

OGRD MEMO #18

June 1, 1992

Washington State University

Guidelines on the Administration of Ethyl Alcohol in Human Experimentation

Introduction

Research on the biological and behavioral effects of the ingestion of ethyl alcohol is often conducted on human subjects. Consistent with the National Advisory Council on Alcohol Abuse and Alcoholism, the University recognizes the legitimate and important need for research involving human subjects. Only through research can we fully understand the actions of alcohol including tolerance, dependence and reinforcement and develop treatment programs for alcoholism.

It is essential that such research conform to the (ethical) principles that govern all research involving human subjects. The ethical considerations underlying the justification for using alcohol in human research result from the fulfillment of three fundamental principles: obtaining fully informed and voluntary consent from the subject, insuring that benefits will result to the subject and harm will not occur, subjects will not be compromised or manipulated. These principles are elaborated upon in a report prepared for the National Institute on Alcohol Abuse and Alcoholism by the National Advisory Council on Alcohol Abuse and Alcoholism and appear within the federal Common Rule policy for the protection of human subjects, FR June 18, 1991, page 28003. The following is a synopsis of those documents with excerpts from guidelines released by the University of Washington and University of Idaho; policy statements contained in Washington State University, OGRD Memo #4; and the guide for students and employees entitled, "Getting Help for Drug and Alcohol Abuse."

I. Purpose of the Guideline

The guideline is not intended to replace the functions or policies of the IRB, University, state or federal regulations. The guideline was prepared from the report released by the National Institute on Alcohol Abuse and Alcoholism and other Washington and Idaho educational institutions and is advisory only. The following general issues deserve consideration while conducting alcohol research involving human subjects.

A. Risk/Benefit

- 1. A careful appraisal of the following risk/benefit criteria determines the appropriateness of a research protocol.
- 2. Normally the risks and benefits pertain to the research subject rather than to society in total. Without a reasonable balance, a protocol cannot be justified ethically.
- 3. The qualifications and experiences of the research team.
- 4. The site for conducting the research may influence the risk/benefit ratio.
- 5. The appropriateness of the qualifications of those who assess the risk/benefit ratio.
- 6. The principal responsibility for approval rests with the IRB.

B. Informed Consent

- 1. The investigator has the responsibility of assuring that the informed consent process provides the subject complete information to make a voluntary informed decision.
- 2. Every informed consent should indicate that the drug, alcohol, is a toxin and a re-enforcing agent which may cause changes in behavior, including repetitive or excessive consumption. Everyone who drinks alcohol is at some risk.
- 3. Every informed consent should indicate who is responsible for treatment/observation periods and follow-up care.
- 4. The cognitive, physiologic and motivational status of the subject is reviewed in terms of his/her ability to fully understand the context of the informed consent.

C. Subject Selection

- 1. Care should be exercised to select appropriate subjects to be used in the research.
- 2. Adequate safeguards are followed to prevent unnecessary risk to the subjects.
- 3. The subject's age, sex, familial or genetic background, prior alcohol or drug use, general medical or psychological condition including alcohol recovery status are considered.

D. Confidentiality

- 1. Once alcohol histories are placed on charts, such charts have to be handled with the same confidentiality afforded other alcohol records.
- 2. The Code of Federal Regulations (CFR) that detail the confidentiality requirements are followed and completely addressed in the Human Subject Review Summary Form.

II. University Procedures for the Review and Approval of Protocols

The responsibility for the development and implementation of research protocols on the ingestion of ethyl alcohol rests with the principal investigator. These procedures apply whenever research involving alcohol in humans is conducted regardless of whether or not funds are sought from an external agency.

When research involving human consumption of alcohol is contemplated, it is the responsibility of the investigator to obtain a copy of OGRD Memo#4 and the Human Subject Review Summary Form, and provide complete information to the IRB on the following key elements.

A. Subjects: (Definition) A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

B. The focus or goals of the research. (Research means the systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge).

C. Design and procedures to be used in conducting the study.

D. Potential benefits received by the individual subjects.

E. Potential risks - physical, psychological, social, legal, privacy, or others. (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 examination or tests).

F. How will potential risks be minimized?

G. Informed consent procedures to be followed.

III. Subjects Who May Not Participate in a Study in Which Alcohol is Consumed

A. Alcoholics who are currently choosing to abstain from alcohol use.

B. Persons who are currently in treatment for alcoholism, problem drinking, or alcohol-related medical problems (unless the administration of alcohol is an integral component of the treatment of alcohol abuse)

C. Persons who have a history of past or present drug dependency involving substances cross-tolerant with alcohol (e.g. barbiturate abusers)

D. Females who are pregnant.

E. Persons who have a history of adverse reactions to the type of alcoholic beverage or the amount of alcohol to be used in the study.

F. Persons who are presently taking medication that may interact with alcohol.

G. Persons who are presently abusing other psychoactive substances.

H. Persons who have any type of neurological defect.

I. Minors.

IV. Project Debriefing Requirements

At the termination of the experiment, persons who have been given enough alcohol to produce a blood level of 0.05gm% or above should be given the choice of one of the following.

A. To be escorted by the experimenter or designated assistant to the subject's place of residence; or

B. To remain in the laboratory setting under supervision until such time as the blood alcohol level falls below the 0.03gm% level (or lower if Federal guidelines require)

Subjects should be given written information concerning their blood alcohol level at the end of an experiment. They should be reminded of possible risks at that level and of potential problems if they proceed to consume more alcohol. They should be given an estimate of the number of hours before they are likely to reach a blood alcohol level of 0.0gm%.

V. University Policy

In compliance with the Drug-Free Workplace Act of 1988, the Drug Free Schools and Communities Act Amendments of 1989, and the State of Washington Executive Order 92-01 establishing the Governor's Policy on a Drug Free Work Place, a guide for students and employees entitled, "Getting Help for Drug and Alcohol Abuse" is provided to all faculty, staff, and students at Washington State

University. The publication contains information on University policy, state and federal law, and resource contacts. All investigators should be familiar with the contents of the document prior to the development of a human subject protocol involving the administration of ethyl alcohol.

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