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| **INSTRUCTIONS FOR RESEARCHER ON THE USE OF THIS TEMPLATE**1. As agreed by the University Research Integrity and Ethics Committee, this Participant Information Sheet is a Cardiff University template that may be modified. The researcher may adapt the document to enhance its relevance, as determined bt the nature of the research being proposed and the participants being invited.
2. Text within [square brackets] provides guidance to researchers. This text should be amended to reflect the particular nature of the research project.
3. Studies involving human tissue samples should refer to the University’s HTA template Participant Information Sheet.
4. Studies involving recruitment from the NHS should refer to the Health Research Authority template Participant Information Sheet.
5. The Participant Information Sheet and all other participant-facing documentation must be submitted as part of your ethical review application. Please ensure that all participant-facing documents include a version number and date.
6. This text box should be deleted when your Participant Information Sheet has been finalised for use.
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**PARTICIPANT INFORMATION SHEET**

**[RESEARCH PROJECT TITLE]**

You are being invited to take part in a research project. Before you decide whether or not to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others, if you wish.

Thank you for reading this.

1. **What is the purpose of this research project?**

[Insert basic background information on the research project, its aims and whether it is a student project. If relevant, include a brief description of any samples required. Keep this paragraph short and use lay language.]

1. **Why have I been invited to take part?**

You have been invited because [insert selection criteria for participants e.g. healthy volunteer, attendance at a particular clinic, known to have a particular condition.]

1. **Do I have to take part?**

No, your participation in this research project is entirely voluntary and it is up to you to decide whether or not to take part. If you decide to take part, we will discuss the research project with you [and ask you to sign a consent form]. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights. [If participants are Cardiff University students, it should be made clear that involvement in this research project will have no effect on their education or progression through a degree course. If participants are receiving care, confirm that their decision to take part or not to take part will not affect the care they receive.]

You are free to withdraw your consent to participate in the research project at any time, without giving a reason, even after signing the consent form.

1. **What will taking part involve?**

[Describe involvement from the potential participant’s perspective. State the overall period of involvement for the participant, how often they will need to participate and the time for each session. Explain what will happen (e.g. interviews, questionnaires, blood tests, scans). If any activity involves the participant being recorded (audio/video/photograph), this must be explicitly stated.]

1. **Will I be paid for taking part?**

Yes/No. [If ‘Yes’, insert details of any payments that will be made for time and expenses.] You should understand that any [data/samples] you give will be as a gift and you will not benefit financially in the future should this research project lead to the development of a new treatment/method/test/assessment.

1. **What are the possible benefits of taking part?**

[State any benefits to the participants that are reasonably expected. It is important not to exaggerate the potential benefits. If there is no intended benefit to the participant from taking part, this should be clearly stated e.g. there will be no direct advantages or benefits to you from taking part, but your contribution will help us understand [insert details].]

1. **What are the possible risks of taking part?**

[Any foreseeable discomforts, risks or disadvantages should be described to potential participants, including the likelihood of their occurring. Consider risk of physical harm, risk to confidentiality, psychological risk and the actions taken to mitigate against risks.]

1. **Will my taking part in this research project be kept confidential?**

All information collected from (or about) you during the research project will be kept confidential and any personal information you provide will be managed in accordance with data protection legislation. Please see ‘What will happen to my Personal Data?’ (below) for further information.

[Consider whether there may be circumstances in which the research team may need to over-ride confidentiality e.g. in exceptional cases, the research team may be legally and/or professionally required to over-ride confidentiality and to disclose information obtained from (or about) you to statutory bodies or relevant agencies. For example, this might arise where the research team has reason to believe that there is a risk to your safety, or the safety of others. Where appropriate, the research team will aim to notify you of the need to break confidentiality (but this may not be appropriate in all cases).]

1. **What will happen to my Personal Data?**

[Personal data, according to the General Data Protection Regulation (GDPR) means any information relating to an identifiable living person who can be directly or indirectly identified in particular by reference to an identifier. This may include information such as an individual's name, address, email address or date of birth. If your research project is using personal data (and note that any research project involving the use of written consent forms will be using personal data), describe the person data that will be collected/used and the arrangements for anonymising it (e.g. use of a research project number). If you are offering choices to the participants regarding anonymity/ identification, this should be made clear. Personal data is not anonymous where researchers have, or are likely to have in the future, access to a key, or other means, which would enable re-identification of the individual to which the personal data relates.]

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. Further information about Data Protection, including:

* your rights
* the legal basis under which Cardiff University processes your personal data for research
* Cardiff University’s Data Protection Policy
* how to contact the Cardiff University Data Protection Officer
* how to contact the Information Commissioner’s Office

may be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection

[It should not be assumed that potential participants have access to the internet, therefore, printed copies of the above-mentioned documentation and privacy notices should be readily available.]

[If collaborating with third parties to undertake this research project, state what personal data will be shared with each party and for what purpose(s). Other institutions may be acting as Data Controllers if they are in a position to identify specific individuals from the personal data. It should be made clear if an external agency is being used to transcribe data. Specify if the personal data will be transferred to parties outside of the European Economic Area and, if so, describe the safeguards that will be in place to protect the personal data.]

Cardiff University will need to share [description of personal data] with [name of third party] for the purposes of this research project.

[You must state the time period over which you will be processing a participant’s personal data.]

After [timeframe], the research team will anonymise all the personal data it has collected from, or about, you in connection with this research project, with the exception of your consent form [including details of any other person data which must be retained].   Your consent form [including details of any other personally identifiable information which must be retained] will be retained for [insert either the timeframe stipulated by the funder of the research project or, if no stipulation, insert the timeframe in accordance with the University Records Retention Schedules] and may be accessed by members of the research team and, where necessary, by members of the University’s governance and audit teams or by regulatory authorities.   Anonymised information will be kept for a minimum of [insert either the timeframe stipulated by the funder of the research or, if no stipulation, insert the timeframe in accordance with the University Records Retention Schedules] but may be published in support of the research project and/or retained indefinitely, where it is likely to have continuing value for research purposes.

[State what will happen to personal data and samples collected up until the point of participant withdrawal from the research project. Note that it will not be possible to withdraw any anonymised data that has already been published or in some cases, where identifiers are irreversibly removed during the course of a research project, from the point at which it has been anonymised.]

1. **What happens to the data at the end of the research project?**

[Include a statement outlining how the data collected during the research project will be used after the end of the research project. Will the data be made publically available and/or shared within the University and/or shared outside of the University? Will any future research using the data be limited to a particular field of research? Will the data be shared via a data repository and will this be openly available to others, or will it be through a restricted access method due to the sensitivity of the research project? Offer reassurances that any personal data will be removed before any form of sharing takes place. For studies involving human tissue samples, refer to the HTA template Participant Information Sheet.]

1. **What will happen to the results of the research project?**

[Inform the participants when the results are likely to be published, where they can obtain a copy of the published results, or, if randomised, whether they will be told in which arm of the research project they were involved.] It is our intention to publish the results of this research project in academic journals and present findings at conferences. Participants will not be identified in any report, publication or presentation. [Insert whether there is an intention to use verbatim quotes from participants.]

1. **What if there is a problem?**

[Set out how complaints will be handled and what redress may be available (i.e. describe the process). In the first instance, notify participants which member of the research team they may contact (e.g. the Chief Investigator), should they wish to raise a complaint. Participants should be informed that, if they feel their complaint has not been handled to their satisfaction, they may contact someone independent from the research team (for example, the Chair of the School Research Ethics Committee).]

If you wish to complain, or have grounds for concerns about any aspect of the manner in which you have been approached or treated during the course of this research, please contact [insert name of research team]. If your complaint is not managed to your satisfaction, please contact [insert name and contact details for the member of staff who handles complaints for your School.]

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, you may have grounds for legal action, but you may have to pay for it.

1. **Who is organising and funding this research project?**

The research is organised by [insert Chief Investigator name and School] in Cardiff University [For studies involving a large research team, the Chief Investigator(s)/Lead Researchers should be listed as a minimum. For student research projects, the student researcher and academic supervisor should be listed as a minimum]. The research is currently funded by [insert funding body].

1. **Who has reviewed this research project?**

This research project has been reviewed and given a favourable opinion by the [insert appropriate School Research Ethics Committee, Cardiff University/external ethics committee].

1. **Further information and contact details**

Should you have any questions relating to this research project, you may contact us during normal working hours:

[Insert contact details of at least one research project contact, including name, address, phone number and email.]

**Thank you for considering to take part in this research project. If you decide to participate, you will be given a copy of the Participant Information Sheet and a signed consent form to keep for your records.**