Participant Information Sheet (PIS) Template

This is not offered as a rigid template, but rather a flexible framework.

We have ***suggested*** sub-headings which you may decide are appropriate to use or not, depending on the type of study you are planning and what is involved.

Remember the aim of a PIS is to provide sufficient information, in an understandable format to support potential participants in making the right decision for them: to take part in your study, or to decline participation.

For an illustration of how thinking about layout can improve your PIS, see the Newland Hill example available from our online guidance.

We would suggest that you visit the full guidance which provides more detail on the content of a PIS, and importantly also discusses appropriate styles / formats and covers some of the principles underpinning consent to take part in research.

Study title

Remember: I.P.O.C - Intervention, Population, Outcome, Comparator (if appropriate) is a rule that helps produce a meaningful study title.

Invitation and brief summary

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's involved? (Full guidance covering what's involved)

Explanation: purpose of and background to the research and invitation

What is the nature of what you are proposing? Why are you doing this research? What is already known? How many will be involved in the study? What alternatives are available to potential participants'? Etc.

You should try to keep this brief and avoiding cutting and pasting directly from a protocol; keep your language understandable.

What would taking part involve?

You should give potential participants an idea of what they should expect if they agree to take part. It is important that you consider their perspective and likely view of any impacts on them, their lives and those close to them.

Potential participants need to know what they are being asked to give consent to, so make it clear what elements are additional to standard care, and/or what elements of standard care they may not receive if they agree to take part.

There will be specific issues pertinent to your particular study and the types of participant you intend to recruit which must be considered here (e.g. adults not able to consent for themselves or children / young people). Specific issues may include:

- *Impacts on possible pregnancy and breast feeding, including young people and pregnancy*
- *In therapeutic research – what are the clinical alternatives and what happens when the research study stops?*
- *Pragmatic trials*
- *Randomisation and blinding*
- *Screening and exclusion*
- *Involvement of participant's GP*
- *Tissue samples*
- *Research databases and tissue banks*
- *Expenses and payments*
- *Genetic research*
- *Exposure to ionising radiation*
- *Accessing ONS, NRS and other registry data*
- *Generic consent etc.*

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 and risks 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.

Further supporting information (full guidance covering further supporting information)

Finally you should provide potential participants with more details of what is involved so that you can fully support them in making an appropriate decision. Some of the issues that might be appropriate here include:

- *What if something goes wrong?*
- *What will happen if I don't want to carry on with the study?*
- *How will my information be kept confidential?*
- *What will happen to the results of this study?*
- *Who is organising and funding this study?*
- *How have patients and the public been involved in this study?*
- *Who has reviewed this study?*
- *Further information and contact details*
- *What to expect during the consent process*
- *What if relevant new information becomes available?*
- *Informing General Practitioner / other healthcare practitioner*
- *What will happen to the samples I give?*
- *Commercial exploitation etc.*

Version control

All of your consent documents (and other study documents) should have a version number and/or date, to ensure that any changes or amendments can be more easily implemented.

The IRAS ID for the study should be included in the PIS.