

National Institute on Alcohol Abuse and Alcoholism

Recommended Council Guidelines on Ethyl Alcohol Administration in Human Experimentation

Prepared by the

National Advisory Council on Alcohol Abuse and Alcoholism

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Alcohol, Drug Abuse, and Mental Health Administration

NOTE:

The National Advisory Council on Alcohol Abuse and Alcoholism advises the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the Secretary of the Department of Health and Human Services (DHHS) on program and policy matters in the field of alcohol abuse and alcoholism. The recommended Council Guidelines represent National Advisory Council recommendations for consideration by research grant applicants, Institutional Review Boards, Initial Review Groups, and others in the alcohol research field. The recommended Council Guidelines are not official Federal NIAAA or DHHS regulation or policy.

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**Recommended Council Guidelines on Ethyl  
Alcohol Administration in Human Experimentation**

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The Belmont Report, April 18, 1979

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**I. PREAMBLE**

It is recognized that much of our knowledge of biological and behavioral actions of alcohol (all references to alcohol in the context of this document are limited to ethyl alcohol), including knowledge relevant to treatment and prevention of alcoholism and alcohol problems, has been attained through research involving alcohol ingestion by human subjects ([see Endnote 1](#)). The National Advisory Council on Alcohol Abuse and Alcoholism ([see Endnote 2](#)) fully recognizes the need for research with human subjects including, as appropriate, research which involves consumption of alcohol by humans. The Council views such research as essential for an understanding of alcohol's actions, including reinforcement, tolerance, and dependence. Such research is critical to development of more effective prevention and treatment programs for alcohol abuse and alcoholism. This research must be developed with full attention paid to the fundamental ethical principles which govern all research with human subjects.

Fundamental ethical principles for research involving human subjects include the concepts of respect for persons, beneficence, and justice. These principles have been well summarized in a report issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavior Research, titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" ([The Belmont Report](#)), (OPRR Reports, NIH, PHS, DHHS, April 1979, FR Doc. 79-12065). The general principles of ethics in human investigation are also addressed in such documents as the Nuremberg Code of 1946, The Helsinki Declaration of 1964 (revised in 1975 and again in 1983), in guidelines from professional organizations, such as the American Psychological Association, and in a number of relevant books including [Ethics and Regulation of Clinical Research](#), authored by Robert J. Levine (Urban and Schwarzenberg, Baltimore-Munich Second Edition 1986). As a comprehensive presentation of the fundamental ethical principles of research is beyond the scope of the Council guidelines, The Belmont Report is provided. It can be located at the following Web site: <http://helix.nih.gov:8001/ohsr/mpa/belmont.phtml>.

From these ethical principles, important aspects of research practice are derived. From “respect for the person” is derived requirements for attainment of meaningful informed and voluntary consent. From “beneficence” is derived the principles of not doing harm and, wherever possible, promoting the well-being of the research subjects and other individuals with a similar disease, or society as a whole. From “justice” is derived principles related to the selection of research subjects: to not place specific subjects at risk merely because of convenient access to a population, a compromised position of the subjects, or the potential of the individuals to be manipulated; to not unduly involve persons in research protocols (when there is more than minimal risk) who are unlikely to be among the beneficiaries of subsequent applications of the research.

The Council notes that responsibility for development and implementation of ethical research protocols falls upon more than one individual or group. It rests first with the principal investigator and next with the Institutional Review Board (IRB), as required by the Code of Federal Regulations (CFR), 45 CFR Part 46, "Protection of Human Subjects." The IRB reviews all HHS conducted or funded research protocols involving human subjects, and IRB approval is required for research involving human subjects. The subsequent levels of review (for projects supported by the Institutes of the Public Health Service) are, in turn, the Initial Review Groups (IRGs) and the National Advisory Council. Though these bodies are not provided the same extensive detail on human subject protocols as provided to IRBs, they are required to call attention to any issues for which there may be ethical concerns. Human subject concerns raised by either the IRG or Council are conveyed to the principal investigator as well as to the applicant's institution. The program staff of the Institute, in consultation with the Office for Protection from Research Risks (OPRR), of the National Institutes of Health, have the responsibility for resolving Council human subject concerns, before any study involving human subjects can be undertaken.

## **II. PURPOSE OF THE GUIDELINES**

The Council guidelines focus on issues related to experimentation involving alcohol administration to human subjects in the context of the ethical principles noted above. The Council guidelines are intended to identify potential problematic issues, and to serve as a guide to help ensure that appropriate consideration is given to relevant issues in the development and review of research protocols involving alcohol administration.

The guidelines are not intended to supplant the functions of the IRB, or of OPRR. The guidelines are advisory to applicants, IRBs, IRGs, and others; they are not codified and do not constitute Federal regulation. Rather, the guidelines are intended to reflect a sensitive, ethical approach which is also consistent with current research practices and experience in the field of alcohol research.

It has been observed that not all IRBs have addressed issues surrounding administration of alcohol uniformly. IRBs, as well as applicant sensitivity to the issues, are often related to prior experience with similar issues in alcohol or related research. The Council suggests that IRBs

should consider obtaining outside expertise when they do not have sufficient familiarity with alcohol research issues.

The recommendations contained within the guidelines are in no way meant to interfere with the recovery for any individual for any disease, including alcoholism. Accordingly, it is recognized at this time that the accepted and appropriate goal of alcoholism treatment is abstinence.

### III. GENERAL ISSUES

The Council recommends consideration of a number of general issues applicable to all alcohol research involving human subjects, regardless of the specific population. These issues are presented here:

**Risk/Benefit:** A careful appraisal of the risk/benefit ratio is a critical aspect in the assessment of the appropriateness of a research protocol. This need derives from the ethical principle of beneficence (see above). In most contexts, the risk pertains to the research subject though, in some circumstances, it could be broader and encompass the group or society. Benefit must be considered first in the context of the research subject. Benefit may also encompass the broader context of other individuals with a similar disease (where applicable) or of humankind. There must be a reasonable balance of risk against potential benefit; without such a reasonable balance, a research protocol cannot be justified ethically. For example, even a minimally invasive study involving merely the drawing of one milliliter of blood may be considered to have an unfavorable risk/benefit ratio in a poorly conceived study. Alternatively, more highly invasive procedures could be judged to have an acceptable risk/benefit ratio in a well-developed and important study.

The qualifications and experience of the research team must be considered in weighing risk/benefit. Depending on the level of expertise of the research team, a project may not be judged to have an acceptable risk/benefit ratio even if the project has a sound scientific hypothesis and a good research design.

Similarly, the site for conduct of the research may influence the risk/benefit decision.

Within this context, the Council recommends consideration of the appropriateness of the qualifications of those who assess the risk/benefit ratio. Such individuals should be experienced and/or knowledgeable in clinical research issues. A particular degree (M.D., Ph.D., etc.) neither qualifies nor disqualifies an individual from participation in this assessment process.

The Council also notes that it is appropriate that the principal responsibility for approval of a research project involving human subjects rests with the IRB. Though both the IRG and Council have a responsibility to consider human subject issues, it is the local institution, and its IRB, which are most aware of the many subtle factors involving the research team's qualifications in similar studies, the suitability of the research site, and local policies and norms affecting the acceptability of proposed procedures.

**Informed Consent:** The Council reiterates the basic principle that the investigator has the responsibility of assuring that the informed consent process gives the research subjects all the information they need to make a voluntary and informed decision. IRBs, as well, should assure that the informed consent documents convey all relevant information in language readily understandable by the research subject or guardian. The Council also believes it appropriate that every informed consent form should indicate that the drug, alcohol, is a toxin and a reinforcing agent which may cause changes in behavior, including repetitive or excessive consumption. Such a statement would appropriately acknowledge that alcohol is not an innocuous substance, and that everyone who drinks alcohol is at some risk.

Also, the Council recommends that due consideration should be given to the cognitive, physiologic, and motivational states of the individuals in terms of their ability to fully understand the context of the informed consent. Individuals who are severely intoxicated or in a confusional withdrawal state are unable to give true informed consent. Alternatively, a blood alcohol concentration (BAC), of zero for the potential subject may not be a required prerequisite, depending upon cognitive capabilities of the individual at that time. If there is a question of a potential subject's ability to give meaningful informed consent, an independent clinician, ethical consultant, or uninvolved third party with appropriate qualifications may be asked to evaluate this ability.

**Subject Selection:** The Council emphasizes the need for care in subject selection so that appropriate subjects are utilized to address the research question and so that adequate safeguards are followed to prevent unnecessary risk to subjects. Included under this issue is the need to avoid using subjects merely because of their easy availability, low social or economic status, or limited capacity to understand the nature of the research. Also included under this category is the need to consider the subject's age, sex, familial or genetic background, prior alcohol use, other drug use, and general medical and psychological condition, including, if appropriate, alcoholism recovery status. The issues relating to subject selection are addressed in more detail in the following section on specific issues.

**Confidentiality:** Investigators should be aware that once alcohol histories are placed in charts, such charts have to be handled with the same confidentiality afforded other alcohol records for which requirements sometimes go beyond those for many other medical or research records. Special Federal requirements that apply to certain alcohol records used in research are addressed in the Code of Federal Regulations (CFR) under 42 CFR Part 2, "Confidentiality of Alcohol and Drug Abuse Patient Records."

#### **IV. SPECIFIC ISSUES**

The Council believes that many of the issues are best expressed in the context of questions to be considered by applicants and IRBs. These are issues which the applicant should be addressing in the context of the risk/benefit analysis. Discussion of these issues is provided immediately following each question.

**Question:** Is the investigator assessing whether the potential subjects have a current or prior drinking problem, and whether or not the subjects are or have been in treatment?

**Council Comment:** These types of factors must be taken into consideration when subjects are recruited. Appropriate care should be taken to not unduly place any individual at risk.

**Question:** Will the protocol involve alcoholics (alcohol-dependent individuals)?

**Council Comment:** Experimentation which requires individuals who are alcohol-dependent or alcoholics to be exposed to alcohol clearly warrants special attention. There are a number of extremely important principles which need to be addressed by anyone considering or evaluating requests to undertake such research. It is noted that these issues differ to a degree, depending on where in the disease/rehabilitative/recovery process the potential subjects are. Further, it is useful to distinguish between these stages in addressing some of the key issues. For example, the likelihood that a subject would otherwise be encountering the agent (alcohol) would clearly differ, depending upon their disease or recovery status. The risk of the investigator inflicting harm is clearly greater when the probability that the subject would be otherwise exposed to alcohol is lower.

When potential subjects include alcoholics who are current, active drinkers, the screening procedures must clearly include a medical examination to assure the absence of any medical or mental condition for which further alcohol exposure at the dose contemplated would be contraindicated. Further, the Council stresses that it is incumbent on the investigator, or his/her agent, to make a serious and concerted effort to link such individuals with treatment. This linkage should be active in bringing together the subject with alcoholism treatment personnel, and not passive as in only providing names of treatment programs and phone numbers to the research subject. Whether or not the subject chooses to remain in the treatment program, it is incumbent on the investigator to actively facilitate entry of the research subject into the program.

The use of subjects who have completed the initial phase of treatment and progressed into rehabilitation or recovery would require an extremely strong scientific justification and risk/benefit assessment. Different factors will need to be considered, including at what stage they are in the rehabilitation program and the alcohol dose employed. Both the research staff and the treatment personnel must consider the potential for untoward effects on the treatment/recovery process. There should be a continuation of treatment after conclusion of research participation for a sufficient period to ensure continued recovery.

At the present time (1989), it is considered inappropriate to administer alcohol to any recovering alcoholic who is abstinent and living a sober life in the community. In taking this position, the Council believes that the issue of risk for relapse outweighs any consideration which may be afforded to the willingness of the subjects to participate in the project though informed and voluntary consent, or the unique requirements within a study to include recovered alcoholics to address the hypothesis posed. This position is derived from an assessment of risk, since the risk of the exposure eliciting relapse (or other health problems) is considered too great to warrant the recovering alcoholic's participation.

**Question:** Is the applicant obtaining a family history in order to determine (and, as appropriate, exclude) individuals who may carry a heightened familial or genetic risk to develop alcohol dependency?

**Council Comment:** It is recognized that, as a group, individuals with a familial or genetic history of alcoholism are at higher risk for the development of alcoholism. Thus, special consideration needs to be given to the risk/benefit assessment before exposing such individuals to alcohol, and even more so when either dosage levels exceed the normal drinking practice of the subject, or when the alcohol-naïve individual is proposed as the subject (see below). It is appropriate to relate both in the assessment of the risk/benefit and in the informed consent process that, in the context of alcoholism, familial or genetic risks do not mean predestiny or predetermination. Rather, the risk translates into vulnerability which should appropriately suggest extra caution on the part of any individual with a family history of alcoholism in the context of any drinking situation, including, but not limited to, the research study.

**Question:** Has the age of the subjects been considered?

**Council Comment:** Alcohol is unique as a beverage because its availability and/or consumption is licit for a substantial segment of the population (in most States, those age 21 or older), but illicit below this age. It is the Council's opinion that persons who are under the State's legally set drinking age should normally not be given alcohol in research protocols. If the hypothesis under test clearly requires the involvement of individuals from that age group, and the risk/benefit assessment is strongly favorable, investigators must be sure to (1) obtain any underage subject's assent to participate in the research; (2) obtain permission from the parent(s) or guardian for the underage subject to participate in the research; and (3) comply with applicable laws of the jurisdiction in which the research is being conducted. As with all research, investigators and IRBs must adhere to the additional requirements for protection of children involved as subjects for research, as contained in HHS Regulations for Protection of Human Subjects, 45 CFR Part 46, Subpart D.

The principles for all research with children dictate that the research first begin with animals or adults before involving children. In addition, the investigative team should include individuals or the access to individuals who are sensitive to the needs of children, such as, as appropriate, social service professionals, pediatricians, or psychologists.

**Question:** Has the need been considered for medical and psychological evaluation of subjects prior to participation in a study?

**Council Comment:** Medical and psychological screening may be appropriate for given studies, depending on the nature of the study, the maximal doses of alcohol used, the subject population, and whether or not they are alcohol-dependent or using other drugs.

**Question:** Has the possibility of pregnancy been assessed for potential female subjects of childbearing age?

**Council Comment:** The possibility of pregnancy should always be assessed and a standard

hormonal pregnancy test included. While menstrual and contraceptive history may be useful, the assessment of a pregnancy status should not be made solely by self-reported information. At the present time (1989), risk/benefit considerations almost always preclude administration of alcohol to pregnant women as this may endanger the fetus.

**Question:** Has the need for access to medical backup services been considered? Has there been discussion of the potential medical consequences and services necessary?

**Council Comment:** Depending on dose and subject population, the nature of the medical backup service will vary. In minimal circumstances, a nurse or physician available "on call" may be appropriate. This may be amplified to require the presence of a nurse with a physician available "on call," to the requirement of the presence of a physician if higher doses of alcohol are used or if there are other issues pertaining to the study population.

**Question:** Will alcohol-naïve individuals be used?

**Council Comment:** The inclusion of alcohol-naïve individuals in a protocol would need to be very strongly justified within the context of both the requirement that such individuals be included to answer the research question posed and a strongly favorable risk/benefit assessment including consideration of benefits for other individuals with the disease or society as a whole.

There are critically important issues which must be borne in mind when considering a protocol involving the exposure of the nondrinking individual to alcohol. It is recognized that the addictive liability of alcohol varies among individuals and is quite likely a function of genetic, psychological, and environmental factors. While those from a genetic or family background with alcoholism are more likely to be at risk, at present the science to identify those individuals with a high addictive liability does not exist. A risk/benefit assessment must include consideration of the likelihood that the individual would otherwise be encountering the agent (alcohol). This likelihood is not necessarily zero; it may depend on a number of factors relevant to the individual, including the environment in which the individual lives and personal decisions of the individual. In any event, the risk/benefit assessment should be strong and compelling before alcohol-naïve individuals are used in research, and the potential subject should clearly understand the risks (as discussed above in the context of informed consent) before his/her consent is obtained.

**Question:** With reference to potential subjects who are either occasional or regular consumers of alcoholic beverages, will the subject ingest or be administered larger amounts of alcohol than they would normally consume in their own drinking contexts?

**Council Comment:** Such an activity should be justified within the context of both the requirements for the scientific questions posed and the risk/benefit assessment.

There is a class of studies that the Council believes should be commented upon under this heading so as to avoid confusion or misinterpretation; these are investigations where the dependent variable under study is the level of alcohol consumption itself. Distinct from protocols where the subject ingests a fixed amount of alcohol, in these studies the impact of various

environmental or other factors on the extent of drinking is assessed. The Council notes that the context of the question stated here is not intended to convey that such research is inappropriate.

**Question:** If the study protocol requires an element of deception or incomplete disclosure, has the consent form indicated the amount of alcohol that would be consumed if the subject receives alcohol rather than a placebo? Is there a thorough debriefing of the subject following the study, explaining why the incomplete disclosure of information was necessary and the usefulness of it?

**Council Comment:** It is recognized that an element of deception or incomplete disclosure of information about the research methods or goals is sometimes required in alcohol as well as other research; for example, in the elucidation of expectancy and placebo effects. Research subjects are, however, entitled to a full debriefing when it was necessary to deceive them. The consent form should clearly indicate that they may receive alcohol and the amount of alcohol they may receive. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research (see also the Informed Consent section of The Belmont Report).

**Question:** Are appropriate provisions made to accommodate the subjects receiving alcohol at the research sites until the alcohol dose has been effectively eliminated?

**Council Comment:** One concern which emerges is the possibility that individuals who have consumed alcohol in a study will, upon leaving the laboratory, drive or operate dangerous equipment. Providing transportation or escorting a subject back to a place of residence (or employment) does not assure that the individual will not engage in hazardous activities.

In addition to having observable behavior return to normal, it is frequently considered appropriate for the BAC to fall below 0.02 gram percent. In environments where the risk of engaging in hazardous activities is minimal, a level of 0.04 may be considered acceptable, again, conditioned upon other observable behavior having attained sufficient normalcy to preclude such immediate concerns as those stated above as well as upon other factors.

It may also be prudent to require the subject with other than zero BAC and no apparent impairment to state in writing that he/she will not drive a car or operate other machinery for several hours after each experimental session.

The consent form should address the estimated period of time that the subject will likely have to stay at the research facility. When dismissed from the laboratory (even with a BAC of 0.02), subjects should be informed of the estimated time that it will take to reach a zero BAC and counseled on the potential performance impairments to be expected during this period.

Given the large variability in pharmacokinetic clearance rates between individuals, the BAC should be determined with a certified or properly calibrated breathalyzer, and not solely on the basis of pharmacokinetic-derived formulas, graphs, or tables. (BAC measurements may not be necessary when subjects are retained overnight.)

It is recognized that participants in a study, even if encouraged to remain at the testing facility,

are free to leave the research setting at any time. Should subjects leave prematurely, they should be escorted back to their residence. Further, the consent form should address this contingency in a statement similar to the following: "If you choose to leave in the middle of the session, you will be sent home with care, by a conveyance provided by us." In some circumstances, consideration may also be given to the use of so-called Ulysses contracts in which subjects agree before the experiment begins to be temporarily restrained (in terms of leaving the facilities) even though they might protest the restraint later, when their BAC is above the safe limits.

**Question:** Does any aspect of the study dictate the need for follow-up of subjects? If so, is this done?

**Council Comment:** Depending on the nature of the study and the subject, it may be appropriate to determine if there will be any delayed reaction from participation in the study. This would be appropriate in some circumstances when (and as otherwise appropriately justified, see above) subjects are alcohol-dependent or the offspring (adult or otherwise) of an alcoholic. It is recognized that such follow-up may be difficult and/or unattainable with some subject types. When this is true, however, the applicant should explain why the particular study population must be used.

**Question:** In the context of the proposed subject population, is the proposed payment to participants likely to be coercive element in recruitment?

**Council Comment:** Payment to research subjects for their time and inconvenience is an acceptable practice in alcohol as well as other biomedical research. Nonetheless, the payment should not be coercive in the sense of tempting individuals to participate.

**Question:** Is the method of payment appropriate for the subject population?

**Council Comment:** In those unusual studies where alcohol-dependent individuals are used as subjects (see above), immediate cash payments are easily convertible for the purchase of alcoholic beverages and, thereby, may not be appropriate. Therefore, care should be given to the manner of payment: Who will get the payment? Where and in what form will payment be made? Can payment be made in a form other than money to avoid purchases of alcoholic beverages?

## **V. CONCLUSION**

These guidelines represent a brief summary of basic principles and issues relating to the administration of alcohol to human subjects. Further information on human subject research may be obtained from the Office of Protection from Research Risks and from staff of the National Institute on Alcohol Abuse and Alcoholism at the following locations.

National Institutes of Health  
Office for Protection from Research Risks  
Cliff Scharke, D.D.S., M.P.H.

6100 Executive Boulevard, Room 3B01  
Bethesda, MD 20892  
301/402-5218

National Institute on Alcohol Abuse and Alcoholism  
Office of Scientific Affairs  
Willco Building, Suite 409  
6000 Executive Boulevard  
Bethesda, Maryland 20892-7003  
301/443-3860

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1) As used in the context of this document, administration of alcohol to human subjects is intended to include studies which involve administration of alcohol by an investigator to a research subject by the oral or any other route, or voluntary oral consumption by a subject in a research setting.

2 The National Advisory Council on Alcohol Abuse and Alcoholism advises the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the Secretary of the Department of Health and Human Services on programs on policy matters in the field of alcohol abuse and alcoholism.

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## APPENDIX

June 1989

### NATIONAL ADVISORY COUNCIL ON ALCOHOL ABUSE AND ALCOHOLISM

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June 1998

NATIONAL ADVISORY COUNCIL ON ALCOHOL ABUSE AND ALCOHOLISM

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