Cover Page

Protocol document version date Sept 27, 2021
Document submitted Nov 25, 2023

NCT # NCT06105138
Title: Cannabidiol Effects on Blood Alcohol Level and Intoxication

Statistical Analysis Plan

Prior to hypothesis testing, we will conduct data wrangling and visualizations on the raw data for all outcomes using the R programming language and packages included in tidyverse (Team 2013; Wickham et al. 2019) (e.g., ggplot2 (Wickham 2016)). To examine changes over time in BrAC, alcohol craving, affect, sedation, and stimulation during the descending limb of the BrAC curve (T2 – T8, see Figure 1) and to compare these changes by sex and condition, we will run a series of Multilevel Structural Equation Models (MSEM;(Mehta and Neale 2005) using Mplus 8 (Muthén and Muthen 2017). Due to the research design, where each participant completed each condition (placebo, 30mg CBD and 200mg CBD) and within each condition there were 7 repeated measures of interest, MSEMs need to be run with a latent growth curve on the within-level to capture the change over time. Repeated measures of interest were taken at timepoints T2-T8, which represent the descending limb of the BrAC curve. We will focus on the descending limb because evidence suggests that some subjective effects of alcohol may be particularly prominent during the descending limb (Pihl et al. 2003; Brick 2006). In addition, prior medication studies have demonstrated that notable medication effects such as reduction in craving and stimulation are observed in both the descending and ascending limb (Ray and Hutchison 2007), but some unique effects such as increased tension may be specific to the descending limb (Ray et al. 2008). Another advantage of focusing on the descending limb is that changes during this time are expected to be approximately linear (e.g., BrAC decreases linearly (Posey and Mozayani 2007)), which supports a more straightforward interpretation of model results. Note that T2= 90 minutes after the start of the alcohol administration session and T8=4.5 hours after the start of the alcohol administration session.

In all models, condition will be treated as a within-person variable, and sex will be treated as a between-person variable. To examine whether condition influenced changes over time, we will regresse the latent slope parameter defined by the latent growth curve model on a dummy coded within-person condition variable. As there are 3 conditions, each model must be run twice to assess all pairwise

comparisons. First with placebo as the referent group (i.e., comparing placebo to 30mg CBD and placebo to 200mg of CBD) and then again with 30mg CBD as the referent group (i.e., to get the comparison of 30mg CBD to 200mg CBD). To determine if sex moderates the condition→change relationship we will create a random slope of condition predicting the latent slope variable and then regressed that random slope on the between-person binary sex variable. This is referred to as the random coefficient prediction method (Preacher et al. 2010, 2016). We will also use this method to determine if the overall change over time is moderated by sex by regressing the random latent slope parameter on the between-person sex variable. The MSEM approach allows paths that include within-level effects to have random intercepts and allows for the creation of Bayesian credible intervals for assessing significance of effects. Bayesian credible intervals provide a robust test of direct and moderation effects, are computationally efficient, and are amenable to a variety of variable characteristics (e.g., hierarchical–nested and non-normal data; (Gelman et al. 2004; Muthén and Asparouhov 2012).

PROTOCOLS

#1903 - Exploring the Effects of Acute Cannabidiol Administration on Blood Alcohol Level and Intoxication in Adult Human Subjects

Protocol Information

Review Type	Status	Approval Date	Continuing Review Date
Expedited	**Superseded**	**Sep 27, 2021**	**--**

Expiration Date	Initial Approval Date	Initial Review Type
Aug 18, 2022	**Mar 09, 2021**	**Full Board**

Feedback

Approval Comment

Amendment [v7] has been reviewed and granted approval by expedited review (§46.110(b)(2)) of minor changes on September 27, 2021. This amendment includes updated recruitment flyer CBD Alcohol Flyer 2. The IRB has determined that the risk level remains unchanged and the safeguards for participants is appropriate. The study was assessed as being in accordance with 45 CFR 46.111 of the 2018 Requirements.
RISK: More than Minimal
SPONSOR: CCTSI

Protocol Amendment Form

Amendment

Amendment Instructions

1. Complete this Amendment overview.
2. Update the sections of your protocol that you are requesting to amend.
3. Upload any amended documentation (consent; assent; attachments)
4. When it is ready to go, click Submit in the menu on the right-hand side of this page.

Note: If you are amending a currently approved document, delete the file that is currently attached and add a Tracked Changes and updated Clean Version. The IRB will approve the project with only the clean version included. Previous versions are available in your protocol version history and do not need to be maintained on the current amendment.

Summarize the proposed changes to the protocol in lay terms.

We have resubmitted a new recruitment flyer for distribution.

Indicate whether you think the level of risk increases, decreases, or does not change the risk determined by the IRB at initial review.

(If level of risk has changed, please update the section 'Risks' in the protocol information.)

No Change

Please document how many participants have been enrolled to date who may be impacted by your proposed changes.

no participants will be impacted by the proposed change

Will you re-consent subjects?

No

General Information

Principal Investigator

Karoly, Hollis Catherine

Lead Unit

Psychology (CO-1876)

Title

Exploring the Effects of Acute Cannabidiol Administration on Blood Alcohol Level and Intoxication in Adult Human Subjects

People

People

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Karoly, Hollis Catherine

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Permissions

Full Access

People Attachments

Attachment

CITICOMPLETIONREPORT_DRENNAN(1).PDF

Name

CITI RCR for grad students

Attachment Type

Other

Comments

Attachment

CITICOMPLETIONREPORT5005905_DRENNAN(1).PDF

Name

CITI group 2

Attachment Type

Other

Comments

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Contact Roles

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Permissions

Full Access

People Attachments

Attachment

HG CITI CERTIFICATION(1).PDF

Name

CITI

Attachment Type

Other

Comments

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Permissions

Full Access

People Attachments

Attachment

CITI RESPONSIBLE CONDUCT_TYLERADAMS.PDF

Name

CITI RCR

Attachment Type

Other

Comments

Attachment

CITI HUMAN RESEARCH_TYLERADAMS.PDF

Name

CITI

Attachment Type

Other

Comments

Attachment

CITI GOOD CLINICAL PRACTICES_TYLERADAMS.PDF

Name

CITI GCP

Attachment Type

Other

Comments

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Contact Roles

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Permissions

Full Access

People Attachments

Attachment

MF CITI CERTIFICATION.PDF

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Melanie_Ford_CITI

Attachment Type

Other

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Researcher Role

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Contact Roles

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Permissions

Full Access

People Attachments

Attachment

LEILA ZULIC SHBR CITI.PNG

Name

CITI

Attachment Type

Other

Comments

Attachment

LEILA ZULIC RCR CITI.PNG

Name

CITI RCR

Attachment Type

Other

Comments

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CSU Status

Researcher Role

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Contact Roles

Admin

Permissions

Full Access

People Attachments

Attachment

SAGE_GROUP1.PDF

Name

CITI

Attachment Type

Other

Comments

Attachment

SAGE_CGP.PDF

Name

GCP

Attachment Type

Other

Comments

Attachment

SAGE_RCR.PDF

Name

RCR

Attachment Type

Other

Comments

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CSU Status

Researcher Role

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Contact Roles

Admin

Permissions

Full Access

People Attachments

Attachment

VB_GROUP1.PDF

Name

CITI

Attachment Type

Other

Comments

Attachment

VB_RCR UNDERGRAD.PDF

Name

CITI RCR Undergrad

Attachment Type

Other

Comments

Attachment

VB_GCP.PDF

Name

CITI GCP

Attachment Type

Other

Comments

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CSU Status

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Contact Roles

Admin

Permissions

Full Access

People Attachments

Attachment

GRAY_CITI.PDF

Name

CITI

Attachment Type

Other

Comments

Attachment

RCR.PDF

Name

RCR

Attachment Type

Other

Comments

Attachment

REFRESHER.PDF

Name

refresher

Attachment Type

Other

Comments

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Permissions

Full Access

People Attachments

Attachment

MEGAN GARDNER WEISHAAR CITI GROUP 1 - 5.2021(1).PDF

Name

CITI

Attachment Type

Other

Comments

Attachment

MEGAN GARDNER WEISHAAR CITI GROUP 2 - 5.2021(1).PDF

Name

CITI2

Attachment Type

Other

Comments

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Full Access

People Attachments

Attachment

CITI_HUMANRESEARCH_MC.PNG

Name

citi training certificate_humanresearch

Attachment Type

Other

Comments

Attachment

CITI_RCR_MC.PNG

No

Legacy eProtocol ID number

If applicable, enter the ID number this study was previously assigned in eProtocol.

20-10303H

General Questionnaire

Application Type

Full Board

Does this study include use of existing data or biospecimens?

No

Does this study include use of student educational records and data?

No

Does this study include the use of human blood, cells, tissues or body fluids?

Yes

Does this study include evaluation of medical equipment or devices?

No

Does this study include evaluation of drugs, biologics, reagents or chemicals?
Yes

Is this study a clinical trial?
No

Does this study include the use of Protected Health Information (PHI)?
No

Is this study a Graduate Level Thesis or Dissertation Project?
No

Is this study another type of class project?
No

Is the project funded?
Yes

Study Participants

Subjects Checklist (Select All that Apply)
Adults

Collaborators

Will Colorado State serve as the Single IRB for other collaborating institutions on this study?
No, Colorado State University is the only participating institution in this study.

Funding

Funding Sources

Funding Type
Other (i.e. State, Local)

KP Proposal Number or OSP Reference Number
147332

Title of Grant (if different from protocol title)
CCTSI

Period of Funding

Is the study occurring at CSU?
Yes

Prime or Subawardee?
Prime

Funding was secured by:
CSU Office of Sponsored Programs

Please provide your IRB Approval documentation to Sponsored Programs upon receipt.

Summary and Purpose

Proposed Start Date	Proposed End Date
February 15, 2021	February 15, 2022

Provide a brief summary or abstract of the project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

Cannabidiol, or CBD, is commonly found in the cannabis plant and has shown promise in treating alcohol use disorders (AUD). Several rodent studies show that CBD decreases alcohol intake. However, only three human studies have ever been conducted on this topic. These studies showed conflicting results regarding the impact of CBD on intoxication and blood-alcohol level. Importantly, existing studies have used synthetic CBD, which is dissimilar from the plant-based CBD products popular in the U.S. Thus, the conclusions that can be drawn from the existing work are limited, and tightly controlled human studies of the effects of plant-based CBD on blood alcohol level, psychomotor intoxication and subjective intoxication following acute alcohol consumption are needed. In this study, we will explore the effects of two doses of plant-based CBD (compared to placebo CBD) on blood alcohol level, motor and balance impairment as craving/desire for alcohol over the course 4 hours after subjects consume a standardized dose of alcohol. We hypothesize that in the CBD condition, blood alcohol level (estimated using a breathalyzer) will be lower, cognitive and motor/balance performance will be better and craving will be lower for all timepoints. These outcomes have implications for understanding the potential of CBD as an AUD treatment.

Describe the purpose for the proposed project.

The purpose of the project is to improve our understanding of how plant-based CBD products may impact alcohol use among individuals who regularly use alcohol. Since alcohol and cannabis co-use is common in the U.S., CBD is commonly found in recreational and medical cannabis products, and animal research suggests that CBD may decrease alcohol intake, it is important to determine whether CBD have applications for reducing drinking in humans. Ultimately, this could have implications regarding the use of CBD as a potential treatment for alcohol use disorders. Primary objectives are to explore how CBD impacts blood alcohol level, as well as cognitive and motor performance during an acute alcohol administration session. Specific Aims are described in detail below: Aim 1. Assess effects of CBD+alcohol vs. placebo+alcohol on breath alcohol level (BrAC). Hypothesis 1. After consuming CBD, subjects will have lower BrAC throughout the 4-hour period compared to when they consume placebo CBD. Aim 2. Assess effects of CBD+alcohol vs. placebo+alcohol on subjective intoxication. Hypothesis 2a. After consuming CBD, subjects will experience decreased alcohol craving across all timepoints post-alcohol consumption compared to when they consume placebo CBD. Hypothesis 2b. Differences in self-reported stimulation and sedation effects will emerge in the CBD condition compared to the placebo condition across all post-alcohol consumption timepoints. We lack sufficient prior evidence to predict the direction of these effects. Aim 3. Assess effects of CBD+alcohol vs. placebo+alcohol on psychomotor intoxication. Hypothesis 3a. CBD will be associated with better performance on an inhibitory control task compared to placebo across all timepoints. Hypothesis 3b. CBD will also be associated with better balance/motor performance at all timepoints after alcohol consumption compared to placebo.

What do the investigators hope to learn from the project?

We hope to gain a better understanding of the impact of CBD on blood alcohol level. We also hope to better understand whether CBD impacts levels of acute alcohol intoxication (specifically as regards craving, subjective effects of alcohol and cognitive and motor impairment). This has implications regarding CBD's potential as a treatment for alcohol use disorder.

Describe how sharing results of this study could influence behavior, practice, theory, future research designs. Specifically, how will study results apply to a larger population than the studied participants?

The results from this research will be disseminated as publications (estimated at least 3-4 papers total spanning all three main study aims) and as symposia/presentations and posters at national and international conferences.

Background

Provide a brief overview of the relevant background. Discuss the present knowledge, appropriate literature and rationale for conducting the research.

Increases in alcohol consumption, high risk drinking and AUD constitute a public health crisis in the U.S.(Grant et al., 2017). Although decades of preclinical and clinical research have shed light on risk factors associated with the etiology and maintenance of AUD, currently available interventions demonstrate only modest efficacy (Dutra et al., 2008; Jonas et al., 2014). Thus, there is increasing interest in exploring alternative AUD treatments targeting novel biological systems. Notably, the endocannabinoid system (ECS) has emerged in recent years as a potential treatment target for AUD (Sloan et al., 2017). In particular, the non-psychoactive cannabinoid cannabidiol (CBD) has shown preclinical promise in ameliorating numerous clinical symptoms of AUD. Specifically, CBD reduces the reinforcing properties of alcohol and decreases drinking motivation and consumption in mice (Viudez-Martínez, García-Gutiérrez, et al., 2018; Viudez-Martínez, García-Gutiérrez, et al., 2018) and attenuates cue-induced and stress-induced alcohol-seeking, reinstatement, anxiety, and impulsivity in a rat model of AUD (Gonzalez-Cuevas et al., 2018). Although we lack a complete understanding of the mechanism(s) through which CBD may reduce alcohol consumption and/or ameliorate the clinical symptoms of AUD, CBD is known to modulate several neural pathways implicated in AUD. For example, in one rodent study, administration of CBD during ethanol self-administration was associated with decreased expression of the opioid receptor OPRM1 gene, the GPR55 gene, and the CB1 gene (all of which code for proteins associated with AUD and the reward response to alcohol (Mague and Blendy, 2010; Musella et al., 2017; Parsons and Hurd, 2015), and increased expression of the CB2 gene in the nucelus accumbens (NAcc). This study also found that CBD was associated with decreased expression of the tyrosine hydroxylase gene (TH; an enzyme critical for regulation of dopamine synthesis, and which influences dopamine levels after alcohol administration) in the ventral tegmental area (VTA). Given that the dopaminergic signaling from the VTA to the NAcc is responsible for mediating the rewarding effects of alcohol (Koob, 1992; Spanagel and Weiss, 1999), and that increased TH expression is observed in association with acute and chronic alcohol (Lee et al., 2005; Oliva et al., 2008; Ortiz et al., 1995), it is possible that modulation of reward-related genes in the VTA and NAcc could contribute to the efficacy of CBD in decreasing alcohol consumption. In another study, CBD administered with the opioid receptor antagonist naltrexone decreased ethanol consumption and drinking motivation in mice to a greater extent than either CBD or naltrexone alone (Viudez-Martínez et al., 2018a). This study also found that serotonin 1A (5HT1A) receptor expression was reduced in the dorsal raphe nucleus after CBD+naltrexone treatment. The serotonergic pathway projecting from the dorsal raphe to the NAcc is activated during reward-associated tasks in mice (Liu et al., 2014). Given that chronic alcohol exposure is associated with increased 5HT1A receptor sensitivity and increased ethanol drinking in mice (Kelaï et al., 2006), these studies suggest that reduction of 5HT1A receptor expression in the dorsal raphe may be one mechanism through which CBD reduces the rewarding properties of alcohol. In sum, CBD modulates several neural pathways implicated in AUD, and the next logical step is to explore the effects of CBD on alcohol consumption and other AUD phenotypes in heavy drinking human subjects, as is proposed in this study.

Please describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, and training).

P.I. Hollis Karoly is a clinical psychologist and neuroscientist studying alcohol and cannabis use. She has been working with this population both clinically and in a research capacity for the past 10 years. Dr. Karoly has a dual PhD in Clinical Psychology and Neuroscience which was awarded in 2018 from CU Boulder. Additionally, she has published over 34 papers on the topic of substance use, and has presented her work and numerous national and international conferences. Dr. Karoly has been conducting research on substance users along the Front Range Urban Corridor since she began her graduate work at CU boulder in 2011. As a post-doc at CU Boulder, she was involved in numerous studies with CU Boulder PIs Dr. Kent Hutchison and Dr. Cinnamon Bidwell studying cannabis and alcohol users across the Front Range. She was also involved in a clinical trial of alcohol dependent individuals in the same geographic region, and independently conducted a dissertation project on alcohol and cannabis co-users while at CU Boulder.

Explain your knowledge of local community attitudes and cultural norms and cultural sensitivities necessary to carry out the research.
Thus, Dr. Karoly has many years of experience working with the substance using population across the Front Range.

Procedures

List all research activity procedures in which a participant will be involved, including follow-up procedures. Please provide details.

Procedure Description
Study Overview. Heavy drinkers (N=40) who do not regularly use cannabis but are not cannabis naïve will be recruited for this pilot study involving 3 half-day visits to our lab at CSU. Interested individuals will be phone screened, and eligible subjects will be scheduled for their first visit. For both visits, subjects will be asked to arrive in the lab at 11:15am and will be asked to have someone drive them to the lab and pick them up at the end of the day if possible. If this is not possible we will call a Lyft for them and cover the cost. At the first visit, they will complete informed consent and a demographics form and several questionnaires on psychological functioning and substance use. Subjects will then consume their their CBD (30 mg or 200 mg) or placebo. Alcohol administration (up to .8g/kg) will occur about 25 min after CBD ingestion, and testing procedures will occur every 30 minutes for the next 4 hours. The timeframe of the visit was selected because maximum plasma concentration of this CBD product occurs in the blood after 45 minutes (Williams et al 2021) Also, peak BrAC occurs for the alcohol dose we are administering (up to .8g/kg) approx. 1 hour after alcohol ingestion. The order of study visits (CBD 30 mg vs. CBD 200 mg vs. placebo) will be counterbalanced across participants, such that participants will be randomly assigned to complete each the three visits in different orders. Also note that the research assistants running the study will also be blinded to participant condition (and a non-blinded graduate student will prepare the CBD product for the subjects before the session). The three study visits will occur 1 week apart. There will also be 3 venous blood draws for Blood Cannabinoids at both visits. Blood draws will occur before CBD/placebo ingestion (to verify no CBD use prior to experiment), before alcohol consumption and 60 min post-alcohol ingestion. Blood will be assayed for CBD, THC and THC metabolites using High Performance Liquid Chromatography-Mass Spectrometry.

This procedure is:
Other Procedure

Please explain:
Overview of procedures/activities.

Procedure Description

Laboratory Sessions (CBD 30 mg Session, CBD 200 mg Session and Placebo-CBD Session). At each subject's first session, they will arrive at the lab at approximately 11:15am, undergo informed consent procedures with a trained research assistant, undergo urine pregnancy and drug screening and receive a breathalyzer test. We will use the Intoximeter Alcosensor IV Breathalyzer, which is the gold standard for alcohol research studies. Urine drug screening will test for the presence of illicit drugs (besides cannabis). If urine drug or pregnancy tests are positive, participants will be disqualified from participation. If BrAC is above 0.000, participants will be rescheduled. If all tests are negative, participants will complete a brief demographics form and psychological fuctioning/substance use questionnaires. Next, they do the first blood draw and will then be given either 30 or 200mg CBD dissolved in water or plain water (as the placebo CBD condition). They will then be asked to wait for 25 minutes in our lab. They will be provided with internet access during this time. Participants are allowed to consume water ad libitum throughout the entire day of the study. Immediately before the alcohol administration procedures begin, subjects will again have their blood drawn and will complete measures of balance/motor performance, inhibitory control, alcohol craving, stimulation and sedation. Specifically, the following measures will be administered to measure alcohol craving, stimulation and sedation: The Biphasic Alcohol Effects Scale (BAES) is a self-report rating scale measuring stimulant and sedative effects of alcohol. It has shown good reliability and validity in AUD. The Subjective High Assessment Scale (SHAS) is a standard self-report measure used to assess subjective responses to alcohol. The Alcohol Urge Questionnaire (AUQ) is a well-established measure of alcohol craving and desire to drink that is commonly used in the context of acute alcohol administration. To test balance/motor function we will use a psychomotor battery designed to capture measures of cognitive and motor impairment in divided attention, decision making, reaction time, motor tracking and balance movements following the intake of drugs or alcohol and designed to be administered repeatedly in a single session to assess changes in impairment without being susceptible to practice effects. Finally, to test inhibitory control we will use the The Flanker Inhibitory Control and Attention Task, which requires participants to focus on a stimulus while inhibiting attention to stimuli flanking it. These measures will be administered on an ipad. Next, participants will consume up to .8g/kg of vodka mixed with orange juice, following procedures from previous alcohol and cannabis co-administration studies. The dose will be reduced 8% for females to adjust for expected BrAC differences between males and females. An .8g/kg dose should produce a peak BrAC of no more than.089% approximately 1 hour after alcohol consumption, which should not significantly exceed the BrAC reached by heavy drinkers during a typical heavy drinking period. There will be a third blood draw at this time (approximately 1 hour after the start of the alcohol administration procedure). As in the three prior human studies of alcohol and CBD co-administration, participants will be asked to consume their alcohol within a 20-min. time period. The above procedures (breathalyzer measurement of BrAC, measures of inhibitory control and balance/motor performance, alcohol craving, stimulation and sedation) will be repeated every 30 min. for 4 hours post-alcohol administration. Participants will be required to reach a BrAC of <.03 before going home, which is estimated to take no more than 4 hours post-alcohol administration, given the elimination rate of alcohol from the body. They will also be required to either have someone pick them up from the lab after the study session is over, or if this is not possible our lab will call them a Lyft, and will cover the cost for them. Participants will be offered snacks after testing is complete to facilitate BrAC reduction. The visit will end at approx. 4:00pm. They will also be required to either have someone pick them up from the lab after the study session is over, or if this is not possible our lab will call them a Lyft. CBD Product. Consistent with the Colorado Department of Agriculture (CDA) and CSU regulations, the 30 mg and 200 mg CBD products will be sourced by Caliper Foods (https://www.caliperfoods.life/), which is a CDA compliant product containing <.3%THC (thus qualifying as hemp rather than cannabis, which means it is allowed on CSU's campus). Subjects will consume Caliper's 5% CBD concentrate liquid in water on the day of their CBD study appointment, and they will consume plain water with no CBD on the day of their placebo-CBD appointment. Caliper's CBD readily solubilizes into water within seconds and does not impact flavor, consistency, texture or appearance of the water. Thus, participants will not be able to tell whether they are consuming water containing CBD or plain water. Note that Individuals who report very high levels of alcohol consumption on the questionnaires, those that report symptoms of severe depression or suicidality, or those that determine that they do need to seek alcohol treatment will be referred to the Psychological Services Center in the CSU Psychology Department (https://psychology.colostate.edu/psc/), Aspenridge recovery (https://www.aspenridgefortcollins.com/) and

Mountain Crest, which provides inpatient MH services (https://www.uchealth.org/locations/uchealth-mountain-crest-behavioral-health-center/). More specifically, if suicidality is revealed during the study session (i.e., if the participant selects a 2 ("I would like to kill myself') or a 3 ("I would kill myself if I have the chance") on BDI item #9), the study procedures will be stopped and the research assistant will call the PI, Dr. Karoly, who has a PhD in Clinical Psychology. Dr. Karoly will then conduct a risk assessment over the phone. If participants indicate that they have plans, means and intent to harm themselves, and Dr. Karoly determines that the participant would be a danger to themselves if allowed to leave the session, procedures for hospitalization will be initiated. At this time, Dr. Bradley Conner (a licensed clinical psychologist in the psychology department) will be called to assist, as a licensed psychologist is needed to sign off on hospitalization procedures. Please note that this is extremely unlikely to happen, given that we will screen individuals out of participating in the study if the report suicidal ideation on the phone screen. However, because we are administering a self-report measure that asks about suicidality, the procedures described above are in place to ensure participant safety.

This procedure is:
Research Activity Involving Participants, Participants Data, or Biospecimens

This procedure is:
Experimental

Where and when will this procedure take place?
Please identify the location of procedures.

Who will conduct this procedure?

Personnel
Karoly, Hollis Catherine

Personnel
Drennan, Meggan L

Personnel
Gutierrez,Hector

Personnel
Adams, Tyler Ann

Personnel
Ford,Melanie

Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study.
Visits will take about 4.5 hours.

Describe how the data will be collected (i.e. in person or online).
In person

Privacy and Confidentiality

Explain how the established data management plan along with consent processes and other elements of the research design address the

following.

Privacy is considered from the perspective of the participant and is a right to be protected. Privacy refers to an individual's interest in controlling others' access to themselves. Based on their privacy interests, participants may want to control:

- The time and place where they give information
- The nature of the information they give
- Who receives and can use the information

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center identified as such by signs on the front of the building.

Describe how you will protect subject's privacy.

Participants are recruited either using targeted mailer or or online. Initial screening is conducted via phone, and prospective participants are asked at the beginning of the call if they are in a location where they feel comfortable answering questions about substance use. The study will be conducted in a secure space in Dr. Karoly's research lab at CSU.

Confidentiality is about data. Confidentiality pertains to protecting information from disclosure based on an agreement between the participant and the researcher. When an individual shares information in a relationship of trust and expects it to be kept private or will be disclosed only with specific permissions, researchers must uphold this agreement and maintain data appropriately.

Describe how you will maintain the confidentiality of subjects' information.

The PI and study staff will have access to identifying information, which will be stored in locked filing cabinets. Research data will be stored separately, in a password-protected documents on a secure, password-protected server.

Biospecimens

Identify which type(s) of biospecimens will be used as part of this research project:

Blood
Fecal/Urine Samples

Are the specimens known to be diseased or dangerous

No

Will tissues be stored for future research projects?

Yes

Will tissues or associated data be sent out of this institution as part of a research agreement under a Data Use Agreement or Material Transfer Agreement?

No

Do you require approval through the Institutional Biosafety Committee (IBC)?

Yes

IBC Project Approval Request Form (PARF)# or pending

Project 21-012B

IBC Agent Approval Request Form (AARF)# or pending

not required

For more information or support, contact the CSU IBC at: RICRO_IBC@colostate.edu

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Drugs and Devices

Identify which drugs, reagents or chemicals will be used as part of this research:

Drug/Agent Name

CBD 30 mg and 200 mg CBD products will be sourced by Caliper Foods

Identify Criteria

Cannabis/Hemp/CBD

Participant Population

Are you interacting or intervening with participants?

Yes

Provide an estimate of the anticipated participant total.

20

Are you analyzing existing data records or biospecimens?

No

Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.) This should match your screening, consent, and recruitment materials.

Please list all inclusion criteria

Participants must be between 21-60 years old, be able to provide consent, be willing to consume CBD during the study, be a heavy drinker (>5 drinks [>4 for women] per occasion) at least 5 days/month in the past 3 months). They must not be a regular or recent cannabis user (used cannabis less than monthly over past year and not in past month), but they must not be cannabis naiive (they must report having using THC or CBD at least once in past year).

Please list all exclusion criteria

Participants will be ineligible if they report daily tobacco use, state that they are currently seeking treatment for AUD or other substance use disorder, are pregnant, breastfeeding or trying to become pregnant, meet criteria for psychotic, bipolar or major depressive disorder with suicidal ideation, report illicit drug use in past 60-days or fail urine drug screen, or have a major medical condition contradicting alcohol or CBD use (e.g., liver disease, heart disease). They are also ineligible if they report taking blood thinners, as CBD may increase the level of blood thinners in a person's body. Regarding the urine drug screen, will be using the 6-panel Germaine™ Laboratories SafeCup™ III Urine Test Cup from Fisher Scientific, catalog number 23-111-320. This product tests for the presence of amphetamines, benzodiazepines, cocain,e THC, methamphetamine and opioids. Individuals that determine that they do need or want to seek alcohol treatment will be referred to the Psychological Services Center in the CSU Psychology Department (https://psychology.colostate.edu/psc/), Aspenridge recovery (https://www.aspenridgefortcollins.com/) and Mountain Crest, which provides inpatient MH services (https://www.uchealth.org/locations/uchealth-mountain-crest-behavioral-health-center/).

What is the rationale for studying the requested group(s) of participants?

Age criteria minimizes noise and reduces the impact of age-related differences on biological and behavioral outcomes. Individuals under 21 are not legally allowed to use alcohol or cannabis, and thus cannot be included in this study. This age criteria is also consistent with my other alcohol and cannabis study protocol which has been previously approved by the IRB (Protocol # 20=10213H). Because the primary aims of the study involve exploring the effects of legal-market cannabis on alcohol consumption and involve an alcohol and CBD administration, we need to recruit heavy alcohol users. Heavy drinking criteria is consistent with The Substance Abuse and Mental Health Service Administration definition. We will recruit individuals who are not regular or recent cannabis users to ensure that they do not have significant CBD or THC in their blood during the visits. However, because subjects are being given CBD (a hemp-based product), they should not be cannabis naïve. Overall, inclusion criteria are

deliberately broad, to increase the range of use patterns represented in the sample.

Will you use a screening procedure, instruments, tools, questionnaires etc.?
Yes

Describe any planned screening procedures. Attach your screening document(s) (e.g., health history questionnaire), if applicable at then end of the form.
Interested subjects will be screened over the phone by a trained research assistant. Phone screening documentation is attached in the attachment section.

Recruitment Process

Describe the procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

Participant Group Descriptor

Adults

Please describe the recruitment process:
Participants will be recruited from the greater Fort Collins/Denver/Boulder metropolitan area in Colorado. We will use flyers in the community as well as targeted mailings that make use of a list of names and addresses of individuals from publicly available records purchased from a marketing firm who fit target demographics and geographical area. In addition to posting flyers, we will print out smaller versions of our flyers and research staff will hand them out to adults in public spaces such as downtown Fort Collins They will approach adults walking in the area and offer a flyer. We will also post ads on social media (e.g., Facebook, craigslist, reddit, etc.). Recruitment materials will direct individuals to call a phone number to reach a professional research assistant to be screened for participation in the study.

Planned Subject Identification Methods
Direct advertising

Will a specific agency or institution provide access to prospective subjects?
No

Please select the recruitment personnel

Karoly, Hollis Catherine
Drennan, Meggan L
Gutierrez,Hector
Adams, Tyler Ann
Ford,Melanie
Weishaar, Megan Marie Gardner
Zulic, Leila

Crain, Sage A

Gray, Bethany Ariel

Brefere,Veronica

No

Planned Recruitment Materials/Methods
***(All advertising must be submitted for review in its final printed/recorded form)**
Note: Attach copies of ALL recruitment materials in the attachment Section
Flyers/posters
Internet ads/postings

Is there any possibility that potential participants may feel coerced to participate?
No

Is there any possibility that potential participants may feel undue influence to participate?
No

Participant Compensation/Costs

Will participants be compensated?
Yes

Form of Compensation

Cash or Check

What is the approximate monetary value?
297

Describe the remuneration plan.
Compensation is $99 per session which will be disbursed in cash following the completion of each session. Maximum compensation for the study is $297. A 1099 will not be issued.

Will a 1099 be issued?
No

Will participants incur any costs to participate in this research?
No

Risks and Benefits

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

tests." [Department of Health and Human Services 45 CFR 46.102(j)]

Please indicate the researchers' evaluation of the overall risk level, and describe all known risks or discomforts associated with the study procedures, as prompted below. Note that any risks identified here should be consistent with risks you will disclose to participants in the consent process.

Greater than Minimal Risk

Are there risks associated with physical well-being?

Yes

Please describe.

Risk of Phlebotomy. When having blood drawn, participants may experience some discomfort as a result of the needle prick in the arm. Some bruising or slight bleeding may occur. Although infection is possible, it is extremely rare, because the needle is sterile and disposable. Occasionally, people feel lightheaded or faint when blood is drawn, but the volume taken will be small (no more than 10mL is drawn for each of three blood draws). Protection Against Risks of Phlebotomy. Individuals trained in phlebotomy will conduct all blood draws. They have completed IBC training, BBP, BSL1, BSL2 and Hazardous Waste trainings and have demonstrated competence in phlebotomy, following the Karoly lab's SOP. Individuals who may draw blood during the study are: Meggan Drennan, Hector Guttierez, Patrick Gonzalez, Leila Zulic and Cody Conner. Risks of Alcohol Administration. Adverse effects of alcohol such as intoxication, acute mood shifts (e.g., feelings of sadness or depression), and odd perceptual experiences are possible. However, individuals are recruited because they are heavy drinkers, defined as consuming >5 drinks [>4 for women] per occasion) at least 5 days/month in the past 3 months. The dose of alcohol given in the study is only designed to bring BAC to a maximum of .089, which is not higher than a typical BAC reached by individuals drinking 4-5 drinks in a single occasion. Thus, individuals in the present study are not likely to experience alcohol intoxication beyond the level that they normally experience in their daily life as a heavy drinker. Protection Against Risks of Alcohol Administration. Several steps will be taken to minimize risk to participants as a result of the acute effects of alcohol including those based on guidelines provided by NIAAA (NIAAA Recommended Council Guidelines on Ethyl Alcohol Administration in Human Experimentation; NIAAA, 2005). More specifically, the following protections are in place: First, participants will be excluded from the study if they have a medical condition, have an alcohol use disorder (AUD) or another substance use disorder (SUD), are current in treatment for or seeking treatment for AUD or another SUD, or have a medical condition that that may contraindicate the consumption of alcohol. Urinalysis drug screens will be used at both laboratory sessions to exclude for any illicit drug use. Participants will only be included in the study if they are current heavy drinkers who report 5 binge drinking episodes per month over the last three months (note that a binge is defined by SAMHSA as consuming 5 drinks per occasion [4 for women]). Study staff will closely monitor participant BAC via breathalyzer throughout the alcohol administration protocols to ensure that BAC never xceeds .089 (which is roughly the equivalent of four standard drinks and is at the legal limit for alcohol impairment) following established alcohol-administration procedures. Thus, the amount of alcohol provided over the sessions will not exceed the dosage level consistent with participants' normal drinking practices. At both laboratory visits, a picture ID will be required to prove age eligibility (> 21 years). Female participants will be required to take a private urine sample pregnancy test on the day of both laboratory sessions. In case of any positive reading, participants will not be eligible to participate. The results of all pregnancy tests will be kept confidential and the tests will be safely discarded. During the laboratory procedures, an experimenter will be present at all times. Participants will be required to remain in the laboratory until their BAC <.03 g/dL. Participants will be supervised by the experimenter during this period. Participants will also have an opportunity to ask questions of the experimenter. In addition, Dr. Karoly (a trained clinical psychologist) will be on call during all study appointments if any participant experiences negative psychological effects. Risks of CBD Administration. There may be mild physical side effects of CBD consumption, including nausea, fatigue and irritability. In addition, CBD can increase the level in your blood of the blood thinner coumadin. Individuals will be screened out and not allowed to participate in this study if they are taking this medication.

Are there risks associated with psychological well-being?

Yes

Please describe.

Psychological Risk Associated with Questionnaires: Participants may experience some discomfort associated with filling out questionnaires and answering personal questions during baseline and follow-up study sessions. They may also experience embarrassment because of items about medical conditions, health- related behaviors, and stigmatized behaviors, such as alcohol use, cannabis use and use of other legal and illegal psychoactive substances. Protection Against Risks Association With Questionnaires. Participants will be forewarned of this possibility and notified that discomfort with questions may be handled by discussing the resultant discomfort with a trained clinician (e.g., the study PI, Dr. Karoly, a clinical psychologist) to help resolve the issue or, in some cases, by declining to answer particularly troubling questions.

Are there risks associated with economic well-being, including employability?

No

Are there risks associated with social well-being, including reputational risks?

Yes

Please describe.

The Risk of Breach of Confidentiality. A confidentiality breach is possible, but highly unlikely given the precautions taken (see below) Protection Against The Risk of Breach of Confidentiality. The study staff will have access to identifying information, which will be stored in locked filing cabinets. Research data will be stored separately in password-protected documents on a secure, password-protected server.

Describe how the benefits of the research justify the likely risks to participants.

Broadly, the findings of this investigation will increase the body of knowledge about the effects of CBD on alcohol consumption among heavy drinkers. Existing research on the effects of alcohol and CBD together is very minimal, and has has largely used either animal models with extracted synthetic CBD (which differs considerably from the plant-based cannabis used by humans). Data are therefore lacking in terms of the effects of plant-based CBD on alcohol consumption. Thus, the proposed study will ultimately add critical information to the knowledge base regarding alcohol and CBD. These results may inform public policy approaches to harm reduction, which is much needed in states that are legalizing cannabis use. In addition, the proposed study will provide an evidence-base that will inform personal decisions and could reduce harm in individuals who are currently using alcohol and cannabis. The results of this study will be disseminated through national and international scientific conferences, publication in peer-reviewed scientific journals, and press releases to mainstream media outlets. Given that this study could generate highly externally valid data to potentially inform harm reduction efforts at relatively low risk to participants, the risks/benefits ratio seems reasonable. The risks associated with participating have been minimized via procedures described above.

Describe direct research benefits to the participants, if any.

None

Describe the indirect research benefits to society.

This study could benefit public health by increasing our understanding of how cannabidiol (CBD) impacts the brain and body when used in combination with alcoohol. This information may help people who use alcohol and/or cannabis to make decisions about their use, and may help clinicians advise patients regarding cannabis and alcohol use.

Data Management

Data management plans, including plans for data sharing, are integral to project development. How you decide to collect, store, share and/or destroy data impacts your consent process, research procedures, data analysis, and publication.

Responses in this section constitute your plan. For guidance on how to answer these questions and plan for the data lifecycle, reference the resources and tools listed here.

Data Management Services at CSU Libraries
General guidance and unfunded projects (DMPTool)
Funder-specific guidance and templates (DMPTool)

If you choose to create a standalone data management plan (DMP) for your own purposes or at the direction of a funding agency, please attach that document to your protocol, also.
A DMP fillable template is available from CSU Libraries.

How will the data be stored and backed up during the research?

Participant confidentiality is strictly held in trust by the PI. Signed paper consent forms will be stored in a locked filing cabinet in Dr. Karoly's lab. All data, including biological data, from the proposed study will be identified by a numerical ID code only. Self-report data for this study will be collected via individual password-protected laptop computers using Qaltrics. Participant data that is not self-report, such as blood cannabinoid levels, will be reported to the PI with excel sheets that only contain deidentified data points coded by participant ID and that are stored on the lab's password protected server. Adverse events will be documented and reported using the CSU Adverse Event forms (i.e. mild/moderate adverse event form; and the serious/unanticipated adverse event form).

Who will be responsible for data and access management, and security?

Data Access Responsibility

Karoly, Hollis Catherine

Who will have access to study records or specimens?

Personnel

Karoly, Hollis Catherine

Personnel

Drennan, Meggan L

Personnel

Gutierrez,Hector

Personnel

Adams, Tyler Ann

Personnel

Ford,Melanie

Personnel

Weishaar, Megan Marie Gardner

Personnel

Gray, Bethany Ariel

Personnel

Zulic, Leila

Personnel

Crain, Sage A

Personnel

Brefere,Veronica

Personnel

Clark, MacKenzie

Will any external personnel have access to study records or specimens?

No

How will you share the data?

No identifiable data will be released.

Will identifiable data collected as part of the research be released in identifiable form? (e.g., pictures, recordings, responses to research questions, quotes)

No

Will the identifying information be destroyed at a specific date? For guidance, please reference any associated contract or grant (if applicable) and/or the CSU Research Data Policy.

No

What is the long-term preservation plan for the dataset?

Data will be retained in excel spreadsheets indefinitely following project completion. A small amount of blood specimens from each subject will also be retained in a -80degree freezer for up to 5 years following study completion, to facilitate further study should the PI obtain additional funds to pay for additional assays (e.g., to measure inflammatory markers or other markers of health that are commonly collected in heavy drinkers). Identifying information will be destroyed 2 years after project completion. It will be permanently deleted from all servers and computers.

Do you intend to deposit your research data/specimens into a repository for future use?

No

Consent/Assent

Consent

The informed consent process involves presenting potential research participants with the key elements of a research study and what their participation will involve before they decide whether to participate. Please visit the IRB website for templates and guidelines on what information to include.

The default process for gaining consent is to use a signed form. Knowing that this does not always make sense, the IRB can approve alterations to what information is included, waive the requirement to get a signature or waive the requirement to obtain consent altogether when the request meets specific criteria.

Follow the prompts below to describe all consent processes and provide justification for any requested alterations or waivers.

Will informed consent be obtained from all research subjects (and/or their parents or legally authorized representatives)?

Yes

CSU Consent Personnel

- Karoly, Hollis Catherine
- Drennan, Meggan L
- Gutierrez,Hector
- Adams, Tyler Ann
- Ford,Melanie
- Zulic, Leila
- Crain, Sage A
- Brefere,Veronica
- Gray, Bethany Ariel
- Weishaar, Megan Marie Gardner
- Clark, MacKenzie

No

Are you requesting a waiver of documentation of consent?

No

Consent

You do not have any procedures that include deception. If you are going to deceive or incompletely inform any subjects about any aspect of this study describe in the procedures section.

List each consent process

Who will obtain subjects consent?

Personnel
Karoly, Hollis Catherine

Personnel
Drennan, Meggan L

Personnel
Gutierrez,Hector

Personnel
Adams, Tyler Ann

Personnel
Ford,Melanie

Personnel
Zulic, Leila

Personnel
Crain, Sage A

Personnel
Brefere,Veronica

Personnel
Gray, Bethany Ariel

Personnel
Weishaar, Megan Marie Gardner

Personnel
Clark, MacKenzie

Which participant group is this consent process for?
Adult

How is consent being obtained?
In person

Conflict of Interests

For guidance on how to answer these questions and information please visit the CSU Conflict of Interest page.

Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?
No

Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?
No

Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?
No

Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?
No

Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?
No

Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?
No

Significant Financial Interest: Please check Yes or No for each item below.

Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.
No

Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.
No

Minimizing Risks and Disclosure to Subjects

Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required to disclose all such conflicts to all research participants in the research consent form.
No

By submitting this form, you are attesting that you have read Colorado State University's policy on Conflict of Interest and agree to abide by its terms. You will update this disclosure form when new or changes in conflict of interest arise, and that you will comply with any conflict

management plan required by the Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

Attachments

Attach all relevant documentation to your research in this section. Please label each item appropriately, so your IRB reviewers understand the purpose and population each document aims to address. Please delete the existing attachment and upload the Tracked Changes version and Clean revised document for review to update or revise any existing attachments.

Any documentation that a participant will see must be reviewed and approved by the IRB, including consent, recruitment, communications, tools, instruments, etc. Additional documents required for review include funding proposals, contracts, letters of agreement, methodology, related approvals, etc. For more information and guidance on what documentation to attach, please visit the IRB website.

Answers within your application indicate that the following documentation is required:

Attachment Type

Consent

Attachment

CONSENT_CBD ALCOHOL_FINAL (2).DOCX

Name

Attachment Type

Recruitment Materials

Attachment

EMAIL SCRIPTS_UPDATE.DOCX

Name

Attachment Type

Grant or Contract

Attachment

CO-X-20-39.PDF

Name

Attachment Type

Drug Documentation

Attachment

CALIPER TS-002, T-P-S-5_ REV 4.0 .PDF

Name

Attachment Type

Drug Documentation

Attachment

COMPARISON OF FIVE CBD PREPARATIONS (1).PDF

Name

Attachment Type

Data Safety and Monitoring Plan

Attachment

KAROLY_DATASAFETYMONITORING_CBD (1).DOCX

Name

Attachment Type

Other

Attachment

KAROLY LAB SAFETY PLAN(1).DOCX

Name

Attachment Type

Other

Attachment

DOA INFO.DOCX

Name

Attachment Type

Other

Attachment

CONSROE1979_ARTICLE_INTERACTIONOFCANNABIDIOLANDALC.PDF

Name

Attachment Type

Screening Tool or Procedure

Attachment

QUALTRICS REVISED CBD_ALCOHOL_PILOT_2021.DOCX

Name

Attachment Type

Screening Tool or Procedure

Attachment

QUALTRICS REVISED CBD_ALCOHOL_SESSION_1_DEMOGRAPHICS__INITIAL_QUESTIONNAIRES.DOCX

Name

Attachment Type

Recruitment Materials

Attachment

ONLINE AD_CBD ALCOHOL STUDY.DOC

Name

Attachment Type

Screening Tool or Procedure

Attachment

PHONESCREENSCRIPT_KAROLY_CBD.DOCX

Name

Attachment Type

eProtocol History

Attachment

PROTOCOL_INITIAL 20-10303H.ZIP

Name

Attachment Type

eProtocol History

Attachment

PROTOCOL_AMEND 1 20-10303H.ZIP

Name

Attachment Type

eProtocol History

Attachment

PROTOCOL_AMEND 2 20-10303H.ZIP

Name

Attachment Type

Other

Attachment

MF CITI CERTIFICATION.PDF

Name

CITI forms--Melanie Ford

Attachment Type

Other

Attachment

HG CITI CERTIFICATION.PDF

Name

CITI training Hector

Attachment Type

Other

Attachment

CITICOMPLETIONREPORT_DRENNAN.PDF

Name

Meggan Drennan CITI

Attachment Type

Other

Attachment

TAYLOR_GROUP1.PDF

Name

CITI_TaylorSullivan

Attachment Type

Other

Attachment

TAYLOR_RCR.PDF

Name

CITI_RCR_ TaylorSullivan

Attachment Type

Other

Attachment

TAYLOR_GCP.PDF

Name

CITI_GCP_Taylor Sullivan

Attachment Type

Attachment

MARISSA_CITI.PDF

Name

Attachment Type

Attachment

MARISSA_RCR.PDF

Name

Attachment Type

Attachment

MARISSA_GCP.PDF

Name

Attachment Type

Other

Attachment

CITI CERT_CODY.PDF

Name

CITI_Cody Conner

Attachment Type

Other

Attachment

TABITHA_CITI CERT.PDF

Name

CITI_TabithaMcMichael

Attachment Type

Other

Attachment

PATRICK_CITI.PDF

Name

CITI

Attachment Type

Other

Attachment

PATRICKRCR.PDF

Name

RCR

Attachment Type

Other

Attachment

CITI_HUMANRESEARCH_MC.PNG

Name

MacKenzie Clark human research citi training certificate

Attachment Type

Other

Attachment

CITI_RCR_MC.PNG

Name

MacKenzie Clark RCR citi training

Attachment Type

Other

Attachment

DANIELLEOLSON_HUMANRESEARCH.PDF

Name

Attachment Type

Other

Attachment

DANIELLEOLSON_RESPONSIBLECONDUCT.PDF

Name

Attachment Type

Recruitment Materials

Attachment

C CBD ALCOHOL FLYER 2.DOCX

The Principal Investigator is ultimately responsible for the conduct of this project. Obligations of the Principal Investigator include the following:

- **Receive IRB approval or determination prior to enrolling any subjects or collecting any data intended for research use.**
- **Manage and maintain all research records, including consent retention, for at least three (3) years after the close of the study, or longer per sponsor requirement.**
- **Ensure that personnel training status remains current.**
- **Provide all subjects a copy of the signed consent form, when applicable.**
- **Keep protocol up to date by submitting amendments for review and approval before instituting changes in any aspect of the study.**
- **Maintain current protocol approval by submitting renewals, as required.**
- **Promptly report any violations, deviations, unanticipated problems or adverse events to the IRB.**
- **Notify the IRB when the study is complete and take steps to close the protocol.**

I understand that as the Principal Investigator I am fully responsible for the execution and management of this

study and that I am responsible for the performance of any sub-investigators or key personnel including their adherence to all applicable policies and regulations. I understand and agree to the obligations listed above.

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge.

Administrative Details Form

Determinations

Review Type

Study Status