PARTICIPANT INFORMATION SHEET
MAGNETIC RESONANCE IMAGING SESSION

Title of Study: Brain Responses to Environmental Influences on Drinking Decisions

Principal Investigator: Michael Amlung, Ph.D., Department of Applied Behavioral Science and Cofrin Logan Center for Addiction Research and Treatment, University of Kansas

Local Principal Investigator: James MacKillop, Ph.D., Peter Boris Centre for Addictions Research, St. Joseph's Healthcare Hamilton, West 5th Campus; Department of Psychiatry and Behavioural Neurosciences, McMaster University

Funding Sources: National Institutes of Health (USA) and the Peter Boris Centre for Addictions Research, St. Joseph's Healthcare Hamilton.

You are being invited to participate in a research study conducted by Dr. James MacKillop at McMaster University and Dr. Michael Amlung at the University of Kansas. Drs. MacKillop and Amlung are researchers and not physicians. You should know this is not a clinical study, no physicians are involved, and this study will not have an impact on clinical care in any way. In order to decide whether or not you want to participate in this study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the study, and the content of this form will be discussed with you. Once you understand the content, you will be asked to sign this form if you wish to participate. Please take your time to make your decision.

There is no conflict of interest that exists in relation to this study, and there is no potential benefit to the investigator(s) beyond the professional benefit from academic achievement or presentation of the results.

WHY IS THIS STUDY BEING DONE?
Alcohol misuse is a public health issue in Canada and other countries, and effective treatment and assessment depends on understanding the intersection between brain and behaviour. This study will use functional magnetic resonance imaging (fMRI) to examine brain activity patterns associated with changes in motivation and decisions related to alcohol. This research may increase knowledge about functional brain changes in alcohol use disorder and may also help improve diagnosis and treatment.

WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this project is to use fMRI to investigate the functional brain changes associated with increases in alcohol demand resulting from exposure to environmental cues, to examine sex differences, and to determine how alcohol-related variables (e.g., weekly drinking level) and psychological performance (e.g., memory, impulsivity, inhibition) affect decision-making and brain responses. All data from this study will be used for research purposes only. In addition, the MRI data collected in this study are for research purposes only and no clinical report will be issued for any research MRI scan.

HOW MANY PEOPLE WILL BE IN THIS STUDY?
We anticipate enrolling a total of 70 participants in the full study.

WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?
This session will last **approximately 3 hours.** If you volunteer to participate, we will ask you to do the following things:

1. Listen to an overview of the session and sign an informed consent form. [30 minutes]
2. Complete a breathalyzer and urine screen test [10 minutes]
3. Fill out a short questionnaire about your recent use of alcohol, tobacco, and drugs; the date of your last menstrual period (females), and medications that you are currently taking. [30 minutes]
4. Undergo a 1-hour MRI scan, as described in detail below. [60 minutes + 15 minutes prep time]

5. Finally, you will be given a debriefing and have an opportunity to ask questions about your experience in the study. You will fill out a receipt and receive your payment for participating in the study. [30 minutes]

Breathalyzer and Urine Screen Test

During the session, you will be screened for alcohol and drug use through a breathalyser and a urine screen. After arrival, we will assess your breath alcohol level by asking you to blow into a breathalyzer, and also collect a urine sample to test for recent drug use. The results of your drug test will be retained as part of your study data kept strictly confidential.

Magnetic Resonance Imaging (MRI)

This session will involve an MRI scan of your brain. The MRI scan will be administered by a qualified MRI Technician at St. Joseph's Healthcare Hamilton's Imaging Research Centre. It is important that you understand what will happen during this procedure. The MRI scan will involve the following activities:

1. You will be asked to take off all metallic objects (i.e., watch, credit cards, coins, jewelry, digital equipment, etc.) and change into a cotton hospital gown in a private changing room.
2. Once you are changed, you will enter the scanner, where the MRI technologist will assist you onto the table, making sure you are comfortable. Earplugs will be given to you to reduce the rhythmic noise from the scanner. You will be asked to do your best to stay still throughout the entire scan. We will minimize any discomfort that may be involved with staying still.
3. This study will obtain a series of images of your brain. During the MRI scan, you will be asked to perform a series of tasks related to choices about alcoholic beverages and money. These choices are all hypothetical meaning that you will not actually receive any of the alcohol or money.
4. You will be able to communicate with staff at all times throughout the scan by using a microphone and/or a press button. This will enable you at any point in time during the magnetic resonance imaging session to ask us to delay or stop the scanning session and/or terminate your participation in the study. There is also an alarm switch, which you can push to end the scan immediately. Remember that your participation in the study is voluntary and you may withdraw at any time.
5. If you need a break throughout the session, you can notify the staff through the microphone. Remember that even during the breaks, you should remain as still as possible.
6. You will immediately be told when the scanning session is over. The technologist will enter the MRI room and assist you in getting up. This will complete your involvement in the MRI and you will be able to change back into your regular clothes.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are a number of potential risks and discomforts associated with this study:

1. **Risks associated with magnetic resonance imaging:** While all forms of diagnostic medical procedures involve some risk, the known risks of MRI are very low. However, accidents, injuries, and even deaths have occurred during MRI procedures. Serious consequences can occur in people who have metal pacemakers, metallic dust in their eyes, metallic prostheses, implants or surgical clips. MRI is also dangerous for anyone wearing metal objects (jewelry, hair clips, eyeglasses, metal on clothing, credit cards, loose change, etc.) Some participants might experience mild discomfort from the loud noise of the scanner and the confined space, which can bring on an anxiety reaction. Occasionally during scanning, participants may also experience slight warming of the skin due to increased energy absorption from radio waves used in magnetic resonance imaging. This technology does not involve radiation like the X-rays you receive when you break a bone. There is no known risk to a fetus, but it is the policy of the Imaging Research Centre that pregnant women cannot participate in this study. If you have any heating or queasy feelings during the study, you can stop the scan by pressing a squeeze bulb alarm given to you by the MRI technologist.

2. **Breach of confidentiality / loss of privacy:** A potential risk is loss of privacy due to inadvertent disclosure of personal information which could lead to embarrassment or damage to your reputation (employment, interpersonal relationships, stigma, etc.). You will also be asked questions pertaining to

illegal behaviours, such as use of drugs. We will protect against these risks by keeping all of your responses and other data strictly confidential. You may also refuse to answer any questions that you do not want to answer.

3. **Discomforts / distress in answering personal questions**: It is possible that you may experience some discomfort resulting from answering some of the personal questions during the interview, on the questionnaires, or on the psychological tests. As mentioned above, you will also be asked questions pertaining to illegal behaviours such as drug use. It is important that you know that your participation in this study is entirely voluntary. You may refuse to answer any questions that you do not want to without any consequences or negative repercussions.

WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?
We cannot promise any personal or medical benefits to you by taking part in this study. The possible benefits for society include conduction of research that will increase our understanding of how the brain supports decision-making related to alcohol and other rewards, and how these decisions are affected by cues.

WHAT INFORMATION WILL BE KEPT PRIVATE?
Your data will not be shared with anyone except with your consent or as required by law. Your data will be identified by a Subject ID Number which will be kept separate from your name. A list linking the number with your name will be kept in a secure place, separate from your data. Your data will be securely stored in a locked office in our research laboratory or on password-protected computers. If the results of this research are published, no information that discloses your identity such as your name will be released or published.

Following requirements from the US National Institutes of Health which is funding this study, descriptive information about this study will be registered on ClinicalTrials.gov. At the conclusion of the study, a summary of the results will be posted to the study record on ClinicalTrials.gov. Data are posted in summary form only and your name is not included on any of the material posted to the website.

For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board (HiREB) or affiliated institutions or sites may consult your research data. However, no records which identify you by name or initials will be allowed to leave the research laboratory. By signing this consent form, you authorize the release of your research data to the HiREB for such monitoring purposes.

CAN PARTICIPATION IN THE STUDY END EARLY?
Your participation in this study is voluntary. You can refuse to participate or withdraw from the study at any time without giving a reason, and without loss of benefits to which you are entitled. You can ask to have information that can be identified as yours returned to you, removed from the research records, or destroyed. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?
If you agree to take part in this study, you will receive a $40 gift card for your time and effort.

WILL THERE BE ANY MONETARY COSTS?
There are no monetary costs to you for participating. We will provide you with vouchers/passes for parking and bus transportation, as needed.

WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?
If you are injured as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CONTACT?
If you have any questions about the research now or later, or if you think you have a research-related injury, please contact Dr. James Mackillop, by telephone at (905) 522-1155, extension 39492.

If you have any questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at (905) 521-2100, extension 42013.

CONSENT STATEMENT
MAGNETIC RESONANCE IMAGING SESSION

Participant:
I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

Name	**Signature**	**Date**

Person obtaining consent:
I have discussed this information sheet and consent form in detail with the participant. I believe the participant understands what is involved in this study.

Name, Role in Study	**Signature**	**Date**

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at (905)521-2100, extension 42013.