

## **Guidance Notes**

This document provides an overview of many potential points of inclusion in a patient information sheet (PIS). It is important to note that the content of the PIS will depend on the particular research project and when creating the PIS consideration should be taken as to what is required for a particular study.

Further considerations must be made for research projects that involve:

- Adults with incapacity (laws differ between the UK 4 nations)
- Child participants
- Tissue samples
- Research Databases and Tissue Banks

Research involving these types of participant groups involves greater regulation and approvals. Guidance can be found at the [Health Research Authority site \(HRA\)](#).

## Version Control

It is essential that all documents are correctly version controlled. More information regarding version control can be found in SHLS-T-004.

## Patient Information Sheet

(Study Title)

(Version Number)

*Potential participants should be given very brief information about your study: just enough to decide if they wish to read further. There may be specific issues to address here when you are inviting someone else to give consent on behalf of another, or you are consulting someone to give their opinion on the inclusion of another (e.g. adults not able to consent for themselves)*

### What is the purpose of this study?

- *Background to the rationale of the study – try to keep this section brief with understandable language. Avoid cutting and pasting directly from the protocol.*
- *Why are you doing this research?*
- *What do you aim to achieve with this study?*
- *How many people will you be inviting to be involved with this research?*

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

- *Has this person been invited to take part as they have a particular condition/attend a certain type of clinic/are they a healthy volunteer?*

### Do I have to take part?

*Example text: “No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.”*

### **What will happen if I take part?**

- *How long participants will have to decide to take part?*
- *Who will take consent and provide an explanation of the consent process?*
- *Number of visits involved and duration. For example, these will be conducted at your standard clinic appointments but will require you to stay xx minutes longer or you will be asked to attend xx extra visits*
- *Screening and inclusion procedures*
- *Other procedures involved (i.e. what procedures the participant is expected to do)*
- *Where procedures will take place*
- *Simple flowcharts or tables outlining the study are useful to include here*
- *Distinguish what will be standard clinical care and what will be research-specific*
- *Describe any randomisation procedures (and explain what randomisation is, in lay language)*
- *Blinding (again, explain in lay language)*
- *Describe any drugs/interventions involved with the study*
- *Any anticipated inconvenience*
- *If participants are providing blood/tissue samples – specify exactly how much will be taken (in lay terms e.g. tea/tablespoons and equivalent mls)*
- *If you intend to use samples for DNA, this must be detailed here – with explicit consent sought for (i) DNA analysis and/or for (ii) genome wide analysis – suggest you provide a basic lay friendly explanation of this*
- *If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform the participant of this.*
- *Exposure to ionising radiation*
- *Research Databases and Tissue Banks*
- *Impacts on possible pregnancy/breast feeding*
- *Will there be any expenses paid (e.g. travel expenses)?*
- *What will happen if new information becomes available?*

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

*It is likely that you cannot guarantee any specific treatment benefits, and this should be made clear to potential participants. However, research does deliver wider benefits to society / others with a similar condition and some indirect benefits might be foreseeable for participants themselves*

### **What are the possible disadvantages of taking part?**

*You should include details of all significant risks of harm, risks to confidentiality and psychological risk. Some specific issues you should consider include:*

- *Impact on possible pregnancy and breast feeding, including young people and pregnancy*
- *Side effects of treatments / therapies in trials*
- *Discovering health related findings*
- *Impact on insurance*
- *Ionising radiation etc.*

*Try to describe the likelihood of adverse things happening, as well as severity in language all potential participants are likely to understand.*

### **What will happen I chose not to carry on with the study?**

- Ensure the PIS explicitly states what will happen to data already collected prior to the withdrawal of consent
- Are participants able to withdraw their samples from further analysis?
- Could withdrawal from the study pose a safety issue to the participant?

### **What happens when the study is completed?**

- *What will happen to data/tissue/samples that have been collected?*
- *How long will information/samples be archived?*
- *Is there potential to use this information in further research? – include details of this here.*

### **Who has reviewed this study?**

- *Have PPI groups been involved in the creation of this study?*
- *Document which NHS Research Ethics committee has provided a favorable ethical opinion to this study*
- *Document that NHS Management Approval has been obtained to conduct this study*

### **How is my data kept confidential?**

*[HRA recommended wording](#) is available. You may wish to provide a link to data if the PIS is an online form or provide a printed copy*

*Include GCUs local information regarding GDPR compliance*

**Who should I contact if I have any further questions about the study?**

- *Provide contact details for researchers involved in this project*
- *Is there an independent contact person for this study?*