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| Participation Information Sheet Template |
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# What is a Participant Information Sheet?

Participant Information Sheets (PIS) give potential participants the necessary understanding for the research study and sources of information to answer any further questions to allow them to give informed consent. In most circumstances it is appropriate to use the information sheet to support conversations with potential participants, rather than being the sole source of information being made available to them.

Potential participants must be able to understand the information given to them and consider any impact the study may have on them. Participants should then be able to make a fully informed decision as to whether to volunteer for the study. The PIS also provides potential participants with information to share with others who may be important to them, and who they would like to involve in their decision as to whether to provide consent to take part in the study.

The PIS should be used together with a Consent Form for the study. The Consent Form essentially summarises key points from the PIS to make sure they are understood, and usually requires the participant to indicate, with their signature, consent to key elements of the research participation.

# When should Participant Information Sheets be used?

A PIS should be used by anyone who intends to conduct a study where a record of information is required from human participants and any ethical issues are involved. This will be needed if you collect any data from participants that will inform the results of your study.

# How should I fill out this template?

The template below sets out several suggested headings and guidance notes to help you develop your informed consent documentation and procedures. The headings are non-exhaustive and it may be the case that additional headings are required for the nature of your study. Conversely, some of the headings may not be relevant to what your study requires.

Under each heading sample wording is provided to indicate how you might go about answering that question. You will need to adapt the sample wording to suit your study, with particular consideration to those involved in your research. Please see the section below on “What should I consider when filling out this template?” for suggestions about how to make your PIS accessible and easy to understand.

For version control, please also include the document date and version number in the footer. This is important for tracking and identifying which document has been ethically reviewed.

# What should I consider when filling out this template?

Please bear in mind when using this template that because not all research studies are the same, the information, style and layout required to enable potential participants to decide if they wish to take part will therefore vary.

The complexities and risks associated with a research study should be considered when drafting the PIS. For example, a simple web-based survey that does not involve capturing personal data, will not require the same level of detail as that of a research study involving invasive procedures.

Different participants will have different information needs, different levels of understanding of technical terminology and different levels of reading comprehension. The level of detail should be appropriate to the nature and complexity of the study.

It is important to use plain English and to use simple, non-technical terms that a lay person will easily understand.

You should use the format best suited to the nature of the information that you wish to give potential participants, and which supports understanding. In terms of written information, the following are worth considering:

* Use short headings that stand out.
* A question and answer format is often effective.
* In some cases, it is appropriate to use larger text or text alternatives i.e. braille.
* Leave 'white space' - avoid large sections of unbroken text or long lists.
* Use bullets for lists.
* Use bold text for emphasis.
* Consider the appropriate page size – it may be that A5, or another paper-size and layout would be more suitable than A4.
* In some cases, it might be more appropriate to use other media to support the consent process; for example images, diagrams, audio, video or online materials etc. When using alternative formats, you should be mindful that some formats may unintentionally discriminate against people who are not comfortable with or who cannot use such technology.

The NHS Health Research Authority (HRA) provides a number of examples in the section “Using different formats to aid understanding” which are useful to see how images, flowcharts and other techniques can help the understanding process: <http://www.hra-decisiontools.org.uk/consent/examples.html>

If you are seeking consent for adults who are not able to give consent themselves, the style of the information sheet will need to be adapted to address the relevant legal representatives, consultees, relatives or friends you are seeking to inform and obtain consent from.

If seeking consent from a child, an information sheet for children and young people should be much shorter and simpler than one designed for obtaining consent from an adult. Images and colour will become more important for such information sheets. The HRA also has published guidance and examples of developing consent documentation for children and young people in the section “Children and young people (UK wide)” here: <http://www.hra-decisiontools.org.uk/consent/examples.html>

# What other resources should I refer to?

* Nottingham Trent University [Research Data Management Policy](https://www.ntu.ac.uk/__data/assets/pdf_file/0022/204637/research-data-management-policy.pdf)
* Nottingham Trent University [Research Privacy Notice](https://www.ntu.ac.uk/policies/research-privacy-notice#why-we-process-your-personal-information)
* Nottingham Trent University [Data Protection Policy](https://www.ntu.ac.uk/__data/assets/pdf_file/0027/583335/data-protection-policy.pdf)
* The [UKRIO Code of Practice for Research](https://ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf)
* Nottingham Trent University [Research Support SharePoint](https://myntuac.sharepoint.com/sites/ResearchSupport)
* Nottingham Trent University [Human Tissue Act Governance SharePoint](https://myntuac.sharepoint.com/sites/NTUHTAG)

**YOU NEED TO SUBMIT A PARTICIPANT INFORMATION SHEET TO THE RESEARCH ETHICS COMMITTEE AS PART OF THE PROCESS OF ETHICAL REVIEW. YOU CAN USE THIS TEMPLATE TO HELP YOU TO DEVELOP YOUR INFORMED CONSENT DOCUMENTATION. ANY GUIDANCE NOTES PROVIDED IN *ITALICS* MUST BE DELETED. PLEASE ADAPT THE EXAMPLE WORDING PROVIDED AS IS APPROPRIATE FOR YOUR STUDY.**

**PARTICIPANT INFORMATION SHEET**

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| --- | --- |
| Title of Study: | [*The title could be the same as in the research proposal or a simplified version understandable to a lay person. The titles must be consistent throughout the PIS and Consent Form].* |
| NTU Reference Number: | [*This will be the Worktribe Ethics ID. You might need to include an NHS or other external Research Ethics Committee ID]* |

1. **Invitation**

We/ I would like to invite you to take part in our/my research study. Before you decide to take part in this study it is important you understand:

* why the research is being done, and
* what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. I / A member of the research team can be contacted if there is anything that is not clear or if you would like to ask questions or get more information.

[*Please add here a short statement designed to introduce you/ the research team including their status and role(s) as a researcher. Include details of any other external collaborators or funders working with Nottingham Trent University for the research*].

This research is being funded by [*give details of the funding agency*]. None of the research team will receive any financial reward by conducting this study, other than their normal salary / bursary as an employee / student of the University [*amend as appropriate for your situation*].

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

[*Please insert here what research questions are being addressed, why, and what its relevance is to participants, the public and the academic community. It is entirely reasonable for projects to be primarily educational- so feel free to state that it is to help you gain a degree if this is a prime purpose of the study.]*

1. **Has this study been reviewed?**

All research by the University involving human participants is reviewed to ensure that participants are treated appropriately, and their rights respected. This study has been considered by Nottingham Trent University’s School of [*insert name*] Research Ethics Committee and has been given a favourable ethics opinion. Further information can be found at: <https://www.ntu.ac.uk/research/research-environment-and-governance/governance-and-integrity>

1. **Why have I been invited?**

[*You should explain how the potential participant was identified. Where the participant has been referred to you from a third party, include details of that third party. You should explain briefly why you need to recruit the potential participants by stating the parameters of the participants you are seeking for the research (e.g. students between ages X and X, users of X product). Where relevant, you should give an indication of the total number of participants. If you are inviting the participant to provide information on behalf of someone or something else (such as providing information on behalf of their organisation), you should clarify this. This paragraph should also give an indication of who else will be participating in the study.*]

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

No, taking part in this research study is entirely voluntary. It is up to you to decide if you want to volunteer for the study. You can say you don’t want to take part in the study at any time without giving a reason even if you said yes before. This means you can stop being part of the study whenever you want but see Section 16 “Can I stop taking part in the study?” for more about this.

1. **What does taking part involve?**

[*This section details what will be involved in your research study from a participant’s point of view, and the order in which they will experience it, as well as the likely impacts on them. You should set out simply the research methods you intend to use. A table or flowchart can sometimes provide clarity when describing a complex research timeline.*

*Consider:*

* *what generally will happen during the participation. For example, the time commitment involved, how often they will need to contribute to the study, where it is taking place*
* *the total duration of the research.*

*You should inform the participant if your study will involve video, audio-taping, photography or taking samples from them. If you are taking samples from participants or handling materials relevant to the Human Tissues Act (HTA) you will need to add in additional information under separate subheadings on this PIS. Please see additional guidance:*

* NHS Health Research Authority [Use of human tissue in research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/use-tissue-research/)
* Nottingham Trent University [Human Tissue Act Governance SharePoint](https://myntuac.sharepoint.com/sites/NTUHTAG)

1. **Am I eligible?**

[*You should explain:*

* *conditions which may exclude individuals from participation; and*
* *whether they can participate if they are involved in other research studies.*]

1. **What are the possible advantages or benefits of taking part?**

[*Direct benefits can be as simple as sharing the participant’s experience, a training session, or payment for participation. However often there is no direct benefit to the participant, but you might want to suggest outcomes such as an improved service or better understanding of something. Do not exaggerate the possible benefits. If there are no direct benefits to the participant, then please state something along the lines of:]*

You will not receive any direct personal benefits from participating but [insert wider group] (or a sub-group of [wider group]) may benefit from the results of this work by [insert details] and some people enjoy the opportunity to share their experiences.

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

[*Here you should include details of any possible disadvantages or risks of participation. Specific examples include:*

* *physical side effects following an experiment (list the relevant side effects)*
* *emotional distress*
* *mild pain or discomfort.*

*You should also explain how the risks are minimised (e.g. safety procedures, risk assessments, medical screening and any first-aid / medical provision, practical steps to minimise pressure or distress). If participants could potentially experience distress, it is helpful to identify statutory and voluntary agencies that might be accessed for help.*]

[*If you do not anticipate any possible disadvantages, concerns and risks you should state this here.]*

1. **Will my expenses be paid?**

[*Explain whether you intend to pay participants for their time and any costs associated with the research or whether there will be some small token of monetary or other value or any other gifts, as a thank you. You should make it clear whether you intend to reimburse travel and other out of pocket expenses (if funding does not permit reimbursement, you should explain that this is the case and make potential participants aware of the situation.*]

1. **What information will be collected?**

[*Explain here what data will be collected (ideally in bullet points). If any specialised equipment is to be used it should be described – particularly if it is attached to, worn by, or inserted in participants. This can include photographs of equipment / sensors on their own, or whilst attached to, or being used by participants where appropriate. Any safety implications should be identified, and steps taken to mitigate risks explained.*

*Details of any personal or sensitive data to be collected should also be provided here; participants should be made aware of any data collection that might be emotionally distressing or intrusive.*]

Your personal data is information that relates to you, where you are named or can be identified even if you are not named. We would like to collect the following personal data about you:

* Name
* Date of Birth
* Postcode

We also need to collect special category data about you. Special category data is data which is personal, but which is sensitive. We would like to collect the following special category data about you:

* Ethnicity
* Religious beliefs

*[You might also want to think about any other sensitive information you will be collecting i.e., business or commercially sensitive information.]*

1. **What is the legal basis for processing my personal data?**

*You need to determine if NTU are the controllers of personal data and confirm the legal basis for processing participants’ personal data. In some instances, NTU may not be the data controller and it might be necessary to include third party privacy notices instead of, or as well as, the NTU privacy notice. This should have already been addressed in your data management plan [DMP]. In most instances NTU will be responsible for the personal data processed for the purposes of research. Therefore, the text that you should include is:*

For more information about how the University will use your personal data for the purposes of research, please see the [NTU Research Privacy Notice](https://www.ntu.ac.uk/policies/research-privacy-notice). [*Please ensure that you always provide a copy of the NTU Research Privacy Notice to participants at the point you provide them with this information sheet and consent form.*].

* When organisations use your personal data, this is referred to as ‘processing’ and an organisation must have a lawful right or basis to process your personal data.
* The consent form provided to you with this information sheet asks for your consent to take part in the research study. This is not the same as us asking for consent as a lawful basis to process your personal data under UK data protection laws (UK GDPR and Data Protection Act 2018).
* Nottingham Trent University does not rely on consent as a lawful basis to process your personal data under the UK data protection laws.
* The legal basis for the University processing your personal data for the research is that the processing is necessary for the University to perform a task in the public interest (as it is in the public interest for us to carry out this research).

[Where we are collecting special categories of personal data under the UK GDPR, we do this because it is necessary for scientific research purposes, as permitted under the UK data protection laws.]

1. **Will my personal data be kept confidential?**

[*Explain arrangements made to ensure that information is kept secure. For example, where participant’s identifiable data will be stored, what security arrangements are in place, what will happen to their personal data once the study has ended, and if identifiable data will be published as part of the results. Please indicate if you wish to keep participants’ contact details on file to either keep them updated about the research or to approach them in the future to take part in other studies. You will need to obtain explicit consent for this in the consent form.]*

[*Explain in what form you will hold information. For example, will you destroy all direct identifiers and store only data from which participants cannot be identified? Anonymisation might be offered as a strategy to ensure confidentiality, although anonymity is not ethically required for all participants, in all studies. Clear explanation of any anonymisation strategies should be given here and any risks of the participant being identified must be clearly stated. Things to consider: will data be fully anonymised, or will it be possible to identify a participant using a combination of available data, or an identifiable key (pseudonymisation)? If data are pseudonymised when will the key be destroyed?]*

*[You should also make it clear whether you intend to publish verbatim comments extracted from an interview transcript or completed questionnaire.]*

[*If any study procedures are likely to reveal incidental findings which might have significance for the health or wellbeing of the participant, the situation must be explained. It is often the case that research procedures are of little diagnostic value but, if they are, then interventions such as informing the participant’s GP should be explained.*]

[*Example wording for pseudonymised data:*]

* For any personal data that we store about you that forms part of the research data, we will replace your names with a unique code (meaning you will not be immediately identifiable to anyone who views the data). There will be a key that links your name to your unique code, and this will be kept separately with access only by the research team. This is called pseudonymised data.
* This key and any other data gathered about you will be stored on secure servers based at the University.
* Any personal data which would identify you, will usually not be passed to anyone outside the study team without your written permission for us to do so. However, the study team may need to pass your personal data to a regulatory authority which has the legal right to access the data for the purposes of conducting an audit or enquiry, in exceptional cases. These agencies treat your personal data in confidence.

[*Example wording for identifiable personal data:*]

* Many participants in this type of research wish to be credited with their contribution to the research (meaning that their name appears in the research).
* If you are happy to be associated with your contribution you can choose to share your real name.
* If you prefer, a false name can be given to your [interview recording], and this will be used in any publications, presentations, teaching materials or other items produced from the research when referring to your contributions. However, it is not possible to entirely remove the possibility that you may be identifiable from the information that you share, for example [*include what might make a participant identifiable if applicable, such as recognising a voice on an oral history recording*]*.*

[*Any limitations regarding confidentiality must be clearly stated. Limits might relate to the safeguarding of the participant or others - example wording is as follows:*]

I may pass on information provided by you in circumstances where I am concerned that there is a risk of harm to you or someone else. In this instance, I must report this information to the relevant agency that can provide assistance*.* [*Limits on confidentiality might also relate to matters such as the action a researcher might make in the event of the participant disclosing an unprosecuted criminal offence or, in the case of a professional practitioner, misconduct.*]

[*Always include the following text:*]Responsible members of Nottingham Trent University may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

[*If your study will involve video/audio-recording, outline what will happen to these recordings in the longer term; and, if transcribed, whether the recordings will be destroyed. If using video or audio recording, please address this in the consent form.*]

1. **What will happen to the results of the research project?**

[*You should be able to tell the participants what will happen to the results of the research and how they will be disseminated i.e., on websites, in journals, conference papers etc. You could also include when the results are likely to be published, and how participants can obtain a copy. You might add that they will not be identified in any report or publication.]*

*[Example wording:]*

* Results will be presented at conferences and written up in journals.
* Results are normally presented in terms of groups of individuals. If any individual data are presented, you will not be identifiable unless you have indicated in writing that you would like to give up your right to anonymity within publications.

1. **Will the research data be used in the future?**

[*You should include a statement indicating that the research data collected during the course of the project might be used for additional or subsequent research.*]

*[Where data is fully anonymised, NTU will make research data open – i.e. publish on a CC-BY licence. Use this example wording where anonymised research data will be retained for future reuse:]*

* Once the research study is complete, your personal data will not be used in any other projects.  [*Interview/video/ audio recordings/ personal information about you such as your name, contact details / pseudonym key*] will be destroyed.
* We will retain research data that would allow others to check and verify our findings. These will be deposited in the [*name of data repository*], which is an archive of research data and will preserve data for at least ten years.
* To maximise the wider benefit of this research to society, anonymous data, **which you cannot be identified from**, will be openly accessible at the end of the research project.
* A CC-BY licence will be applied to this publicly shared data. This will allow anyone else (including researchers, businesses, governments, charities, and the general public) to use the anonymised data for any purpose that they wish, providing they state that the University and research team were the original creators.

*[If you are unable to fully anonymise the research data or retain a copy of the pseudonym key, access control should be applied to the research data. This means that data will be stored in a secure archive, for example the NTU Data Archive or UK Data Service, which restricts access to the data and governs reuse. Specific consent in the consent form will be needed if published material and/or the underlying data identifies, or has the potential to identify, the participant. Use this example wording for controlled research data for research reuse].*

* We will retain research data that would allow others to check and verify our findings. These will be deposited in the [*name of data repository*], which is an archive of research data and will preserve data for at least ten years.
* To maximise the benefit of this research to society, data might be shared with researchers external to NTU.
* Whilst we will try to fully anonymise data where possible, if you could potentially be indirectly identified through any information you have given, only approved researchers will have access to this data for the purpose of ethically approved research. It is unlikely that those researchers will be able to reidentify you. However, should this occur, they are bound by legal and ethical requirements to protect your identity.

1. **Can I stop taking part in the study?**

Yes, you are free to stop taking part completely in the study at any time. You don’t have to say why you want to stop. If you do want to stop, contact me/ the research team using the contact details at the end of this information sheet.

*[It is important to manage expectations about what you can offer regarding withdrawal. You need to consider how you will be able to respond to withdrawal requests depending upon how you store the data. It is advisable to decide a cut-off point after which the withdrawal of research data is not possible.]*

If you withdraw up to INSERT DATE , the information you gave us can be destroyed and won’t be included in the study. However, if you withdraw after INSERT DATE, anonymised information may be retained as part of the study, or may have already been published, but all of your personal information, which could identify you, will be destroyed.

1. **Who can I contact if I have any questions or concerns about the study?**

* If you have a question about any aspect or any part of this study, firstly you should contact the researcher(s):

Name**:** [*Insert*]

Email**:** [*Insert*]

* If you have a concern or complaint, you should contact the Supervisor/ Head of Department:

Name**:** [*Insert*]

Email**:** [*Insert*]

* You should contact the Chair of the [*Insert name*] Research Ethics Committee if you have concerns with how the research was undertaken or how you were treated:

Name**:** [*Insert*]

Email**:** [*Insert*]

* You should contact NTU Data Protection Officer (DPO) if you have a query about how your data is used by the University, you would like to report a data security breach (e.g. if you think your personal data has been lost or disclosed inappropriately), or you would like to complain about how the University has used your personal data. You can contact the DPO by emailing [DPO@ntu.ac.uk](mailto:DPO@ntu.ac.uk)

**Thank you**

Thank you for taking time to read this information sheet and for considering volunteering for this research.