

Guidance on Research involving Alcohol Administration

The University of New Mexico conducts research on many types of disorders, including substance abuse and other addictive behaviors. Therefore, it is important to provide recommendations and establish guidelines for working with research participants who may become intoxicated as part of participation in a research study.

Considerations

- Principal Investigators (PIs) are ultimately responsible for ensuring the safety of their research participants and staff. If it is anticipated that the study will involve intoxicated participants, it is recommended that research staff are appropriately trained and a study specific checklist or plan be developed using this guidance.
- Participants should be appropriately screened, depending on the nature of the research, including verification of legal drinking age.
- Consider whether proposed participants are drug or alcohol abusers, and whether their participation is likely to expose them to harm.
- If potential participants have completed the initial phase of treatment for addiction and progressed into rehabilitation or recovery, their involvement in research in which alcohol will be administered requires extremely strong scientific justification and risk/benefit assessment.
- It is considered inappropriate to administer alcohol to any recovering alcoholic who is abstinent and living a sober life in the community.
- Adequate provisions must be made to eliminate the risk of alcohol impairment before the participant leaves the research site.
- It is the PI's responsibility to procure all necessary equipment for their studies, including breathalyzer, pregnancy tests, specimen cups, and any other materials needed for testing (e.g. calibration supplies, latex gloves, food/drink, droppers/pipettes, etc.). Equipment used to assess blood alcohol level (BAL) must be routinely calibrated and a procedure for assessing accuracy and reliability of the equipment is required in the research protocol.

Recommended Guidelines

Screening participants for an alcohol challenge study:

- Potential participants should be screened and excluded for alcohol dependence (recommend use of Alcohol Dependence Scale (Harvey A. Skinner and John L. Horn); score of 8 or higher is considered dependent). Consider providing these individuals with referrals for community addiction resources (e.g. UNM Alcohol Clinic).
- Exclude individuals who are in recovery for alcohol or drug addiction.
- Screen individuals for medications that are contraindicated for alcohol use including, but not limited to:
 - antidepressants,
 - anxiolytics,
 - daily insulin,
 - long term antibiotics or pain medication,
 - medications for ADD or ADHD (e.g. Ritalin, Adderall).
- Possibility of pregnancy in females should be assessed using urine testing prior to each

alcohol administration.

- Consider excluding individuals who are trying to reduce their alcohol consumption.

Participants who become intoxicated from participation in a study:

- In New Mexico, a person can be arrested for driving with a BAL (blood alcohol level) **>.000**. A person can be convicted of DWI even if the breath or blood test is below the legal limit (.080) if it is proven that their ability to drive was impaired to the slightest degree by drugs or alcohol. Therefore, it is recommended that you do not allow any participant (or potential participant) to drive themselves home with a BAL **>.000**. In order to release participants with a BAL **>.000**, you must have documented IRB approval to do so, as well as a clearly documented procedure for release of these participants.
- Participants who have a BAL **>.000** can be offered a variety of options for release:
 - Have a friend or family member pick them up.
 - Wait until their BAL = **.000** and then drive home.
 - Cab ride home.
 - (If medically indicated), walk the person to UNM Hospital Emergency Room or call 911. Do not leave the participant unsupervised until a resolution is reached (so that they do not leave and drive intoxicated).
- During detoxification, allow participants to wait and rest in a comfortable area with bathroom facilities nearby that do not require unnecessary effort to access. Provide water, non-alcoholic beverages, and snacks as needed.
- A detoxification checklist is provided (Appendix 1) that contains sample procedures to follow and document the detoxification process.
- If the participant has a BAL $\geq .08$ (considered legally intoxicated) and insists on driving home and/or leaves without authorization, and/or is belligerent and you are worried about your safety and/or the safety of others, notify police with jurisdiction over the geographical areas of the performance site (e.g. APD or UNM police).

See NIAAA guidelines: <http://niaaa.nih.gov/Resources/ResearchResources/job22.htm>

Appendix 1 Detoxification Checklist

If person is intoxicated from participation in a research study:

- Allow the participant to wait and rest in a comfortable area with bathroom facilities nearby that do not require unnecessary effort to access. Provide food and water as needed.
- Monitor the participant on a continuous or near-continuous basis in a way that is non-intrusive.
- Take a breathalyzer reading every 30 minutes until their BAL = .000. Release BAC values should be confirmed by at least two readings.

BAL	Time	Level
30 min		
60 min		
90 min		
120 min		

NOTE: Participants are not to drive home; in NM, you can get arrested for driving with a BAL >.000. It is important to not leave the participant unsupervised until the individual is sober.

If their BAL increases, they are not willing to retake a breathalyzer, or if their BAL does not decrease in the allotted timeframe:

- Document that the following were suggested by initialing each option:
 - _____ 1. Have a friend or family member pick them up.
 - _____ 2. Wait until their BAL is .000 and then drive home.
 - _____ 3. Provide them with a cab ride home.
 - _____ 4. (If medically indicated), walk them to UNM Hospital Emergency Room or call 911.
- Document which option the participant has chosen:

If the participant has a BAL \geq .08 and insists on driving home and/or leaves unadvised, and/or is belligerent and you are worried about your safety and/or the safety of others, you must call campus security or the police. This is the only time you can violate confidentiality.

If this step is necessary, explain what happened and why this step was taken.

Researcher Signature/Date: _____