Considerations when Conducting Alcohol Administration Studies

In 2023 the National Institute on Alcohol Abuse and Alcoholism (NIAAA) updated its 2001 guidance, "Administering Alcohol in Human Studies". This document reflects the updated guidance and puts forth a set of requirements and recommendations for researchers who administer alcohol during the course of their research involving human participants. The Virginia Tech's Institutional Review Board will consider these requirements and recommendations when reviewing research and have the right to approve, approve with modifications, and disapprove research.

Participant population (inclusion/exclusion criteria)

- Alcohol should not be administered to:
  - Alcohol-naïve participants;
  - Individuals who have sustained a period of abstinence while living in the community;
  - Anyone under the minimum drinking age of 21; and
  - Pregnant women.
- Special consideration needs to be given to the risk/benefit assessment of individuals who are at risk for the development of alcohol use disorder (AUD), including individuals with a family history of abuse or other alcohol-related problems. If the research must include individuals with AUD, the researcher must include:
  - Medical exams, evaluations, and screening to ensure the participant does not have any conditions for which further alcohol exposure would interfere with other medical conditions or treatment; and
  - Assessments of current treatment-seeking status, duration of abstinence with the treatment regiment, and the risks entailed through exposure to alcohol.
- Individuals who are seeking treatment for AUD or alcohol-related problems must be excluded from the research, unless there is a strong justification for why the research cannot be done without these individuals.
- For studies that intend to elicit a reaction such as withdrawals or cravings, duration of abstinence should be consistent with what is typically experienced by the participant.
- If it is necessary to include participants over the age of 65, they must be carefully screened and monitored for health conditions and potential adverse medical consequences associated with alcohol administration.

Alcohol Exposure Levels

- The inclusion/exclusion criteria should be evaluated to ensure that participants alcohol consumption does not exceed their normal consumption and lead to a higher blood alcohol concentration (BAC); should be based on consumption within the last year.
- Consent form should clearly state the amount of alcohol to be consumed (no. of drinks), their concentration, total volume, route of administration, and time allotted for consumption.
- Participants should not consumer more alcohol than they are comfortable with.
- Consumption should not exceed the target BAC.

- Consumption will vary based on the participants age, gender, height, and weight.

Post Administration

- Participants must not be discharged until their BAC is between 0 - .02%.
- Participants should be informed that even after they have reached the ideal BAC threshold:
    - There is the potential for prolonged impairment;
    - Operating complex machinery or performing functions that require concentration should be avoided; and
    - They may experience hangover symptoms.
- Follow-up assessments should be performed on anyone that has an adverse reaction, reports high-risk drinking patterns, or is diagnosed with AUD. Interventions and treatment referrals should be offered when appropriate.

Medical Oversight

There are many factors that can influence or lead to adverse medical consequences of alcohol administration. This can be compounded when alcohol is administered with another drug. All of these must be factored into the risk assessment and in characterizing the potential adverse consequences. A study physician or clinician should be available to assess risks and provide medical oversight throughout the study.

Depending on the nature of the research and the experience level and expertise of the research team in conducting alcohol administration studies, the research team should consider the following options for meeting the requirement for medical oversight.

1. Require the study team to include a study physician or clinician as a member of the research team.
2. Require the study team to have a physician or clinician, who is familiar with the study, on call.

References and Resources:

National Institute on Alcohol Abuse and Alcoholism Guidance for Conducting Alcohol Administration Studies with Human Participants, 2023