NOTES – PLEASE DELETE THIS SECTION AND THE GUIDANCE NOTES IN ITALICS BELOW BEFORE USE WITH PARTICIPANTS:

This is provided as a flexible framework, not a fixed template. Sub-headings and suggestions for content are provided which meet best-practice guidelines and current data protection regulation requirements, but you must complete the sections as appropriate with details relevant to your research. This template should be used in conjunction with the University of Exeter consent form template and both documents should be dated and version controlled. Participants should be given a copy of the participant information sheet and consent form to keep.

The purpose of a participant information sheet is to provide enough information, in a format suitable for the audience, to allow potential participants to make a decision about whether to participate or to decline participation. Please consider the wording and layout carefully to ensure that the explanations are as clear as they can be – do not cut and paste from research proposals or protocols and use lay language, not scientific or technical language. You may need to consider providing different information sheets and consent forms for different participant groups, perhaps based on what you will ask them to do or on, for example, their age group.

No new information should be presented in the consent form that is not discussed in the participant information sheet. If you are proposing to use an alternative or opt-out consent methods, proposing to deceive participants about the nature of the study or to involve children, you may wish to contact your discipline ethics officer or the Research Ethics and Governance Office for advice prior to submitting your application for ethical review. Any research involving adults who lack capacity to give consent must be discussed as early as possible with the Research Ethics and Governance team.

Researchers applying to the Health Research Authority for approval should contact the Research Ethics and Governance Office for guidance and use the participant information sheet and consent form templates available at <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/>



**Participant Information Sheet**

*(Insert participant group here, where relevant and if more than one participant group is involved)*

**Title of Project:**

**Researcher name:**

**Invitation and brief summary:**

*Give brief information about your study/project – this is just to allow potential participants to decide if they want to read any further and to thank them for their interest. Include a statement such as ‘Please take time to consider the information carefully and to discuss it with family or friends if you wish, or to ask the researcher questions.’ There may be also be specific issues to address here when you are inviting someone else to give consent on behalf of another (e.g. parental consent for a child).*

**Purpose of the research:**

*What is the nature of the research? Why are you doing this research? What is already known?*

**Why have I been approached?**

*Explain here why you have approached this particular participant group and how you have obtained their information -this may be via a third party. Or you may highlight here where the study has been brought to the attention of a particular participant group type, or where advertised. This section should also explain how many groups, or different types of participants are involved in the project and how many participants in each group you hope to recruit, adding a total that you hope to recruit for the project overall.*

**What would taking part involve?**

*Give a clear and detailed description of what the participants will be asked to do. Explain what will happen and in what order, a step-by-step guide. For example, how many visits and/or approximate time taken for each step? Describe how and what data will be collected and used during the project; distinguish clearly between personal, identifiable or pseudonymised data and anonymised research data and provide more detail if sensitive personal data is being collected and used.*

*It sometimes helps to create a flow chart of what happens and when –this can sometimes be easier to understand depending on the participant group and the complexity of the project. You could also add pictures, diagrams or photographs if this helps to explain the process.*

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

*It is unlikely that you can promise any specific benefits, and this should be made clear. Research does deliver wider benefits to society and some indirect benefits might be foreseeable for participants.*

**What are the possible disadvantages and risks of taking part?**

*As relevant for your research, you should include details of all potential risks of physical/psychological harm, risks to confidentiality/anonymity and any mitigation measures that are in place (or say that you do not believe that taking part in the research has any foreseeable risks to participants). Risks should be described in terms of likelihood as well as severity and should be described in language that participants will understand. You could consider:*

* *Are any questions/discussions/parts of an interview likely to be upsetting? What support will be available to participants? Will you direct them to other support mechanisms?*
* *Potential risks of any procedures or interventions involved (e.g. blood/saliva/urine samples, biopsy) both during and after procedures, making sure that each type of procedure is explained.*
* *Is there a possibility of discovering health related/secondary findings? If so what would you do and would they be directed back to their healthcare professional e.g. GP?*
* *What will happen if something goes wrong?*

**What will happen if I don't want to carry on with the study?**

*Reassure participants that they can stop taking part at any time without having to give a reason and describe how participants can ask to withdraw and confirm that their data can be destroyed. However, if the data collection method means that a certain amount of data will have been collected up to the point at which they wish to withdraw and cannot be destroyed (e.g. focus group or data that has already been anonymised with no link to individual participants remaining), then describe the process that will be followed and specify which data will be kept.*

**How will my information be kept confidential?**

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University’s processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University’s Data Protection Officer by emailing [dataprotection@exeter.ac.uk](mailto:dataprotection@exeter.ac.uk) or at [www.exeter.ac.uk/dataprotection](http://www.exeter.ac.uk/dataprotection/)

*Please include the above statement and then describe how the data will be collected, stored, and where relevant, transferred. Be clear about how long the data will be kept and how it will be destroyed. Distinguish clearly between personal, identifiable or pseudonymised data and anonymised research data. Would you like to be able to use the data in future research or to be able to share anonymised research data with other researchers in future? If so, explain the process here and remember that this will need to be included in the accompanying consent form.*

*Are there any circumstances where confidentiality might need to be broken, for example if the participant discloses a risk to themselves or others? If so, explain here*

*If relevant to the project you can explain the process for participants to opt for their contact details to be kept to be informed about the outcomes of the project or about future research. Again you will need to ensure you obtain consent to do so on the accompanying consent form and explain how their contact details will be kept securely during this period. It is good practice to provide a brief report about any study that they have participated in although this is not reason enough on its own to retain their contact details. Any news/outcomes of the study can be made available via a neutral point (e.g. project website) and participants should be informed of where the details will be available.*

**Will I receive any payment for taking part?**

*With some research there will be insufficient funding available to offer any vouchers or payments. However, you do need to explain whether participants will be reimbursed for their expenses or given any payments/vouchers If a participant is expected to make an additional visit or travel outside of their normal routine then it is fair to offer to reimburse travel expenses and these types of cost will need to be planned for in a project. Vouchers or payments should be suitable in type, of low value to prevent a feeling of coercion to take part and should follow the University’s guidelines.*

*(If appropriate)* **What will happen to the samples I give?**

*Describe how any sample(s) collected will be used and whether they will be transferred to any other organisation or facility as part of the study process. If you would like permission to keep and use any remaining tissue for future research/transfer to a tissue bank, please describe and Confirm when the samples will be destroyed.*

**What will happen to the results of this study?**

*How and where (in summary) do you intend to disseminate the results e.g. academic publications, conferences, meetings with service providers or community groups, depositing data in an archive? Will you be making information on the outcomes of the project available to participants at the end of the project via a neutral point, if so where and when will they be accessible (Newsletter, bulletins, website)?*

**Who is organising and funding this study?**

*Provide a brief summary of the research team and funders (if applicable)*

**Who has reviewed this study?**

This project has been reviewed by the […] Research Ethics Committee at the University of Exeter (Reference Number….), *or give details of any other relevant review or approval by a regulatory authority where this applies.*

**Further information and contact details**

*Describe how participants can contact the research team for further information and/or to take part.*

*Please also include contact details for someone that the participant can contact if they are not happy with any aspect of the project and wish to complain – this could be a project supervisor, department Ethics Officer or Ethics Committee Chair. You can also give the following contact details:*

Gail Seymour, Research Ethics and Governance Manager

[g.m.seymour@exeter.ac.uk](mailto:g.m.seymour@exeter.ac.uk), 01392 726621

Thank you for your interest in this project