

**Informed Consent Document**

**Study Title: Men, Mood, and Attention Study: Examination of Alcohol, State Anger, and Emotion Regulation Sexual Aggression**

NCT#: NCT04192448

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Morehead State University

MOREHEAD STATE UNIVERSITY  
CONSENT FORM  
MEN, MOOD, AND ACTIONS STUDY

Principal Investigator:

Elizabeth Neilson, Assistant Professor, Department of Psychology, 606-783-2313

Investigator's Statement:

We are asking you to be in a psychological research study. The purpose of this consent form is to give you the information you will need to help decide whether to be in the study or not. Please listen carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything about the research or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in the study or not. This process is called "informed consent". We will give you a copy of this form for your records.

PURPOSE AND BENEFITS

The purpose of this study is to examine the relationship between social drinking, emotional arousal, attention, and male-female interactions. Information regarding the potential relationship between alcohol consumption and attention, and sexually oriented perceptions and responses may be useful to society as a whole in that education efforts can be made regarding the influence of alcohol on such interactions.

PROCEDURES

This study is divided into two sessions. In the first session you will fill out a number of questionnaires via computer. You will be instructed on the proper use of the computer-based surveys by a same-sex experimenter. The questionnaires will assess personality, alcohol and drug use, sexuality, and sexual victimization and aggression background factors. Examples of the most sensitive questions include the following: (1.) After a few drinks of alcohol, I am more likely to have sex on a first date (agree or disagree); (2.) During the last 12 months, how many alcoholic drinks did you have a typical day when you drank alcohol? and (3.) Have you ever questioned a woman's commitment to the relationship to have sex with a woman when she didn't want to?; You are free not to answer any questions you do not wish to answer. You will be given privacy to complete the questionnaires and the experimenter will return only after you have given the completion signal. The questionnaire session will take approximately one hour.

The second session will involve beverage consumption, a task to change your mood (mood induction), followed by an attention task, and reading a sexually explicit scenario. We will randomly assign participants (like pulling numbers out of a hat) to drink either alcohol or a non-alcoholic beverage. You will be told whether or not you are given alcohol. Because you may be asked to drink alcohol, and dosage is determined by weight, you will be weighed by the experimenter prior to the start of the laboratory session. The amount of alcohol given is intended to raise your blood alcohol content (BAC) to .08gm%, which is the equivalent of 4-5 one-ounce drinks of liquor or 12-ounce bottles of beer. Under Kentucky State law, a BAC of .08gm% is regarded as the legal limit for drunkenness.

You must consume the beverage given to you within 9 minutes and then wait until your BAC reaches a pre-determined target BAC level before continuing with the study. You will be given a standard breath test to measure your BAC every 3-5 minutes. At the end of the experiment, if your BAC is above .03gm%, you will be required to remain in the lab until it falls below .04gm%.

Once you have reached the target BAC level, the mood induction and attention procedures will take place. This activity will take approximately five minutes. After this activity, we will ask you to

complete an attention task. You will be asked to correctly identify and mark letters on a piece of paper in a 2 minute period.

After completion of the attention task, you will read a sexual scenario and be asked to answer questions concerning your reactions to the scenario. Questions will be asked via computer, and you will respond using the computer.

Upon completion of the experiment you will be escorted to a separate room to relax while your BAC returns to normal. Breath tests will be done periodically to measure your progress. While waiting for your alcohol level to reach normal levels, you will have several choices of entertainment, food and drinks. Your participation will take approximately three to seven hours, depending on your alcohol dosage.

#### RISKS, STRESS OR DISCOMFORT

Answering some of the questions during the Questionnaire session may make you feel uncomfortable due to their very personal content. Please try to answer all questions as honestly as possible. In order to ensure confidentiality, all questionnaires and other data forms will be identified with only a code number. Researchers will review the data at a later date and will not be able to connect that data to you as an individual.

During the Experimental session you will be consuming a beverage, which may or may not contain alcohol. The following steps are being taken to minimize risks associated with alcohol consumption:

- a) You were asked to take a breath test before you began the session in the laboratory. If your reading had shown any alcohol in your blood, you would have been excused from the study.
- b) If you are currently taking any drugs that may not mix well with alcohol your appointment will be rescheduled for another time.
- c) You will be asked to take a number of breath tests at the end of the experiment. We will examine the amount of alcohol in your breath samples in order to advise you of approximately how much time must pass before your blood alcohol level will return to zero. In signing this form, you agree to submit to these breathalyzer tests at the end of the session.

Though it is unlikely, there is the possibility that you could become slightly nauseous or dizzy should you consume alcohol. However, these feelings, should they occur, will be no greater than what you would feel during a normal episode of moderate drinking.

During the Experimental session you will also be reading erotic materials. These materials are designed to stimulate genital arousal. To minimize the risk of psychological stress or discomfort caused by the exposure the following steps will be taken:

- a) An experimenter of your same gender will supervise your participation in these procedures.
- b) To protect your privacy during the scenario, you will be left alone in the laboratory with minimal interruptions from the experimenter. The door will be locked and only the experimenter will have the key. A doorbell system will be available to contact the experimenter if you would like to terminate the procedure at any time.

If you feel severely distressed following your exposure to the erotic material you may contact the Principal Investigator, Elizabeth Neilson (606-783-2313) directly with your concerns.

If you think you have a medical problem or illness related to this research, contact one of the researchers listed at the top of the form who will treat you or refer you for treatment.

SOURCE OF FUNDING

The study team and/or the Morehead State University is receiving financial support from the National Institutes of Health via the Kentucky IDeA Biomedical Research Infrastructure Network..

OTHER INFORMATION

You will be paid \$10.00 per hour for participating, for a maximum payment of \$80. Your identity will remain confidential and will not be connected with your data once you leave the lab. We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at Morehead State University, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

You are free to withdraw your participation at any time. You will be compensated for all time spent in the lab. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. We are required to notify MSU Campus police when participants complete the study and inform them of the final BAL of all participants when they depart the study. MSU Campus police are not informed of the identity of any participant and will have no access to participant data. A member of the MSU campus police is available to assess any participant who may be manifestly under the influence of alcohol following conclusion of study participation. Participants in the study are subject to Commonwealth of Kentucky statutes regarding offenses related to alcohol intoxication in a public place and operating a motor vehicle under the influence of alcohol. Neither the research staff nor anyone else will ever be able to connect your name with the responses you make during the experiment. Your name will only appear on this consent form, which you are asked to sign. Your name will not be linked to the information you provide. The research assistant will answer any questions you have about the study at this time.

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Printed name of experimenter	Signature of experimenter	Date
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Subject's Statement:

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later on about the research I can ask one of the investigators listed above, or if I have been harmed by participating in this study, I can ask one of the investigators listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (606) 783-2541. I will receive a copy of this consent form.

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Printed name of subject	Signature of subject	Date
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