Document Coversheet

Study Title: Randomized Trial of a Social Media-Delivered Intervention

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	8/1/2025
NCT Number:	NCT03441321
IRB Number	56153
Coversheet created:	12/3/2025

PROTOCOL TYPE (VERSION 5)

IRB Approval
8/1/2025
IRB # 56153
IRB1

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.

EXPEDITED CERTIFICATION

0 unresolved comment(s)

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

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

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

Check the appropriate categories that apply to your research project:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONTINUATION REVIEW/FINAL REVIEW

0 unresolved comment(s)

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

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

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

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1. Status of the Research

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

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

*Possibility that review will move from Full to Expedited.

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

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

Attachments

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3. Informed Consent

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

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

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

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

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

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

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

○ Yes ◉ No

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

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

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

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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

Randomized Trial of a Social Media-Delivered Intervention

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.

Social Media Intervention

Anticipated Ending Date of Research Project: 6/25/2026

Maximum number of human subjects (or records/specimens to be reviewed) 400

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:	Jerod	Room# & Bldg:	464 Healthy Kentucky Research Building
Last Name:	Stapleton	Speed Sort#:	0679
Middle Name	Lynn		
Department:	Department of Health, Behavi…	Dept Code:	7P150
PI's Employee/Student ID#:	12488228	Rank:	Associate Professor
PI's Telephone #:	8595622802	Degree:	Ph.D.
PI's e-mail address:	jlst329@uky.edu	PI's FAX Number:	8592570071
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	8/16/2022
		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 25

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

Inclusion Criteria: 1) female, 2) 18-25 years old, 3) high-risk tanner (defined as using an indoor tanning bed, or intentionally tanning outdoors, at least 10 times in the previous 12 months), and 4) regular use of Facebook (defined as logging on to Facebook at least 5-6 times per week in the past 4 weeks).

Exclusion Criteria: Males will be excluded because the theoretical framework and approach guiding the intervention utilizes body image theory, which was designed to reflect the unique and developmentally appropriate experiences of young adult women. In addition, the majority of high-risk tanners are young women.

Proposed Dates of Enrollment: Participants will be recruited in groups starting in November 2021 and ending in May 2023.

Proposed Sample Composition: 400 young adult females. The sample will be primarily White as tanning rates are highest in this population. However, all race and ethnicities will be included if individuals meet the inclusion criteria.

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	6	0	0
Asian:	0	16	0	0
Black/African American:	0	3	0	0
Latinx:	0	42	0	0
Native Hawaiian/Pacific Islander:	0	3	0	0
White:	0	310	0	0
American Arab/Middle Eastern/North African:	0	0	0	0
Indigenous People Around the World:	0	0	0	0
More than One Race:	0	10	0	0
Unknown or Not Reported:	0	0	0	0

If unknown, please explain why:

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large

record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

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

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☑ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking (translated long or short form)
- ☐ International Citizens
- ☑ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☐ Patients
- ☐ Appalachian Population

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults
- Economically or Educationally Disadvantaged Persons

Other Resources:

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see also the E-IRB Research Description section on this same topic]
- International Citizens [DoD SOP may apply]
- Military Personnel and/or DoD Civilian Employees

Assessment of the potential recruitment of subjects with impaired consent capacity (or likelihood):

☐ Check this box if your study does NOT involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

Does this study focus on adult subjects with any conditions that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes and you are not filing for exemption certification, go to "Form T", complete the form, and attach it using the button below.

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

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.

Consent Procedures: We requested a waiver of documentation of the informed consent in order to use an online survey cover letter for the baseline survey to inform participants about the study. All procedures will be conducted online and participants will be recruited from across the United States, making it impractical to obtain a signed consent form. Participants who screen as eligible and are interested in the study will be sent an email with instructions for completing the online baseline survey using a study-specific unique PIN and the link to the online survey (typically within 2 business days of completing the screening assessment). Once participants log-on to the survey, the cover letter will be the first page and they will check a box to indicate that they read and agree with the study procedures. Participants will not be permitted to access the survey if they do not provide consent.

Documenting Consent: Participants will only be permitted to access the baseline survey if they agree to the consent form. Their indication of agreement on this will be saved with the online survey data.

Minimizing Coercion: The voluntary nature of participation will be described in the survey consent cover letter.
There are multiple channels for participants to contact study staff to discuss problems, voice concerns, ask questions, or obtain information. We will include the contact information of UK study staff and for the Office of Research Integrity (ORI) on the end page of all online surveys so that participants will know how to address questions, concerns, or complaints. During the Facebook groups, participants can directly contact the study moderator account.

Research staff will receive training on how to respond to common questions that participants may have about the study procedures. If a participant has a question that is not included on this list or brings a problem, concern, or complaint to the study staff, staff will immediately contact Drs. Stapleton and McLouth to alert them of the complaint. Drs. Stapleton and McLouth will then discuss the complaint to determine the level of severity and best course of action. When appropriate, Dr. Stapleton will directly contact the participant to address minor concerns. If the concern is a major issue, Dr. Stapleton will immediately contact the RCO or designee in the ORI with the complaint to determine the proper course of action. He will also inform the participant that he has will inquire into the circumstances of the complaint, consult with the RCO or ORI designee regarding a solution, and response to the complaint as soon as possible.

☐ 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:

This is a minimal risk study.

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):

A cover letter on the initial baseline survey will be used to obtain electronic consent. Study procedures involve completing surveys that do not contain sensitive information and participating in a Facebook group. All procedures will be conducted online and participants will be recruited from across the United States, making it impractical to obtain a signed consent form.

○ **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.

56153

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
Deffendall	Caitlin	Data Analysis/Processing	SP	N	N		P	Y	12/15/2023	Y	N	09/06/2024	N	Y
Leip	Allison	Project Assistance/Support	SP	Y	N		P	Y	09/23/2023	Y	N	02/03/2021	N	Y
McLouth	Laurie	Co-Investigator	SP	N	N	Ph.D.	P	Y	11/07/2022	Y	N	12/17/2019	N	Y
Shelton	Brent	Data Analysis/Processing	SP	N	N	Ph.D.	P	Y	06/14/2023	Y	N	02/25/2021	N	Y
Blair	Courtney	Data Collection	SP	N	N	BS	P	Y	09/13/2024	Y	Y	09/06/2024	N	Y
Christian	Amy	Recruitment	SP	N	N	BS	P	Y	04/09/2024	Y	Y	09/06/2024	N	Y
Hamilton	Victoria	Project Assistance/Support	DP	Y	N		S	Y	01/16/2023	Y	Y	09/06/2024	N	N
Kahl	Joan	Recruitment	DP	Y	N	MS		Y	11/14/2023	Y	Y	09/06/2024	N	N
Merritt	Allison	Study Coordinator	DP	Y	Y	MPH	P	N	02/13/2022	Y	Y	09/24/2023	N	N

RESEARCH DESCRIPTION

0 unresolved comment(s)

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

Pro Tips:

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

Background

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

Purpose: The use of artificial ultraviolet indoor tanning beds is associated with an increased risk of skin cancer, including the deadly melanoma. This project involves testing a novel behavioral intervention delivered via the social media site Facebook that is designed to reduce high-risk indoor and outdoor tanning behaviors among young adult women. If effective, the intervention may be widely disseminated and has the potential to help reverse concerning melanoma trends observed among young women.

Background: The number of U.S. adults treated annually for melanoma has nearly doubled in the past 15 years (Guy, Watson, Richardson, & Lushniak, 2016) and the incidence rate is projected to again double by 2030 (Gershenwald & Guy, 2016). This growth is partly attributed to the popularity of artificial ultraviolet-emitting indoor tanning beds (Boniol, Autier, Boyle, & Gandini, 2012; Lazovich et al., 2016; Wehner et al., 2014) used by nearly 10 million Americans every year (Guy, Berkowitz, Holman, & Hartman, 2015). Most concerning, nearly 1 in 5 young adult white females use indoor tanning ten or more times each year (i.e., high-risk tanning)(Guy, Berkowitz, Watson, Holman, & Richardson, 2013), a rate that is associated with a substantially increased risk of melanoma (Cust et al., 2011; Lazovich et al., 2016; Lazovich et al., 2010). Additionally, while overall rates of tanning bed use have begun to decline in the United States, there is evidence that rates of frequent, higher-risk tanning remain high among tanners. There is also emerging evidence of a shift in preferences toward outdoor tanning among young women, representing a shift in skin cancer behavioral risk factors. Recent COVID restrictions are likely to have reduced access to indoor tanning and may have accelerated these trends.

The prevailing tanning intervention approach is to inform tanners of the appearance-damaging effects of tanning. This approach has been found to be effective among typical tanners (Gibbons, Gerrard, Lane, Mahler, & Kulik, 2005; Greene & Brinn, 2003; Greene, Campo, & Banerjee, 2010; Hillhouse et al., 2016; Hillhouse, Turrisi, Stapleton, & Robinson, 2008; Hillhouse & Turrisi, 2002; Lazovich et al., 2013) and in particular among those who are unaware of these risks (Stapleton, Turrisi, Hillhouse, Robinson, & Abar, 2010). However, high-risk tanners are often already knowledgeable of these risks and consider the risks to be less important than the proximal benefits of tanning such as appearance-enhancement and increased confidence (Banerjee, Hay, & Greene, 2012; Cafri, Thompson, Jacobsen, & Hillhouse, 2009; Hillhouse et al., 2008; Knight, Kirincich, Farmer, & Hood, 2002). The 2014 Surgeon General's Call to Action to Prevent Skin Cancer identified a critical need for the development of novel behavioral interventions targeted toward high-risk tanners (Surgeon General's Call to Action to Prevent Skin Cancer, 2014).

Research from our team and others has begun to utilize body image theory to explore why tanning is "worth" the risks for tanners. Body image theory, originally developed to explain disordered eating behaviors among young women, demonstrates how sociocultural forces negatively impact how some women think and feel about their bodily appearance in ways that lead to appearance-altering behaviors. Indoor tanning researchers have shown that tanners perceive sociocultural pressures to tan, strongly value tanning as an important aspect of their own attractiveness, and experience relief from body image concerns with tanning (Cafri et al., 2009; Cafri et al., 2008; Gillen & Markey, 2012; Stapleton, Turrisi, & Hillhouse, 2008; Stapleton, Turrisi, Todaro, & Robinson, 2009; Thompson, Ata, Roehrig, & Chait, 2012; Yoo & Kim, 2012). Disordered eating interventions (e.g. Heinicke, Paxton, McLean, and Wertheim, 2007; Stewart, Carter, Drinkwater, Hainsworth, & Fairburn, 2001; Stice, Rohde, Durant, and Shaw, 2012) have had great success by targeting risky body image factors and boosting positive body image through the use of persuasive techniques based in cognitive dissonance theory (Festinger, 1962; Stice, Shaw, Becker, & Rohde, 2008). These techniques encourage participants to endorse, and ultimately adopt as their own, attitudinal perspectives that are counter to and conflict with their negative body image beliefs. Drawing from this research, we recently developed a dissonance-based intervention, delivered via a website, that was designed to encourage indoor and outdoor tanning cessation among young women tanners by reducing their perceived pressure to tan and the value placed on tanning. Our preliminary trial of this approach with 186 tanners produced high participant acceptability and promising reductions in tanning behavior (Stapleton et al., 2015). This project involves taking the core content and active ingredients of the website to develop and test an intervention that is delivered via private and hidden groups using the social media site Facebook. The decision to utilize a Facebook-delivered intervention was primarily driven by the opportunity to integrate group-based interactions into the intervention, which facilitate stronger attitude and behavior change in disordered eating dissonance-based interventions (typically delivered within small groups) (Green, Scott, Diyankova, & Gasser, 2005; Stice et al., 2012; Stice et al., 2008). In addition, social media allows us to embed the intervention content into individuals' normal routines (Pagoto et al., 2016). Our pilot work demonstrates promise in the approach of engaging tanners with body image-focused content delivered via a secret Facebook group.

Objectives

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

To conduct a randomized control trial to examine the efficacy of a Facebook-delivered behavioral intervention vs. a Facebook-delivered control condition on reducing tanning behavior among high-risk tanners.

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.

Reliance Agreement and UConn roles in study:
After further conversation with our Co-Investigator at the University of Connecticut, a reliance agreement was signed between the University of Kentucky and the University of Connecticut that names UK as the IRB of record for this protocol (signed IAA attached). The Co-I at UConn will help this study by moderating half of the Facebook groups to ensure participant questions related to the intervention content are answered, as well as to ensure consistent timing and delivery of intervention content across groups. UConn will have access to active participants while they are members of the Facebook groups, but UConn will not have access to any survey data collected from participants, as well as any personally identifying information outside of the Facebook group. UConn will not help with analyzing survey data or contacting participants to ensure delivery of incentive payment after the intervention ends. UConn will help with downloading engagement data from the Facebook groups, such as the number of likes and comments on intervention posts. UConn will be using the same intervention posts as the team at the University of Kentucky, examples of these posts have been approved by UK IRB in previous iterations and are attached to this protocol for viewing.

The goal of the study is to test a behavioral intervention designed to reduce tanning behaviors. The intervention will be delivered via Facebook over an 8-week span. We will conduct a randomized control trial of the efficacy of the intervention with 400 young women ages 18-25 who report high-risk tanning (i.e., at least 10 indoor or outdoor tanning sessions in the past 12 months). Recruitment will primarily rely on electronic study advertisements distributed by research recruitment companies Qualtrics Sample Providers (QSP) and Oxford Communications to individuals in their participant panels as well as postings on social media and other online platforms. Study ads will link directly to a brief online study eligibility screening assessment programmed using UK's Qualtrics online survey software. Eligible participants will be provided a brief overview of the study at the end of the screening survey and those who indicate their interest in the study will be contacted by our study team to complete the online informed consent and baseline survey. Participants will be randomly assigned to a condition following completion of the baseline assessment in blocks of 100 participants to achieve our target group size of 50 participants. To ensure study participants and coordinators are sufficiently blinded we are randomizing treatment assignments in blocks with varying sizes, ranging from 4 to 8. We will be using a "telephone randomization" methodology, conducted by the statistician. . This design ensures that treatment groups will be balanced in the event of a truncated recruitment. Following randomization, participants will join a study-specific “private and hidden” group where membership and content is limited to invited group members. Participants’ group membership and in-group activities will not be publicly viewable to outside Facebook users regardless of personal account settings. Facebook groups will run for 8 weeks and contain up to 50 members each. At 3-months post-baseline, participants will be prompted to complete an online survey (follow-up 1), followed by additional surveys 8-months (follow-up 2) and 18-months post-baseline (follow-up 3). Surveys will take up to 30 minutes to complete. Incentives will be $30 gift cards for completing each of the baseline and 3- and 8-month follow-ups and $40 for the 18-month follow-up.

Attachments

Subject Recruitment Methods & Advertising

Describe how the study team will identify and recruit subjects. Please consider the following items and provide additional information as needed so that the IRB can follow each step of the recruitment process.

- How will the study team identify potential participants?
- Who will first contact the potential subjects, and how?
- Will you use advertisements? If so, how will you distribute those?
- How and where will the research team meet with potential participants?
- If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations.
- How you will minimize undue influence in recruitment?
- Attach copies of all recruiting and advertising materials (emails, verbal scripts, flyers, posts, messages, etc.).

For additional information on recruiting and advertising:

- IRB Application Instructions - Advertisements
- PI Guide to Identification and Recruitment of Human Subjects for Research

We plan to utilize the following recruitment approaches: 1.) electronic study ads distributed by Qualtrics Sample Providers (QSP) to participants in their survey panel 2). Electronic ads distributed by Oxford Communications to participants in their survey panel, 3.) electronic study ads posted on social media and other online platforms using University of Kentucky's CCTS research account, 4). UK CCTS research participant database registries and 5.) electronic study ads posted on social media and other online platforms 6.) snowballing sampling 7.) Flyers posted on UK's campus and the surrounding areas.

1.) Plans for the Identification and Recruitment of Participants- Qualtrics Sample Providers: The primary source of participants will be obtained by the internet research recruitment company Qualtrics Sample Providers (QSP) from their participant panels that comply with, or exceed, all applicable industry standards. QSP will distribute study ads with a link to an online screening survey to participants already enrolled in their panel. Participants who are interested in learning more about the study will follow the link to a brief screening survey that will assess their demographic characteristics, tanning bed use, outdoor tanning, Facebook use and two other behaviors to reduce the potential for false responses to meet study criteria. Potential subjects that are ineligible by their responses to the screener will be redirected to a page with a message informing them of their ineligibility for the trial. Participants who are eligible will receive a brief description of the study procedures and will be presented with the option to provide their contact information to be contacted by UK staff if they are interested in enrolling in the study. This information is stored directly in the online survey database accessed by the UK research team for the next study step of obtaining consent. Thus, QSP's involvement in the research is solely to distribute study ads and all remaining study procedures will be conducted by UK.

2.) Plans for the Identification and Recruitment of Participants- Oxford Communications: An additional source of participants will be obtained by the internet research recruitment company Oxford Communications from their participant panels that comply with, or exceed, all applicable industry standards. Oxford will distribute study ads with a link to an online screening survey to participants already enrolled in their panel. Participants who are interested in learning more about the study will follow the link to a brief screening survey that will assess their demographic characteristics, tanning bed use, outdoor tanning, Facebook use and two other behaviors to reduce the potential for false responses to meet study criteria. Potential subjects that are deemed ineligible by their responses to the screener will be redirected to a page with a message informing them of their ineligibility for the trial. Participants who are eligible will receive a brief description of the study procedures and will be presented with the option to provide their contact information to be contacted by UK staff if they are interested in enrolling in the study. This information is stored directly in the online survey database accessed by the UK research team for the next study step of obtaining consent. Thus, Oxford's involvement in the research is solely to distribute study ads and all remaining study procedures will be conducted by UK.

3.) Plans for the Identification and Recruitment of Participants- Online Study Advertisements using UKY CCTS services: This study will be advertised on recruitment internet webpages in digital form (e.g., UKclinicalresearch.com, ResearchMatch.org, UK Public Relations and HealthCare, CCTS and may utilize Google Adwords). The study will be promoted via social media, including Facebook boost ads, UK_CCTS Facebook, UK_CCTS Twitter, UK CCTS Instagram, UKclinicalresearch, YouTube, UK and UKHC social media, and 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 CCTS will also ask, '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 HC monitor screens.

4.) Plans for the Identification and Recruitment of Participants- UKY Research Participant Registries: 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 and they may contact them with more information about their research study. If the participant selects "No, thanks", researcher or proxy will not receive any information from de-identified participant.

5.) Plans for the Identification and Recruitment of Participants- Social Media and other online platforms: Potential participants may be identified by posting UK CCTS created electronic study ads posted on social media and other internet sites not affiliated with CCTS. This may include national Facebook groups or internet forum sites such as Reddit that target the demographics of this study such as young women centered fitness and health related groups, social activity groups, and wellness or stress-relief focused groups. The CCTS ads posted on these sites will direct interested persons to the screening survey. If a person has a positive screen indicating they are eligible for the study, there will be an additional prompt for the potential participant to opt-in to sharing their contact information with the research staff and to be contacted by the research staff. New social media advertisement content has been created based on the original content created by the CCTS. These new social media ads are now included for approval after going through UK PR approval.

6.) Plans for the Identification and Recruitment of Participants- Snowball Sampling: Thank you emails that go out to participants who complete the study enrollment and baseline procedures may contain a link to a Facebook page with the brief study description shown in the study ad and link to the study screening survey so that participants can share the Facebook page with friends that they think may be interested in the study. We will only rely on snowball sampling if recruitment is lower than anticipated from the online ads. Snowball sampling has been shown to be an effect way to reach sub-populations of young adults when conducting minimal risk health behavior research. The inclusion of this link in our thank you correspondences rather than directly asking participants to share this information will reduce undue pressure from investigators.

7.) Plans for the Identification and Recruitment of Participants- Posting of flyers on UK's campus and surrounding areas. CCTS designed posters with links to the screening survey will be posted in high-traffic locations on campus such as poster boards in classroom buildings, libraries, and on-campus food and drink service locations. Additionally, flyers will be posted in community locations that are frequented by the demographic such as coffee shops. New study advertisement flyers have been created based on the original designs by the CCTS and are included for approval after being approved by UK PR.

Setting for Interactions with Participants: QSP and Oxford will only be involved in sending study advertisements to potential participants from members already enrolled in their participant panel by sending them email invitations. QSP will have access to the Qualtrics survey used for recruitment and screening and will have access to the contact information provided by interested and eligible participants (which is likely to be the same as the contact information that participants have already provided to QSP when signing up to join the participant panel). Oxford Communications will not have access to any of the personal information or data collected in the screening survey. UK staff will obtain contact information directly from responses stored in the screening survey database and all subsequent participant contacts related to data collection and data handling will be conducted by the UK team via phone, web, or social media as described in the study procedures.

Privacy: Participants will provide their names and contact information on the brief screening assessment survey. We will download all responses to the screening survey at least every 3 business days during active recruitment in order to delete the data that is stored in the Qualtrics online survey platform after participants complete the screening survey. Downloaded screening data will then be stored in password protected files and names will be replaced with PIN numbers in the data files as described in the confidentiality section of the protocol.

Avoiding Undue Influences: Participants will be recruited from the general population and we anticipate no reason that potential subjects would feel coerced to participate.
Advertising will occur in two primary ways. First, Qualtrics Sample Providers (QSP) will email study ads to participants in their panels. The current version is attached for approval (Qualtrics Advertisement_Protocol 56153_Feb 2021). Additionally, Oxford Communication will disperse study ads to potential participants in a manner similar to QSP. Secondly, we will use UK CCTS advertisement services included posting on Google Adwords and posts on CCTS social media and online sites to advertise for the study. We will also use CCTS's access to ResearchMatch and other online participant recruitment databases.

Attachments

Attach Type	File Name
Advertising	Recruitment Text and Screening Survey_Qualtrics and Oxford_ Nov.2021.docx
Advertising	HBS-001 flyer_stamped.pdf
Advertising	HBS-001 MON stamped.pdf
Advertising	HBS-001 research match stamped.pdf
Advertising	HBS-001 social media stamped.pdf
Advertising	Stapleton_Flyer_15-STAMPED.pdf
Advertising	Stapleton_Flyer_16-STAMPED.pdf
Advertising	Stapleton_Flyer_17-STAMPED.pdf
Advertising	Stapleton_Flyer_18-STAMPED.pdf
Advertising	Stapleton_Flyer_19-STAMPED.pdf
Advertising	Stapleton_social media_1-STAMPED.pdf
Advertising	Stapleton_social media_2-STAMPED.pdf
Advertising	Stapleton_social media_3-STAMPED.pdf
Advertising	Stapleton_social media_4-STAMPED.pdf
Advertising	Stapleton_social media_5-STAMPED.pdf
Advertising	Stapleton_social media_6-STAMPED.pdf
Advertising	Stapleton_social media_7-STAMPED.pdf
Advertising	Stapleton_social media_8-STAMPED.pdf
Advertising	Stapleton_social media_9-STAMPED.pdf
Advertising	Stapleton_social media_10-STAMPEd.pdf
Advertising	Stapleton_social media_11-STAMPED.pdf
Advertising	Stapleton_social media_12-STAMPED.pdf
Advertising	Stapleton_social media_13-STAMPED.pdf
Advertising	Stapleton_social media_14-STAMPED.pdf

Research Procedures

Describe how the research will be conducted.

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

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.

There are three primary aspects of the research procedures in this study after screening has occurred: 1.) study enrollment and baseline procedures, 2.) participation in one of two Facebook groups, and 3.) a series of follow-up surveys. UK project staff will monitor all survey activities and track participants' engagement with study procedures.

Study Enrollment and Baseline Procedures: UK study research staff will obtain the contact information for interested participants from the screening survey and send an email invitation and text alert to the online baseline survey (which contains the survey consent cover letter) to each interested participant. As part of the survey invitation, participants will be provided with a personalized identification number (PIN) to use to access the online survey. Participants can only gain access to the survey by entering their PIN. To protect participant's identities we will not program questions that ask participants to report their names or other identifying information on the initial or follow-up survey. A series of reminder emails and text messages will be sent to those who did not complete the survey. Following completion of the 30 minute baseline survey, participants will be sent a thank you email with a code to redeem an electronic Amazon gift card. The final step in the baseline procedures will be a brief 10-minute webinar designed to instruct participants on the process of joining and participating in the Facebook group.

Facebook Groups: Following completion of the baseline survey and the study introduction webinar, participants will join a study-specific "private and hidden" group where membership and content is limited to invited group members.
The Facebook groups are matched on length and some content with differences in the types of information and topics covered in the posts between the intervention and active control group. Facebook groups will run for 8 weeks and contain 25 members each. Given that ideal intervention length and group size have not been established (Pagoto et al., 2016), we based our decision on our preliminary pilot Facebook study and the few published trials of Facebook group interventions.

A social media specialist at the University of Connecticut, under the supervision of Dr. Stapleton and the grant study co-Investigator at UConn (Dr. Sherry Pagoto) will lead the study moderator Facebook account. This entails making the posts, actively monitoring participants' Facebook postings, and providing comments or reactions (e.g., "liking") to various posts for the purpose of reinforcing participant activity and stimulating stagnant posts. Research assistants at UK already on this protocol's personnel list along with Dr. Stapleton will also have access to the group moderator Facebook account so that the activity of the groups can be closely monitored by Drs. Stapleton and Pagoto during nights and weekends while the Facebook groups are active. The UConn staff will create and distribute regular engagement reports during active Facebook data collection periods. Drs. Stapleton and Pagoto will hold regular telephone meetings to review these reports. This activity performed by UConn falls under the IAA signed by UK and UConn making UK the IRB of record.

We will develop a content library of posts which will be posted in the appropriate groups on the schedule time and day by a study-specific moderator account. We will make 2 group posts each day, a frequency suggested by social media marketers to engage participants without overburdening them (Ross, 2014). Posts will fall into two general categories. The first type, called Your Thoughts posts, pose questions and thought exercises designed to elicit comments and conversations from members. These posts promote active intervention involvement and encourage participants to engage with counter-attitudinal perspectives in a group format which bolsters the effects of disordered eating dissonance-based interventions (Green et al., 2005; Stice et al., 2008). The second type, Shareables, are posts that are informative and do not specifically ask participants for feedback.

The planned intervention content is described in this document based on the Quorum Review IRB's recommendations for review for social media research: "communications should be described in general terms by category" with "representative samples of each should be provided". The focus of these posts will fall into the 3 general categories shown in the attached document (Examples of Facebook Posts_Stapleton). Examples of planned posts that are from our pilot study are shown for each category.
Participants in the control condition will also participate in private and hidden Facebook groups that utilize content from the intervention content library except that posts related to body image or indoor tanning will be replaced by posts related to other health topics of interest identified by young women in our pilot research (e.g., physical activity, healthy eating, alcohol misuse prevention, stress reduction, sleep). Posts will be matched across conditions in terms of the ratio of Your Thoughts and Shareables posts. This design will ensure the intervention and control condition are matched as much as possible on total social media exposure, amount and type of content delivered, and intervention engagement. The design also avoids threats from demoralization among control users who expect but do not receive health content in a no-treatment control.

Follow-Up Surveys: Surveys will be distributed at 3-, 8-, and 18-months following the baseline surveys using the same procedures as the baseline survey. However, follow-up surveys will not contain the survey consent cover letter.

Attachments

Attach Type	File Name
ResearchProcedures	Examples of Facebook Posts_Stapleton.docx

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.

The screening survey is attached as file named "Recruitment Text and Screening Survey_Qualtrics and Oxford_Nov 2021".

The baseline survey is attached as file named "Baseline Survey for Stapleton Project_Nov.21 IRB". The first of three follow-up assessments is attached as a file named "FB R01 Follow up Survey 3 months _ Stapleton". The second of three follow-up assessments is attached as a file named FB R0 Follow up survey 8 months_Stapleton" We will modify the protocol to include the final follow-up assessment (which will contain very similar questions) and receive approval prior to distributing them to participants for the RCT.
Surveys questions with established psychometric properties and validity were chosen and include a variety of demographic questions, social media use, and various health behaviors designed to reduce the focus on tanning only in the assessments. Questions about body image, body dissatisfaction, mindfulness, values, and psychological flexibility will allow us to explore the association of these factors with engagement in the Facebook study and intervention perceptions collected in the focus groups. The post-intervention follow-up survey for the usability trial will also contain brief assessments of intervention perceptions. The primary outcome will be indoor or outdoor tanning behavior assessed on the 8-month survey. Secondary outcomes include indoor or outdoor tanning at 18-months, tanning intentions, and skin burns from indoor or outdoor tanning. Variables that capture hypothesized mediators of intervention effects include: openness to changing tanning behavior, perceived pressure to tan, importance of tanning, tanning dissatisfaction, and body acceptance.

Attachments

Attach Type	File Name
DataCollection	Recruitment Text and Screening Survey_Qualtrics and Oxford_ Nov.2021.docx
DataCollection	Baseline Survey for Stapleton Project_Nov.21 IRB.docx
DataCollection	Recruitment Text and Screening Survey_Tracked Changes.docx
DataCollection	FB R01 Follow up Survey 3 months _ Stapleton.docx
DataCollection	FB R01 Follow Up Survey 8 months_Stapleton.pdf
DataCollection	FB R01 Follow Up Survey 18 months_Stapleton.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.

Expertise: The study PI, Dr. Stapleton, has extensive training and experience in conducting behavioral intervention research, has conducted several studies with the target population using electronic data collection, and has Principal Investigators on multiple federally funded research grants. Dr. Stapleton and his UConn colleague, Dr. Sherry Pagoto, have also conducted several research studies using Facebook or other social media sites as well as studies of young women who use indoor tanning. The study investigators will directly supervise all research staff in their day-to-day project tasks. We will develop study procedural manuals and hold staff trainings to ensure that all research staff are adequately informed about the protocol, the research procedures, and their duties and functions.

Data Collection Staff: Staff from the Behavioral and Community-Based Research Shared Resource Facility (BCBR-SRF) at UK's Markey Cancer Center (Kahl, Christian, and Blair) will assist in the development of the online surveys as well as their administration and tracking of responses. They will be in charge of monitoring incoming screening responses, inviting participants to the baseline assessments, inviting participants to the Facebook groups, and conducting the follow-up assessments.

Social Media Staff: The primary role of research team members for the Facebook group research is to lead the group moderator study account. We will collaborate with staff from the UConn Center for mHealth and Social Media, co-founded by Dr. Sherry Pagoto (co-I), a center devoted to mHealth technologies for understanding eating behavior, physical activity, diabetes, substance abuse, medication adherence, stress and depression. Dr. Pagoto will co-lead the social media team with Dr. Stapleton. The UConn study team will be

primarily responsible for the technical development and administration of the Facebook intervention. Dr. Pagoto will supervise the UConn social media specialist in creating and implementing the intervention content in the Facebook feed format as well as actively monitoring and supervising the Facebook group feeds. The UConn staff will create and distribute regular engagement reports during active Facebook data collection periods. At UK. Dr. Stapleton will also have access to the study moderator account in order to monitor all ongoing study interactions with participants. Drs. Stapleton and Pagoto will hold regular telephone meetings to review these reports. UConn's social media activity for the project is covered under the IAA signed by UK and UConn.

Survey software: The baseline and follow-up online surveys will be created using Qualtrics survey software hosted by UK.

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.

The potential risks to human subjects are minimal. It is possible that participants may feel psychological or social discomfort while responding to survey questions or Facebook group discussions that ask about their indoor tanning behavior, body image, or stressful aspects of their lives. These risks are described in the survey cover letter consent. Participants will be allowed to withdraw if they are uncomfortable with any aspect of the study. Project investigators and staff will closely monitor all Facebook comments and we will identify an individualized plan for referring participants to appropriate resources if concerns arise. Specifically, if a participant appears to be experiencing distress as a result of their participation, Dr. Stapleton will consult directly with Drs. Laurie McLouth and Sherry Pagoto (both clinical psychologists) on the proper course of action. We have conducted two pilot trials of this Facebook group and have not had any participants raise significant concerns that required referral to the IRB.
There is no direct benefit to the subjects participating in this research study. However, if successful, the intervention may lead participants to reduce their tanning behaviors which would decrease their future risk for developing skin cancer. The primary benefit of the study is the knowledge to be gained and the potential for learning about ways to effectively design and improve educational and prevention programs. If efficacious, the intervention could be disseminated on a wide-scale which may help to reduce the rates of melanoma cancers among young adult women. The potential knowledge and societal benefits outweigh the minimal risks involved with participation.

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).

Not applicable to the current behavioral intervention study.

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Records, Privacy, and Confidentiality

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

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

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

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

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

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

Online surveys will be used to collect self-report data on health behaviors and related psychosocial factors.
This project is funded by the National Institutes of Health and was automatically issued a Certificate of Confidentiality at time of funding. Data will be retained for a minimum of 6 years after study closure and if deleted will be done so using UK Policy A13-050 and UK Policy A05-055.

Online data collection confidentiality: We will take extensive precautions to protect the confidentiality of participants. This study will collect Personal Identifiers (name, address, phone number, and email address) at the time of screening assessment solely for the purposes of correspondence with participants regarding survey procedures and for making subject payments. We will download all responses to the screening survey at least every 3 business days during active recruitment in order to delete the data from being stored in the Qualtrics online survey platform. Once data is downloaded and online data is deleted, the downloaded data will then be stored in password protected files and names will be replaced with PIN numbers. Each study participant will be assigned a unique numeric identifier, or Personal Identification Number (PIN). One master list will link PINs to the personal identifiers and will be maintained in a password-protected file and in a password-protect folder that is stored separately from stored data on a protected UK server. PI will not be collected on the baseline or follow-up assessments and no PI will be stored in survey databases. All survey and personal data will be collected with Qualtrics online surveys. Thus, Facebook will not have access to any of the data. The master lists linking identifiable information with participant PINs will be deleted 6 years after the study completion date for the purposes of having complete documentation of subject payments. Protected Health Information (PHI) will not be collected.

Participant survey data will be collected online using Qualtrics survey software, provided by UK as a method of online survey data collection. Qualtrics uses Transport Layer Security (TLS) encryption (also known as HTTPS) for all transmitted data. Qualtrics servers are protected by high-end firewall systems, and scans are performed regularly to ensure that any vulnerabilities are quickly found and patched. Complete penetration tests are performed yearly. All services have quick failover points and redundant hardware, with complete backups performed nightly. Qualtrics' services are hosted by trusted data centers that are independently audited using the industry standard SSAE-16 method. Qualtrics deploys the general requirements set forth by many Federal Acts, including the FISMA Act of 2002 and meets or exceeds. We meet or exceed the minimum requirements as outlined in FIPS Publication 200.

Facebook privacy: The use of private and hidden Facebook groups to deliver the intervention helps to assure participants' privacy during study participation. The privacy settings for Facebook private and hidden groups are configured such that participants' messages and participation within the study group will only be visible to other invited members of the closed group and are not other non-group Facebook users. The use of a private and hidden group also means that other social media members whom are not in our study will not know that an individual is participating in the group. Participants are not asked to reveal sensitive information so the risks of breach of confidentiality are minimal. All survey and personal data will be collected with Qualtrics online surveys. Thus, Facebook will not have access to any of this data. Group engagement data (such as the number of likes and comments on posts within the private and hidden group) will be extracted using Grytics and exported to REDCap. No personal data from the participants' profiles will be accessed or downloaded.
Safeguards to prevent breach of confidentiality in our online methods are described in the confidentiality section.

Project investigators and staff will closely monitor all Facebook comments and we will develop a plan for referring participants to appropriate resources if concerns arise. If a participant appears to be experiencing distress as a result of their participation, Dr. Stapleton will consult directly with Drs. Laurie McLouth and Sherry Pagoto (both clinical psychologist) on the proper course of action.

This project is funded by the National Institutes of Health and was automatically issued a COC at time of funding.

Participants may withdraw from the study at any time. Additionally, participants may be terminated from study activities if they drop from participation, do not complete all screening procedures, falsify their data, or post inappropriate or harassing content that violates University of Kentucky or Facebooks policy on the social network group. The moderator is trained to monitor for and remove offending content and provide warning to participants who engage in inappropriate or harassing behavior. We will remove the participant if the behavior persists. This is to protect all participants.

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

Payment

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

Participants will be emailed the redemption codes for a $30 Amazon gift card immediately after completing each of the baseline, 3-month, and 8-month follow-up surveys and a $40 gift card for completing the 18-month follow-up. Participants will be compensated for

each survey they log on to and begin taking, regardless of the level of completion of the survey items.

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.

We do not anticipate any costs or expenses for participants while completing study procedures.

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.

We will use the following plan, recently adapted to UK, which was deemed as acceptable by our National Institute of Health review panel.

A data safety and monitoring plan (DSMP) will be implemented for this project. We will not, however, set up an independent Data Safety and Monitoring Board because this trial is minimal risk. Drs. Stapleton, Pagoto, and McLouth will monitor the progress of the trial monthly. The research team will review and discuss via a teleconference any such critical events to ensure that our methods have not been intrusive or disruptive and that our data are secure. If modifications are needed, they will be implemented immediately. Adverse event reporting will be initiated by the principal investigator and will follow standard reporting procedures in the University of Kentucky's Office of Research Integrity and Institutional Review Board Standard Operating Procedures. Dr. Stapleton will monitor accrual to the study and adherence to the overall protocol, verify the completion of informed consent forms, and ensure that data collection and storage procedures are being followed appropriately. He will report on results of this monitoring to Drs. Pagoto and McLouth every 3 months during active data collection. Any action taken by the UK ORI or IRB or research team that results in a temporary or permanent suspension of the study will be communicated immediately by Dr. Stapleton to the grant program officer and to the Department of Health and Human Services.

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

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

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

The information collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like name, or date of birth.

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-Initiated FDA-Regulated Research

Is this an investigator-initiated study that:

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

PI-Sponsored FDA-Regulated Research

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

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

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

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?
○ Yes ○ No
If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.
Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ○ Yes ◉ No

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

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

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

Drugs are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

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).

See 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)

Medical devices are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals.

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:

University of Connecticut

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

Attach Type	File Name
-IRB Authorization Agreement	IAA between UK and UConn - Stapleton - 56153 pe.pdf

B) If your research involves collaboration with any sites and/or personnel outside the University of Kentucky, then it is considered multisite research and IRB reliance issues will need to be addressed. This may include national multi-center trials as well local studies involving sites/personnel external to UK. If you would like to request that the University of Kentucky IRB (UK IRB) serve as the lead IRB for your study, or if you would like the UK IRB to defer review to another IRB, please contact the IRBReliance@uky.edu.

RESEARCH ATTRIBUTES

0 unresolved comment(s)

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

Contact the Clinical Research Support Office (CRSO) if your study provides clinical services (e.g., labs, biopsies, tissue samples, physical exams, PT, counseling) regardless of payer (grant, federal, UK, industry)), utilizes UKHC space, or meets the NIH definition of a clinical trial (thereby requiring registry with CT.gov) as your study will need to be entered in OnCore to ensure appropriate regulatory tracking and billing. Visit CRSO FAQs for more information; requests for CCTS/CRSO services can be submitted via their service request form. For other questions, you can contact the CRSO Director, Jessica Heskel, at jhesk2@uky.edu.

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

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*

- ☐ Genetic Research
- ☐ NIH Genomic Data Sharing (GDS) (databases such as GWAS, dbGaP, GenBank)
- ☐ Treatment with Human Cells, Tissues, and Cellular and Tissue Based Products
- ☐ Individual Expanded Access or Compassionate Use
- ☐ International Research
- ☐ Planned Emergency Research Involving Exception from Informed Consent
- ☐ Recombinant DNA
- ☐ Registry or data repository creation
- ☐ Stem Cell Research
- ☐ Suicide Ideation or Behavior Research
- ☑ Survey Research
- ☐ Transplants
- ☐ Use, storage and disposal of radioactive material and radiation producing devices
- ☐ Vaccine Trials

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

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "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

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Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

Assurance/Certification Attachments

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

◉ Yes ○ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☑ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC) - Attach required IBC materials
- Radiation Safety Committee (RSC) - For applicability, see instructions
- 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
Protocol	2020-009 56135_PRMC Memo_Not A Clinical Trial_Stapleton.pdf

NOTE: [Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

To view the materials currently attached to your application, click “All Attachments” on the left menu bar.

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

All IRB applications require additional assurances by a Department Chairperson or equivalent (DA), and when applicable, a Faculty Advisor or equivalent (FA). This signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. The person assigned as DA *should not* also be listed in the Study Personnel section, and the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, refer to "What does the Department Chairperson's Assurance Statement on the IRB application mean?"

For a detailed illustration of how to complete this section, please review the short online video tutorial "Signatures (Assurance) Section - How to Complete." Otherwise, follow the steps below.

Required Signatures:

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

The PI, and personnel chosen as a contact, will receive an email notification that edits are needed, and can find the draft application in both the "Draft" folder and the "Signatures 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	
Julia	Costich	Department Authorization	Dept of Health Mgmt & Policy		08/26/2024 11:17 AM	View/Sign
Jerod	Stapleton	Principal Investigator	Department of Health, Behavior		12/20/2019 12:16 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.

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SUBMISSION INFORMATION

0 unresolved comment(s)

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

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

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

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

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

Principal Investigator's Assurance Statement

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

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

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

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

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

Your protocol has been submitted.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.090	ecr236	8/1/2025 12:53:15 PM
	DataCollection	FB R01 Follow Up Survey 18 months_Stapleton.pdf	FB R01 Follow Up Survey 18 months_Stapleton	0.110	jlst329	9/6/2024 10:57:12 AM
	Advertising	Stapleton_social media_14-STAMPED.pdf	social media graphic 14_PR approved	0.144	asme225	3/2/2023 2:56:21 PM
	Advertising	Stapleton_social media_13-STAMPED.pdf	social media graphic 13_PR approved	0.143	asme225	3/2/2023 2:56:06 PM
	Advertising	Stapleton_social media_12-STAMPED.pdf	social media graphic 12_PR approved	0.211	asme225	3/2/2023 2:55:52 PM
	Advertising	Stapleton_social media_11-STAMPED.pdf	social media graphic 11_PR approved	0.128	asme225	3/2/2023 2:55:37 PM
	Advertising	Stapleton_social media_10-STAMPEd.pdf	social media graphic 10_PR approved	0.209	asme225	3/2/2023 2:55:13 PM
	Advertising	Stapleton_social media_9-STAMPED.pdf	social media graphic 9_PR approved	0.194	asme225	3/2/2023 2:54:58 PM
	Advertising	Stapleton_social media_8-STAMPED.pdf	social media graphic 8_PR approved	0.106	asme225	3/2/2023 2:54:42 PM
	Advertising	Stapleton_social media_7-STAMPED.pdf	social media graphic 7_PR approved	0.204	asme225	3/2/2023 2:54:26 PM
	Advertising	Stapleton_social media_6-STAMPED.pdf	social media graphic 6_PR approved	0.121	asme225	3/2/2023 2:54:11 PM
	Advertising	Stapleton_social media_5-STAMPED.pdf	social media graphic 5_PR approved	0.157	asme225	3/2/2023 2:53:58 PM
	Advertising	Stapleton_social media_4-STAMPED.pdf	social media graphic 4_PR approved	0.151	asme225	3/2/2023 2:52:34 PM
	Advertising	Stapleton_social media_3-STAMPED.pdf	social media graphic 3_PR approved	0.110	asme225	3/2/2023 2:52:18 PM
	Advertising	Stapleton_social media_2-STAMPED.pdf	social media graphic 2_PR approved	0.267	asme225	3/2/2023 2:52:04 PM
	Advertising	Stapleton_social media_1-STAMPED.pdf	social media graphic 1_PR approved	0.118	asme225	3/2/2023 2:51:48 PM
	Advertising	Stapleton_Flyer_19-STAMPED.pdf	Recruitment Flyer 5_PR Approved	0.143	asme225	3/2/2023 2:44:52 PM
	Advertising	Stapleton_Flyer_18-STAMPED.pdf	Recruitment Flyer 4_PR Approved	0.187	asme225	3/2/2023 2:44:32 PM
	Advertising	Stapleton_Flyer_17-STAMPED.pdf	Recruitment Flyer 3_PR Approved	0.156	asme225	3/2/2023 2:44:10 PM
	Advertising	Stapleton_Flyer_16-STAMPED.pdf	Recruitment Flyer 2_PR Approved	0.167	asme225	3/2/2023 2:43:32 PM
	Advertising	Stapleton_Flyer_15-STAMPED.pdf	Recruitment Flyer 1_PR Approved	0.149	asme225	3/2/2023 2:43:05 PM
	DataCollection	FB R01 Follow Up Survey 8 months_Stapleton.pdf	Follow Up Survey 2 (8 months post baseline)	0.106	asme225	10/26/2022 3:31:01 PM
	DataCollection	FB R01 Follow up Survey 3 months _ Stapleton.docx	Follow Up Survey 1	0.282	asme225	5/24/2022 3:43:22 PM
	-IRB Authorization Agreement	IAA between UK and UConn - Stapleton - 56153 pe.pdf		0.353	asme225	1/20/2022 1:25:43 PM
	DataCollection	Recruitment Text and Screening Survey_Tracked Changes.docx	Tracked changes of previously approved screening survey	0.025	asme225	11/22/2021 3:45:00 PM
	DataCollection	Baseline Survey for Stapleton Project_Nov.21 IRB.docx	Baseline Survey	0.281	asme225	11/15/2021 12:08:37 PM
	DataCollection	Recruitment Text and Screening Survey_Qualtrics and Oxford_ Nov.2021.docx	Screening Survey	0.029	asme225	11/15/2021 12:05:13 PM

	ResearchProcedures	Examples of Facebook Posts_Stapleton.docx	Examples of Facebook Posts	16.615	asme225	11/15/2021 12:00:51 PM
	Advertising	HBS-001 social media stamped.pdf	social media stamped	1.028	asme225	11/15/2021 11:53:10 AM
	Advertising	HBS-001 research match stamped.pdf	research match stamped	0.099	asme225	11/15/2021 11:52:56 AM
	Advertising	HBS-001 MON stamped.pdf	Mon stamped	0.940	asme225	11/15/2021 11:52:42 AM
	Advertising	HBS-001 flyer_stamped.pdf	flyer stamped	0.275	asme225	11/15/2021 11:52:28 AM
	Advertising	Recruitment Text and Screening Survey_Qualtrics and Oxford_ Nov.2021.docx	Recruitment text and screening survey	0.029	asme225	11/15/2021 11:49:33 AM
	AddInfoProtocol	2020-009 56135_PRMC Memo_Not A Clinical Trial_Stapleton.pdf	PRMC Approval	0.203	jlsmit6	3/3/2020 3:06:29 PM

Protocol Changes

Protocol Number: 56153

Click link to sort Changed Date
HIPAA HIPAADeIdentificationCertForm changed by jlst329 on 7/31/2025 4:04:24 PM
~~N~~
Informed Consent ElectronicConsent changed by jlst329 on 7/31/2025 4:06:12 PM
Y
Project Information IsSubEnrollDataSpecimen changed by jlst329 on 8/1/2025 9:06:57 AM
~~Y~~N
Project Information ProjectEndDate changed by jlst329 on 8/1/2025 9:06:57 AM
6/25/2025~~5~~6 12:00:00 AM
Research Attributes EpidemiologicBehavioralStudies changed by jlst329 on 7/31/2025 4:06:26 PM
Y
Research Attributes MaterialOfHumanOrigin changed by jlst329 on 7/31/2025 4:06:26 PM
N
Research Attributes OutcomesHealthServicesResearch changed by jlst329 on 7/31/2025 4:06:26 PM
N
Research Attributes PatientOrientedResearch changed by jlst329 on 7/31/2025 4:06:26 PM
Y
Research Sites MultisiteLeadInvestigator changed by jlst329 on 7/31/2025 4:04:39 PM
~~Y~~

Study Personnel Changes:

Continuation/Final Review Comment by Elisa Crill - ORI to PI on 8/1/2025 8:54:16 AM
Please attend to the following screening comments before this submission will be ready for IRB review:

1) If the project is now data analysis only, in the Project Information section, please change your response to "no" for the question "After approval, will the study be open to enrollment of new subjects or new data/specimen collection?"

2) In the Project Information section, please extend the anticipated project end date by at least a year from today's date to cover you until the next annual review would be due.

Please contact me if you have any questions or concerns: elisa.crill@uky.edu, 859-257-1639, or message me on Teams. Thank you!

STATISTICAL DESIGN

Statistical Design

Analytic Plan for Grant Aim 2: **Efficacy.** Frequencies for categorical outcomes and means, standard deviations and histograms for continuous outcomes will summarize the distributions of outcomes as well as demographics across the treatment groups. Under intention-to-treat analyses, two-sided tests for the effect of treatment will be conducted at the 0.05 level. If more than 10% of the outcomes are missing, methods for missing data will be considered. In particular, demographics for those with and without missing outcomes will be compared. If data may be considered missing at random, methods such as multiple imputation will be applied and compared.

Primary outcome analyses: Multilevel models (e.g., random coefficient) will be used to test the primary study hypothesis that participants who received the intervention will report less total tanning behavior at a 8-month follow-up compared to those who received the control. The level 1 model represents individuals that are nested within Facebook groups (the level 2 model). In particular, the effect of intervention will be considered a random effect that may vary by block (i.e., Facebook group). Thus, the model for analysis will use following form as a starting point: $Y_{ij} = \beta_{0j} + \beta_{1j}T + \varepsilon_{ij}$, where Y_{ij} represents the number of tanning sessions used for the ith individual within the jth block, T is an indicator for whether the individual was randomized to the treatment or control. As such, the analysis accounts for (by including the random intercept β_{0j}) random differences between blocks (e.g., prior tanning behavior) and allows the effect of the intervention to vary by block (with β_{1j}). If necessary, sensitivity analyses may control for individual-level covariates. We will use this same modeling framework to examine secondary efficacy outcomes including tanning intentions and burns at 8-months and indoor tanning behavior at 18-months.

Sensitivity Analyses: We will compare baseline characteristics by condition and modify the above analyses to adjust for any differences. In addition, if the assumption of normality is strongly violated, appropriate transformations (i.e., square root) or additional analysis methods will be considered. For example, if there are a large number of zeroes for the primary outcome, analyses may consider the outcome to be a zero-inflated Poisson distribution.

Analytic Plan for Grant Aim 3: Mediators. Mediator analysis will be used to assess whether participant attitudinal factors (level 1 variables), such as perceived importance of being tan or body dissatisfaction, mediate the effect of the intervention. In particular, for each potential mediator, the four component steps140 will be examined via regression models similar to those described above. The contribution of the mediated effect will be assessed directly using the approach recommended by Kenny and colleagues141 for multilevel models, we will calculate the product of the two pieces of the mediating path (from intervention group assignment to mediating variable and from mediating variable to outcome). Bootstrap procedures will be utilized to formally test for significance of the mediating pathway.