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EFFECTIVE: February 9, 2004 REVISED: February 4, 2005	PROTOCOL FOR THE MANAGEMENT OF RESEARCH SUBJECTS WHO CONSUME ALCOHOL FOR RESEARCH PURPOSES ON CAMPUS.		

A. General Conditions:

- 1) The study must be conducted in compliance with all government regulations and legislation concerning alcohol use.
- 2) Prior to commencing the study, researchers must inform the Campus Police that they are conducting research on campus that involves inducing a state of drunkenness in research participants and that they will notify the Campus Police immediately in the event a subject leaves before being deemed sober.
- 3) Researchers must review terms and conditions with potential research subjects emphasizing the requirement that the subject may not leave unless they are deemed sober by the research staff.
- 4) Confirm that the subject is not under the influence of alcohol at the time they consent to the research or arrive to participate.
- 5) Obtain written consent from participants
- 6) Confirm with the subject when they arrive for testing that they have allowed sufficient time for participation. Reiterate that they must not leave until they are considered sober by the research staff.
- 7) Ensure the testing takes place in a site that has a washroom incorporated into it or ensure subjects will be accompanied by research staff of the same sex to nearby washroom facilities.
- 8) Non-alcoholic beverages and food must be provided for the subjects. Once the testing portion of the session is over, the participants should be encouraged to eat and/or drink before they leave the test site.
- 9) There must be an approved first-aid kit on site and staff trained in its use.
- 10) Researchers must ensure there is sufficient research staff on hand to supervise the session and ensure constant observation of the research participant(s) .
- 11) All emergency numbers and procedures should be posted in a readily accessible place and in close proximity to a telephone.
- 12) When a subject is deemed sober and able to leave the testing site the researchers must offer to provide transportation or confirm that they intent to take public transportation or are being picked up by someone else. If the subject indicates that they are driving themselves, research staff must remind them that it is recommended that they don't drive for 12 hours and reiterate offers to provide transportation.

B. In the event a research subject wants to leave the testing site before they are deemed to be sober, the following procedures *must* be applied.

- 1) Talk calmly and quietly to the research subject.
- 2) Try and determine why the subject wants to leave. E.g. If they are late for another appointment assist them in making telephone calls or delivering messages to notify others that they will be delayed.
- 3) Try and engage the subject in another activity E.g. watching television, playing a game etc.
- 4) Encourage the subjects to sit down and eat or drink.
- 5) Remind the subject in a non-threatening manner that they had promised to adhere to the rules about not leaving until the research staff said they could.

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- 6) If the situation escalates, and as a last resort, remind the subject that if they leave before deemed sober the Campus Police will be called.
- 7) If it becomes apparent that a subject may leave before it is appropriate for him/her to do so, the research staff must contact the Campus Police before the subject leaves to alert them that their services may be required imminently and the location. (If the subject subsequently agrees to remain the research staff should then call the Campus Police to tell them they will not be needed.)
- 8) If a reasoned approach does not work and subjects demand to leave before meeting acceptable criteria, the research staff must contact the Campus Police as the person leaves and report the departure emphasizing the fact that the subject has consumed alcohol and has not met acceptable sobriety standards.
- 9) If the Principal Investigator is not on-site during the testing s/he must be notified immediately that a subject has left without approval and the Campus Police have been called. Alternatively, a co-investigator or the Departmental Chair should be notified if the Principal Investigator cannot be contacted.
- 10) This incident must also be reported to the Office of Research Ethics within 24 hours.
- 11) At no time should researchers or their staff put themselves in danger of being assaulted or injured in their efforts to persuade subjects to remain on site.

C. Informed Consent Documentation

For all studies involving the ingestion of alcohol in addition to the REBs usual requirements for the letter of information and/or the consent documentation, the following wording and emphasis (i.e. capitalization) must be included in the letter of information and consent form or declaration.

1) Required phrasing in the letter of information

[Wording to be included in section on study procedures.](#)

At the end of each treatment session you will be asked to take breathalyser tests and sobriety tests until you are no longer considered alcohol impaired. For the breathalyser test you will be required to blow into a plastic tube. The sobriety test will include things like asking you to close your eyes and touch your nose with your forefinger, walk heel-to-toe along a line on the floor or answer simple questions.

[Wording to be included in Risks section](#)

The beverages may cause intoxication, drunkenness, dizziness, stomach upset, tiredness and/or headaches. You may also experience, physical and/or mental impairment for 1 to 2 or more hours after you have consumed the alcoholic beverages. In order to protect you, a trained professional will be in attendance at all times and you will not be allowed to leave the study site until you have a breathalyser reading of less than 30mg/100ml AND show no impairment in the sobriety tests. The attendant, experienced in the objective assessment of impaired states, will be required to document that you are not impaired before you will be permitted to depart from the

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study area. IT IS STRONGLY RECOMMENDED THAT YOU NOT DRIVE A VEHICLE OR OPERATE HEAVY OR DANGEROUS MACHINERY FOR A PERIOD OF 12 HOURS AFTER YOU HAVE BEEN RELEASED FROM THE STUDY SITE. If you require transportation from the study site please inform the research staff and transportation will be provided at no cost to you.

Wording to be included in Voluntary Participation section

Participation in this study is voluntary and you may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your employment or academic status. However if you have consumed any of the alcohol YOU WILL NOT BE ALLOWED TO LEAVE THE STUDY SITE UNTIL YOU HAVE A BREATHALYSER READING OF LESS THAN 30MG/100ML AND SHOW NO IMPAIRMENT IN THE SOBRIETY TESTS.

To participate in this study you must acknowledge and agree to the following conditions:

- YOU COULD BE PHYSICALLY RESTRAINED TO PREVENT YOUR LEAVING PRIOR TO MEETING THE ABOVE CONDITIONS.
- YOU WILL NOT WITHDRAW YOUR CONSENT TO THE STUDY CONDITIONS FOR A PERIOD OF AT LEAST 24 HOURS AFTER STARTING THE STUDY PROCEDURES IE. CONSUME ALCOHOL
- YOUR ATTENDANCE ON CAMPUS FOR THE PURPOSE OF PARTICIPATING IN THIS STUDY IS CONDITIONAL UPON YOU AGREEING TO ALL THE CONDITIONS EXPLAINED IN THIS LETTER AND IF YOU IGNORE THESE CONDITIONS YOU WOULD BE CONSIDERED A TRESPASSER AND CAMPUS POLICE MAY BE CALLED TO INTERVENE.

(Wording to be included for studies involving multiple sessions)

If you show significant impairment in one session and/or are physically or verbally abusive you will not be permitted to participate in the remaining sessions involving the consumption of alcohol.

2) Required format for consent form/declaration for studies involving the ingestion of alcohol.

- Use institutional letterhead
- Include Study title
- Include Investigators and affiliation e.g. Professor Brian Smith, Department of Anatomy UWO

I have read the letter of information and have had the nature of the study explained to me. All my questions have been answered to my satisfaction. I agree to participate.

I acknowledge and agree that:

- I will not be allowed to leave the test facility until I have a breathalyser reading of less than 30mg/100ml AND show no impairment in the sobriety tests.

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- I may be physically restrained to prevent my leaving prior to meeting the above conditions.
- I will not withdraw my consent to the study conditions for a period of at least 24 hours after starting the study procedures I.e. consuming alcohol in the course of the study
- My attendance on campus for the purpose of participating in this study is conditional upon agreeing to all the conditions explained in the letter of information and if I ignore these conditions I would be considered a trespasser and Campus Police may be called to intervene.
- I am under no impairment in making this informed consent.

Signature of Research Participant

Print Name

Date

Signature of Person Obtaining Consent

Print Name

Date