**Participant Information Sheet (PIS) Guidance**

Human participants in experiments can only give *informed* consent if they have received sufficient information about the study they are to take part in. This information should be provided to the participant prior to having them sign the consent form, and therefore prior to the start of the experiment. The information may be conveyed to the participant in the following formats:

* E-mail/letter to the participant
* Information provided at the start of an online experiment
* Information sheet handed to the participant
* Transcript of the verbal information provided to the participant
* For special populations: letter to parent, legal guardian, care giver etc. (whoever is best placed to provide informed consent).
* Experimental Hours advert (School of Psychological Science)

When applying for ethical approval, the  [School of Psychological Science Research Ethics Committee](https://uob.sharepoint.com/sites/life-sciences/SitePages/Psychological-Science.aspx) (SPSREC) needs to examine the information provided to the participants in order to gauge whether participants have received sufficient information to make an informed decision about their participation. As a result, experimenters need to supply the SPSREC with a document that outlines the information they intend to give participants. The next page aims to guide experimenters through the process of preparing such a document. Also provided are example information sheets for two experiments that occupy different parts of the “ethical sensitivity spectrum”: Example 1 can be considered to be ethically more sensitive (administration of substances), whereas Example 2 can be regarded as almost ethically innocuous (lexical decision).

Clearly, in most studies some aspect of the work is kept hidden from the participant (and sometimes active deception may be necessary; see application form for a definition). It is up to the experimenter and the SPSREC to judge whether participants will receive sufficient information to give consent, and whether any form of deception is justified in terms of the risks and benefits of the work.

Finally, take care to choose a terminology that is tailored to whoever gives consent. One should inform parents, care givers, or lay members of the public using language devoid of complicated and technical jargon.

**Background**

You should consider providing some description of the wider context of the study.

1. General area of research/broad aims of the current study.
2. Theoretical and/or practical contribution of the work.

In many cases, a complete explanation of the specific purpose of the study will be given in the debriefing phase. However, sometimes (e.g. developmental work with children) there will be little or no debrief. In such cases it is all the more important to clearly state the purpose of the research in the information that is provided to the person giving consent (e.g. parent).[[1]](#footnote-1)

**Experimental procedures**

A description of the procedures the participant will be subjected to in the course of the experiment. If there is any aspect of these procedures that the participant might conceivably object to, you have a responsibility to inform the participant of this particular aspect.

1. Selection criteria (if applicable, and if stating these is unlikely to cause upset).
2. Equipment used.
3. The participant’s task(s).
4. The type of data collected.
5. Estimate of the timescales involved.
6. Statement of risk, potential stress or discomfort.
7. Benefits/rewards to the participant (e.g. payment, experimental hours).
8. Reminder of the right to withdraw at any time, without having to give a reason. When dealing with special populations (e.g. children) the experimenter should carefully monitor the emotional state of the participant. If the participant appears uncomfortable, distressed, and/or avoidant the study should not continue.

**Data handling**

*After* having completed the study, we recommend that participants are given an option to give consent to their data being included in further analyses. Note that in some cases this consent can only be obtained before testing starts (e.g. when consent is obtained from a third party, as in developmental research).

1. Are the data anonymous or confidential?
	* Anonymous: participants should be made aware that they *cannot* withdraw their data from the study once they have consented.
	* Confidential:
		+ Will the data *ever* be anonymised?
			- yes: provide indication of timescale involved (e.g. after last testing session).
			- no.
		+ Measures taken to ensure that data are kept secure (GDPR, https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/).
2. Will “personal” data ever be in the public domain?
	* Personal data: name, identity, audiovisual recordings of the participant, photographs of the participant, etc.
	* If such data are to be used in the public domain (e.g. in presentations or journal articles), permission should be sought from the participant.
3. Who controls the data?
	* Typically this will be the University of Bristol.
	* If shared with other institutions, provide assurance that data are treated according with DPA (or equivalent legal measures in the country of the institution of your collaborators).

**Other information**

1. Ethical approval code
2. Contact details of main experimenter to whom further questions about the study can be addressed.
3. Statement of whom to direct any concerns about the study. We suggest the following: “If you have any concerns regarding your participation in this study please direct them to the university Research Governance Team (RGT) via research-ethics@bristol.ac.uk.”

**Example 1: Information sheet given/sent to participants**

Ethical approval code xxxxx

**Attentional bias training and cue reactivity among social drinkers**

Before you decide to take part in this study, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with friends, relatives or your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

*Background*

This is a study to measure the effects of exposure to alcohol-related pictures on subsequent cravings for alcohol. Understanding the effects of alcohol-related cues on cravings for alcohol is important in helping to explain why people drink. We are attempting to understand more about how the impact of alcohol-related cues differs between people and across situations. Our results may eventually be published in a scientific journal, and may also be reported at scientific meetings.

*Procedures*

You have been chosen, because you are a social alcohol drinker, aged 18 to 40. You should not use alcohol to excess (50 units / week for men; 35 units / week for women), or have a family history of alcoholism, and should not be using other illicit drugs (such as cannabis). However, participation in the study is entirely voluntary. It is up to you to decide whether or not to do this. If you do decide to take part, we would ask you to sign a consent form and give you a copy of this information sheet and the consent form to keep. If you decide to take part you are still free to withdraw from the study at any time. If you decide not to take part, or to withdraw, you do not have to give a reason, nobody would be upset.

If you took part, we would ask you to avoid drinking alcohol for 24 hours prior to the study. You would first give a breath sample to confirm your alcohol drinking status, and then complete some short questionnaires. You would then be asked to complete a computer-based reaction time task, during which you would be presented with alcohol-related and neutral pictures. Next, you would be presented with a series of alcohol cues, and be asked to rate your mood and craving for alcohol. You would also be asked to rate the pleasantness of two drinks, one alcoholic and one non-alcoholic.

Upon completion of the session we will inform you in more detail about the hypotheses we are testing, and you will have the opportunity to ask further questions. The time spent on the study will contribute towards the Experimental Hours scheme (3 hours). If you are not part of this scheme we will reimburse you £15.

You might experience moderate cravings for alcohol during and immediately after the experiment, but we do not expect these effects to last very long. You will consume a small amount of alcohol during the study, and should bear this in mind after the study (i.e., not drive or operate machinery).

*Your data*

All data collected in this study will be anonymised. There is no record that links the data collected from you with personal data from which you could be identified (i.e. the signed consent form). Upon completion of the experiment we ask you to give consent to include your data in further analyses. You are free to withdraw your data from the study at that point. Once you have given consent, we cannot withdraw your data at a later stage because of the anonymised nature of the study.

If you have any questions at any time about the study, please do not hesitate to contact <Experimenter’s name + contact details>.

If you have any concerns regarding your participation in this study please direct them to the university Research Governance Team (RGT) via research-ethics@bristol.ac.uk.**Example 2: Information through Experimental Hours advert**

*Study Name*:Words and nonwords - can you tell the difference?

*Description*: This study investigates the way in which the human visual system recognises words during reading. The task that you are asked to do is a lexical decision task: you will be presented with a series of letter strings on a computer screen, and you will have to decide for each one whether it is a word (“door”) or a nonword (“blap”) by pressing one of two keys on a computer keyboard. We are interested in the speed and accuracy with which you are able to perform this decision.

All the data collected from you will be anonymised and there will be no record that links the data collected from you with personal data from which you could be identified. Note that you are free to withdraw from the experiment at any time, without having to give a reason. In addition, you can decide not to consent to having your data included in further analyses.

*Eligibility Requirements*:To be eligible to take part in this study you must have no uncorrected visual abnormalities (e.g. colour blindness).

*Duration*:60 minutes

*Credits*:1 Credit

*Researcher*: <Experimenter’s name + contact details>

*Principal Investigator:* <PI’s/Supervisor’s name + contact details>

*Ethics Approval Code*: xxxxx

If you have any concerns regarding your participation in this study please direct them to the university Research Governance Team (RGT) via research-ethics@bristol.ac.uk.

1. This is the view of the Society for Research in Child Development on the topic of providing information in studies involving children. http://www.srcd.org/ethicalstandards.html [↑](#footnote-ref-1)