**Participant Information Guidance Document**

**Information for human participants**

Participants involved in research 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 your study. The information may be conveyed to the participant in the following formats:

1. E-mail/letter to the participant
2. Information sheet handed to the participant
3. Transcript of the verbal information provided to the participant
4. For special populations: letter to parent, legal guardian, care giver etc. (whoever is best placed to provide informed consent).

When applying for ethical approval, the Faculty of Arts Research Ethics Committee (FREC) 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 FREC with a document that outlines the information they intend to give participants. The next page aims to guide researchers through the process of preparing such a document.

It is up to the researchers and the FREC to judge whether participants will receive sufficient information to give consent 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)

**Research 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 behavioural task.
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. 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, participants need 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 (Data Protection Act).
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).
4. **How will the data be made available at the end of the project? (You must declare your level of access)**

Research funders and publishers increasingly require researchers to find a way to provide access to their research data, even if that data initially includes personal information.

The University of Bristol requires you to assign an expected access level to your research data, your selection will be checked and signed off by the Ethics Committee. If you intend to create multiple datasets with different anticipated access levels you should select the most restrictive access level you expect to use. The four access levels are:

* 1. Open – my data can be made openly available through a data repository
	2. Registration required – my data should only be available to bona fide researchers, on request
	3. Controlled – any access requests for my data should be referred to committee for review on a case-by-case basis
	4. Closed – my data should not available for sharing

If, during the course of your research, you believe that your nominated access level will no longer be appropriate you should inform your Faculty Ethics Officer.

You must also ensure that you get the appropriate level of consent from participants at the start of the project to allow for onward use.  If you need more information about this please see the guidance on sensitive data <http://data.bris.ac.uk/research/storage-and-security/sensitive-data/> or contact data-bris@bristol.ac.uk

**Guidance on access levels**

**Open** – this level can be assigned where consent has been given by participants to make their anonymised data publicly available through a repository, in addition the risk assessment of re-identification of this anonymised data has been classed as low. These data sets can be made openly available through data repositories, including the Bristol Research Data Repository.

**Registration required** – this level can be assigned where consent has been given by participants to make their anonymised data available to bona fide researchers on request, within the terms of participant consent and the risk assessment of re-identification of the anonymised data is low.  If the data is deposited with the University of Bristol Research Data Repository requests will be facilitated by the Research Data Service.

**Controlled** – this covers cases where historical consent for sharing is very limited and/or the risk assessment of re-identification is classed as medium to high.  If the data is deposited with the University of Bristol Research Data Repository the Research Data Service will forward on requests to a Data Access Committee who will work with you as the PI to decide if/what data is appropriate to be made available.

**Closed** – this covers data that is not available for sharing (except by regulators) because of ethical, IPR, prior exclusive agreements or other constraints.  This should only be assigned if you have got prior agreement from the funder that they are willing to allow the data to be completely closed.

**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 related to your participation in this study, please direct them to the Research Governance Team, 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

“**Principle 2.** INFORMED CONSENT: Before seeking consent or assent from the child, the investigator should inform the child of all features of the research that may affect his or her willingness to participate and should answer the child's questions in terms appropriate to the child's comprehension. The investigator should respect the child's freedom to choose to participate in the research or not by giving the child the opportunity to give or not give assent to participation as well as to choose to discontinue participation at any time. Assent means that the child shows some form of agreement to participate without necessarily comprehending the full significance of the research necessary to give informed consent. Investigators working with infants should take special effort to explain the research procedures to the parents and be especially sensitive to any indicators of discomfort in the infant. In spite of the paramount importance of obtaining consent, instances can arise in which consent or any kind of contact with the participant would make the research impossible to carry out. Non-intrusive field research is a common example. Conceivably, such research can be carried out ethically if it is conducted in public places, participants’ anonymity is totally protected, and there are no foreseeable negative consequences to the participant. However, judgments on whether such research is ethical in particular circumstances should be made in consultation with an Institutional Review Board.

**Principle 3.** PARENTAL CONSENT: The informed consent of parents, legal guardians or those who act in loco parentis (e.g., teachers, superintendents of institutions) similarly should be obtained, preferably in writing. Informed consent requires that parents or other responsible adults be informed of all the features of the research that may affect their willingness to allow the child to participate. This information should include the profession and institution affiliation of the investigator. Not only should the right of the responsible adults to refuse consent be respected, but also they should be informed that they may refuse to participate without incurring any penalty to them or to the child.

**Principle 12.** INFORMING PARTICIPANTS: Immediately after the data are collected, the investigator should clarify for the research participant any misconceptions that may have arisen. The investigator also recognizes a duty to report general findings to participants in terms appropriate to their understanding. Where scientific or humane values justify withholding information, every effort should be made so that withholding the information has no damaging consequences for the participant.” [↑](#footnote-ref-1)