Document Coversheet

Study Title: Tobacco Product Susceptibility and Substitutability by Rurality and Alcohol Use

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	8/27/2026
NCT Number:	NCT07010601
IRB Number	76582
Coversheet created:	9/2/2026

Statistical Analysis Plan:

For hypothetical demand of novel products, intensity of demand (i.e., likelihood to use a novel product when cost is low/0), and sensitivity to price (i.e., alpha, maximum expenditure) will be compared by alcohol tobacco use group and including relative rurality as a covariate and fixed effects. Participant will be nested within condition as random effects. Non-linear mixed effects modeling will be used to determine how likelihood to use novel products based on flavor, nicotine content, and consumption type affect intensity of demand and sensitivity to price. In the case of convergence issues, linear mixed-effects models will be used to determine intensity (intercept) and relative price sensitivity (slope of likelihood by cost interaction). For experimental tobacco marketplace substitution, non-linear mixed effects models will be used based on tobacco product type for fixed-price product categories (i.e., combustible, non-combustible, quit, e-cigarettes, cigarettes) to determine which product categories function as substitutes within marketplaces, alcohol use status, relative rurality, and current tobacco product use as fixed effects. Participants will be nested within tobacco product category as random effects. If there are issues with non-linear model fitting due to issues of convergence, linear mixed-effect modeling will be used to determine slope (i.e., adjusting price by fixed-price tobacco product category interaction) and which products served as substitutes for the adjusting price item based on marketplace type.

IRB Approval
8/27/2026
IRB # 76582
Exempt

Protocol #: 76582
Short Title: Crowdsourcing SOP
Submitted Date: 08/26/26

PROTOCOL TYPE (VERSION 5)

0 unresolved comment(s)

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 Exempt Review Webpage.

EXEMPTION CATEGORIES

0 unresolved comment(s)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MODIFICATION REQUEST SECTION

0 unresolved comment(s)

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

Select One:

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

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

( ) Yes (•) No

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

( ) Yes (•) No

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

For each proposed modification, include a justification.

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

Corrected some typos/errors in "Covarying Engagement Survey"

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

Standard Operating Procedures for Conducting Research Using Crowdsourcing

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.

Crowdsourcing SOP

Anticipated Ending Date of Research Project: 2/13/2027

Maximum number of human subjects (or records/specimens to be reviewed) 24000

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 a UK-affiliated 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*).

Non-UK individuals ("external") are not eligible for the role of Principal Investigator and cannot create a new application, nor will they be listed in the "Change Principal Investigator" search tool.

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" (if the link is disabled, be sure to answer the SFI question and save the section to activate it);
- 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:	Mikhail	Room# & Bldg:	2195 Harrodsburg Rd STE125
Last Name:	Koffarnus	Speed Sort#:	40504
Middle Name	N.		
Department:	Family and Community Medici…	Dept Code:	7H460
PI's Employee/Student ID#:	12467425	Rank:	Associate
PI's Telephone #:	8593236402	Degree:	PhD
PI's e-mail address:	koffarnus@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	8/20/2025
		RCR Trained:	Yes

Do you, the PI/researcher, have a significant financial interest (SFI) 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 100

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

Participants will be recruited through crowdsourcing platforms such as Testable, Prolific, Qualtrics Panels, and Amazon Mechanical Turk. Participants on MTurk will be included if they live in the United States, have a Human Intelligence Task (HIT) approval rating of at least 99%, and at least 100 approved HITs. These criteria have been used successfully in prior, similar crowdsourcing research investigating substance use and decision making conducted by our lab that we intend to replicate. We will modify these MTurk inclusion criteria for other crowdsourcing platforms to best match the procedures used on MTurk.

Additional inclusion criteria for the Cannabis/Nicotine Withdrawal Crowdsourcing:
Participants will be included if they have endorsed daily cigarette use during the past year and at least weekly cannabis use within the last year.

Additional inclusion criteria for the SUPRA Crowdsourcing Pilot:
Percentage comprehension test to determine eligibility but no specific demographic/substance use criteria.

Additional inclusion criteria for the SUPRA Longitudinal Pilot:
Percentage comprehension test to determine eligibility and those in Prolific who have identified as drinking at least once a week.

Additional inclusion criteria for the Experimental Tobacco Marketplace Pilot
Percentage comprehension test to determine eligibility and those in Prolific who have identified as being a current cigarette smoker as well as smoking at least 25 days in the past month.

Additional inclusion criteria for the CM VA Prolific study.
Veterans who have indicated alcoholism on the AUDIT-C, veteran status, or are direct family members with veterans and have utilized the VA clinic.

Additional inclusion criteria for the Nicotine Pouch Substitution Study.
18+ year old cigarette smokers and nicotine pouch users in the United States.

Additional inclusion criteria for the AppalTRUST Tobacco/Alcohol Study
Group assignment will be determined by alcohol use disorder identification test score (AUDIT) and current cigarette/e-cigarette use.

Additional inclusion criteria for the Tobacco Alcohol Marijuana Study
Participants must be >18 years of age and use either tobacco, alcohol or marijuana (>1 use per month).

Additional inclusion criteria for "The Covarying of Mental Health, Alcohol/Substance Use, and Treatment Engagement" study
Participants must be >=18 and we will try to recruit an equal number of participants based on alcohol use using Prolific's built in screeners.

References:
Cunningham, J.A., Godhino, A., & Kushnir, V. (2017). Using mechanical turk to recruit participants for internet intervention research: Experience from recruitment for four trials targeting hazardous alcohol consumption. BMC Medical Research Methodology, 17(1), Article 156.
Morris, V., Amlung, M., Kaplan, B.A., Reed, D.D., Petker, T., & MacKillop, J. (2017). Using crowdsourcing to examine behavioral economic measures of alcohol value and proportionate alcohol reinforcement. Experimental and Clinical Psychopharmacology, 25(4), 314-321.
Rzeszutek, M.J., Gipson-Reichart, C.D., Kaplan, B.A., & Koffarnus, M.N. (2022). Using crowdsourcing to study differential effects of cross-drug withdrawal for cigarettes and opioids in a behavioral economic demand framework. Experimental and Clinical Psychopharmacology, 1555-6824, 1064-1297.

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:	40	40		
Asian:	275	285		

Black/African American:	625	645		
Latinx:	890	920		
Native Hawaiian/Pacific Islander:	10	10		
White:	3,555	3,675		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:	0	0		20,500

If unknown, please explain why:

Unknown is increased to account for participants to be screened and for which full demographics will not be collected.

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 [Department of Defense (DoD) 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
- Additional Consent Templates (e.g., registry/bank, survey, deception/debrief, FDA expanded access, case report)
- AI Informed Consent Sample Language

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- If another site is serving as the IRB for the project, attach the form as a “Reliance Consent Form” so the document will not receive a UK IRB approval stamp; the reviewing IRB will need to stamp the consent forms.
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.
  Document Types that do NOT get an IRB approval stamp are:
  - "Highlighted Changes",
  - "Phone Script", and
  - "Reliance Consent Form",
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must:

   a) provide a response in the text box below describing how investigators will obtain consent/assent, and
   b) check the box for at least one of the consent items and/or check mark one of the waivers

2. If applicable attach each corresponding document(s) **as a read-only PDF**.
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

☐ Not applicable

Check All That Apply

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

Attachments

Attach Type	File Name
Survey Consent	Covarying Engagement Cover Letter V1.pdf
Survey Consent	NP Screener Consent 9_24_25.pdf
Survey Consent	NP Full Survey Consent 9_24_25.pdf

Survey Consent	01_CLEAN_ScreenerConsent_RxPathology.pdf
Survey Consent	CLEAN_T_Main_Consent_RxPathology.pdf
Survey Consent	CLEAN_NT_Main_Consent_RxPathology copy.pdf
Survey Consent	AppalTRUST Tobacco Alcohol ETM consent v2.pdf
Survey Consent	AppalTRUST Tobacco Alcohol Screener Consent v2.pdf
Survey Consent	Tobacco Alcohol Cannabis Screener Consent.pdf
Survey Consent	Tobacco Alcohol Cannabis Main Survey Consent.pdf
Survey Consent	AppalTRUST Tobacco Alcohol no ETM Consent v1.pdf
Survey Consent	VA interview consent statement 120224.pdf
Survey Consent	Nicotine Pouch Cover Letter Clean.pdf
Survey Consent	CM VA Cover letter clean.pdf
Survey Consent	SUPRA Cover Letter Clean 1.27.23.pdf
Survey Consent	Informed Consent CanNic Clean 1.27.23.pdf
Survey Consent	ETM Pilot Cover Letter Clean.pdf
Informed Consent/Parental Permission	01_TRACKED_ScreenerConsent_RxPathology.pdf

Informed Consent Process:

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

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)
- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

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

◉ Yes ○ No

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

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

Special considerations may include:

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

Potential participants will be shown the consent form prior to any participation. By clicking the next button on the survey, thus continuing on to the rest of the survey, participants will be providing their consent.
Participants will be allowed to complain or request information from the research time at any time without consequence. Participants may also contact the IRB if they have concerns they do not wish to share with us or if they feel that we are not adequately addressing their concerns. We will provide contact information to participants on the consent form, which will be distributed freely to prospective, current, and past participants.

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, complete, Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except

for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting a waiver of the requirement for the informed consent process.

☐ I am requesting an alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered and/or omitted, and justify the alteration.

SECTION 2.

Explain how each condition applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

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

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

☑ Request for Waiver of Signatures

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (e.g., a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to the subject, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study.

*If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the **Cover Letter Template** as a guide. There is an English and a Spanish version.*

○ **Option 1**

Describe how your study meets these criteria:

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

◉ **Option 2**

Describe how your study meets these criteria:

a) The research presents no more than minimal risk to the participant:

The proposed project is a survey that will be administered through Amazon Mechanical Turk, Testable, Prolific, Qualtrics Panels, or other crowdsourcing platforms.

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):

Because this survey research is being administered on crowdsourcing platforms, obtaining signed consent forms is not feasible. We included a cover letter which indicates that informed consent is implied if the participant submits the completed assessment.

○ **Option 3**

Describe how your study meets these criteria:

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

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

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

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

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

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

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

To add an individual via the below feature:

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

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's HSP FAQ page, the RCR Home page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (HSPTrainingSupport@uky.edu) for credit.

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Bou Mansour	Carl	Study Coordinator	DP	Y	Y		P	Y	11/08/2023	Y	N	11/16/2023	N	Y
Haney	Kimberly	Data Collection	SP	Y	N		P	Y	04/25/2024	Y	N	12/03/2024	N	Y
Highfield	Morgan	Project Assistance/Support	SP	N	N		P	Y	02/25/2025	Y	N	11/03/2025	N	Y
Lauckner	Carolyn	Co-Investigator	SP	Y	N	PhD	P	Y	06/11/2026	Y	N	08/19/2024	N	Y
Middleton	William	Co-Investigator	DP	Y	Y	PhD	P	Y	06/10/2024	Y	N	06/11/2024	N	Y
Pennington	Jeffery	Project Assistance/Support	SP	N	N		P	Y	08/26/2024	Y	N	11/03/2025	N	Y
Regnier	Sean	Co-Investigator	DP	Y	Y	PhD	P	Y	04/29/2024	Y	N	09/05/2025	N	Y
Rzeszutek	Mark	Co-Investigator	DP	Y	Y		P	Y	07/14/2024	Y	N	02/18/2022	N	Y
Schaefer	Jill	Study Coordinator	DP	Y	Y		P	Y	06/06/2025	Y	N	06/17/2024	N	Y
Shorey Fennell	Bethany	Co-Investigator	DP	Y	N	PhD	P	Y	12/12/2023	Y	N	04/04/2025	N	Y
Wakeman	Kathleen	Data Collection	SP	Y	N		S	Y	07/23/2026	Y	N	12/20/2024	N	Y
Crill	Elisa	Co-Investigator	DP	Y	Y		P	Y	09/26/2025	Y	Y	06/26/2023	N	Y
Iglehart	Sarah	Co-Investigator	DP	Y	Y			Y	12/02/2025	Y	Y	08/13/2026	N	N
Kaplan	Brent	Co-Investigator	DP	Y	Y		P	N	02/18/2020		Y	05/15/2023	N	N
Traxler	Haily	Co-Investigator	DP	Y	Y		N	Y	07/09/2024	Y	Y	08/13/2026	N	Y

RESEARCH DESCRIPTION

0 unresolved comment(s)

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

Pro Tips:

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

Background

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

Recruiting individuals with substance use disorders into research studies is often challenging (Miller & Sonderlund, 2010). The use of crowdsourcing platforms makes it possible to study populations and behaviors that are historically difficult to study (Strickland & Stoops, 2019). The use of crowdsourcing is advantageous because it allows for rapid data collection that is low effort for both participants and researchers. It also allows for the study of substance use disorders without requiring participants to administer drugs. The purpose of this protocol is to have a standard set of criteria and operating procedures internally within our lab. Individual studies are indicated by name for ease of record-keeping within the protocol. Additional protocols will be added and described following their title in the appropriate sections. General standards that are used for all studies are indicated under "General:".

Cannabis/Nicotine Withdrawal Crowdsourcing:
Two patterns that help to characterize addiction pathology are overvaluation of substances of abuse and decreased tolerance to delayed rewards (Bickel et al., 2014). Decision making in individuals who use drugs is often different than in non-users, with drug users displaying more risky behaviors. A way of studying these behavioral patterns is through the use of behavioral economic methods. Delay discounting is a behavioral economic task that involves asking participants to make choices between small, immediately available rewards, and larger, delayed rewards. Individuals with substance use disorders tend to prefer smaller, immediate rewards to larger, delayed rewards to a greater extent than individuals without substance use disorders. The demand analysis is another behavioral economic task that can be employed using a variety of methods. One common method employed in individuals with substance use disorders is the hypothetical purchase task. This involves asking participants to indicate the quantity of a drug that they would purchase if it were offered at a range of prices, with highest prices expected to suppress demand for the substance.
A strong positive association between cigarette and marijuana use exists, which could have implications for quitting efforts in dual users (Wang et al., 2016). The purpose of the current study is to recruit dual nicotine and marijuana users to complete a series of behavioral economic, decision making, substance use, and demographic assessments in order to characterize their use and decision making patterns.

SUPRA Crowdsourcing Pilot:
Suicide is the 12th leading cause of death in the US for all ages and the 2nd leading cause of death for young adults.(National Institute of Mental Health, 2021; Suicide Statistics and Facts, 2022) There are 47,000 deaths by suicide per year (National Institute of Mental Health, n.d.) and the annual cost of suicide in the US is estimated to be up to $93.5 billion.(Shepard et al., 2016) Acute alcohol consumption appears to be involved in up to 36% of completed suicides,(Boenisch et al., 2010; Kaplan et al., 2013) while those with alcohol use disorder (AUD) may account for 20-40% of completed suicides.(Pompili et al., 2010) Because of the strong association between suicidality (i.e., risk of suicide based on suicidal thoughts and behaviors) and AUD, targeting AUD may be a meaningful candidate to decrease suicide risk for those with AUD. Better understanding of the relationship between alcohol and suicidality could help to identify those most at risk at suicidality or emphasize the importance on alcohol reduction as a measure to decrease deaths by suicide. Unfortunately, little is known about specific processes that result in the relationship between the two. While the direction of causality between alcohol use and suicidality is not known, differences in decision-making based on behavioral economic measures such delay discounting have been associated with both, suggesting a potential moderation or mediation relationship. Briefly, delay discounting refers to the devaluation of a reward or outcome based on its delay, and is considered to be a measure of self-control. (Odum, 2011) For example, those who with AUD are less self-controlled based on delay discounting,(Amlung et al., 2017) while lethality of suicide attempt has sometimes been associated with higher or lower self-control based on the population studied.(Cáceda et al., 2014; Dombrovski et al., 2012, 2013; Liu et al., 2012) However, to our knowledge there is only one study that incorporated any form of discounting, those with a substance use disorder, and any measure of suicidality.(Liu et al., 2012) However, no suicide studies use other forms of discounting, such as probability discounting,(Rachlin et al., 1991) which is devaluation of an outcome based on its uncertainty. Typically, probability discounting is considered a measure for risk taking.(Green & Myerson, 2013) Identification of correlates and predictors of suicidality are important, as individuals can be reluctant to answer direct questions about suicidality honestly due to involuntary hospitalization or impacts outside of treatment.(Blanchard & Farber, 2020; Ganzini et al., 2013) Proxy measures, such as alcohol use and specific patterns of decision-making could help to identify those with AUD who may be reluctant to disclose their suicidal thoughts or behaviors. Identification of these proxies could improve understanding of processes that may be involved in AUD and suicidality while also helping identify those more at risk and inform best-practices in alcohol use treatment.

SUPRA Longitudinal Pilot :

Similar to the SUPRA Crowdsourcing Pilot, we are conducting another crowdsourcing study using Prolific but limiting the sample to individuals who use alcohol at least weekly and repeating the survey for participants at two time points, two weeks apart. The purpose of this is to 1) verify results of the SUPRA Crowdsourcing Pilot on MTurk with another participant pool (Prolific) and to 2) assess test/retest reliability and how responses might change over a brief time window of two to three weeks. Conducting this study at multiple time points with the same participants will help to establish the relationships between measures of discounting (Green & Myerson, 2013; Odum, 2011; Rachlin & Jones, 2008) with other theories of self-harm such as the interpersonal theory of suicide (IPTS; Van Orden et al., 2010). To our knowledge, no study exists that incorporates a timeline-followback for alcohol use, discounting, and their relationships to the IPTS.

ETM Pilot:
In 2009, the Food and Drug Administration (FDA) was granted authority to regulate tobacco products to benefit public health. In the years since, the FDA has proposed potential regulatory actions that may benefit public health, including regulating the maximum nicotine content in combustible cigarettes and restricting flavors of combusted and non-combusted tobacco products. Estimating the impact of any proposed regulatory action is complicated by the existence of a complex tobacco marketplace containing multiple products that are economic substitutes for one another and the frequent introduction of new tobacco products by manufacturers. To do this, we are using a experimental tobacco market place (e.g., Quisenberry et al., 2016) to assess how different tobacco products might be substitutable as prices for them change.

CM VA Prolific Study:
Alcohol misuse is a prevalent issue among veterans. Electronic medical records from the U.S. Department of Veterans Affairs (VA) identify 10% of veterans as having alcohol use disorder (AUD) (Seal et al., 2010). Psychological problems may exacerbate these numbers, as post-traumatic stress disorder is highly common among veterans and is highly associated with AUD (Dworking et al.,m 2018). To manage high rates of AUD, the VA is one of the only medical organizations approved to practice contingency management (CM). CM is one of the most effective interventions for alcohol and drug use (Petry, 2011). Current VA policy is to reward negative alcohol urinalysis tests with voucher-tokens of escalating amounts to the VA Canteen (a store housed within many VA clinics) (Petry et al., 2014). Research shows that more fungible rewards (cash, restricted debit cards) may be more effective at inducing negative urine tests for drug use in the general population (Festinger et al., 2014). However, the VA is hesitant to shift to these rewards due to their chance of misuse. Our study plans to assess the difference in efficacy and acceptability of VA Vouchers compared to unrestricted and restricted debit cards. To our knowledge, no study of this type has been conducted on VA users. To do this, we are conducting an online survey of VA clinic users and comparing their readiness to change their drinking habits across these rewards using purchase tasks.

CM VA Prolific Follow-up Interviews:
To follow up with participants from the CM VA Prolific Study, we will invite some participants from this study to complete structured interviews. Participants will be invited through Prolific and per Prolific's terms, we will not collect any identifying information from participants. Interviews will be conducted through Zoom and will be recorded for transcribing. Any incidentally identifying information (e.g., mentions of names) will not be transcribed. An interview script will be followed (see attachments). All video recordings and transcripts will be stored on secure UK computing resources and only accessible to individuals named on this protocol.

Nicotine Pouch Substitution Study
Smoking is a prominent public health issue. Traditional Nicotine Replacement Therapy (NRT) suffers from being a poor substitute for cigarettes. Novel tobacco products, such as nicotine pouches, show promise as potential low-harm substitutes. We wish to assess the substitutability of cigarettes for nicotine pouches at different dosages and price points. Our study will consist of 2000 screened participants online on the crowdsourcing software Prolific, with roughly 200 eligible participants. Our study plans. Our study will include the use of an electronic tobacco marketplace. To our knowledge, no electronic tobacco marketplace has been used to assess substitution of nicotine pouches for cigarettes.

AppalTRUST Tobacco Alcohol Study:
A high priority research area for the Federal Drug Administration Center for Tobacco Products (FDA CTP) is determining who will start using tobacco products and who will stop using tobacco products. A population that has a disproportionately high amount of tobacco use are people living in rural areas. This indicates that some aspect of rurality is related to tobacco product susceptibility and decreased tobacco cessation rates. People in rural areas also typically have higher rates of alcohol use, which is also associated with higher tobacco use and decreased tobacco cessation rates. The purpose of this study is to (1) examine how rurality and alcohol use may affect susceptibility to existing and novel tobacco products and (2) examine how rurality and alcohol use may affect likelihood for tobacco users to substitute to tobacco cessation products. To accomplish this, we will use behavioral economic measures to assess how people respond to novel tobacco products (high and low nicotine, flavored and unflavored), as well as use the experimental tobacco marketplace to determine how current users might switch to products associated with cessation. Because rurality is a spectrum, we will be using an index of relative rurality (IRR) to better quantify how rurality and alcohol use affect these tobacco-related behaviors.

Tobacco Alcohol Cannabis Study
Tobacco use is associated with use of cannabis and alcohol. Legislation is rapidly altering the tobacco and marijuana marketplace, however the effects of limiting product flavors and availability on consumption of other addictive products is unknown. In this study we assess demand characterists (assessing how much individuals value tobacco, cannabis, and alcohol products with differing characteristics) and cross-price elasticity (the degree to which individuals are likely to switch from tobacco to cannabis to alcohol or vice versa) of tobacco, alcohol and cannabis. This research will be conducted using a state of the art Experimental Tobacco MArketplace (See ETM pilot an dAppalTRUST Tobacco Alcohol Study). We will recruit 12,000 participants using Prolific Crowdsourcing software and screen for an elgiible 1,500 participants who will complete a series of behavioral economic, demographic, and addiction behavior questions alongside several experimental tobacco marketplaces.

Disability Contextualized Reinforcer Pathology Study
People with Disabilities (PWD) have nearly double the prevalence of tobacco use compared to people without disabilities. This disparity, and other health disparities in this population can be attributed to substantial health inequities and barriers including a significant lack of treatment-focused research & underrepresentation in public health surveillance. These barriers highlight a potential lack of available alternative reinforcers typically experienced by the general population, potentially due to these inequities. Environmental differences (i.e., a lack of available alternatives) may contribute to increased reinforcing value of tobacco for PWD, a key assumption of the contextualized reinforcer pathology model. Behavioral economics can bridge the connection between environmental and within-subject determinants of substance use by framing behavior within a discrete choice context.

Nicotine Pouch Pilot (NIH Pilot #2372)
This is a study to assess the effects of nicotine concentration on demand for and substitution from nicotine pouches (NP) among a sample of crowdsourced nicotine pouch(NP) users, and to assess the effects of relative rurality on these indices. Nicotine pouches are a novel tobacco product of great regulatory interest, as use rates have steadily increased since their inception in US markets in 2008. Nicotine concentration for NP's has also increased at a worrying rate. Food and Drug Administration Center for Tobacco Products (FDA CTP) Priority Research Areas have changed to address this new public health challenge, and include assessing the impact of nicotine concentration on tobacco use preferences and behaviors, including poly use and switching. Behavioral economic methods are a prime method to explore these priorities. The Experimental Tobacco Marketplace (ETM) is one such behavioral economic tool that can assess the degree to which individuals value NP's (demand characteristics), and how likely they are to switch from NP's to other products (substitution). Demand characteristics of NP's and substitution from NP's is currently poorly understood, and no study has assessed how these behavioral economic indices are affected by nicotine concentration, which is known to affect addictive potential and severity of other products. Rural individuals are especially vulnerable to novel tobacco product marketing and have fewer resources to combat tobacco use. As such, NP's represent a potential health disparity for rural individuals which should be assessed. Our proposed study seeks to assess whether demand characteristics and substitution patterns differ based on degree of rurality, and whether this moderates indices relationships with nicotine concentration. This research supports both FDA CTP priority areas and AppalTRUST's mission of identifying tobacco related health disparities among rural individuals and would provide valuable information on a product that has yet to be studied in-depth.

The Covarying of Mental Health, Alcohol/Substance Use, and Treatment Engagement
This study is to determine if there is differential treatment interest and engagement based alcohol and other substance use, mental health related to suicidal thoughts and behaviors, and reward learning. In this study, we will also collect information regarding large language model usage, previous mental health and substance use treatment history, and behavioral economic measures. Most individuals who use substances do not seek substance use treatment. Thus, predicting who is likely to seek treatment, or possible barriers in the form of current opinions may inform treatment seeking behavior. Additionally, we can also use measures of reward learning to potentially better predict and understand these relationships, along with how alcohol and other substance use may relate to suicidal thoughts and behaviors.

Objectives

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

Cannabis/Nicotine Withdrawal Crowdsourcing:
Characterize decision making in individuals who engage in substance use and misuse through a variety of decision-making (e.g., substance equivalence questions, gambling questions), diagnostic (e.g., Cannabis Use Disorder Identification Test; Fagerstrom Test for Nicotine Dependence, DSM-V for substance use disorders, Quick Structured Clinical Interview for DSM-5 disorders), behavioral economics (e.g., demand analyses, delay discounting), and demographics assessments administered through Amazon Mechanical Turk, Testable, Qualtrics Panels, Prolific, or other crowdsourcing platforms.

SUPRA Crowdsourcing Pilot:
The objectives of this study are to provide preliminary data related to substance use (primarily alcohol use), mental health, history of suicidal thoughts and behaviors, and behavioral economic decision-making. The questions and survey instruments will allow for a detailed analysis of different forms of discounting (social, probability, and delay) to compare with current alcohol use, severity of alcohol use, and history of suicidal thoughts and behaviors. Results of this study will be used to guide future research to better identify potential markers and risk factors for suicidal thoughts and behaviors, ultimately improving prevention efforts.

SUPRA Longitudinal Pilot:
The objectives of this study are to replicate results of the SUPRA Crowdsourcing Pilot described above, while also extending it to a longitudinal research design to assess stability of revenant variables over two cross-sectional surveys made available approximately two weeks apart. This will allow for confirmation of previous research results, but additions of other measures and their stability over time will help to clarify common processes that may be involved in alcohol use and suicidal thoughts and behaviors.

ETM Pilot:
The objectives are to test our new implementation of the experimental tobacco market place under a variety of different conditions to determine best methodological practices for its use.

CM VA Prolific Study:
The objectives are to compare different CM rewards across VA users' readiness to change drinking behavior and examine how these reward types interact with demographic and clinical characteristics.

CM VA Prolific Follow-up Interviews:
The objectives of this follow-up study are to learn more about veterans' views about alcohol use, alcohol use treatment, and Veterans

Administration services.

Nicotine Pouch Pilot
The objective is to examine the substitutability of nicotine pouches for at different dosages and price points.

AppalTRUST Tobacco Alcohol Study:
One objective of this study is to determine demand for novel hypothetical nicotine products as a function of relative rurality, alcohol use, and current tobacco use status. Another objective of this study is to examine substitution patterns for current cigarette, e-cigarette, or dual users.

Tobacco Alcohol Cannabis Study
The objectives of this study are to determine demand for tobacco, alcohol, and cannabis products in a complex marketplace with a variety of products and flavors available. Further, we wish to understand how restriction of different products or flavors may impact substitution.

Disability Contextualized Reinforcer Pathology Study
How do behavioral economic measures and the availability of alternative reinforcers differ among PWD and people without disabilities who smoke cigarettes? Do disparities in these measures partially explain increased rates of tobacco use in this population?

Nicotine Pouch Pilot
To compare demand characteristics and substitution patterns across varying dosages of nicotine pouches in an experimental tobacco marketplace. To assess the effects of relative rurality on these characteristics. To trial a behavioral economic method to assess different aspects of demand using food based vignettes.

The Covarying of Mental Health, Alcohol/Substance Use, and Treatment Engagement
The purpose of this is to determine how current mental health and substance use affect treatment engagement, as well as how behavioral economic indicators may help elucidate mechanistic relationships between substance use and suicidal thoughts and behaviors.

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.
- If the study design includes using or developing Artificial Intelligence (AI), see “AI Protocol Submission Guidance for Researchers” on the Artificial Intelligence/Machine Learning in Human Research webpage for additional information.

Cannabis/Nicotine Withdrawal Crowdsourcing:
Participants will complete a battery of diagnostic substance use, decision-making, behavioral economic, and demographics questions. These tasks provide information about demographics and severity of dependence on cannabis and nicotine in relation to decision making. These tasks will help to determine whether and how decision making is influenced by demographic factors and substance use dependence severity. The order of the tasks may be randomized across participants to minimize order effects.

SUPRA Crowdsourcing Pilot:
Cross-sectional anonymous survey via crowdsourcing platforms. All participants will complete all tasks and associations between results will be used as the primary analysis. These will consist of the 5-trial variants of delay, probability, and social monetary discounting for gains and losses, behavioral economic demand for alcohol, the Beck Depression Inventory, Beck Anxiety Inventory, Self-Injurious Thoughts and Behaviors Inventory- Short Form, Columbia Suicide Severity Rating Scale, Acquired Capability for Suicide Scale, Interpersonal Needs Questionnaire, Social Desirability Scale-Short Form, Alcohol Use Disorders Identification Test, Obsessive-Compulsive Drinking Scale, Drug Abuse Screening Test, and Functional Analysis of Alcohol Use scale

SUPRA Longitudinal Pilot:
Two anonymous surveys via Prolific made available approximately two weeks apart. All participants will complete all tasks and associations between results will be used as the primary analysis. These will consist of the 5-trial variants of delay, probability, and social monetary discounting for gains and losses, two-week timeline followback for alcohol use, behavioral economic demand for alcohol, the Beck Depression Inventory, Beck Anxiety Inventory, Self-Injurious Thoughts and Behaviors Inventory- Short Form, Columbia Suicide Severity Rating Scale, Acquired Capability for Suicide Scale, Interpersonal Needs Questionnaire, Social Desirability Scale-Short Form, Alcohol Use Disorders Identification Test, Alcohol Withdrawal Symptom Checklist, Drug Abuse Screening Test, and Functional Analysis of Alcohol Use scale.

ETM Pilot:
Cross-sectional anonymous survey via crowdsourcing platforms. All participants will complete the Qualtrics survey, and two versions of experimental tobacco marketplace sequences. There will be 2 (budget vs no budget) x2 (resetting vs non resetting checkout) x2 (ascending vs random price order) x2 (all flavors vs your preferred flavor) combinations of scenarios. Study A will be between subjects where we aim for 50 participants to complete 1 of each of these scenarios (~800 total). Study 2 will be within subjects where participants will complete all 16 combinations of these in random order.

CM VA Prolific Study:
Online survey via crowdsourcing platforms. All participants will complete a series of demographic, clinical, and behavioral questions alongside completing 4 readiness-to-change-drinking-behavior scenarios, each corresponding with a different type of CM reward. We are aiming for 50-100 participants.

CM VA Prolific Follow-up Interviews:
Structured qualitative interviews. Participants will be participants from the CM VA Prolific Study above, so no additional survey information is necessary to collect. We will be able to associate their data across study by Prolific ID. No names or identifying information is collected in either study. We will survey approximately 15 participants.

Nicotine Pouch Substitution Study
Online survey via crowdsourcing platforms. All participants will complete a series of demographic, clinical, and behavioral questions alongside completing 4 electronic tobacco marketplace scenarios, each corresponding with a different dosage of nicotine in nicotine pouches. We are aiming for 200 participants.

AppalTRUST Tobacco Alcohol Study:
Cross-sectional anonymous survey via crowdsourcing platforms. All participants will be screened and compensated $2.15 for a completed screener. Afterwards, if eligible based on responses, they will be assigned to one of four groups in a 2 (tobacco user vs non-user) x 2 (risky alcohol user vs low/no risk alcohol user) design, which is based on alcohol use determined by the AUDIT and current daily (> 25 days in a month) cigarette/e-cigarette use.

Tobacco Alcohol Cannabis Study:
Cross-sectional anonymous survey via crowdsourcing platforms. All participants will be screened and compensated $0.20 for a completed screener. Afterwards, if eligible based on responses, they will be assigned to one of three groups (tobacco user, marijuana user, user of both) depending on product use). Use of product is determined by using a relevant product 1+ times a month. We will screen approximately 12,000 participants, and include 1,500 participants in our full study split evenly between groups.

Disability Contextualized Reinforcer Pathology Study
Cross-sectional anonymous research survey via crowdsourcing platforms. Participants will be compensated $0.30 for completing the screener survey, which will take approximately 2 minutes and $8 for completing the main survey, which will take approximately 30 minutes.

Nicotine Pouch Pilot
Cross-sectional anonymous survey via crowdsourcing platforms. All participants will be screened and compensated $0.20 for a completed screener. Afterwards, if eligible based on responses, they will be given access to the full study. We will screen approximately 4,000 participants, and include 400 participants who will complete a series of demographic, clinical, and decision making assesment. Participants will be redirected to an experimental tobacco marketplace to assess demand. Full participants will be compensated $14.00 for the survey+marketplace.

The Covarying of Mental Health, Alcohol/Substance Use, and Treatment Engagement
Cross-sectional anonymous survey via Prolific. Participants will be compensated $10 for full completion of the survey. Our target is to recruit ~1000 participants for this study.

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

General:

Any advertising of this study will take place on crowdsourcing platforms such as Amazon Mechanical Turk, Testable, Prolific, or Qualtrics Panels. We will make the task available to potential participants. Potential participants who are eligible and interested may complete the assessment. Participants will be recruited through the crowdsourcing platform if they meet the outlined criteria. Location, approved tasks, and task approval rating are tracked through the crowdsourcing platforms.

Cannabis/Nicotine Withdrawal Crowdsourcing:
Once participants begin the assessment, they will be asked additional qualifying questions about their current and lifetime substance use and other relevant demographic information. Participants who meet criteria for inclusion will be asked additional questions. For all participants who are ineligible, the assessment will end.

SUPRA Crowdsourcing Pilot:
Other than approval rating and completed tasks, potential participants will complete a percentage comprehension task to determine ability to follow instructions/English comprehension and/or screen out persons using a bot (automated script). Participants who do not pass this screener will not continue onto the remainder of the survey.

SUPRA Longitudinal Pilot:
Other than approval rating of 95% and being prescreened in Prolific based on drinking at least weekly, potential participants will complete a percentage comprehension task to determine ability to follow instructions/English comprehension and/or screen out persons using a bot (automated script). Participants who do not pass this screener will not continue onto the remainder of the survey. Only those who provided their Prolific IDs on the first survey will be able to access the second survey. How the study is presented on Prolific has been provided in the files "SUPRA Longitudinal Advertising S1.jpg" and "SUPRA Longitudinal Advertising S2.jpg".

ETM Pilot:
Approval rating of 95% and being prescreened in Prolific based on current smoking status, participants will need to smoke at least 25 days out of the past 30, and pass a percentage comprehension test. Wordings that will appear on Prolific appear in the "ETM Pilot Description.pdf".

CM VA Prolific Study:
Participants will be screened on Prolific for Veteran Status. These participants will be directed to a 1-minute screener that determines eligibility (scores indicating misuse on the AUDIT-C, access to VA). Unsuccessful participants will be paid ~20 cents for their time. Successful participants will move on to complete a 20-25 minute survey and be compensated through Prolific standard payment.

CM VA Prolific Follow-up Interviews:
Participants will be those who have completed the CM VA Prolific Study above, and will therefore have the same eligibility criteria. Participants will be compensated $40 for completion of the interview. Partial completion will be prorated based on the portion completed.

Nicotine Pouch Substitution Study:
Participants will be screened on Prolific for smokingStatus. These participants will be directed to a 1-minute screener that determines eligibility (18+ years, nicotine pouch users). Unsuccessful participants will be paid ~20 cents for their time. Successful participants will move on to complete a 20-25 minute survey and be compensated through Prolific standard payment.

AppalTRUST Tobacco Alcohol Study:
Participants will be recruited from Prolific and screened for cigarette/e-cigarette use and alcohol use. Participants will all complete a brief general screener for $2.15 which will be used to determine eligibility/group assignment. To be eligible as a tobacco user, they must use cigarettes or e-cigarettes at least 25 days of the month. To be identified as a risky alcohol user, they must score higher or equal to an 8 on the AUDIT. Then, compensation will be based on which Qualtrics survey they complete.

Tobacco Alcohol Cannabis Study
Participants will be recruited from Prolific and screened for tobacco and marijuana use and alcohol . Participants will all complete a brief general screener for $0.20 which will be used to determine eligibility/group assignment. To be eligible as a tobacco user, they must use cigarettes or e-cigarettes at least 1 days of the month. To be eligible as a marijuana user, they must consume 1 or more delta-9 THC product at least once a month. Elgiible participants will then complete the main survey ~30 minutes, and will be sorted into 2-4 experimental tobacco marketplaces depending on product use. Each marketplace is estimated to take 20 minutes. Participants will be compensated $12.00 an hour.

Disability Contextualized Reinforcer Pathology Study
All participants must be at least 18 years old and living in the United States. Participants will be included in one of four potential groups based on their disability (i.e., “Yes”/”No” to any ACS or NSHD question) and smoking (i.e., Smoking at least 1 cigarette/day or Not a smoker) status determined by an initial eligibility screener on Qualtrics. Participants will be compensated $0.30 for completing the screener survey, which will take approximately 2 minutes. Participants who smoke cigarettes will be compensated $10 (estimated completion time of 40 minutes). Participants who do not smoke will be compensated $7.50 (estimated time of 30 minutes).

Nicotine Pouch Pilot:
Participants will be screened on Prolific for smokingStatus. These participants will be directed to a 1-minute screener that determines eligibility (18+ years, nicotine pouch users). Unsuccessful participants will be paid ~20 cents for their time. Successful participants will move on to complete a 20-25 minute survey and be compensated through Prolific standard payment.

The Covarying of Mental Health, Alcohol/Substance Use, and Treatment Engagement
Same as general, but we will try to obtain an even spread of alcohol use as determined by Prolific's built in screeners.

Attachments

Attach Type	File Name
Advertising	MTurk Instructions.docx
Advertising	SUPRA MTurk Advertising.pdf
Advertising	SUPRA Longitudinal Advertising S1.jpg
Advertising	SUPRA Longitudinal Advertising S2.jpg
Advertising	CM VA Advertising.docx
Advertising	Prolific Description RAM VA.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.

Cannabis/Nicotine Withdrawal Crowdsourcing:
Participants will complete demographic questions (e.g., age, race, income, quality of life, usual cigarette brand, cannabis use patterns). Participants will also complete diagnostic assessments to measure the degree of dependence on cannabis and nicotine. These include the Fagerstrom Test for Nicotine Dependence, the Cannabis Use Disorder Identification Test, a series of DSM-V questions, and the Quick SCID 5 (Structured Clinical Interview for DSM-5 Disorders). Participants will complete questions that characterize valuation of cannabis and nicotine and decision making patterns, including questions asking participants to determine the amount of cannabis and nicotine equal to $100 and a series of questions about gambling history. Finally, participants will complete behavioral economic tasks, which will further characterize drug valuation. Hypothetical purchase tasks will be used to evaluate the value of nicotine and cannabis across a range of prices to measure changes in demand for drugs when a monetary alternatives are available. Delay discounting tasks will be used to evaluate how participants value immediate versus delayed rewards of differing magnitudes, as it is characteristic of drug users to value immediate rewards more than non-drug users.
The results of these assessments will be correlated to identify any relationships between demographics, substance use severity, and decision making. Additional data analysis will including assessing demand and delay discounting in relation to demographics and substance use severity.

SUPRA Crowdsourcing Pilot:
See research materials "SUPRA MTurk V1.pdf" for complete survey. Estimated time to completion of the survey is 20-45 minutes. Participants will first complete a screener which is meant to determine competence and compliance with instructions via percentage comprehension. If they are eligible based on this, they will have to complete a CAPTCHA (bot detection) to continue onto the main survey. Following this they will complete discounting tasks that involve hypothetical monetary outcomes with varying delays, probabilities, or social distances for both monetary gains and losses. These will be presented in a random order. Participants will be asked about their decision-making during the monetary tasks in an open-ended question. Then, participants will complete hypothetical alcohol purchase tasks for three scenarios, a "good" day, a "bad" day, and "typical" day. These will also be presented in random order. Participants will be asked about their decision-making during the purchase tasks in an open-ended question.
Following this, participants will be complete the Beck Depression Inventory, Beck Anxiety Inventory, Social Desirability Scale-Short Form, Acquired Capability for Suicide Scale, and Interpersonal Needs Questionnaire.
Then, participants will complete questions related to suicidal thoughts and behaviors of themselves or others. Prior to this section, there is a preamble indicating there are prefer not to answer options, as well as the resources listed above ("If you need guidance or feel that you are in crisis, National Suicide Prevention Lifeline (988 or 1-800-273-8255) https://988lifeline.org/ or Crisis Text Line (text HOME to 741741) are resources that are available to you"). The questions asked are the Columbia Suicide Severity Rating Scale, Self-Injurious Thoughts and Behaviors-Short Form, and Suicide Exposure Questionnaire. After completing this section, participants will we presented with the crisis lines listed above. Because participants are anonymous, we are following guidelines based on the University of Kentucky's research involving suicide guidelines (https://www.research.uky.edu/uploads/ori-d1340000-suicide-ideationor-behavior-among-research-participants-pdf) and thus are providing information for national services. Following questions related to suicide, participants will complete the Obsessive Compulsive Drinking Scale, Alcohol Use Disorders Identification Test, and the Drug Abuse Screening Test.
Lastly, participants will be able to leave optional comments on the survey, and then be given a completion code to get compensation for the task

SUPRA Longitudinal Pilot:
See research materials "SUPRA Longitudinal S1 Survey.pdf" and "SUPRA Longitudinal S2 Survey.pdf" for complete surveys. The S1 variant is the initial survey, with additional information for the follow-up survey, whereas the S2 variant does not refer to a second upcoming survey. The remainder of the content is identical. Estimated time to completion of the survey is approximately 40 minutes and participants will be compensated $8.00 for each of the two surveys they complete. Participants will first complete a screener which is meant to determine competence and compliance with instructions via percentage comprehension. If they are eligible based on this, they will have to complete a CAPTCHA (bot detection) to continue onto the main survey. They will then complete basic demographics and an alcohol use timeline followback assessing their past two week alcohol use. Following this they will complete discounting tasks that involve hypothetical monetary outcomes with varying delays, probabilities, or social distances for both monetary gains and losses. These will be presented in a random order. Participants will be asked about their decision-making during the monetary tasks in an open-ended question. Then, participants will complete a hypothetical alcohol purchase task for one scenario, a "typical" day.
Following this, participants will be complete the Beck Depression Inventory, Beck Anxiety Inventory, Future Time Perspective-Short Form, Acquired Capability for Suicide Scale, and Interpersonal Needs Questionnaire.
Then, participants will complete questions related to suicidal thoughts and behaviors of themselves or others. Prior to this section, there is a preamble indicating there are prefer not to answer options, as well as the resources listed above ("If you need guidance or

feel that you are in crisis, National Suicide Prevention Lifeline (988 or 1-800-273-8255) https://988lifeline.org/ or Crisis Text Line (text HOME to 741741) are resources that are available to you"). The questions asked are the Columbia Suicide Severity Rating Scale, Self-Injurious Thoughts and Behaviors-Short Form, and Suicide Exposure Questionnaire. After completing this section, participants will we presented again with the crisis lines listed above. Because participants are anonymous, we are following guidelines based on the University of Kentucky's research involving suicide guidelines (https://www.research.uky.edu/uploads/ori-d1340000-suicide-ideationor-behavior-among-research-participants-pdf) and thus are providing information for national services. Following questions related to suicide, participants will complete the Functional Analysis of Alcohol Use Assessment, Alcohol Withdrawal Symptoms Checklist, Alcohol Use Disorders Identification Test, and the Drug Abuse Screening Test.
Lastly, participants will be able to leave optional comments on the survey, and then be given a link which will indicate to Prolific to indicate their completion and to get compensation for the task.

ETM Pilot:
See research materials "ETM Pilot Survey v2.pdf" for complete surveys. See "ETM Description v2.pdf" for description of different conditions and additional wordings that will be presented to participants. All participants will complete a Qualtrics survey incorporating questions about demographics, tobacco product use, hypothetical paired choice tasks, equivalence tasks, hypothetical purchase tasks, Fagerstrom Test of Nicotine Dependence, Activity Level Questionnaire - Tobacco Use Version, followed by the assigned Experimental Tobacco Marketplace conditions.

CM VA Prolific Study:
See research materials "CM VA Survey" for the complete survey. All participant will complete a Qualtrics survey incorporating questions about demographics, alcohol and drug use, hypothetical purchase tasks, hypothetical CM scenarios, and tests of alcohol dependence. Participants will be screened for roughly 1-2 minutes to determine eligibility by answering demographic, health care utilization, and alcohol use disorder questions. Then they will proceed to complete the survey, be redirected to Prolific, and be compensated.

CM VA Prolific Follow-up Interviews:
See "CoMMIT_InterviewProtocol.pdf" for the interview script. Interviews will be conducted by research study staff. Interviews are expected to take 45-60 minutes.

AppalTRUST Tobacco Alcohol:
See research materials "AppalTRUST Tobacco Alcohol Screener.pdf" and "AppalTRUST Tobacco Alcohol Survey.pdf" for complete surveys. See "AppalTRUST Tobacco Alcohol Descriptopn.pdf" for description of different conditions and additional wordings that will be presented to participants. All participants will complete the screener, and then if eligible and spaces are available, will be able to complete the survey based on their responses. If not assigned to a tobacco user group, participants will not be shown tobacco use questions.

Tobacco Alcohol Cannabis Study:
See research materials 'Tobacco Alcohol Cannabis Main Qualtrics Suvey 6_19' and 'Tobacco Alcohol Cannabis D8D9 Survey 6_19' for the complete survey. See "Tobacco Alcohol Cannabis ETM Scenario Table" for a complete list of marketplace scenarios and which products will be available in each marketplace. All participants will complete a screener that asks only whether they use a tobacco or cannabis product. ETM assignment will be based on preferred product use.

Disability Contextualized Reinforcer Pathology Study:
See Disability_CRP_Screener and Regnier_CRP_Disability_Survey for complete surveys.

Nicotine Pouch Pilot
See 'NP Pilot Screener Survey' and 'NP Pilot Full Survey 9_24 for complete surveys. All participants will complete a screener to deterimine whether they use nicotine pouches. Those that do will be redirected to the main survey. Upon completion of the main survey participants will be redirected to the Experimental Tobacco Marketplace. This marketplace is based on real world online tobacco stores, with product images and prices based on characteristics determined by in person screens of real world tobacco stores in Appalachia. Participants will complete 5 marketplaces with a variety of tobacco products available, and asked how many nicotine pouches they will purchase across varying prices. Participants are free to purchase other tobacco products instead, which will determine substitution. Each marketplace will be identical except the dosage of nicotine pouches will ascend across marketplaces.

The Covarying of Mental Health, Alcohol/Substance Use, and Treatment Engagement
See "Covarying Engagement Survey" for complete instruments.

Attachments

Attach Type	File Name
ResearchProcedures	NP Pilot Screener Survey.pdf
ResearchProcedures	NP Pilot Full Survey 9_24.pdf
ResearchProcedures	Disability_CRP_Screener.pdf
ResearchProcedures	Regnier_CRP_Disability_Survey.pdf
ResearchProcedures	Tobacco Alcohol Cannabis Main Qualtrics Survey.pdf
ResearchProcedures	Tobacco Alcohol Cannabis ETM scenario table.pdf
ResearchProcedures	AppalTRUST Tobacco Alcohol Descriptions v1.pdf
ResearchProcedures	ETM Pilot Description v3.pdf
ResearchProcedures	ETM Description v2.pdf
ResearchProcedures	ETM Pilot Description.pdf

ResearchProcedures	Tobacco Alcohol Cannabis Main Qualtrics Survey 6_19.pdf
ResearchProcedures	Tobacco Alcohol Cannabis D8D9 Survey 6_19.pdf
ResearchProcedures	Covarying Engagement Survey V3 - Clean.pdf
ResearchProcedures	Covarying Engagement Survey V3 - Highlighted.pdf

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.
- See the general guidelines in the "AI Design Description" under AI Protocol Submission Guidance for Researchers on the Artificial Intelligence/Machine Learning in Human Research webpage if Artificial Intelligence (AI) is being used to collect and/or analyze data.

Cannabis/Nicotine Withdrawal Crowdsourcing:
Demographics: Participants will be asked a series of questions about their age, gender, race, income, quality of life, cigarette brand, age first drank alcohol, etc.
Hypothetical Paired Choice Tasks (delay discounting): Participants will be asked a series of questions to determine their preference between small, immediate rewards, and larger, delayed rewards.
Equivalence Tasks: Participants will be asked to indicate the monetary equivalent of different amounts of drugs (e.g., how many cigarettes are worth $100 to you right now?)
Hypothetical Purchase Tasks: Participants will be asked to indicate the quantity of a commodity (e.g., cigarettes) they would purchase at a range of price points. Participants will sometimes be asked to complete these tasks by imagining they are in withdrawal from a substance.
Cross-commodity Purchase Tasks: Participants will be asked to indicate the quantity of a commodity (e.g., cigarettes) they would purchase at a range of price points when the price of another commodity was manipulated (e.g., cannabis). Participants will sometimes be asked to complete these tasks by imagining they are in withdrawal for one substance.
Cannabis Use Disorder Identification Test (CUDIT): Participants will complete a 10-item questionnaire used to identify problematic or harmful cannabis use within the last 6 months.
Fagerstrom Test of Nicotine Dependence (FTND): Participants will complete this assessment to measure their degree of cigarette dependence.
DSM-V self-report: This assessment will be used to assess substance use disorders. This is typically administered clinically, therefore we will conduct a self-report version.
Quick SCID 5: Participants will complete this assessment as another approach to diagnosing substance use disorders. The results of this assessment will be compared against the DSM-V self-report.
Gambling Inventory: Assesses problematic gambling behavior.
Other Substance Use Questions: Participants will be asked questions about their use of e-cigarettes and cannabis, including preferred methods of consumption and amounts consumed.

SUPRA Crowdsourcing Pilot:
Monetary Discounting- Delay discounting has been associated with a variety of health behaviors. Probability discounting, which is considered a measure of risk, is conceptually related to dangerous behavior. Social discounting, considered a measure of altruistic choice, is conceptually related to the interpersonal theory of suicide.
Hypothetical alcohol purchase tasks (APT)- These tasks are shown to be sensitive to maladaptive drinking. The different scenarios, which are novel, can determine if different situations increase the likelihood of drinking above baseline, relevant for mental health.
Beck Depression Inventory (BDI)- Measure of depression, related to suicidality and alcohol use
Beck Anxiety Inventory (BAI)- Measure of anxiety, related to suicidality
Social Desirability Scale-Short Form (SDS-SF)- Measure of honesty, also useful to determine if participants are giving "desirable" research answer
Acquired Capability for Suicide Scale (ACSS)- Tests constructs from the interpersonal theory of suicide related to capability to self-harm
Interpersonal Needs Questionnaire (INQ)- Tests constructs from the interpersonal theory of suicide related to thwarted belongingness
Columbia Suicide Severity Rating Scale (C-SSRS)- Brief and commonly used survey to assess suicide risk
Self-Injurious Thoughts and Behaviors-Short Form (SITBI-SF)- More detailed survey to capture finer historical information regarding current and past suicidal thoughts and behaviors.
Suicide Exposure Questionnaire (SEQ)- Questions related to being exposed to suicides/attempts, closeness to the person, and how much it affected them.
Obsessive Compulsive Drinking Scale (OCDS)- Assesses thoughts and behaviors towards alcohol
Alcohol Use Disorders Identification Test (AUDIT)- Assesses general use and alcohol use severity
Drug Abuse Screening Test (DAST)- Assess general non-alcohol drug use severity

SUPRA Longitudinal Pilot:
Alcohol Use Timeline Followback (TLFB) - Brief instrument that asks participants how many standard units of alcohol each day, going back to two weeks prior to the date of the survey.
Monetary Discounting- Delay discounting has been associated with a variety of health behaviors. Probability discounting, which is

considered a measure of risk, is conceptually related to dangerous behavior. Social discounting, considered a measure of altruistic choice, is conceptually related to the interpersonal theory of suicide.
Hypothetical alcohol purchase task (APT)- Task that asks about hypothetical purchasing of alcohol across a range of prices.
Beck Depression Inventory (BDI)- Measure of depression, related to suicidality and alcohol use
Beck Anxiety Inventory (BAI)- Measure of anxiety, related to suicidality
Future Time Perception Short Form (FTP-SF)- Measure of time perception and positivity for the future.
Acquired Capability for Suicide Scale (ACSS)- Tests constructs from the interpersonal theory of suicide related to capability to self-harm
Interpersonal Needs Questionnaire (INQ)- Tests constructs from the interpersonal theory of suicide related to thwarted belongingness
Columbia Suicide Severity Rating Scale (C-SSRS)- Brief and commonly used survey to assess suicide risk
Self-Injurious Thoughts and Behaviors-Short Form (SITBI-SF)- More detailed survey to capture finer historical information regarding current and past suicidal thoughts and behaviors.
Suicide Exposure Questionnaire (SEQ)- Questions related to being exposed to suicides/attempts, closeness to the person, and how much it affected them.
Alcohol Use Disorders Identification Test (AUDIT)- Assesses general use and alcohol use severity
Alcohol Withdrawal Symptom Checklist (AWSC)-Assesses subjective measures of alcohol withdrawal
Drug Abuse Screening Test (DAST)- Assess general non-alcohol drug use severity

ETM Pilot:
Demographics: Participants will be asked a series of questions about their age, gender, race, income, quality of life, cigarette brand, age first drank alcohol, etc.
Tobacco Product Use: Participants will be asked questions about their use of various tobacco products, including preferred methods of consumption and amounts consumed.
Hypothetical Paired Choice Tasks (delay discounting): Participants will be asked a series of questions to determine their preference between small, immediate rewards, and larger, delayed rewards.
Equivalence Tasks: Participants will be asked to indicate the monetary equivalent of different amounts of drugs (e.g., how many cigarettes are worth $100 to you right now?)
Hypothetical Purchase Tasks: Participants will be asked to indicate the quantity of a commodity (e.g., cigarettes) they would purchase at a range of price points.
Fagerstrom Test of Nicotine Dependence (FTND): Participants will complete this assessment to measure their degree of cigarette dependence.
Activity Level Questionnaire - Tobacco Use Version: A series of questions on activities engaged in with and without tobacco, and their relative enjoyment based on the presence of tobacco use.
Experimental Tobacco Marketplace: A web-based application that simulates an online storefront (e.g., amazon). Similar to the hypothetical purchase task, but used to assess cross-commodity substitution based off of increasing prices.

CM VA Prolific Study:
Demographics: Participants will be asked a series of questions about their age, gender, race, income, education, utilization of health care services (including VA use and barriers to VA use), health, military service, marital status, etc.
AUDIT-C: Measure of alcohol misuse, used as a part of our screener.
Likelihood to stop drinking: 4 scenarios asking participants to rate how likely they would be to abstain from drinking for a single day given various monetary increments of 4 different reward types, including: VA Canteen Vouchers, Restricted Debit Cards, Unrestricted Debit Cards, and VA Gift Cards.
PC-PTSD-5: A measure of post traumatic stress disorder, standard DSM-V screener.
DSM-V alcohol: the DSM-V's screener for alcohol use disorder.
Alcohol Audit: A measure of alcohol consumption, including binge drinking and the type of alcohol consumed.
Alcohol 2-Week Timeline Followback: The participant traces their alcohol use every day for the past 2 weeks.
$1000 Minute Delay Discounting (Gains): This task measures participants' temporal discounting.
Alcohol Purchase Task: Measure of each individuals subjective valuation of alcohol.
C-SSRS Suicide Questionnaire: A standard suicidality screener, we include both a pre-and post-amble that give access to help lines and service numbers.
Alcohol Withdrawal Scale-C: Measures the severity of withdrawal participants would have should they abstain from drinking.
Alcohol Valuation: This measures the intensity of demand for alcohol.
Readiness to change: Measures how ready participants are to give up drinking.

CM VA Prolific Follow-up Interviews:
Qualitative structured interviews (see attached script).

AppalTRUST Tobacco Alcohol Screener:
General Demographics
Tobacco product use questions
CDC Disability Questions
Self-Identified Disability
Alcohol Use Disorders Identification Test (AUDIT)- Assesses general use and alcohol use severity
Drug Abuse Screening Test (DAST)- Assess general non-alcohol drug use severity
*Fagerstrom Test of Nicotine Dependence (FTND): Participants will complete this assessment to measure their degree of nicotine dependence.
Columbia Suicide Severity Rating Scale (C-SSRS)- Brief and commonly used survey to assess suicide risk
Death Exposure Questionnaire (SEQ)- Questions related to being exposed to suicides/attempts/overdoses/substance use deaths, closeness to the person, and how much it affected them.

Alternative Activies Questionnaire - Questions related to alternative drug free reinforcement.

AppalTRUST Tobacco Alcohol Full Study:
Tasks or versions of tasks indicated with * are only displayed to those that report either alcohol use or tobacco use.
Monetary Discounting- Delay discounting has been associated with a variety of health behaviors. Probability discounting, which is considered a measure of risk, is conceptually related to dangerous behavior. Social discounting, considered a measure of altruistic choice.
*Hypothetical alcohol purchase task (APT)- These tasks are shown to be sensitive to maladaptive drinking.
*Hypothetical cigarette/e-cigarette purchase tasks (C/EPT)- These tasks are shown to be sensitive to nicotine dependence.
*Activity Level Questionnaires - Alcohol/Tobacco use versions: A series of questions on activities engaged in with and without alcohol/tobacco, and their relative enjoyment based on the presence of alcohol/tobacco use. (Because of the length of this tool, tobacco users will only receive the tobacco version of this)
* Proportional Time and Enjoyability Rating Scale: A series of questions that ask general activity categories and time with/without alcohol/tobacco.
* Revised Activity Level Questionnaires - Alternative versions of the Activity Level Questionnaires included for validation.
Timeline follow backs - Questions related to how many units of tobacco/alcohol consumed in the past two weeks.
Hypothetical novel nicotine product purchase tasks (HPPT): Similar to the APT and CPT/EPT, there will be 12 different HPPTs that are 3 (oral, vaped, combusted) x 2 (flavored/flavorless) x 2 (low/high nicotine).
*Experimental Tobacco Marketplace: A web-based application that simulates an online storefront (e.g., amazon). Similar to the hypothetical purchase task, but used to assess cross-commodity substitution based off of increasing prices. There will be three versions, a cigarette ascending price, e-cigarette ascending price, and combined cigarette/e-cigarette ascending price version.

Tobacco Alcohol Cannabis Study:
See "TTobacco Alcohol Cannabis Main Qualtrics Survey 6_19" and "Tobacco Alcohol Cannabis D8D9 Survey 6_19" for the survey items included in this study.
Product specific tasks are repeated for both tobacco, alcohol and marijuana.
Product use- determines which products participants use >1 time per month
Susceptibility to Tobacco- determines individuals likelihood of trying new tobacco products
Product specifics- determines flavors and product types used
Discounting Tasks- Discounting has been associated with a variety of health behaviors. Probability discounting, which is considered a measure of risk, is conceptually related to dangerous behavior. Social discounting, considered a measure of altruistic choice.
Product Likelihood Demand- determines demand characteristics of respective products
General Demographcis
Alcohol Use Disorders Identification Test (AUDIT)- Assesses general use and alcohol use severity
DSMV Alcohol/tobacco/cannabis- assesses whether individuals meet DSMV criteria for substance use disorders
Alcohol consumption questions
Tobacco/drinking/cannabis use purchase tasks
product withdrawal question- assesses the severity and likelihood of withdrawal from projects
Cannabis Use Disorders Identification Test (CUDIT)- Assesses general use and cannabis use severity
Cross price elasticity tasks- determines substitution between different products
Experimental Tobacco Marketplace- : A web-based application that simulates an online storefront (e.g., amazon). Similar to the hypothetical purchase task, but used to assess cross-commodity substitution based off of increasing prices. Assesses demand characteristics and substitution across a variety of regulatory scenarios
Delta 8 vs Delta 9 product rank choice preferences- determines which products participants are likely to switch to in the case of cannabis legislations that restrict either/or Delta-9 THC and Delta-8 THC.

Disability Contextualized Reinforcer Pathology Study:
Proportional Time and Enjoyability Rating Scale: A series of questions that ask general activity categories and time with/without alcohol/tobacco.
Revised Activity Level Questionnaires - Alternative versions of the Activity Level Questionnaires
Monetary Discounting- Delay discounting has been associated with a variety of health behaviors. Probability discounting, which is considered a measure of risk, is conceptually related to dangerous behavior. Social discounting, considered a measure of altruistic choice.
C-SSRS Suicide Questionnaire: A standard suicidality screener
Cigarette Quit Interest Questions
American Community Survey Disability Questions
National Survey on Health and Disability Questions
World Health Organization Disability Assessment Schedule
Alternative Activities Questionnaire - Questions related to alternative drug free reinforcement.
Susceptibility to tobacco questions
Nicotine dependence questions
Alcohol use severity questions

Nicotine Pouch Pilot
See 'NP Pilot Full Survey 9_24' for the full list of survey items included in this study.
Drug and tobacco use- participants will be asked what drugs and tobacco products they use
Nicotine pouch usage- Participants will be asked how many nicotine pouch packs they purchased in the past month alongside the flavor characteristics and their interpretations of flavor characteristics for nicotine pouches
Cigarette usage- participants will be asked about their cigarette usage in the past month
E-cigarette usage- participants will be asked about their e-cigarette usage in the past month

Smokeless tobacco usage-participants will be asked about their smokeless tobacco usage in the past month
little cigar usage-participants will be asked about their little cigar usage in the past month
nicotine replacement therapy usage-participants will be asked about their NRT usage in the past month
Demographics- participants will indicate a standard set of demographics including age, sex, zip code, rurality, state, household size, educational attainment, household income and race/ethnicity
Anxiety- participants will complete the General Anxiety Disorder 7
Depression- Participants will complete the Patient Health Questionaire 8
Faegerstrom test of nicotine dependence for smokeless tobacco and nicotine pouches- participants will complete a modified version of the FTND-ST which assesses their dependance on nicotine pouches
Nicotine pouch withdrawal- participants will indicate item associated with different aspects of withdrawal from nicotine pouches
Nicotine pouch quitting aid- participants will indicate whether they used nicotine pouches to switch from other tobacco products and indicate how successful their transition was
Week nicotine pouch purchase task- determines demand characteristics of nicotine pouches
Food rank- participants will rank 20 food items on their order of desireability. This is done to assess demand for both positively reinforcing and aversive stimuli
Food Cost- participants will indicate how much they think their #1 ranked food and #20 ranked food would cost.
Pay to Consume- participants will complete purchase tasks indicating how much they would pay to consume their #1 and #20 ranked foods
Earn to Consume-participants will complete purchase tasks indicating how much they would need to be paid to consume their #1 and #20 ranked foods
Pay to Avoid- participants will complete purchase tasks indicating how much they would need to be paid to nott consume their #1 and #20 ranked foods
Favorite Earn to Avoid- participants will complete purchase tasks indicating how much they would need to be paid to not consume their #1 ranked food
Experimental Tobacco Marketplace- A web-based application that simulates an online storefront (e.g., amazon). Similar to the hypothetical purchase task, but used to assess cross-commodity substitution based off of increasing prices. Assesses demand characteristics and substitution of 5 different dosages of nicotine pouches.

The Covarying of Mental Health, Alcohol/Substance Use, and Treatment Engagement
Alcohol Use Disorder Identification Test - Screens for alcohol use severity
Alcohol Quit Intentions - Questions to assess interest in cutting down or quitting drinking
Past 30-Day Tobacco Product Use
Fagerstrom Test for Nicotine Dependence - Tests for general nicotine dependence
Tobacco Quit Intentions - Questions to assess interest in cutting down or quitting tobacco use
Drug Use Disorder Identification Test - Screens for non alcohol/tobacco use severity.
Drug Quit Intentions - Questions to assess interest in cutting down drug use.
Columbia Suicide Severity Rating Scale Short Form - Brief questions on lifetime and recent suicidal thoughts and behaviors
Ideation or Behaviors with Substance Use - scale to ask relative use of substances while experience suicidal thoughts and behaviors
Exposure to Deaths Scale - Questions related to exposure to death by suicide, overdose, longterm death, and suicide attempt
General Demographics
Generative AI Usage - Questions related to chatbot usage
Generative AI Opinions - Questions related to opinions of chatbot usage
Mental Health Treatment and Trust - Questions related to opinions of treatment history and opinion of mental health professionals
Alcohol Substance Use Treatment and Trust - Questions related to opinions of treatment history and opinion of alcohol/substance use treatment professionals
Mental Health Self Perceptions -Self efficacy regarding managing mental health
Alcohol Use Self Perceptions - Self efficacy regarding managing alcohol use
Dimensional Anhedonia Rating Scale - Assesses appetitive and anticipatory anhedonia
Reward Probability Index - Assesses different dimensions of receiving reinforcement
Monetary Discounting - Discounting for delayed, probabilistic, and social distanced monetary outcomes.
Substance Free Activities - Two scales assessing liking substance free activities and ease of accessing substance free activities
Alcohol Discounting - Discounting for immediate or delayed alcohol
Alcohol Demand - Questions related to 14 price point purchase tasks and 3 question demand questions.

Attachments

Attach Type	File Name
DataCollection	ETM Pilot Survey v1.pdf
DataCollection	ETM Pilot Survey v3.pdf
DataCollection	SUPRA MTurk V1.pdf
DataCollection	MTurk Assessments.pdf
DataCollection	SUPRA Longitudinal S1 Survey.pdf
DataCollection	SUPRA Longitudinal S2 Survey.pdf
DataCollection	ETM Pilot Survey v2.pdf
DataCollection	CM VA Survey.pdf
DataCollection	CoMMIT_InterviewProtocol.pdf
DataCollection	CoMMIT_InterviewProtocol v2.pdf
DataCollection	AppalTRUST Tobacco Alcohol Screener v1.pdf
DataCollection	AppalTRUST Tobacco Alcohol Survey v1.pdf
DataCollection	CoMMIT_InterviewProtocol v3.pdf

DataCollection	Tobacco Alcohol Cannabis Main Qualtrics Survey.pdf
DataCollection	Tobacco Alcohol Cannabis ETM scenario table.pdf
DataCollection	Tobacco Alcohol Cannabis Main Qualtrics Survey 6_19.pdf
DataCollection	Tobacco Alcohol Cannabis D8D9 Survey 6_19.pdf
DataCollection	AppalTRUST Tobacco Alcohol Screener v2 highlighted.pdf
DataCollection	AppalTRUST Tobacco Alcohol Screener v2.pdf
DataCollection	AppalTRUST Tobacco Alcohol Full Survey v2 highlighted.pdf
DataCollection	AppalTRUST Tobacco Alcohol Full Survey v2.pdf
DataCollection	NP Pilot Full Survey 9_24.pdf
DataCollection	NP Pilot Screener Survey.pdf
DataCollection	NP Pilot ETM.pdf

Resources

Describe the availability of the resources and adequacy of the facilities that you will use to perform the research. Such resources may include:

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;
- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;
- Resources for communication with subjects, such as language translation/interpretation services.

The PI and the research team will oversee the research. Time to collecting data will be minimal as the task will be posted and kept online until the requested sample size is met. All surveys will be generated using Qualtrics. They will be posted on a crowdsourcing platform such as Amazon Mechanical Turk, Testable, Prolific, or Qualtrics Panels. Data will be stored on Qualtrics and exported for analysis by researchers regularly. Exported data will be stored on secure servers on password protected computers.

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.

General:
The main risk is loss of confidentiality due to a data breach. Only the research team will have access to the data. Data will be stored on secure servers. No attempt will be made to link participants' responses to personally identifying information.

Cannabis Nicotine Withdrawal Crowdsourcing:
Answering questions related to substances may result in risks of discomfort or embarrassment. We expect no more risks than are found in everyday life.
There are no direct benefits to participants. However, the information we obtain from these assessments may help to better characterize drug use and misuse. These results may lead to better interventions and treatments in the future through identification of relationships between use severity, demographics, and decision making patterns.

SUPRA Crowdsourcing Pilot:
Answering questions related to substance use and mental health may cause discomfort or embarrassment. Asking questions related to suicide does not appear to increase participant's risk (Blades et al., 2018), but we are providing national resources regardless if a participant endorses current or previous suicidal thoughts or behaviors as per the University of Kentucky research on suicidal thoughts and behaviors guidelines (https://www.research.uky.edu/uploads/ori-d1340000-suicide-ideationor-behavior-among-research-participants-pdf) .

SUPRA Longitudinal Pilot:
Same as SUPRA Crowdsourcing Pilot

ETM Pilot:
Same as general.

CM VA Prolific:
Same as general.

CM VA Prolific Follow-up Interviews:
To protect against loss of confidentiality, we will follow strict data management procedures. Access to data will be permitted only to the researchers, who will be trained in HIPAA procedures and will sign confidentiality agreements. Any contact information we learn about through interviews will not be retained. To protect confidentiality, participants will be assigned a unique study identification number. Moreover, members of the research team (e.g., research assistants) will be required to participate in training in the areas of ethics, clinical trials, confidentiality protection, and human subjects protection.

AppalTRUST Tobacco Alcohol Study:
Same as SUPRA Crowdsourcing Pilot.

Tobacco Alcohol Cannabis Study:
Same as general.

Disability Contextualized Reinforcer Pathology Study:
Same as general.

Nicotine Pouch Pilot
Same as general.

The Covarying of Mental Health, Alcohol/Substance Use, and Treatment Engagement
Same as SUPRA

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).

General:
The alternative to participating in this research is to not participate in it. Participants will be informed that they are free to withdraw from the study at any time. Because this is not a treatment study, there are no alternative treatments to participation.

SUPRA Crowdsourcing Pilot:
Because this is not a treatment study there at not opportunities per se, but due to the nature of the study we do provide information for those in need "If you need guidance or feel that you are in crisis, National Suicide Prevention Lifeline (988 or 1-800-273-8255) https://988lifeline.org/ or Crisis Text Line (text HOME to 741741) are resources that are available to you". This information occurs on the first page of the survey (cover letter), before questions related to suicide, after questions related to suicide, and at the end of the survey. Participants are able to cease their participation at any time. We have also included "prefer not to answer" options for questions related to suicidal thoughts and behaviors.

SUPRA Longitudinal Pilot:
Same as SUPRA Crowdsourcing Pilot.

ETM Pilot:
Same as general

CM VA Prolific Study:
Because this is not a treatment study there at not opportunities per se, but due to the nature of the study we do provide information for those in need "If you need guidance or feel that you are in crisis, National Suicide Prevention Lifeline (988 or 1-800-273-8255) https://988lifeline.org/ or Crisis Text Line (text HOME to 741741) are resources that are available to you". This information occurs on the first page of the survey (cover letter), before questions related to suicide, after questions related to suicide, and at the end of the survey. Participants are able to cease their participation at any time. We have also included "prefer not to answer" options for questions related to suicidal thoughts and behaviors.

CM VA Prolific Follow-up Interviews:
Same as general.

AppalTRUST Tobacco Alcohol Study:
Same as general.

Tobacco Alcohol Cannabis Study:
Same as general.

Disability Contextualized Reinforcer Pathology Study:
Same as general.

Nicotine Pouch Pilot
Same as general.

The Covarying of Mental Health, Alcohol/Substance Use, and Treatment Engagement
Same as SUPRA

Back to Top

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.

If the study will use Artificial Intelligence (AI) to collect and/or analyze data, see the “Data Security” section under AI Protocol Submission Guidance for Researchers on the Artificial Intelligence/Machine Learning in Human Research webpage.

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

The new data security compliance requirements under 28 CFR Part 202 are in effect as of 10/6/25. For any questions please contact Sara Poll, UK’s Research Security Administrator, researchsecurity@uky.edu

Surveys will be administered through Qualtrics and distributed using crowdsourcing platforms such as Amazon Mechanical Turk, Testable, Prolific, or Qualtrics Panels. Data will be exported by the research team periodically and will be stored on secure servers accessible only by research staff.
Only authorized individuals on the IRB protocol will have access to the data stored on Qualtrics' servers. Data will be downloaded directly to the University of Kentucky's secure servers or a password-protected computer where only authorized individuals on the IRB protocol will have access.
Data/research records will be retained for a minimum of 6 years after study closure. Data will be saved on password-protected servers owned by the University of Kentucky or a password-protected computer to where only authorized individuals on the IRB protocol will have access.
We will inform participants that they are free to discontinue at any time and may opt not to answer any sensitive questions not necessary for the research.

We will make no attempt to link participants' responses to personally identifying information. Data will be stored on secure servers accessible only by the research staff.

☑ **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.

Compensation will be equal to an hourly rate of approximately $10-$14 per hour (depending on how quickly the participant completes the task), with a maximum up to $28 for two hours (prorated; e.g., $6 for 30 min time), depending on extent of completion and attention to attending questions. Due to the additional burden associated with zoom interviews, participants will be compensated $40 for the CM VA Prolific Follow-up Interviews study.

Costs to Subjects

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

There are no monetary costs associating with participation. Participants may lose time that they would otherwise spend doing other things by participating in this study.

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. NOTE: FDA outcomes/real-world data is not generally considered an investigation.

- 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.

General:
Given the minimal risk of the study, we do not plan to include measures asking about participants' safety. However, participants may discontinue the survey at any time.

SUPRA Crowdsourcing Pilot:
The study is minimal risk. However, because we are asking questions about suicidal thoughts and behaviors, we are included resources such as the 988lifeline and Crisis Text line at the consent, before and after questions pertaining to suicide, and at the end of the study. Asking questions related to suicide does not appear to increase participant's risk (Blades et al., 2018), but we are providing national resources regardless if a participant endorses current or previous suicidal thoughts or behaviors.

SUPRA Longitudinal Pilot:
Same as SUPRA Crowdsourcing Pilot.

ETM Pilot:
Same as General

CM VA Prolific Study:
Same as General.

CM VA Prolific Follow-up Interviews:
Same as general.

AppalTRUST Tobacco Alcohol Study:
Same as general.

Tobacco Alcohol Cannabis Study:
Same as general.

Disability Contextualized Reinforcer Pathology Study:
Same as general.

Nicotine Pouch Pilot:
Same as general.

The Covarying of Mental Health, Alcohol/Substance Use, and Treatment Engagement
Same as SUPRA.

Back to Top

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

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

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research
- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used

- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

Survey responses will be kept for future analysis. These data may be used in the future for additional publications (e.g., meta-analyses, secondary analyses) and presentations. All data will be stripped of identifiable information (e.g., Amazon Worker IDs, other IDs assigned by crowdsourcing platforms) prior to any data analyses. No data with identifying information will be shared with individuals outside of the research team at any time. If data are shared with individuals outside of the research team, the data will be completely stripped of any potentially identifying information.
All data will be stored on secure servers. At no time will the research team attempt to link participants' responses to personally identifying information. Data will be downloaded directly onto the University of Kentucky's secure servers or a password protected computer where only authorized individuals will have access. IDs assigned through the crowdsourcing platform will be stored in a separate, secure location from the data used for analyses on the University of Kentucky's secure servers. At no time will crowdsourcing IDs be shared with anybody outside of the research team.
Because identifiable information will be stripped from the data, the risks to participants are minimal. If data are made publicly available, they will be stripped of any identifying information.

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) - Pharmacy Services (requires linkblue login). 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 of significant risk? [FDA Significant Risk (SR)/Nonsignificant Risk (NSR) Guidance]

- 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 or the study only collects standard of care outcomes and real-world data.

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

Attachments

RESEARCH SITES

0 unresolved comment(s)

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

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

UK Sites

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

Schools/Education Institutions

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

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

Other Medical Facilities

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

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

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

- A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.
- Supportive documentation, including letters of support, can be attached below. When attaching reliance documents, please ensure that you select the correct 'Document Type' from the drop-down menu. See below for the "**Document Types**" in bold, followed by examples of reliance documents for each type:
  - **Individual Investigator Agreement (IIA)**
    - A completed Individual Investigator Agreement

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

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

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

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

- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK sites.
- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

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

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

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

Attachments

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

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.

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? **If yes, your study meets the NIH definition of a clinical trial.**
○ Yes ◉ No

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

- ☐ Academic Degree/Required Research
- ☑ Alcohol/Drug/Substance Abuse Research
- ☐ Biological Specimen Bank Creation (for sharing)
- ☐ Cancer Research
- ☐ CCTS-Center for Clinical & Translational Science
- ☐ Certificate of Confidentiality
- ☐ Collection of Biological Specimens for banking and use
- ☐ Community-Based Participatory Research
- ☐ Deception
- ☐ Educational/Student Records (e.g., GPA, test scores)
- ☐ Emergency Use (Single Patient)
- ☐ Gene Transfer
- ☐ Genetic Research
- ☐ NIH Genomic Data Sharing (GDS) (databases such as GWAS, dbGaP, GenBank)
- ☐ Treatment with Human Cells, Tissues, and Cellular and Tissue Based Products
- ☐ Individual Expanded Access or Compassionate Use

For additional requirements and information:

- Academic - Faculty Advisor's supervision and signature assurance required
- Alcohol or Substance Abuse Research in Survival Handbook
- Specimen/Tissue Banks/Data Registries - For Biospecimen Banks or Repositories; Biospecimens in Research; Genetic Research; and/or Data Registries
- Cancer - Markey Cancer Center (MCC) Protocol Review Monitoring Committee (PRMC)
- CCTS (Center for Clinical and Translational Science)
- Certificate of Confidentiality
- Community-Based Participatory Research
- Deception and Debriefing
- Student Records - see Family Educational Rights and Privacy Act (FERPA) Guidance
- Emergency Use Procedures for Investigational Drugs/Devices

☐ 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	• Institutional Biosafety Information Human Gene Therapy - For gene transfer research, also go to the E-IRB Application Other Review Committees section, and checkmark Institutional Biosafety Committee • NIH GDS - UK Genomic Data Sharing Guidance • Cellular Treatment - FDA Human Cells, Tissues, and Cellular and Tissue-Based Products • Expanded Access Program for Drugs and Devices • International, Non-English, Foreign Culture • Planned Emergency Research - UK Exception from Informed Consent for Planned Emergency Research (EFIC) • Institutional Biosafety Information Recombinant/synthetic nucleic acids - also go to the E-IRB Application Other Review Committees section, and checkmark Institutional Biosafety Committee • OHRP Human Embryonic Stem Cells Guidance • Suicidality and Research Ethics • HRSA Organ Procurement & Transplantation Network (OPTN) HOPE act • Use of Radioactive Materials (Radiation Safety) • Institutional Biosafety Committee (IBC) - For vaccine trials, also go to the E-IRB Application Other Review Committees section, and checkmark Institutional Biosafety Committee

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:

This research will be supported by startup funds awarded to the PI, Dr. Mikhail Koffarnus, by the University of Kentucky. Some research funds were awarded to Dr. Mark Rzeszutek as a part of the SUPRA postdoc pilot. These funds are supporting the SUPRA Crowdsourcing Pilot and SUPRA Longitudinal Pilot survey. Research funds for the ETM Pilot were supported by U54 DA058256 awarded to Mikhail Koffarnus. Research funds for the Nicotine Pouch Pilot were supported by the AppalTRUST Pilot Award. Research funds for the Covarying Engagement Study were supported by K99AA031309 awarded to Mark Rzeszutek.

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.):

University of Kentucky, NIH

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 Department of Defense (DoD) for details)

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

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

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

Assurance/Certification Attachments

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

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

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

○ Yes ◉ No

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

Additional Information

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

Attachments

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

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

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

Approval Letter Details:

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

Additional Materials:

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

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

Protocol/Other Attachments

Attach Type	File Name
Other	MTurk edit screen.docx
Other	Limited Review Form SUPRA 5-15-23.pdf
Other	Limited Review Form Cannabis Nicotine 5-15-23.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?" and/or "What does the Faculty Advisor'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	View/Sign	Return to PI	Return to Signee
Roberto	Cardarelli	Department Authorization	Family and Community Medicine		04/07/2022 01:13 PM	View/Sign		
Mikhail	Koffarnus	Principal Investigator	Family and Community Medicine		04/07/2022 12:39 PM	View/Sign		

Department Authorization

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

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

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

Principal Investigator's Assurance Statement

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

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

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

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

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

SUBMISSION INFORMATION

0 unresolved comment(s)

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

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

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

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

Your protocol has been submitted.

Download all

Download	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.106	jlkear0	8/27/2026 3:33:17 PM
	Stamped Consent Form	Informed Consent CanNic Clean 1.27.23.pdf		0.080	jlkear0	8/27/2026 3:33:16 PM
	Stamped Consent Form	ETM Pilot Cover Letter Clean.pdf		0.088	jlkear0	8/27/2026 3:33:16 PM
	Stamped Consent Form	01_TRACKED_ScreenerConsent_RxPathology.pdf		0.163	jlkear0	8/27/2026 3:33:16 PM
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	Stamped Consent Form	CM VA Cover letter clean.pdf		0.044	jlkear0	8/27/2026 3:33:15 PM
	Stamped Consent Form	SUPRA Cover Letter Clean 1.27.23.pdf		0.080	jlkear0	8/27/2026 3:33:15 PM
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						AM
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	AdditionInfoConsiderations	Limited Review Form 5-20-22.pdf	Limited Review Form 6-1-22	0.623	hktr224	6/1/2022 1:22:34 PM

Protocol Changes

Protocol Number: 76582

No Changes

There are no recorded changes tracked for this protocol.

Study Personnel Changes:

No comments