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| School of Psychological Science  12a Priory Road  BRISTOL BS8 1TU  United Kingdom  [*PI phone]*  [*PI email address]*  www.bristol.ac.uk | |

**\*\*IMPORTANT NOTE\*\***

**Templates are provided for guidance. They should be used as a start point in document development. Researchers are responsible for ensuring that documents meet the research and governance requirements for their specific study. Not all sections may be relevant and/or others may need to be added.**

**Sections of standardised text are included in some sections. READ each CAREFULLY before you decide whether you should include.**

**REMEMBER TO DELETE THIS TEXT BOX PRIOR TO PRINTING YOUR DOCUMENTS.**

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| **PARTICIPANT INFORMATION SHEET**  **[*Study title*]**  [*Researchers*]  *You are being invited to take part in a research study. Before you decide, 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 others 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 and remember that your participation is voluntary*.  **What is the purpose of the study?**  **Why have I been invited?**  [*You have been invited because you have enquired about our studies or have asked to receive further information following reading the summary version described in the letter of invitation or in a study advertisement*.]  **Do I have to take part?**  [*It is up to you to decide whether or not to take part. If you do decide to take part you would be given this information sheet to keep and be asked to sign a consent form prior to any further procedures (excluding an initial telephone screening). If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, would not affect your future or be held against you in any way*.]  **Am I eligible to take part?**  **Please note you must be aged over 18 to volunteer and may be asked to provide identification as proof of age.**  *“Please read all of these criteria very carefully and contact the researcher if you have any doubts regarding your eligibility. If you do not pass the screening on the study day, you will not be able to take part, and we cannot offer reimbursement for screening failures.”*  In order to take part you should:   * [*ADD INCLUSION CRITERIA*]   You would **not** be able to take part in the study if you:   * [*ADD ANY ADDITIONAL EXCLUSION CRITERIA*]   **Expenses and reimbursement**  *“Participants who are ineligible on the testing day based on the criteria described above, will not be reimbursed or given course credit. Please read these criteria carefully to ensure that you are eligible.” [ADD IN DETAILS OF ANY REIMBURSEMENT]*  **How much time will the study take?**  [*Your time commitment in the study is as follows…*]  **What will I have to do?**  [*PROCEDURES*]  **What are the possible disadvantages and risks of taking part?**  [*IDENTIFY ANY RISKS.*  *Your life insurance or private medical insurance could be affected by taking part and if you have private medical insurance you should check with the company before agreeing to participate*.]  **What are the side effects of any treatment received when taking part?**  **What are the possible benefits of taking part?**  [*You would not directly benefit from taking part in this research study and your participation is voluntary. However, the information we get from this study may help us to understand INSERT.*]  **What if there is a problem?**  [*Any complaint about the way you have been dealt with during the study or any possible harm you might suffer would be addressed.*  *If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you've been approached or treated during the course of this study, please contact INSERT STUDY CONTACT.* ]  **Will my taking part in this study be kept confidential?**  [*Yes. Your identity and personal information that could identify you (e.g., name, email address, date of birth) will be kept securely by the study team and will not be shared publicly or with other research groups. On occasion this information may be made available to university research staff and government bodies which monitor whether research studies are performed properly. However, this will only be in the context of monitoring and this information will not be used to contact you or to make your participation in this study known.*  *This research study will adhere to General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018. We will be using information from you in order to undertake this study and will act as the data controller for this. This means that we are responsible for looking after your information and using it properly. We will keep identifiable information about you (name, email address) until one year after the study, but this will not be shared or be part of your study data. If you agree to take part in a study, data about you will be processed for a task in the public interest, which is consistent with the University Charter for scientific research.*  *Any data that you provide will be held by a third party, Gorilla (https://gorilla.sc/), who may in turn share it with other third parties based overseas. Any content and personal data that you provide could be accessed by Gorilla.]*  **What would happen to the results of the research study?**  *[During the study, we will collect two types of data: screening data and study data. Both types of data are anonymised. This means we give the data a unique identification number and your personal information (e.g., name, date of birth, email address) is removed, so that you cannot be identified by this information.*  *Screening data are collected before you are fully enrolled onto the study. They identify whether you are eligible for the study, but they are not part of the study data. We keep these data securely within our research group but do not share it.*  *Study data refer to the information gathered once you are enrolled onto the study. These data are collected to answer our research questions.*  *When the study has been completed, we would analyse the study data we have collected and report the findings. This would be reported in an appropriate scientific journal or presented at a scientific meeting. You would not be identified in any way and if you would like a copy of the final paper, you may request this.*  *As your study data are anonymised, it would not be possible to identify you by name from any aspect of documentation or reporting for this research study.*  *Your rights to access your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.*  *At the end of the study your data would become “open data”. This means that it would be stored in an online database so that it is publicly available. Your screening data would not be shared.*  *What is open data?*  *Open data means that study data are made available, free of charge, to anyone interested in the research, or who wishes to conduct their own analysis of the data. We would therefore have no control over how these data are used. However, all data would be anonymised before being made available and therefore there would be no way to identify you from the study data.*  *Why open data?*  *Sharing research data and findings is considered best scientific practice and is a requirement of many funding bodies and scientific journals. As a large proportion of research is publicly funded, the outcomes of the research should be made publicly available. Sharing data helps to maximise the impact of investment through wider use, and encourages new avenues of research*.]  **Can I withdraw my study data after I have participated in the study?**  [*Yes. If you decide that you do not want your data to be used you can contact the study team and request that your data are withdrawn. You can do this up to one year after the study ends or up until the point the data are shared as “open data” (whichever comes first). At this point links between your identity and your anonymised data set would be destroyed, and therefore we would no longer be able to withdraw your data as we would no longer be able to identity which data set is yours*.]  **Who is organising and funding the research?**  **Who has reviewed the study?**  *[INSERT details of ethics committee and reference number]* **Who can I contact for further information?** ***If you participate in this study you would be given a copy of this information sheet and a signed consent form to keep.*** |