# Participant Information Sheet for FULL TITLE SU Template

# Getting started

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| **SU Logo** on all documents**Header** Short title, IRAS number and version number **Footer** Page Number and Date |

# General Content

The content of your Participant Information Sheet (PIS) should describe clearly what a potential participant should expect if they agreed to take part in your study. You should simply provide sufficient and appropriate information on which they can base an informed decision. We would suggest that you consider covering the following areas in your PIS. These areas are designed to act as a framework, not a rigid template

1. **Title**
2. **Invitation and Summary**
3. **More details of what is involved**
	1. **Explanation:**
	2. **What would taking part involve?**
	3. **What are the possible benefits of taking part?**
	4. **What are the possible disadvantages and risks of taking part?**
4. **Supporting information**
	1. **What will happen if I do not want to carry on with the study?**
	2. **What will happen to the results of this study?**
	3. **Who is organising and funding this study?**
	4. **Who has reviewed this study?**
	5. **Dissemination and publications information**
	6. **Will my information be kept confidential? GDPR statement**
	7. **Who to complain to for Data/Management/Health issues?**
	8. **Further information and contact details**

# Student Project

First paragraph of the PIS should state that is a student project and the Funder should be mentioned.

# In More Depth

1. Title
2. Invitation

You should make it clear that you are inviting potential participants to consider taking part in your research and that participation is entirely voluntary. You should explain briefly how potential participants have been identified and why they have been selected.

*Example text:*

*SU and specific department would like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about XX minutes. Please feel free to talk to others about the study if you wish. The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then we give you more detailed information about the conduct of the study. Do ask if anything is unclear.*

**Summary**

You should provide a **short** summary of the proposed research, which covers the following:

* What research question is being addressed?
* How is it of relevance and importance to participants / patients and public?
* Broadly what areas (disease, therapy or service) are being studied?
* What drug, device or procedure is being tested?
* What will the participant have to do?
* What will it mean to participants to take part?
* Who would be eligible?
* The sites where the study will be conducted
* How long will the study last; when will it start and end?
* Do not to go into too much detail but try to ensure that potential participants can get a clear but concise picture of the research you are asking them to take part in.
* More details of what is involved
* Supporting information
1. Explanation: This should cover:
	1. purpose of and background to the research and invitation
* What is the nature and purpose of your research?
* What is already known (or not known) and how will this study help you learn more? (Be clear and succinct in your explanation).
* What interventions are additional to standard care (i.e. research elements), making it clear what potential participants are being asked to consider giving their consent to.
* Is your research study primarily educational? It is entirely reasonable for research studies to be primarily educational, but this should be made clear to potential participants at the outset.
* Is your research a therapeutic study? Therapeutic studies may require an explanation of the condition and other possible treatment alternatives.
* How many others will be in the study?
* Re-iterate the invitation to take part and explain why they specifically are being approached.
	1. What would taking part involve? This should cover:
* How long the participant will be involved in the research?
* How long the research will last? (If this is different);
* If and how often they will need to meet a researcher, attend a research session, visit a clinic or their GP?
* How long will these visits last?
* What exactly will happen and what information is to be collected e.g. access to personal information samples / questionnaire, interview, discussion group, measurement, sample collection, blood tests, x-rays (carried out in addition to standard care or treatment), etc?
* Will participants be asked for information on particularly sensitive issues? Knowing whether an issue may be considered sensitive demands an understanding of your research population and what they might consider to be sensitive**. If a focus group will it be in a private room etc**.
* For patients, how will participation in the research study affect or blend with their standard, clinical care?
* Any plans for long-term monitoring/follow-up?
* Whether your study will involve **video/audio-taping or photography**? **Specific consent will be needed if published material would identify participants etc. and explain transcription methods.**
* Potential participants must be made aware that if they agree to take part in your research you will be collecting data / information about them, their health and/or treatment. You must make it clear to them:
	1. What are the possible benefits of taking part?
* It is usually not possible to promise any direct benefits of taking part to potential participants, even though sometimes participants can end up benefiting directly.
* You need to ensure that potential participants are aware that you do not know what the outcome will be, and this is why you are conducting the research.
* Consultation with the community, service users or patient groups may help you identify indirect benefits that could come from taking part in the research, such as:
* Empowering participants to learn more about their condition,
* Supporting or adding to existing diagnoses where more may be learnt about their condition,
* Being seen more often and/or feeling more supported as a consequence of their involvement in the research etc.
* The most likely benefits will be experienced by others with a similar condition, in the future, rather than the participants themselves, as a consequence of discovery through research.
	1. What are the possible disadvantages and risks of taking part?
* A fair and honest evaluation of the consequences of research, including possible significant benefits and harms and their relative likelihoods, must be described to potential participants.
* You should consider that:
* Explaining risk to potential participants in a meaningful way is not easy. However potential participants must be given an honest assessment of the likelihood that something might go wrong, and the consequent level of harm that might be caused.
* Assessing risk is a subjective judgment based on what you already know about this intervention.
* Consultation with the community, service users or patient groups can help you to determine what is likely to be a significant risk, and to design effective ways of presenting risk to potential participants (including careful use of graphic presentation).
* We often don't know the precise level of risk that research carries. You may only be able to present uncertainty or qualified estimates of risk to potential participants. These can often be placed in context e.g. how often has this drug been given to people, or what experience is there of using a certain technique etc.
* Each research study will have its own inherent risks, specific to the interventions involved, the types of participant recruited, the methods of assessment used etc.
* Incidental findings if they arise and how they will be handled.
1. Supporting Information
	1. What will happen if I don't want to carry on with the study?
	* Potential participants must be told that the decision to take part in your research is entirely voluntary, and that they can change their minds at a later stage.
	* Potential participants will need to be assured that any such decision they may make to withdraw (or to decline the invitation to be involved in the first place) will not affect the care they receive from any relevant service (e.g. for patients, from the NHS).
	* You should make it clear at the outset what they should expect if they were to withdraw their consent.
	1. What will happen to the results of this study?
	* You should inform potential participants of your intentions with respect to publishing research findings, as well as how you intend to feedback findings to participants themselves. (This might include how you are going to handle individual health related findings, as well as overall outcomes of the study).
	* You should also provide relevant assurance that individual participants will not be identifiable from any report or publication placed in the public domain.
	* If you think there is a risk that identifiable information may be published, you must ask potential participants for their explicit consent for this, having ensured that they understand the potential implications of agreeing to this.
	1. Who is organising and funding this study?
	* You should tell potential participants which organisation(s) is/are sponsoring and which is/are funding your research (e.g. medical research charity, pharmaceutical company, academic institution, NHS organisation etc).
	1. Who has reviewed this study?
	* You should include some form of assurance to potential participants that your study has been reviewed and specifically details the Name and reference number of the approving research ethics committee.
	* The following is suggested wording:

All research in the NHS is looked at by an independent group of people. Peer reviewed or scientific committee

The research also passes through a Research Ethics Committee, to protect the participants. This study has been reviewed and given favourable opinion by\_\_\_\_\_\_\_\_\_\_\_\_\_Research Ethics Committee.

* 1. Will my information be kept confidential? GDPR data confidential

**Insert wording from Res Gov GDPR Help Sheet and**

**use separate HRA standalone explanation sheet .**

* 1. Who to complain to for Data/Management/Health issues?
* **Data  issues**  GDPR IOC contact details
	+ The data controller for this project will be Swansea University. The University Data Protection Officer provides oversight of university activities involving the processing of personal data, and can be contacted at the Vice Chancellors Office: dataprotection@swansea.ac.ukYour personal data will be processed for the purposes outlined in this information sheet
* **Health issues**  Health watchdog contact details The full details recommended by the NHS trust R&D office’
	+ Example
	+ SBU Community Health Council
	+ First Floor, Cimla Hospital, Neath , SA11 3SU
	+ Tel: 01639 683490 <http://www.wales.nhs.uk/sitesplus/902/home>
* **Management issues** Head of College contact details
	1. Further information and contact details
	+ Specific information about this research study: usually this would be provided by someone who is part of the research team; this could be you or some other member of your team.
	+ Potential participants should be given a name and contact details. If you also have a study website, details of where to find this should be included.
	+ Who they should approach if they are unhappy with the study: this would be a contact if participants have any concerns about your study and their involvement in it.
	+ For some studies, you may need to provide an emergency contact number that is manned 'out-of-hours'.

If you are conducting a study over a number of different sites, you should make sure that all of the contacts you provide are appropriate for each of the sites involved.

## Specific questions

For some specific types of study, you may also need to cover the following:

1. Adults not able to consent for themselves (MCA)
2. Pregnancy
3. Young people (age appropriate)
4. Therapeutic research - clinical alternatives
5. Side effects of treatments / therapies in trials
6. Randomisation and blinding
7. Screening and exclusion
8. Involvement of participant’s GP (contact details and permission)
9. Tissue samples (HTA)
10. Expenses and payments
11. Discovering health related findings
12. Genetic research
13. Radiation: Ionising Radiation (Medical Exposure) Regulations (IRMER)

More information at <http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html>