alcohol use). We will investigate differences in AYA enrollment, retention, or adherence by sociodemographic and clinical characteristics (e.g., cancer type) to identify populations for a future study.

1.4.2.2 PRELIMINARY DATA ON FUTURE TRIAL-RELATED OUTCOMES.

The primary outcome variable related to a future efficacy trial is alcohol use (as measured by the PROMIS Alcohol Use 7a and number of drinking days). The primary intermediate variables are self-efficacy and readiness to change drinking. We will describe pre-post changes in intermediate and outcome variables using descriptive statistics. T-tests will examine whether pre-post changes in TRAC differ significantly from pre-post changes in control. The goal of these analyses will be to estimate standard deviations for use in future studies. In exploratory analyses, we will include intermediate variables as covariates to model the relation between outcome variables and hypothesized mediators.

1.4.2.3 FIDELITY

We will calculate inter-rater reliability for fidelity scores between raters of intervention fidelity.

KEY INFORMATION FOR *Tracking and Reducing Alcohol Consumption for Adolescent and Young Adult Survivors of Cancer (TRAC-AYA):*

We are asking you to choose whether or not to volunteer for a research study testing a health promotion program for survivors of adolescent and young adult (AYA) cancer. The goal of this program is to help AYA survivors reduce their alcohol use, as research has found that drinking alcohol can have negative consequences for cancer survivors. The study will provide free alcohol reduction counseling during a 4-week program delivered using cell phones, called TRAC-AYA. You are being asked to participate in this study because you are: 1) a survivor of childhood, adolescent, or young adult cancer, 2) between the ages of 18 years and 39, 3) someone who consumes at least a moderate amount of alcohol, as identified by your responses on an earlier questionnaire. This page aims to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

If you agree to participate, you will be asked to complete a 4-week alcohol reduction program delivered using cell phones. You will be randomly placed into one of two groups (Group A and Group B). Group A will receive the TRAC-AYA program, while Group B will receive alcohol monitoring and education. Using two groups allows the researchers to better examine the effects of the program. You will also complete several questionnaires regarding your health behaviors, mental health, and attitudes. Overall, your participation in this research will span 10 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you choose to participate and are placed in Group A, you will receive free alcohol reduction counseling, which may reduce your alcohol use and impact your overall health. Participants in Group B may benefit from monitoring their alcohol use by having increased self-awareness as to levels of alcohol use and triggers for drinking. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is a potential risk of discomfort or distress when completing the questionnaires or program sessions. You have the right to skip any questions and you may leave the study at any time without penalty. There is also a risk of loss of confidentiality, as identifying information will be collected in order to monitor your data throughout the course of the planned research. However, this is unlikely considering the careful plans in place regarding data management and protection. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Carolyn Lauckner, PhD of the University of Kentucky, Department of Behavioral Science at 859-562-3335 or carolyn.lauckner@uky.edu.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You will not qualify to participate if you are not a survivor of childhood, adolescent, or young adult cancer, are not 3 months-15 years post-treatment, are not currently between the ages of 18 and 39, do not reside in the United States, do not use any alcohol or use alcohol only at low levels, and/or do not speak English.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The study will be conducted remotely through phone sessions and Internet-based questionnaires. Study equipment and materials will be shipped to your home address. The total amount of time you will be asked to volunteer for this study is approximately 10-13 hours, depending on which group you are assigned to.

WHAT WILL YOU BE ASKED TO DO?

If you decide to participate, you will be asked to complete the 4-week TRAC-AYA alcohol reduction program or engage in alcohol monitoring and education. This program is not considered standard of care; it is intended to be an optional supplemental activity. You will be randomly placed into one of two groups (Group A or Group B). We will use a random number generator to determine which group you will be placed into. Group A will receive the 4-week TRAC-AYA program and complete alcohol monitoring, while Group B will receive education and alcohol monitoring. Both Group A and Group B will complete alcohol monitoring for 6 weeks.

All participants will be shipped a mobile breathalyzer, cell phone (if needed), and program materials. These materials will contain instructions for downloading and finding the breathalyzer app. You will be trained to use the breathalyzer, which you will use to monitor your alcohol use during the study. The breathalyzer will connect wirelessly to your cell phone and transmit your blood alcohol level to an app. If you do not own a cell phone compatible with the breathalyzer app, you will be provided a study phone to use. On each day of the 6-week study period, you will be texted in the morning to complete a short survey about your alcohol use, and once in the evening and asked to complete a breathalyzer reading before you go to bed that night. The breathalyzer reading and survey should take you no more than 5 minutes. Once the 6 weeks of monitoring are completed, you will return your cell phone via mail (if you used a study phone). You will be able to keep your breathalyzer.

Additionally, all participants will complete two electronic questionnaires that ask a variety of questions, including some about your alcohol consumption, drug use, mental health, and your attitudes toward technology. These questionnaires will take approximately 45-60 minutes each and can be done online using a computer, tablet, or mobile phone. You will take this questionnaire at the beginning of your enrollment and at the 6-week point. Once you have completed the follow-up questionnaire, the study coordinator will contact you to schedule a 20-30-minute exit interview. This interview will be audio recorded and transcribed and will be concern your experiences with monitoring your alcohol use. Group A participants will also be asked for feedback regarding the TRAC-AYA program. At the 10-week point, you will complete an additional follow-up questionnaire, which will take approximately 45-60 minutes and can be done online using a computer, tablet, or mobile phone.

In addition to these monitoring and assessment tasks, if you are placed into Group A, you will meet weekly via phone or videoconference with a counselor to discuss alcohol use. Each of these sessions will be recorded. You will also complete a short 5-minute questionnaire after each session to provide feedback and a short survey after your first session about your expectations regarding TRAC-AYA.

See Appendix for a detailed overview of the primary study activities.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

For all participants, there is the potential risk of discomfort or emotional distress when completing questionnaires or program sessions. To protect against distress, you have the freedom to skip any questions in assessments that make you uncomfortable. You are also free to conclude any ongoing program session without penalty.

You will be required to provide contact information for at least one emergency contact. We also will ask that you provide one “back-up” contact who we will reach out to if we are unable to reach you at any point during the study,

however, this is optional. We will not specify the nature of this research study to these individuals. In cases of extreme distress, adverse events, or threats of self-harm, the researchers will contact your emergency contact and your medical care team if you are a patient at UK HealthCare. Your medical care team will be required to refer you if you show signs that you may hurt yourself or others. If they believe it is necessary and immediate harm to yourself or others is possible, they will contact emergency services to provide transportation to your local emergency department for assessment and intake. You and/or your insurance plans will be responsible for all costs incurred related to emergency transportation.

There is a risk of loss of confidentiality, as identifying information will be collected to monitor your data throughout the course of the planned research. There are also risks associated with using mobile phones for health, as they are less secure methods of communication. By agreeing to participate in this study, you are stating that you understand the risks associated with discussing health information over mobile connections and with to participate in spite of these risks. If identifying information is released to an unauthorized party, your alcohol use or other health information could be revealed to unwanted individuals. This could potentially cause harm, but is unlikely considering the careful plans in place regarding data management and protection.

Unknown risks. Though the procedures used in this study have been used before, there may be risks, discomforts, or side effects that are not yet known.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

If you participate in this research and are placed in Group A, you may benefit from receiving free alcohol reduction counseling, which could reduce your alcohol use and impact your overall health. Group B participants may benefit from monitoring alcohol use, which could increase your own awareness of your level of consumption and triggers for drinking. All participants will receive these benefits with minimal effort, as the program can be entirely delivered via mobile phone.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

You do not have to be in this study to continue receiving treatment at your healthcare facility.

As an alternative to participating in this study there are other options available to you: medications and counseling such as cognitive behavioral therapy, 12-step facilitation and motivational interviewing have been found to aid in the treatment of unhealthy alcohol use. If you are not eligible to participate or decline to participate you may still receive treatment and other services to which you are otherwise entitled. Additionally, you can call the SAMSHA's National Helpline at 1-800-662-HELP (4357). This Helpline is a confidential, free, 24-hours-a-day service that can help you to find community resources and treatment for reducing your alcohol use.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs to participate, however, participation requires access to the Internet and a smartphone. We will loan a smartphone to those who need one to complete study tasks. If you choose to use your personal phone, you will be responsible for the cost of the data, minutes, and texts used during the study. Should medical care be necessary during the study, you and/or your insurance plans will be responsible for all costs incurred related to your treatment.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. During this program, we will collect your contact information to use for scheduling, delivering program materials, and monitoring your data. This identifying information will be kept separately from any and all data you provide us—linked only by an ID number. Only the researchers will have access to a code key, which will link your ID number to your contact information. Once data collection is complete, this key will be permanently deleted and all identifying information will be removed from records. The study staff

will keep any paper copies of study files locked in a file cabinet in a private office. We will use a study number rather than your name on study records when we can.

To secure data on mobile phones, you will be taught how to delete messages if you are worried about your information being compromised. Both you and your counselor will be trained and required to secure your phones using a password. A web-based service that allows complete control over data will be chosen to deliver your self-monitoring reminders, and any data collected during this process will be downloaded to a secure computer and deleted from the website following the completion of data collection.

If you choose to use a study phone instead of your own smartphone: These phones will be capable of being remotely wiped in the case of loss or theft to protect your information. If at any point you lose your phone or have it stolen, notify the researchers IMMEDIATELY at 502-240-2119. After you conclude the program, the phone you used will undergo a factory reset to remove any traces of data or identifying information.

To ensure the study is conducted properly, officials at the National Cancer Institute or the University of Kentucky may look at or copy pertinent portions of records that identify you.

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy Policies outside of the control of the University of Kentucky.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

Certificates of Confidentiality (CoC):

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study. By signing this consent, you agree that your healthcare providers and associated staff affiliated, contracted with, or with access to records of the University of Kentucky (UK) may see your information from research studies and consider and use that information in the course of medical care and related activities.

You will need to provide your social security number. This is in order for you to be compensated for your time. If you do not provide this number, you will not be compensated. If you earn $600 or more by participating in any research, it is potentially reportable for tax purposes.

All research records and/or identifiers will be stored for at least 6 years following the end of the study, per IRB requirements.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- you communicate inappropriately with or harass study staff (e.g. sending messages unrelated to the study, sending personal photos),
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

The study intervention, medication, and/or device will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons.

If at any point during the study you lose or damage the provided phone (if applicable), you will be dismissed and unable to earn any further incentive payments. However, you will be entitled to the payments you earned prior to the loss of or damage to the equipment.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Carolyn Lauckner, PhD at 859-562-3335 immediately. Dr. Lauckner will determine what time of treatment, if any, is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

Throughout the study, you will receive Amazon e-gift cards on the following schedule. On the rare occurrence that a program session is delayed (Group A), you may receive additional compensation equivalent to the monitoring tasks completed, but no more than $30.

- After baseline questionnaire: $20
- At 6 weeks: Up to $230 for completing daily monitoring tasks
- After follow-up questionnaire: $25
- After exit interview: $10
- After delayed follow-up questionnaire (at 10 weeks): $30

TOTAL POSSIBLE: $315

These incentives will be paid to you via Amazon e-gift card. The link to redeem e-gift cards will be emailed or texted directly to you. Money on the e-gift card will be available as soon as you redeem it.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 1-2 times per year.

Do you give your permission to be contacted in the future by Carolyn Lauckner, PhD regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 50 people to do so at the University of Kentucky.

The National Cancer Institute is providing financial support and/or material for this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information or samples collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information or samples may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information or samples stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that be accessed, used, and/or released includes:

- Name
- Medical record number
- Email address
- Phone number
- Mailing address
- Cancer treatment date of initiation and completion
- Date of upcoming cancer care appointment
- Age
- ZIP code
- Race/Ethnicity
- Gender
- Amount of alcohol consumed

The researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- UK HealthCare and their representatives;
- Health systems outside of UK for which you have a patient relationship;
- National Institutes of Health (NIH);
- National Cancer Institute (NCI).

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be

shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the Authorization:

- Send a written letter to Carolyn Lauckner, PhD at 467 Healthy Kentucky Research Building, University of Kentucky, 760 Press Avenue, Lexington, KY 40536 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

APPENDIX A

DETAILED OVERVIEW OF THE PRIMARY STUDY ACTIVITIES

GROUP A (TRAC-AYA Group):

Tasks	Maximum Time Commitment
Questionnaire #1	45 min
Orientation Session	1 hr
Session 1	1 hr
Treatment expectations survey	10 min
Sessions 2-4	30 min each; 1.5 hrs total
Post-session questionnaires	5 min each; 20 min total
Daily monitoring (42 days)	10 min/day; 7 hrs total
Questionnaire #2	45 min
Exit interview	30 min
Questionnaire #3	45 min
TOTAL TIME	**13 hrs, 45 min**

GROUP B (Education and Monitoring Only):

Tasks	Maximum Time Commitment
Questionnaire #1	45 min
Orientation Session	1 hr
Daily monitoring (42 days)	10 min/day; 7 hrs total
Questionnaire #2	45 min
Exit interview	30 min
Questionnaire #3	45 min
TOTAL TIME	**10 hrs, 45 min**

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- **Appendix A: Detailed overview of the primary study activities**

You will receive a copy of this consent form after it has been signed.

_____ **Signature of research subject**	_____ **Date**
_____ **Printed name of research subject**	
_____ Printed name of [authorized] person obtaining informed consent	_____ Date