Document Coversheet

Study Title: Impaired Risk Awareness During Intoxication in DUI Offenders

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KEY INFORMATION FOR IMPAIRED RISK AWARENESS DURING INTOXICATION IN DUI OFFENDERS:

We are asking you to choose whether or not to volunteer for a research study to test the efficacy of experiential-based training to reduce risky alcohol use. We are asking you because you are a social drinker between 21 and 45 years of age who drinks at least twice weekly. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

You are invited to participate in a research study that is testing the efficacy of experiential-based training to increase peoples' perceptions of risk associated with alcohol use. You will attend a familiarization session at the University of Kentucky in which you will get familiar with lab procedures, fill out questionnaires, and practice hand-eye performance tasks and assessments. This session will take about 2 hours. You will return for two pre-training sessions to assess your behavioral reactions and perceived level of intoxication after drinking a dose of alcohol. You will return within one week after completing the pre-training assessment to attend one training session in which you receive structured training to accurately estimate your breath alcohol concentration (BAC) after drinking a dose of alcohol. After training, you will return for two post-training visits to test your behavioral reactions and perceived level of intoxication after drinking a dose of alcohol. The two post-training visits will occur 1 month after training is complete. You will receive an alcoholic beverage during all 5 testing sessions and the sessions will last up to 6 hours each as your BAC must fall below 0.02 g% before you may leave. Alcohol consumption also will be assessed at monthly intervals over a 2-month follow-up. At the end of each month, you will receive a secure email with a custom link and instructions to complete assessments of your recent drinking over the past month.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You are being invited to take part in this research study because you are a social drinker between 21 and 45 years of age who drinks at least twice weekly, who is in good physical health, and has no problems concerning the consumption of alcoholic beverages. If you volunteer to take part in this study, you will be one of about 120 people involved in the study at the University of Kentucky.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You should not participate in this study if you have an alcohol use disorder or other drug use disorder, significant psychiatric disorders, are seeking treatment for alcohol or substance abuse, if you do not drink alcohol, if you are pregnant or breastfeeding, if you do not weigh between 100-210 lbs, if you are under 21 years of age or are over 45 years of age, or have a medical condition in which drinking alcohol could be harmful to you.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you chose not to volunteer. If you decide to take part in the study, you still have the right to decide, at any time, that you no longer want to continue. No one will think badly of you or treat you differently if you decide not to take part in this study. There are no risks to you if you decide to end the study early. However, if you have received alcohol during one of the laboratory visits and then decide you no longer wish to continue, you will be required to remain in the laboratory until your blood alcohol falls to a safe level (0.02%) and the research staff judges you safe to leave. Treatment referrals may also be offered at this time and will include psychological services such as The Harris Center at 859-257-6853.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the principal investigator, Mark Fillmore, Ph.D. of the University of Kentucky, Department of Psychology, at 859-257-4728. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You will be excluded from participation in this study if you have a history of physical or psychiatric disease, are pregnant or breastfeeding, have a drinking or a drug use problem, have a psychiatric disorder (schizophrenia, bipolar, etc.), or a medical condition in which drinking alcohol could be harmful to you. You will also be excluded if you do not drink alcohol, if you do not weigh between 100-210 lbs, if you do not drive regularly, if you have not held a driver's license for at least 5 years, if you arrive at the lab with a non-zero blood alcohol level or test urine-positive for other psychoactive drugs, if you are under 21 years of age or are over 45 years of age or diagnosed with other medical conditions that would warrant exclusion from the study. Transportation may be provided if you arrive with a non-zero blood alcohol level or test urine-positive for other psychoactive drugs.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted in the Department of Psychology (Kastle Hall) at the University of Kentucky. You will attend a familiarization session in which you will get familiar with lab procedures, fill out questionnaires, and practice hand-eye coordination tasks and assessments. This session will take about 2 hours. You will return for two pre-training sessions to assess your behavioral reactions and perceived level of intoxication after drinking a dose of alcohol. These sessions will last up to 6 hours each. You will return within one week after completing the pre-training assessment to attend one training session in which you receive structured training to accurately estimate your breath alcohol concentration (BAC) after drinking a dose of alcohol. This session will last up to 6 hours. After training, you will return for two post-training visits to test your behavioral reactions and perceived level of intoxication after drinking a dose of alcohol. The two post-training visits will occur 1 month after training is complete and will also last up to 6 hours each. You will receive an alcoholic beverage during all 5 testing sessions and the sessions will last up to 6 hours each as your blood alcohol concentration (BAC) must fall below 0.02 g% before you may leave. Alcohol consumption also will be assessed at monthly intervals over a 2-month follow-up. At the end of each month, you will receive a secure email with a custom link and instructions to complete assessments of your recent drinking over the past month.

WHAT WILL YOU BE ASKED TO DO?

You will be tested individually. Test sessions will occur on separate days with a minimum of two days between sessions and a maximum inter-session interval of one week. Sessions begin between 10:00 AM and 6:00 PM. You will be asked to abstain from alcohol and other drug use for 24 hours prior to sessions. You will also be asked to fast for 4 hours before each session. Breath and urine samples are obtained prior to sessions to verify zero BACs, check for recent drug use, and confirm that women are not pregnant. If you test positive for a drug, and it is determined that the drug is not regularly used, the session is rescheduled. If you test positive a second time, you will be discontinued. You will attend a familiarization session in which you will get familiar with lab procedures, fill out questionnaires, and practice hand-eye performance tasks and assessments. These questionnaires ask about your medical history and your drug and alcohol use, i.e., what drugs you use and how often. These questionnaires also assess basic personality traits and driving history with respect to number of accidents, speeding tickets, etc. The questionnaires will take about 45 minutes to complete during the 2-hour familiarization session.

After the familiarization session, you will return for two pre-training, alcohol dose-administration sessions. You will complete the assessment battery 6 times following dose administration: 30, 70, 180, 240, 300, and 360 minutes (6 hrs). An Intoxilyzer SD-5 (CMI Inc.) will analyze breath samples beginning 30 minutes after drinking onset.

You will return for one training session that occurs within one week after completing the pre-training sessions. You will be administered a dose of alcohol and receive structured training to accurately estimate your breath alcohol concentration (BAC) and accurately appraise the behavioral impairing effects of alcohol.

After completing the training session, you will be re-tested. The post-training assessment of alcohol responses is identical to the pre-training assessment. Post-training assessment will be conducted at 1-month post-training to evaluate retention effects.

During the laboratory tests, you will receive a drink of alcohol. The amount of alcohol will vary across sessions but will have a maximum dose of 0.65 g/kg absolute alcohol that produces a peak blood-alcohol level of 0.085%. The alcohol is mixed with a carbonated, non-caffeinated, lemon-flavored soda and is consumed within 10 minutes. A breathalyzer will measure your BAC during these sessions. After testing is complete, you will relax in a recreational setting in the laboratory until your blood alcohol level falls to 0.02%. You are also provided with a meal at this time.

It is also very important that you do not drive to any sessions in which alcohol will be administered because you will not be allowed to drive after these sessions conclude. If you live off-campus and are not in walking-distance to the study, we will provide you with transportation to and from these sessions by Uber at no cost to you (within Fayette County only). You can also make your own arrangements for a ride to and from these sessions.

Alcohol consumption also will be assessed at monthly intervals over a 2-month follow-up to evaluate the training efficacy. You will complete monthly on-line assessments of your alcohol use online. At the end of each month, you will receive a secure email with a custom link and instructions to complete the assessments of your drinking for the past month.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Participation in this study involves no risks beyond those associated with moderate alcohol intoxication (i.e., a little sleepiness at the end of the session). Given the alcohol doses used in this study, it is a very rare occurrence that an individual will experience either nausea or vomiting. In addition to the risks listed, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study. However, you will receive educational materials about the general behavioral effects of alcohol that can help guide your choices with respect to responsible drinking. In addition, you will have a better understanding of behavioral science research and knowledge about how such research is conducted.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

Participation in this study involves no financial costs to you or your third-party insurance provider.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. Every effort will be made to maintain the confidentiality of your study records. All data will be coded by participant number only and any personal identifiers linking participants to their reports on questionnaires will be detached and destroyed as soon as participation is completed, or disqualification occurs. Data are transferred via a secure website that time- and date-stamps data so accuracy of data collection can be monitored. Data from experimental sessions will be collected using a computerized data collection and management system. All data are stored in a unique file on the hard-drive of the computer and are electronically backed-up at the end of each session. In all instances, the data files do not contain the name of the subject; but instead, each subject is identified by a unique four-digit number. The computer file linking subject names and numbers will be encrypted and only investigators will have access. The data from the study may be published, however, you will not be identified by name. Your identity will remain confidential unless you give prior written approval. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Your name, address and social security number will be listed on the receipt for payment that you receive, as required by the Internal Revenue Service; but no information about your participation in this research project will be released. Also, because this research is regulated by the National Institute of Health (NIH) and The University of Kentucky, staff from these and other DHHS agencies may look at or copy pertinent portions of records that identify you. However, it is the policy of these agencies and of these investigators that every attempt will be made to resist demands to

release information that identifies you. When results of this study are published, your name will not be used. We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

Certificates of Confidentiality (CoC):

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or specimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH, which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

There are no risks to you if you decide to end the study early. However, if you have already consumed your dose of alcohol, you will still have to wait in our laboratory until your blood alcohol concentration (BAC) has decreased to 0.02% and the research staff judges you safe to leave. Transportation home will be provided as needed within Fayette County.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Lon Hays, M.D. at 859-323-6021 immediately. Lon Hays, M.D. will determine what type of treatment, if any, that is best for you at that time. If it is an emergency, you should contact the 24-hour on call physician by calling 859-226-7063 or paging 859-330-2216.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility. You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will be paid $585 for complete data collection which includes $30 for the familiarization session, $75 for each of the 5 laboratory testing sessions, $15 for each of the 2 online surveys, and a $150 completion bonus. The completion bonus is earned if every component of the study is complete (familiarization session, 5 alcohol sessions, and 2 online surveys). If you do not complete the study, either because you were excluded from participation or because you chose to terminate the procedure, you will receive payment for sessions completed. Payment will be provided in the form of a reloadable credit card. You will receive your card and your first payment of $255 after you complete the familiarization session, both pre-training visits, and the training visit. You will earn another $150 after completing the 2 post-training visits. You will earn $15 after each online survey. Your completion bonus of $150 will be earned after the 2nd online survey is completed. These payments will be loaded onto your reloadable credit card. Record of the payment will be recorded for income tax purposes.

With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by Lon Hays, M.D. to determine if it is in your best interest to contact you. If so, Mark Fillmore, Ph.D. will contact you using the information you provided. With the help of Lon Hays, M.D., they will present possible risks or benefits of receiving the information. At that time, you can choose to receive or refuse the result or finding. If you would like more information about this, call Mark Fillmore, Ph.D. at 859-257-4728.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 5 times per year.

Do you give your permission to be contacted in the future by the lab of Mark Fillmore, Ph.D. regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 120 people to do so at the University of Kentucky. NIH is providing financial support and/or material for this study. A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. Also, we will verify DUI convictions using the State District Court Record Reporting Systems (e.g., Kentucky Courts Records Online©, Courtnet©).

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?

Your information or samples collected for this study will not be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ _____ **Signature of research subject** **Date** _____ **Printed name of research subject**
_____ _____ Printed name of [authorized] person obtaining informed consent Date _____ Signature of Principal Investigator or Sub/Co-Investigator