



Principal Investigator (PI) Handbook: Administration of Alcohol in Human Research

In addition to Human Research Protection Program (HRPP) approval of a research study proposal, other approvals must be in place for the purchase and storage (if applicable) of alcohol and the campus space to be used for administration of alcohol for research purposes.

This handbook includes required approvals and resources for planning your study.

****The *Supplemental HRPP Questionnaire* on page 12 must be submitted in eCompliance along with your HRPP Protocol. The study will not be reviewed without this supplemental questionnaire.**

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PI Guidance for Administration of Alcohol in Human Subjects Studies

1. **PI requirements:** The Principal Investigator (PI) or Faculty Supervisor of the research protocol must be a KU faculty member or have Office of Research Principal Investigator status.
2. **Study Team requirements:**
 - All study team members who handle alcohol must be 21 years of age or older.
 - All study team members must have taken the [Biomedical Research - Basic/Refresher CITI module](#) within the past 3 years.
 - The PI, or Faculty Supervisor of a student PI, is expected to train study team members in experimental procedures and risks and safeguards, including emergency response, for human subjects.
3. **IRB review of studies**
 - All studies involving administration of alcohol in human research will require full IRB review. Plan at least 4-8 weeks for approval. If proposing space other than the CLC, additional time may be needed to secure approval.
 - The IRB will consider studies that adequately address:
 - Proper screening of subjects to eliminate people with contraindicated medical conditions or medications, have a history of or meet DSM-5 criteria of moderate or severe alcohol use disorder, current participation in an alcohol or substance use treatment program, or history of alcohol or substance use disorder, seeking treatment, planning on reducing use in the near future, or subjects who are alcohol naïve.
 - Adequate staffing, equipment, and supplies
 - Emergency response plan
 - Experimental procedure that raises blood alcohol level no higher than a level that the subject has reached with self-administration on at least some occasions in the past year.
 - Recruiting from a class where the activity fulfills a requirement or offers extra credit for the course is strongly discouraged.
 - PI and study team must not recruit students from classes they teach
4. **Consent form language**
 - For pregnancy-capable people: Consuming alcohol while pregnant is associated with health risks. You may choose to take a pregnancy test to be sure you are NOT pregnant prior to participating in the study. The pregnancy test will be provided by research staff at no charge to you. If you are pregnant, you will not be eligible to participate further in the study.

- Leaving prior to adequate detox
 - Your blood alcohol level will be monitored, and you will be released to take a cab home when your BAC is 0.04 or less. A BAC of 0.02 is the maximum amount of alcohol allowed to drive a vehicle.
 - If you decide to leave the study location prior to BAC returning to a safe level, staff will encourage you to stay to ensure your safety. If you still decide to leave with a BAC over .04, research staff may call authorities to alert them for your safety.
 - Screening for eligibility – You are encouraged to talk with your medical care provider prior to the study session if you have any health concerns listed on the [List of Contraindicated Medications and Medical Conditions](#), to better understand the risks posed by your personal health status.

5. Who can be a participant?

- Adults over the age of 21
- Screening tools and general procedures
 - *Questionnaire (AUDIT)* for alcohol use disorder to rule out:
 - Contraindicated medications or medical conditions
 - Current alcohol use disorder or participation in treatment program

6. Acceptable dosing and recovery schedules, including max dosing anticipated.

- Refer to *List of Resources* in the Administration of Alcohol in Human Research PI Handbook for BAC charts and calculator
- The maximum anticipated BAC should not exceed a level that the subject has reached with self-administration on at least some occasions in the past year.

7. Participant Release and Emergency Response Plan

- The study team should provide safe transportation home after detoxification
 - BAC must be 0.02 or lower to fully release participants
 - If BAC is above 0.02, participants must be provided a paid vehicle to their home address.
 - The study team must notify the KU Police Department when conducting a study involving the administration of alcohol to provide dates when participants will be provided alcohol.

8. Record-keeping and security

- Records must be kept regarding dosage, number of drinks (and ounces) consumed by individuals
- Appropriate security plan for storing personal identifiable information (PII), including responses to screening questionnaires and other study data

9. Scientific justification

- Required if there has been no peer review or if study is outside of parameters above and in the Policy on Administration of Alcohol in Human Research.
 - Literature review of previous studies. How this is building upon previous studies, and how methodology compares to other studies.

10. Approved location: Studies must occur in pre-approved spaces on the KU-Lawrence campuses. Study proposals that will not use the infrastructure of the Cofrin Logan Center for Addiction Research and Treatment (CLC) will need to provide justification for conducting the research outside the CLC and will need to obtain additional approvals for appropriate facilities, alcohol storage, and sufficient equipment and supplies to support the study sessions.

- Cofrin Logan Center (*preferred*)
 - Researchers interested in collaborating with the CLC should contact the CLC to discuss feasibility prior to submitting the study to HRPP.
- For approval of location other than the CLC, refer to *Appendix A in the Supplemental HRPP Questionnaire* for addressing space considerations in your IRB application. HRPP will review and coordinate approval of the space through the appropriate University offices. Allow extra time to prepare a proposal for space other than CLC.
- The KU Lawrence campus does not yet have clinical facilities to support overnight stays for human research projects.

11. Research use and authority for purchase of alcohol: Use of alcohol in human research is considered a non-beverage (i.e. research) use according to Kansas law.

- Unless collaboration arrangements have been made with the CLC, the PI or Faculty Supervisor is responsible for purchasing the alcohol and returning documentation to KUCR.
- Purchase of alcohol for use in human research must be in accordance with the procedures for one-time purchase permits granted to research institutions.
- All alcohol for human research at KU-Lawrence must be purchased using KU or KUCR funds.
- KUCR Fiscal Affairs will apply for the permit and submit documentation to the State of Kansas, as required.
- The PI is responsible for ensuring the security of the alcohol and for tracking purchase and usage of alcohol using the *Inventory-usage Log template* or substantially similar form.

12. Storage and security of alcohol must be in accordance with Environment, Health and Safety (EHS) requirements. In addition, alcohol is a controlled substance and must be kept with proper security.

- For collaborations with the CLC, the CLC will be responsible for storing alcohol. PI and all study team members must follow CLC procedures for handling and documentation of alcohol use.

- Alcohol must be stored in a designated, lockable room, in a locked cabinet with limited access, on the KU campus.
- Individual containers of alcohol must be no more than 5 liters or 1.3 gallons.
- Total volume of alcohol in all containers must be under 10 gallons in one location.
- Greater amounts of alcohol than described above must have [KUEHS](#) approval and appropriate hazardous material containment.
- Any unused alcohol must be disposed of in accordance with EHS hazardous materials disposition requirements.

13. Minimum equipment and supplies

- For collaborations with the CLC, the CLC will provide appropriate equipment and supplies
- For non-CLC collaborations, the following considerations are needed:
 - Quality of equipment, sufficiency of supplies
 - (certain grade and adequately calibrated) Breathalyzer
 - Scale for weighing participants (for calculating dosage and detox time)
 - Measuring + mixing equipment
 - Pregnancy tests
 - Snacks and drinks for detox
 - Printed copy of protocol and consent procedures for research staff

Participant Screening Template

A. AUDIT (Alcohol Use Disorders Identification Test)

As a WHO-approved instrument, the AUDIT is in the public domain. Please reference the AUDIT directly for scoring.

Please select your gender.

- ☐ Male
- ☐ Female

1. How often do you have a drink containing alcohol?

- ☐ Never (0)
- ☐ Monthly or less (1)
- ☐ 2-4 times a month (2)
- ☐ 2-3 times a week (3)
- ☐ 4 or more times a week (4)

2. How many standard drinks containing alcohol do you have on a typical day when drinking?

- ☐ 1 or 2 (0)
- ☐ 3 or 4 (1)
- ☐ 5 or 6 (2)
- ☐ 7 to 9 (3)
- ☐ 10 or more (4)

3. How often do you have six or more drinks on one occasion?

- ☐ Never (0)
- ☐ Less than monthly (1)
- ☐ Monthly (2)
- ☐ Weekly (3)
- ☐ Daily or almost daily (4)

4. During the past year, how often have you found that you were not able to stop drinking once you had started?

- ☐ Never (0)
- ☐ Less than monthly (1)
- ☐ Monthly (2)
- ☐ Weekly (3)
- ☐ Daily or almost daily (4)

5. During the past year, how often have you failed to do what was normally expected of you because of drinking?

- ☐ Never (0)
- ☐ Less than monthly (1)
- ☐ Monthly (2)
- ☐ Weekly (3)
- ☐ Daily or almost daily (4)

6. During the past year, how often have you needed a drink in the morning to get yourself going after a heavy drinking session?

- ☐ Never (0)
- ☐ Less than monthly (1)
- ☐ Monthly (2)
- ☐ Weekly (3)
- ☐ Daily or almost daily (4)

7. During the past year, how often have you had a feeling of guilt or remorse after drinking?

- ☐ Never (0)
- ☐ Less than monthly (1)
- ☐ Monthly (2)
- ☐ Weekly (3)
- ☐ Daily or almost daily (4)

8. During the past year, how often have you been unable to remember what happened the night before because you had been drinking?

- ☐ Never (0)
- ☐ Less than monthly (1)
- ☐ Monthly (2)
- ☐ Weekly (3)
- ☐ Daily or almost daily (4)

9. Have you or someone else been injured as a result of your drinking?

- ☐ No (0)
- ☐ Yes, but not in the past year (2)
- ☐ Yes, during the past year (4)

10. Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested you cut down?

- ☐ No (0)
- ☐ Yes, but not in the past year (2)
- ☐ Yes, during the past year (4)

B. Age

1. What is your current age? _____

C. Alcohol Use

1. Have you ever had an allergic reaction to alcohol (e.g., irritated skin, swelling, etc.)?

- ☐ Yes
- ☐ No

2. Are you currently trying to reduce your alcohol intake?

- ☐ Yes
- ☐ No

3. Are you currently participating in an alcohol or substance use treatment program? (e.g., therapy, medication management)

- ☐ Yes
- ☐ No

4. Have you had at least one alcoholic beverage in the past 30 days?

- ☐ Yes
- ☐ No

D. Medications and Health Conditions

1. Do you currently take medications for alcohol or substance use disorders? (e.g., disulfiram, acamprosate, buprenorphine, methadone, or naltrexone)

☐ Yes

☐ No

2. Please list all medications you are currently taking, including prescriptions and non-prescribed medications.

3. Please list any health conditions you have that could be impacted by alcohol use. Such as:

☐ Cardiac (heart) conditions

☐ Diabetes

☐ Liver disease

☐ Compromised immune system

4. Are you currently pregnant, nursing, think you may be pregnant, or planning to become pregnant?

☐ Yes

☐ No

Usage log for non-beverage use of alcohol in human research

Study number, title: Alcohol must be stored in a locked cabinet in a locked room on campus.
 PI name: Individual containers must not be larger than 5 liters (1.3 gal).
 PI telephone, email: Total volume stored (all containers) must not exceed 10 gallons.
 Building, Room: If more than one container will be stored,
 Cabinet key-holder: log purchases on INVENTORY tab; refer to Container Ref No on USAGE tab
 Funding source:

Date	Container Ref. No.	Description	Activity	Start amount	Amount used	End amount	Responsible study team member
			Purchase		n/a	n/a	
			Research use				

Resources

KU will not provide funds for accessing resources, and KU does not endorse any of these resources.

NIAAA (National Institute on Alcohol Abuse and Alcoholism)

[Council Guidelines for Administering Alcohol in Human Studies](#)

BLOOD ALCOHOL LEVELS

[Notre Dame BAL Chart](#)

[UC-Davis BAL Chart by Weight](#)

[NIAAA Alcohol Overdose](#)

[Blood Alcohol Concentration \(BAC\) Calculator](#)

ALCOHOL RISKS TO HEALTH

[NIAAA Alcohol Effects on the Body NIAAA](#)

[Alcohol Effects on Health](#)

MEDICATION INTERACTIONS

[NIAAA Harmful Interactions](#)

KS LAW and PROCEDURES

[KS Statutes K.S.A. 41 Intoxicating Liquors and Beverages](#)

[KS Statute K.S.A. 15 Uniform Act Regulating Traffic; Rules of The Road](#)

[Handbook for Non-Beverage Alcohol Users](#)

[Non-beverage Permit Application and Agreement](#)

[Non-beverage Permit Online Application Site](#)

KU POLICIES

[Alcohol Service at Events Mandatory Alcohol](#)

[Education Policy Alcohol & Drug Policies](#)

[Brochure Cost Accounting, KUCR](#)

[Administration of Alcohol in Human Research](#)

*****Download a copy of the Alcohol in Human Research Supplemental Questionnaire (.docx) to submit with your HRPP protocol.**

Alcohol in Human Research Supplemental Questionnaire

All fields are required. Upload your completed questionnaire as an attachment to your new study submission in eCompliance.

PI:	Faculty Supervisor:
Short title:	

Anticipated duration of study: _____ months / years

Location of Alcohol Administration (must be on KU campus)

☐ **Cofrin Logan Center (CLC) facilities**

I have discussed my study with Cofrin Logan Center and have received permission to conduct the study in the facility, pending HRPP approval.

☐ **Other location:** I plan to use another campus facility. Facility must be proposed and approved through the Office of Research before HRPP approval for the study is granted.

Purchase and Storage of Alcohol

☐ Alcohol will be obtained through CLC

☐ Alcohol will not be purchased through the CLC

1. List the source(s) of the funds to be used for alcohol purchase (must be KU or KUCR): [Click or tap here to enter text.](#)
2. Approximate amount of alcohol anticipated to be used in the 12 months following approval (e.g., # participants x # amount administered x #sessions range): [Click or tap here to enter text.](#)
3. Describe where alcohol will be stored. [Click or tap here to enter text.](#)
4. Describe how you will monitor participants' alcohol intake. Explain how you will calculate the amount of alcohol to be given to a participant. [Click or tap here to enter text.](#)
5. Describe your plan for transfer or disposal of unused alcohol. [Click or tap here to enter text.](#)

Participant screening procedures

Describe your screening procedures, including how you will eliminate individuals with contraindicated medical conditions or medications, or people who may have an alcohol use disorder.

Click or tap here to enter text.

Administration procedures

Describe procedures for administering alcohol to participants, including staff to participant ratio, approximate duration of sessions, and target blood alcohol concentration. If you will administer over a level that the subject has reached with self-administration on at least some occasions in the past year, provide a scientific justification for administering this amount.

Click or tap here to enter text.

Participant detoxification and release plan

1. Describe your procedures for monitoring participants during the detoxification procedure. List any items provided to participants during detoxification (e.g., food, drinks, games). Click or tap here to enter text.
2. Describe your procedure and requirements for releasing participants from participation. *Please note that **BAC must be .04 or lower** to release participants.* Click or tap here to enter text.

Emergency plan

Describe your emergency response procedures if a participant has a medical emergency or leaves prior to appropriate detoxification. List any resources that will be used (e.g., KU Public Safety, Watkins Health Services, 911, etc.). Click or tap here to enter text.

Certifications:

All study team members who will handle alcohol are 21 or older.

KU investigator acknowledgement statement

- ☐ I understand that KU or KUCR funds must be used to purchase alcohol for non-beverage use in human research and that the receipt with a copy of the permit must be submitted to KUCR Fiscal Affairs, which will file required documentation with the Kansas Department of Revenue.
- ☐ I understand alcohol is a controlled substance and that alcohol purchased for human subject research use must only be used for university-approved research purposes and in accordance with [Kansas Liquor Laws](#) and University policy.
- ☐ I understand that any breaches of approved use must be reported, including unauthorized use or the discovery of apparent undocumented use. PI must report breaches through a Report of New Information (RNI) in eCompliance.

Appendix A

Use only if you plan to conduct research at another facility other than CLC.

Considerations for Approval of KU-Lawrence Campus Facilities for Administration of Alcohol in Human Research

Describe the location (include buildings and room numbers) where you plan to conduct the study.

Describe how the space you intend to use meets each of the criteria checked below.

Click or tap here to enter text.

Building/Location

- ☐ Separate locations for study procedures and detoxification/recovery
- ☐ Space is private and closed to the public
 - ☐ Not possible for people external to the study to enter the facility or room
- ☐ On KU Lawrence campus, not in classroom space
- ☐ Separate locations for study procedures and detoxification/recovery
- ☐ Adequate space for administration of alcohol
 - ☐ Comfortable location
 - ☐ Close proximity to restrooms
- ☐ Adequate space for detoxification procedures
 - ☐ Comfortable room/seating
 - ☐ Close proximity to restrooms
 - ☐ Activities available to pass the time (e.g., TV, media, reading material, games)

Storage of Alcohol or Other Controlled Substances or Devices

- ☐ Storage is secure (e.g., locked cabinet in locked room, limited access)
- ☐ Usage records are kept
- ☐ Amount of alcohol does not exceed EHS parameters listed on PI Guidance

Equipment

- ☐ Professional-grade breathalyzer
- ☐ Scale for weight of subjects (to figure dosage, calculate max BAC)
- ☐ Adequate pregnancy tests available for all participants who could be pregnant
- ☐ Food for detoxification/recovery
- ☐ Soft drinks for detoxification/recovery

Permission/Approval/Record-Keeping

- ☐ Administration of alcohol in human subjects (HRPP)
- ☐ Facility setup and location on campus (Office of Research)
- ☐ Calibration schedule and records for breathalyzer
- ☐ Usage logs of alcohol supply
- ☐ Notifications to Public Safety