

# PROCEDURAL PROTOCOL APPLICATION

**STUDIES INVOLVING ALCOHOL CONSUMPTION WITH ADULT VOLUNTEERS**

## SCOPE: Methodology for which procedural protocol approval is sought

The effects of alcohol misuse are widespread and a serious problem for Scotland (Grey & Leyland, 2015), both socially and on an individual health basis. In particular, the impact of alcohol on the developing brain is of specific concern due to adolescent binge-drinking culture, and its prevalence within the university undergraduate population. It is therefore imperative to build on existing research by investigating the damage which alcohol misuse can impart on the brain and behaviour, in a safe and controlled environment.

The current document proposes a carefully considered, consistent approach to administering alcohol for future research within the Psychology department.

Alcohol studies will involve participants over the age of 18 who knowingly consent to consume a moderate quantity of alcohol before taking part in a research task. Participants will receive a dosage of alcohol that is scaled dependent on factors including experimental design and gender/height/weight. They will receive regular breathalyser tests to ensure they remain within the intended BAC% (Blood Alcohol Content) parameters of the study. Participants will be accompanied by the researchers at all times and, following the study, will be encouraged to remain in the laboratory (or other safe environment) until their BAC% has returned to at least below the Scottish government safe driving limit of 0.05%, and preferably to 0%.

## What is a moderate quantity of alcohol?

Our previous studies in Stirling have all administered alcohol at a low dosage, to elicit a target BAC% in participants of 0.03%, i.e., the minimum BAC% required for the duration of the study. To put this in context, the legal drink drive limit for Scotland is 0.05%, whereas for England it is 0.08%. At a BAC% of 0.03%, roughly equivalent to 50ml of 37.5% proof spirit, participants are likely to experience mild disinhibition, relaxation and increased talkativeness, and slight impairments in concentration. Depending upon the study, we envisage administering alcohol to achieve a target BAC% of 0.08%, with an upper bound limit of 0.1%.

In this scenario, participants could experience stronger effects of alcohol, resulting in disinhibition, extraversion, and impairments to reasoning, depth perception, and peripheral vision. We consider a target BAC% of 0.08%, often used in research, as a standard upper limit, and a BAC% minimum of 0.06% equivalent to a moderate dosage of alcohol (Wetherill and Fromme, 2011; Hartzler and Fromme, 2003; Soderlund, Grady, Easdon and Tulving, 2007; Duka, Critchley and Kyriaki, 2013).

## How are alcohol dosages scaled?

The procedure we use to determine alcohol dosage was developed using formulae available from Watson (1989). It is predicated on the assumption that in order to reach a target BAC%, the alcohol dose to be administered is a function of the participant’s height, weight, age, gender, total body water (TBW); duration of the drinking period (DDP); time to peak BAC% (TPB); and alcohol metabolism rate (MR). We use 0.015 g/100 ml/hr as the average metabolism rate for all participants. In addition, we assume that participants reach their peak BAC% at 0.5 hr after cessation of drinking.

*Alcohol Dose (g) = (10 x BAC% x TBW)*

*0.8 + 10MR(DDP + TPB)(TBW)*

*0.8*

TBW is determined separately for male and female participants by using gender-specific regression equations provided by Watson:

*Male TBW = 2.447 - 0.09516 x age + 0.1074 x height(cm) + 0.3362 x weight(kg) Female TBW = -2.097 + 0.1069 x height(cm) + 0.2.466 x weight(kg)*

## How is BAC% monitored?

BAC can be determined through breath-alcohol sensor (BrAS) devices; these devices are portable and mush less invasive than blood sampling. The most commonly used BrAS devices employ an electrochemical sensor, which uses a fuel cell design. Ethanol vapour in the breath is fed into the anode compartment where it is oxidized to several possible products, mainly acetaldehyde, acetic acid, and CO2. Protons migrate through the membrane and electrons are transported through the external circuit and into the cathode compartment where they combine with oxygen (from air) to form water. The current or charge transferred is directly related to concentration/amount of ethanol introduced into anode compartment. Thus, after calibration, the sensor can determine ethanol concentrations in unknown samples. For professional level sensors, the accuracy of the tests administered after calibration is ±5% at 0.38 mg/L of exhaled breath.

All participants upon entry into the laboratory will be asked to undergo a breathalyser test, to confirm the absence of alcohol in the bloodstream. After consumption of an alcoholic drink, participant BAC% will then be monitored in timed intervals dependent upon the nature of the study. For example, if the duration of the study after drinking alcohol is 30 minutes, the participant will (1) have 5 minutes to consume an alcoholic drink; (2) wait 10 minutes before the restarting the study; (3) be administered a breathalyser test 20 minutes after the consumption of the alcoholic beverage; (4) be administered a second breathalyser test at the end of the study, 40 minutes after drinking alcohol. In total, three tests are offered during the study, one before consumption and two after. If a longer experiment protocol is followed we may administer a further small dosage of alcohol if needed, at a rate of 0.1g/kg body weight pure alcohol. To be clear, under these protocols no experiment should last longer than one hour

# TRAINING OF RESEARCH STAFF

All new researchers will be trained to (1) measure and calculate the correct alcohol dosage for each participant, (2) be proficient in the use of a breathalyser and know when to administer tests, and (3) provide an appropriate level of participant care; see the attached training checklist to be completed by the lead researchers. Under no circumstances will an inexperienced researcher be left in sole charge of an alcohol study.

# METHODS FOR RECRUITING PARTICIPANTS

Participants for alcohol studies are typically recruited via posters placed around the University campus, Stirling portal adverts, and Psychweb – a token reward system for psychology undergraduate students in Stirling. It is possible that recruitment may also extend to carefully selected organisations within the wider community (for example, nearby further or higher education institutions, or relevant groups/organisations), however these circumstances would be rare and only if experimental design demanded a population beyond the typical Stirling student or staff member. It is acceptable to mention financial rewards in advertisements for alcohol studies, where people volunteer themselves to take part, and there is no significant risk to the participant.

Due to the legal and ethical considerations surrounding alcohol, recruitment advertisements will all include the following information:

* That participants must be over the age of 18 to take part;
* That they must bring photographic ID, which includes date of birth, to the lab for checking by a researcher;
* That female participants are not allowed to take part if they believe there is a chance they may be pregnant;
* That participants should not take part if they are currently taking any prescription medication (excluding the contraceptive pill).
* That participants should not take part if they currently have, or have had in recent history, a substance abuse problem.
* A request that they do not drive themselves to, and from, the testing session. They will instead be asked to make other travel arrangements, for example on foot, by public transport, or be driven by a friend.

# INFORMATION PROVIDED TO THE PARTICIPANT

The specific details provided to participants will vary depending on the study, but will always be given using our information sheet template (see attached), and will always include:

* The name of the study;
* The name(s) and status(es) (e.g. doctoral student) of the researchers carrying out the study and how to contact them;
* A brief rationale of the study, including its purpose and value;
* That participants are required to be over the age of 18, and that they should bring photographic I.D., which includes date of birth, to the study for checks by a researcher;
* That female participants should not take part if they believe there is a chance they may be pregnant;
* Why potential participants are being invited to take part in the research;
* An explanation of what the potential participant will do, including location and estimated duration of study;
* That they can choose whether to take part and, if they agree, that they can withdraw at any time without penalty by advising the researchers of their decision;
* Information about any additional personal information which would be obtained (e.g. height, weight);
* Information about who would have access to this data, how it will be stored, and what will happen to the data at the end of the study;
* That data will be anonymised;
* What benefits (direct or indirect) may accrue to the participants in the study;
* What risks are involved in the study;
* That the project has received ethics clearance through the University of Stirling’s ethical approval process for research including human participants;
* Where applicable, that research may be written up as a student’s thesis and how the personal data included in that thesis will be published and stored;
* The procedure for raising a concern or making a complaint.

# CONSENT OF PARTICIPANTS

All participants will always sign a consent form, prior to consumption of alcohol, which will be given using our consent form template (see attached), and will always include:

* The name of the study;
* The name(s) and status(es) (e.g. doctoral student) of the researchers carrying out the study and how to contact them;
* Declarations that the participant:
	+ Has read the participant information sheet;
	+ Has had the opportunity to ask questions about the study and has received satisfactory answers to questions, and any additional details requested;
	+ Understands that s/he may be asked to consume a moderate amount of alcohol and will be asked to remain in the laboratory until BAC% return to a safe level;
	+ Understands that s/he may withdraw from the study without penalty at any time by advising the researchers of this decision but that they will be invited to remain in the laboratory until BAC% returns to a safe level;
	+ Understands that any accident or incident arising from the participant leaving the laboratory prior to BAC% returning to a safe level will be entirely at their own risk. The University will accept no liability for participants rejecting researcher advice.
	+ Understands that the project has been reviewed by and received ethics clearance through the relevant University of Stirling’s Research Ethics Committee;
	+ Understands who will have access to personal data provided, how the data will be stored, and what will happen to the data at the end of the project;
	+ Understands how to raise a concern and make a complaint;
	+ Agrees to participate in the study.

Participants will sign, print and date their names and the researchers who secure consent will also sign, print and date their names.

# FINANCIAL AND OTHER REWARDS

Participants are compensated for their time with either course credit tokens (via Psychweb) or with money at the rate of £7.50 per hour.

# POTENTIAL RISKS TO PARTICIPANTS / RESEARCHERS / OTHERS

## Risk to participants

* + - **Pregnancy**

At participant sign-up, our exclusion criteria will clearly state that participants who believe they could be pregnant may not take part in the study. Upon arrival at the laboratory, information and consent forms will remind participants of this exclusion. To be clear, participants will have to inform the researchers if they believe there may be a chance of being pregnant, in-line with NHS protocol for other invasive procedures and pregnancy (e.g., CT scans or x-rays). Please see our justification for employing these methods at the end of this protocol.

## Alcohol consumption

To cope with the known side effects of drinking alcohol, we will invite participants to remain in the laboratory until there is no alcohol remaining in their system. However, since we can’t hold participants in the laboratory against their will, if participants wish to leave early we will inform them when their breathalyser tests fall below the Scottish government legal drink drive limits. It should be noted that the University is covered by liability insurance in case any claims are made against the researchers as a result of taking part in this study. Should a participant become unwell after consuming alcohol, the session will be terminated.

## Leaving under intoxication

While we cannot prohibit participants from leaving the laboratory while still under the influence of alcohol, we can mitigate the risks in the following ways:

* Advise during consent / briefing that they will be invited to remain in the laboratory until their BAC% returns below the Scottish government safe driving limit, and preferably to 0%;
* Point out that there will be a disclaimer in the consent form which states that any accident or incident arising from the participant leaving the laboratory prior to BAC% returning to a safe level will be entirely at their own risk. The University will accept no liability for participants rejecting researcher advice.
* There are facilities within the division to ensure participant comfort and entertainment. These include a seating area, PC’s and magazines. Tea, coffee, water etc. is also available;
* Breathalyser tests will be administered at regular intervals once the experiment has finished and the participant kept updated with their BAC%;
* The University carries Public Liability Insurance covering all risks, in case any claims are made against the researchers. [(https://www.stir.ac.uk/media/internal/finance/images/documents/SummaryofInsuranc](http://www.stir.ac.uk/media/internal/finance/images/documents/SummaryofInsuranc) e2013.pdf)

## Cumulative Cancer Risk

Alcohol has been causally linked to many forms of cancer, e.g., cancers of the oral cavity, pharynx, larynx, oesophagus, liver, colorectum, and breast. Critically, present and past alcohol consumption has been attributed to these causally linked cancers in both men (32%) and women (5%) across a European cohort (Schutze et al., 2011). These risks are inflated for both men and women by cumulative heavy alcohol consumption in a number of participants. However, Chen et al., (2011) show that, after controlling for cumulative alcohol consumption, binge drinking, not frequency of drinking, is associated with greater breast cancer risk in females.

Our protocol outlines proposals to give participants a quantity of alcohol that is roughly equivalent to 2 units (~50ml of 37.5% Vodka), and the recommended government guidelines for alcohol consumption are 14 units in males and 7 in females per week. We will therefore

(1) ask participants to factor in the amount of alcohol they drink in any experiment as part of their normal weekly alcohol intake, and (2) if we are testing participants over multiple experiments, to separate the experiments by at least one week in time to minimise the cumulative risks of heavy alcohol drinking.

## Risks to researchers

It is also the responsibility of the researcher to review their own health before each data collection session and, if ill, to cancel any sessions at the earliest available opportunity. Basic procedures such as hand washing before and after any contact with a participant, and during preparation for administering alcohol are mandatory. Any reusable materials will be thoroughly cleaned before use with another participant (e.g., cups, glasses, etc.).

Standard risk assessments of experimental environments and standard procedures are completed and reviewed by appropriately trained personnel. Any study which requires modification from these exemplars should undergo a tailored review prior to commencement.

# MONITORING AND REPORTING OF ADVERSE OR UNFORESEEN EVENTS

If a participant should become unwell during the test session, the session will be terminated. Such a case would be reported in the division’s Safety Book. First aid help is available through the designated health and safety officers.

# DATA PROTECTION ISSUES

Participants will be given a code number, and this, rather than the name, will be used to label all data from the study (e.g. computerised files, paper records). All data collected will therefore be stored anonymously, unless otherwise stated and approved through ethics. If a participant wishes to withdraw after data collection finishes, then the participant will need to contact the researcher and provide the identifying number. At which point all data will be deleted that is related to that participant number. Only researchers mentioned on the ethics application are allowed to review raw data provided on any individual project.

**Appendix**

## Document 1. Information Sheet

Version date: **March 2018 [amend per study]**

Name of Researcher(s) and status Email: researcher.name@stir.ac.uk Approval Reference: GUEPXXX

Participant Information Sheet

We would like to invite you to take part in a research project. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If there is anything that you do not understand, or if you would like more information, please let the researcher(s) know. Thank you for reading this.

1. **Title of Project**
2. **Brief description/aim of project (including purpose and value of the study)**
3. **Why have I been invited to take part?**

EXAMPLE TEXT: You have been invited because….

## Can I take part?

If you suffer from any mental health issues, take medication which may interact with alcohol, are recovering from any substance addiction or may be pregnant, then you will be unable to take part in this study. Please let the researcher(s) know if any of these criteria applies to you. You will also be excluded from taking part if you have any alcohol in your system at the start of the experiment.

You cannot take part if you are under 18 and you must provide photographic ID before the study can commence.

## Do I have to take part?

SUGGESTED TEXT: No. It is up to you to decide if you want to take part in this study. We will describe the study and go through this information sheet with you to answer any questions you

may have. If you do decide to take part, we will ask you to sign a consent form, and will provide you with our contact details along with a description of the purpose of the experiment, in case you have any further questions. It is important for you to know that you are still free to withdraw from the study at any time, without needing to give a reason and without penalty, i.e. withdrawal will not affect your [DELETE AS APPLICABLE: grade, course credits, treatment etc.]. You can also withdraw your data within [ADD AS APPROPRIATE: timeframe].

## What will happen if I take part?

*Make sure the participant knows what is expected of them.*

SUGGESTED TEXT: You will be asked to drink a moderate quantity of alcohol (37.5% Vodka) to achieve a Breath Alcohol Concentration (BAC %) of XXX%, roughly equivalent to X large measures of a spirit. We will ask you to consume this vodka, neatly with no mixer, in X measures over the course of X minutes. The vodka will be chilled to reduce taste intensity. Afterwards we will breathalyse you to record your BAC % before beginning the experiment. [DELETE AS APPROPRIATE: Halfway through the experiment, we will administer a small dosage of alcohol as a ‘top‐up’ to maintain a moderate BAC % for the remainder of the study.]

At the end of the study we will invite you to remain in the lab until your BAC % returns to an acceptable level. We recommend that this is below the Scottish legal driving limit. Sofas, PCs, magazines and tea/coffee/water will be made available while you wait and for your comfort.

SUGGESTED TEXT: Before we begin the study, we will record your height, weight and gender. This is to help us work out the alcohol dosage you need in order to reach the desired BAC% for this study. We will also breathalyse you before we start.

SUGGESTED TEXT: You will need to complete [x] questionnaires/interviews/experiment SUGGESTED TEXT: The [DELETE AS APPROPRIATE: questionnaire/interview/sampling] should take approximately [minutes/hours].

SUGGESTED TEXT: You will be asked to return [x] number of times

*Where will the study take place? Will/Will not be follow up visits?*

## Are there any potential risks in taking part?

SUGGESTED TEXT: The risks associated with alcohol being administered in this study will be monitored and controlled. A moderate scaled dosage of alcohol will be administered in the form of vodka shots. The experimenters will ask you to remain in the laboratory until there is no alcohol left in your system, however, if you choose to leave early, they will use breathalysers to

ensure that when you do leave your blood alcohol concentration is below the legal drink drive limit. The risks to you from taking part in this study are minimal, however, please be aware that there are risks to drinking alcohol which are well documented, and are as follows: (1) Consumption of large amounts of alcohol in a single session can lead to dizziness, nausea, loss of motor control and coordination, and loss of some cognitive functioning. The severity of these symptoms increases dependent upon how much alcohol is drunk. (2) Chronic alcohol consumption, i.e., regular heavy drinking, leads to many problems (as listed above) and also increases the risk of long‐term health problems such as cancers of the mouth, throat, liver, colon, & breast. (3) Drinking alcohol while pregnant can severely damage development of the foetus. To minimise the risks of taking part in the experiment to you, we strongly advise you to factor in to your weekly alcohol intake the amount of alcohol you will consume here today.

## Are there any benefits in taking part?

SUGGESTED TEXT: There will be no direct benefit to you from taking part in this research. [DELETE AS APPROPRIATE: You will receive [x amount/voucher/course credit/gift] for [taking part/reasonable travel costs/meals/childcare].

## What happens to the data I provide? [examples of text – pick the most applicable]

SUGGESTED TEXT: The research data will be kept anonymous using…

SUGGESTED TEXT: Personal/confidential information will be stored anonymously using… SUGGESTED TEXT: The [researcher/research team/ supervisor/ collaborators/ translators/ transcribers] will have access to personal/sensitive data/research data *(but will have signed a confidentiality agreement).*

SUGGESTED TEXT: At the end of the study, the data will be [DELETE AS APPROPRIATE: destroyed/stored on a secure server for Xmonths/years].

*Where, due to the nature of the research, it may not be possible to safeguard the confidentiality of the data – reasons should be stated and the consequences for the participant should be explained.*

***Be clear with participants the circumstances under it would be necessary to break confidentiality. Within UK law, obligations to disclose exist in relation to child protection offences, the physical abuse of vulnerable adults, money laundering and crimes covered by the prevention of terrorism legislation.***

1. **[OPTIONAL/IF APPLICABLE] Recorded media**

*Participant’s permission must be obtained to record their activities on audio or video media. You must provide a clear explanation of how these will be used.*

*If the recordings will form part of a publication/broadcast or be deposited in an archive a separate release form should be prepared for each item used.*

1. **[OPTIONAL/IF APPLICABLE] Future uses of the data**

SUGGESTED TEXT: Due to the nature of this research, it is very likely that other researchers may find the data to be useful in answering other research questions. We will ask for your explicit consent for your data to be shared in this way and, if you agree, we will ensure that the data collected is untraceable back to you before letting others use it. *(Consider whether you are able to make this guarantee)*

## Will the research be published?

SUGGESTED TEXT: The research may/will be published in…. You will/will not be identifiable in any report/publication.

SUGGESTED TEXT STUDENTS: This research will be used for my undergraduate/postgraduate project/thesis.

*Where will the participants be able to access a copy of the published results?*

*Where will the results be presented? At conferences/in journal articles/workshops/mass media?* SUGGESTED TEXT FOR STAFF: The University of Stirling is committed to making the outputs of research publically accessible and supports this commitment through our online open access repository STORRE. Unless funder/publisher requirements prevent us this research will be publicly disseminated through our open access repository.

1. **[OPTIONAL/IF APPLICABLE]: Who is organising and funding the research?**

SUGGESTED TEXT: [x] is sponsoring/funding this research

## Who has reviewed this research project?

SUGGESTED TEXT: This project has been ethically approved via The University of Stirling [General University Ethics Panel/NHS, Invasive & Clinical Research Ethics Committee/ Animal Welfare and Ethics Review Body].

## Who do I contact if I have concerns about this study or I wish to complain?

SUGGESTED TEXT: If you would like to discuss the research with someone……

*You should give the participants your contact details and the contact details for one other individual within your Faculty (usually Head of Division), in case they wish to obtain further information about the project.*

SUGGESTED TEXT: You will be given a copy of this information sheet to keep. SUGGESTED TEXT: **Thank you for your participation.**

## Document 2. Consent Form

Participant Consent Form

Study Number [Insert] Participant number [Insert]

## Research Project Title:

|  |
| --- |
| Please initial box |
| SUGGESTED TEXT: I understand that this project has been reviewed and received clearance through [DELETE AS APPROPRIATE: the University of Stirling’s Research Ethics Committee (GUEP) and the NHS,Invasive or Clinical Research Committee (NICR)]. |  |
| SUGGESTED TEXT: I confirm that I have read and understood the [DELETE AS APPROPRIATE: information sheet/letter] dated [insert date] explaining the above research project and I have had theopportunity to ask questions about the project and have had these answered satisfactorily. |  |
| SUGGESTED TEXT: I confirm that I am over the age of 18, and I have presented photographicconfirmation of this to the researchers. |  |
| SUGGESTED TEXT: I understand the exclusion criteria for the study outlined in the information sheet,and confirm that I am eligible to take part in this study. |  |
| SUGGESTED TEXT: I understand that I will be asked to consume a moderate amount of alcohol, and that I will be invited to remain in the laboratory until my blood alcohol % reduces is at least below therecommended Scottish government legal driving limit. |  |
| SUGGESTED TEXT: I understand that my participation is voluntary and that I am free to withdraw at anytime during the study and withdraw my data within [provide timeframe] without giving a reason, and without any penalty. |  |
| SUGGESTED TEXT: I understand that while I am free to withdraw from the study at any time, I havebeen advised I should remain in the laboratory until my BAC% returns to a safe level (at least below the recommended Scottish government drink legal drink driving limit). |  |
| SUGGESTED TEXT: I understand that, should I decide to leave the laboratory before my BAC% has returned to a safe level, then the University of Stirling will accept no liability for any resulting accidentor incident. My departure from the laboratory will be entirely at my own risk. |  |
| SUGGESTED TEXT: I understand that my responses will be kept anonymous [if true] and I givepermission for members of the research team to have access to my anonymised responses [if true]. |  |
| OPTIONAL DELETE AS APPROPRIATE: I consent to being [audio recorded/video recorded/having myphoto taken] |  |
| OPTIONAL DELETE AS APPROPRIATE: I understand how [audio/video/photographs] will be used in research outputs. I am aware that I will not be named in any research outputs but I could be identifiedby people I know through the stories I tell. |  |
| OPTIONAL DELETE AS APPROPRIATE: I agree for research data collected in the study to be given to |  |

|  |  |
| --- | --- |
| researchers, including those working outside the EU to be used in other research studies. I understandthat any data that leave the research group will be fully anonymised so that I cannot be identified. |  |
| OPTIONAL DELETE AS APPROPRIATE: I give my permission for the data collected during this currentstudy to be used in future research. |  |
| OPTIONAL DELETE AS APPROPRIATE: I give my permission for my personal data to be kept in a securedatabase for the purpose of contacting me about future studies. |  |
| SUGGESTED TEXT: I have been asked how I travelled to the laboratory and (if required) was offeredadvice on public/other transport methods available. |  |
| SUGGESTED TEXT: I understand how to raise a concern or make a complaint relating to this study. |  |
| SUGGESTED TEXT: I agree to take part in this study |  |

**Name of Participant Signature:**

**Date:** Click here to enter a date

## Name of Researcher Signature:

**Date:** Click here to enter a date

**Researcher Training Checklist – Administering Alcohol:** This form should be used for all researchers/students administering alcohol to participants in the PIL lab, and should be completed by a qualified researcher. When completed, please print and send to the lab manager, Catriona Bruce, for our records.

**Name of researcher/student:**

**Number of training sessions completed:**

**Name of supervising trainer: Date:**

The named researcher/student above has completed sufficient training in these given criteria below (check boxes), and is therefore qualified to conduct alcohol studies at the PIL lab.

## Participant Welfare:

* Information sheets & ID check; Consent forms; Debriefing
* Participant comfort throughout testing
* Accident handling and departmental first aid protocols

## Administering Alcohol Dosage:

* Measurement of height/weight
* Calculating correct alcohol dosage
* Use of Breathalyser

## Laboratory Hygiene:

* Sterilisation of glassware & breathalyser
* Storage of equipment
* Notification of faulty equipment
* Consumables (includes all stock such as towels, shampoo, sticks, gel, etc.)
* Cleaning lab workbenches & computer desks

## Any additional comments:

**Justification for dealing with low risk of pregnancy:**

This document is to clearly outline our arguments against the inclusion of urine pregnancy tests as a required part of alcohol studies at Stirling. Ultimately, we should be aiming to minimise risks to participants, and the administering of urine sample pregnancy tests raises many other ethical concerns and risks, which we detail below. Note that this list is not exhaustive.

**NHS protocol:** The NHS does not administer urine sample pregnancy tests for invasive procedures for which pregnancy would be grounds for exclusion (e.g., CT scans, x‐rays). We see no valid reason why our criteria must be more stringent than the NHS when we are administering low dosages of ethanol, which is legal and can be freely consumed by anyone over the age of 18.

**False results:** Most manufacturers claim high accuracy in their pregnancy tests, e.g., ClearBlue claims 99% accuracy, even during early stages of pregnancy. However, these claims are largely false in cases of early pregnancy detection (Cole et al., 2005). For example, Clearblue Easy Earliest Results detected 80% of pregnancies in Cole et al. (2005), while other products tested performed considerably worse (sensitivity of five other products indicated detection of 16% or less of pregnancies). Furthermore, performance on urine sample pregnancy tests is hampered by how dilute the urine sample is.

The majority of over the counter pregnancy tests claim high accuracy due to the control of false positives in the test, i.e., a positive test result when the person is actually not pregnant. However, false negative results are arguably more dangerous for the purpose of our protocol, since this would mean that a participant may be pregnant and would be able to participate in experiments consuming alcohol. Recent evidence from online surveys of women taking early pregnancy tests, i.e., before their expected period, indicate a 1.1% false positive rate but **5.4% false negative** outcome (from 1541 tests taken, sampled in 1100 women; see [http://www.madeformums.com/pregnancy/early‐pregnancy‐tests‐surv](http://www.madeformums.com/pregnancy/early)ey‐‐‐the‐results/37007.html).

Pregnancy tests are diagnostic. The consequences of a false positive result are that we must refer our participants to their GP for further tests to confirm/deny the original test result, causing unnecessary participant stress and anxiety, data protection and confidentiality issues, and possible further legal action. The consequence of a false negative result is that we could also face legal action.

**Recording of sensitive data:** If we asked female participants to take a urine sample pregnancy test, the data from the test is recorded, leaving a physical record. This raises all kinds of issues regarding acquisition of sensitive data, data storage, and confidentiality.

**Invasion of privacy:** We strongly believe that asking female participants to undergo a pregnancy test is a violation of that individual’s privacy, especially since that data would be recorded.

**Breaking a bond of trust:** By requiring all our female participants to take urine sample pregnancy tests we are insinuating that we do not trust their judgements about their own body. Our exclusion criteria already ask participants not to take part in experiments if they are taking any medication (apart from the oral contraceptive pill) or if they believe they may be pregnant. We do not require a drug test from all of our participants when they enter the laboratory; in fact, we believe that both our male and female participants would be honest when signing up to an experiment. Therefore, there is no reason why we should doubt our female participants’ honesty and integrity on the issue of pregnancy, and we should trust that they can take responsibility for their own health.