**Please note that this is a template therefore it will need tailoring to meet your study requirements in a style suitable for the target audience.**

**All elements of the consent form should be described in detail in here and all elements of the PIS should be reflected in the consent form.**

**Delete this header once ready for submission. And delete all comments /instructions in red.**

**Participant Information Sheet (PIS)**

**Study title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**REC Reference Number: \_\_\_\_\_\_\_\_\_ IRAS ID: \_\_\_\_\_\_\_\_\_\_\_** ***(DELETE IF NOT APPLICABLE)***

**Participants will be given a copy of this information sheet**

***Invitation Paragraph***

(Say who you are e.g. PhD student/lecturer and the purpose of the information sheet. Text could be along the lines of….). *We/I are/am a* PhD/MSc student/Staff at the *City St George’s University of London School of Health and Medical Sciences* ***or*** *St George’s University Hospitals NHS Foundation Trust*. I would like to invite you to participate in this research project *which forms part of my PhD/MSc/Degree research*. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

This study has been given a favourable ethical opinion by the St George`s School Research Ethics Committee.

***What is the purpose of the study?***

The aim of this study is to …………..*(what research questions you will be addressing?)*

I am specifically interested in……………….

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

I am inviting ……….*(please give details on inclusion criteria)*

I am aiming to recruit *xx* participants for this study.

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

No, participation is voluntary. You do not have to take part. You should read this information sheet and if you have any questions you should ask the research team.

***What will happen to me if I take part?***

* *How many visits/tasks will they have to make, to* ***where*** *and to whom*
* *How long will visits/tasks take, what will happen during participation (questionnaire/interview/focus group)*
* *How long will the participant be involved in the study*
* *Will any audio/video recordings be taken, transcript availability (recordings are optional or required for participation). Need incorporate in consent form.*
* *How will consent be recorded*
* *What personal information/data/tissue will be taken*
* *Will they be contacted for future research*
* *It should be clear that participants are free to withdraw from the study at any time without giving reason*
* *Details of the last point at which their data can be removed from the study.*
* *If using anonymous surveys ensure it is clear that /submission of a questionnaire implies consent (and for which data can't typically be withdrawn).*
* *If using online surveys the participants need to know whether incomplete datasets will be included.*

If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. I will then …………….

The procedures take approximately *XXXXX* and will be based at………

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

*Any benefits, e.g.:*

* *Access to future treatment*
* *Helping shape future research and/or care/treatment*
* *State if any reimbursements or compensation for their time, make it clear if participant will not be entitled to reimbursement if they were*

*Any risks, e.g.:*

* *The limits to confidentiality*
* *The need for disclosure of information to a third party*
* *Possibility for distress*
* *Potential adverse reactions*

The information we will get from the study will……………….

The main disadvantage to taking part in the study is that …………………….

*If there is a possibility of distress they must indicate where support will be available.*

The project is being funded by ……(where applicable)……………………...

***What if something goes wrong?***

If you wish to make a complaint about the conduct of the study you can contact using the details below for further advice and information:

*Supervisor (for student), Head of Institute (for staff)- Name, Full address, email, and phone number*

The ***University/Trust*** has in force the relevant insurance policies which apply to this study. If you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should follow the instructions given above.

***Who should I contact for further information?***

If you have any questions or require more information about this study, please contact me using the following contact details:

*Name, Full address, email, and phone number (only university email address and work phone number)*

***What data will be collected? How and where data will be stored? How long data will be kept?***

As a publicly-funded organisation, we have to ensure when we use identifiable personal information from people who have agreed to take part in research, this data is processed fairly and lawfully and is done so on the basis of **public interest**. This means that when you agree to take part in this research study, we will use your data in the ways needed to conduct and analyse the research study.

* *Give details for personal data, consent form, research data*
* *What data will be collected and by whom?*
* *Will you collect any personal data (e. g. name, location, IP address)?*
* *Will you collect any special category data?*

*Special category data’ is personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.*

* *Will you use pseudo/anonymised data?*
* *How personal data will be handled securely, during collection, analysis, storage and transfer e.g. using encryption and password protected access, or lockable cabinets for hard data; personal data and consent forms may be kept separate from non-identifiable data; coding might be used to reduce the risk of identification.*
* *Consent forms will be scanned, and originals will be destroyed as confidential waste at City St George’s, University London. The copies will be stored on password protected City St George’s University London file storage place.*
* *You may also need to store contact details for the duration of the study, for example, to allow the study team to maintain contact with participants during the study. If so, please state this and provide as much detail as possible.*
* *For healthcare studies you should include a section on how biological samples will be handled. In simple terms, explain how samples will be processed, stored, analysed and what will happen to unused samples.*
* *The University would normally expect any audio/visual recordings to be transcribed, checked with participants, and then immediately deleted/destroyed.*
* *How long the personal data, consent form, research data will be kept?*
* *All research data will be included in published research outputs and should be securely stored for minimum of 5 years*

***Who is Handling My Data?***

City St George’s University of London as the sponsor, will act as the ‘Data Controller’ for this study. We will process your personal data on behalf of the controller and are responsible for looking after your information and using it properly. This information will include *[your name/contact details/other identifiers etc.]*, which is regarded as ‘personal data’ and *[your NHS number/health information, etc.]*, which is regarded as a ‘special category personal data’ (defined above). We will use this information as explained in the ‘What is the purpose of the study’ section above.

***What happens if I change my mind?***

You have the right to change your mind and withdraw any time during the study without giving a reason.

* *Following your participation, you can also withdraw your data up until…*
* *Please note that anonymous data (e.g. anonymous questionnaires) cannot be withdrawn after they have been submitted.*
* *Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you decide to withdraw your data from the study, we may not be able to do so. We will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.*

You can find out more about how we use your information:

[**https://www.sgul.ac.uk/privacy**](https://www.sgul.ac.uk/privacy)

Or contact our university Data Protection Officer at:

**Email:** **dataprotection@sgul.ac.uk**

**Tel: 020 8725 0668**

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

* *Produce a final report summarising the main findings, which will be sent to participants (optional)*
* *The information you provide will be analysed and written up as part of my dissertation/thesis*
* *Disseminate the research findings through publication and conferences*

***Will my data be used for future research? (optional, choose which is most appropriate for your study)***

* *Anonymised/Pseudonymised data will be deposited or submitted to an open source online research data repository at the end of the study.*
* *Anonymised means, that all personal data are deleted and no longer accessible and therefore the research data cannot be traced back to an individual. Anonymity can only be guaranteed if participants can no longer be singled out from the research data. Be particularly careful not to assure anonymisation of data in situations where individuals may be indirectly identifiable via recordings (e.g. focus groups or procedures involving face-to-face contact or video recording, etc.) or through small data sets*
* *Data that has been pseudonymised through key-coding and removal of personal identifiers still falls within the scope of the GDPR. This is because the data that allows identification of that person still exists, just not all in one place. Pseudonymised data can help reduce privacy risks by making it more difficult to identify individuals, but it is still personal data. If you are using pseudonymisation, i.e. linking data using a code, this should be explained with details on who can access the codes so as to enable an individual to be identified.*
* *Participants need to be informed if any of data will be used for future research. Where it will be held and who will have access to it.*
* *When you agree to take part in a research study, the information we collect may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in research in this country or abroad. Your information will only be used by organisations and researchers to conduct research and processed on the basis of public interest.*
* *This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research, and cannot be used to contact you or to affect you. It will not be used to make decisions about future services available to you, such as insurance.*

***What if I want to complain about the way data is handled?***

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO) (<https://ico.org.uk/>).

***Data Protection Privacy Notice***

St George`s University London conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.sgul.ac.uk/about/our-professional-services/information-services/information-governance/data-protection/data-protection-policy>).

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the St George London University is required by law to disclose it.

For the purposes of data protection law, the University is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. It will keep identifiable information about you for 5 years after the study has finished after which time any link between you and your information will be removed.

**Thank you for reading this information sheet and for considering taking part in this research.**