

# Participant Information Sheet

Note for Researcher: A participant information sheet (PIS) should be printed on University of Essex headed paper when undertaken by University staff or students. If a project involves more than one organisation, for example research involving an NHS Trust, it might be necessary to include other logos.

The PIS should normally contain the following information but please be aware that this is offered as a flexible framework rather than as a rigid template. Sub-headings have been suggested but you will need to decide whether they are appropriate for your research depending on the type of project and what it entails for the participants and their data in the future.

It is important to remember that the aim of a PIS is to provide sufficient information, in an understandable format, to support potential participants in making an informed decision that is right for them as to whether to take part in your research.

The PIS must have a footer to identify the document and to assist with version control which includes:

1. The title of the document: This may simply be ‘Participant Information Sheet’ but, if you have more than one group of participants, you may have more than one PIS. It is important to be able to distinguish easily between different PIS.
2. The version number: Each time the PIS is updated, the version number will need to be amended so that there can be an accurate record of the current version.
3. The date of the document: As with the version number, this assists with maintaining an accurate record of the current version.
4. ERAMS reference: This provides a link between the PIS and the application for ethical approval.

# Project title

The project title should be simple and self-explanatory to a lay person and should normally be the same as that provided on the application for ethical approval and, if relevant, funding award. In some cases, the title on a PIS might not match for quite justifiable reasons. If this should be the case, the PIS title should be provided on the application for ethical approval as a sub-title to the overall title of the project. Acronyms should be avoided.

# Invitation paragraph

This should provide details of who you are and your affiliation, i.e. your status, your department, and your institution. Your should then explain that the potential participant is

being asked to take part in a research study. The following is an example of how this might be phrased:

‘My name is [name] and I am a Senior Lecturer in the Department of xx at the University of Essex. I would like to invite you to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.’

# What is the purpose of the study?

The background and the aim of the study should be provided clearly and succinctly. You should say how long the project will run and outline the overall design of the study. There are situation when it is not possible to provide full details of the purpose because this will adversely affect the results in some way. If this is the case, you should provide as much information as possible in the PIS and plan to provide a debriefing document at an appropriate point after data collection has taken place.

If the study is being undertaken in relation to an education qualification, e.g. doctoral research, this should be made clear at this point.

# Why have I been invited to participate?

You should explain why and how the potential participant was chosen and how many other people will be invited to participate.

# Do I have to take part?

You should explain that taking part in the research is entirely voluntary. There must be a clear statement that participants have the right to withdraw at any time for whatever reason and without explanation or penalty.

If your study involves recruitment of students or pupils you must explain that their decision to participate or not will have no impact on their marks, assessments or future studies.

Similarly, if the study involves the recruitment of participants from an organisation, company, or service, a decision to participate or not will have no impact on their current or future employment or on their access to the service.

The following is an example of how this might be expressed: -

'It is up to you to decide whether or not you wish to take part in this research study. If you do decide to take part you will be asked to provide written consent. You are free to withdraw at any time, without giving a reason. Withdrawal with have no impact on your marks, assessments or future studies.’

Details of how they can withdraw, including the contact details for a named individual, and what happens to any information that they have already provided needs to be included.

Potential participants need to be aware if there are limitations on their right to withdraw. For

example, if the data were to be collected anonymously, it might not be possible to identify their data in order to withdraw them. Alternatively, the data might be anonymised within a certain timeframe so withdrawal of data would only be possible up to the point of anonymization.

# What will happen to me if I take part?

It will help you to provide the required information for this section if you try to ‘put yourself in the subject’s shoes’. It is essential that you use language and terminology that would be understood by a lay person. In the case of children or those with limited mental capacity, it is important to use age appropriate language or possibly images rather than words.

You should explain what exactly will happen, i.e. your method(s} of data collection. For example, will you be using questionnaires; interviews; discussion groups; measurements; sample collection; accessing personal information from elsewhere. If data collection will be undertaken in person, you should provide an indication of who will be collecting data, e.g. will it be the named Principal Investigator or Co-Investigator(s) or will it be a research assistant who is part of the team.

You must provide details of how long a participant will be involved in the research overall; whether data collection will take place on more than one occasion and, if so, how many occasions; and how long each session will last.

You must inform the participant if you intend to use video or audio recording or photography. In addition, specific consent will be needed if published material identifies the subject.

# What are the possible disadvantages and risks of taking part?

You should describe any disadvantages or 'costs' involved in taking part in the study, including the time involved. You should include details of all significant risks of harm, risks to confidentiality and psychological risk. Try to describe the likelihood of any adverse events in language that all potential participants are likely to understand.

Please note that a clear warning must be given where there could be harm to an unborn child or to individuals living with certain conditions such as epilepsy so that participants can make an informed decision not to take part. In the latter instance, a researcher should consider carefully whether they are equipped to manage the situation should an intervention cause a participant to have an epileptic seizure. If not, the choice to take part should not be left to the participant but should be part of the research design, i.e. epilepsy would be an exclusion criteria.

# What are the possible benefits of taking part?

You should outline any direct benefits for the potential participant and any other beneficial outcomes of the study, including furthering our understanding of the topic. It is likely that you cannot guarantee any specific benefits, and this should be made clear to potential participants. It is important not to exaggerate the possible benefits.

# What information will be collected?

You should explain to potential participants in clear and understandable language, free from jargon and acronyms, what information will be collected from and / or about them. Will the data collected be identifiable or will it be anonymous? If the data are identifiable will they be anonymised and, if so, at what point?

# Will my information be kept confidential?

You should explain to potential participants how their confidentiality will be safeguarded within legal limitations during and after the study. If there is a chance that, during the course of your research, a participant will disclose information that leads you to believe that they or others are at risk of harm, you may have a duty of care to inform an appropriate authority. In such circumstances, you will need to include a statement about this in your PIS.

Potential participants should be informed about how their data, whether electronic or on paper, will be managed and stored. Research data must be kept securely at all times, not only to protect the subjects of the research but also researchers themselves, so it is important to have a data management plan. For example, PCs, laptops and other devices must be password protected and data files should be encrypted. If you are working in the field and have internet access, it is probably best to store data securely in a Box folder or transfer it to a University of Essex secured shared drive rather than keeping it on a local laptop. In this way, you will avoid the risk of losing your data through theft or confiscation and automatic back-ups will be undertaken.

You will need to provide potential participants with details of who will have access to their research data, both during a project and after it has been completed. Note that, if your research includes interviews or discussion groups, this could involve a transcriber or a transcription service and participants need to be advised accordingly.

You must include a statement about the period for which you intend to retain the research data generated by the project. It is recommended that research data should be retained for a period of at least ten years after the completion of the project although it should be noted that the University’s Research Data Management Policy requires that research data are made available for access and re-use where legally, ethically and commercially appropriate, taking note of any relevant safeguards.

If you provide a data retention period for potential participants, you must also provide details of how you intend to destroy the data, whether in paper or electronic form, at the end of that period.

If you plan to share anonymised data through, for example, a research data repository after the project has been completed you need to inform potential participants of this at the start of the project and obtain their consent to do so. Many funders of research require and the University encourages data sharing in a suitable format so it is important that you have planned for this.

# What is the legal basis for using the data and who is the Data Controller?

You need to inform the participant of the legal basis for processing their data. For research undertaken by staff and students, this would normally be consent. The GDPR states that consent must be freely-given, specific, informed and unambiguous – given by a statement or a clear affirmative action. If you have followed the University’s guidance on PIS and consent forms, you will be complying with the GDPR. However, there may be exceptions to this rule so, if you feel that it will not be possible to obtain the necessary consent, you need to discuss this with the University’s Information Assurance Manager ([dpo@essex.ac.uk](mailto:dpo@essex.ac.uk)) so that you can include the correct legal basis in your PIS. Please note that you will still have to justify not obtaining informed consent to the ethics reviewers in your application for ethical approval.

In addition to the legal basis, you must also include details of who the Data Controller will be and contact details. The Data Controller will normally be the University of Essex and the contact will be, University Information Assurance Manager ([dpo@essex.ac.uk](mailto:dpo@essex.ac.uk)). Again, if you believe that the Data Controller should be another individual, you should discuss this with the Information Assurance Manager before your application for ethical approval is submitted.

# What should I do if I want to take part?

Explain exactly how the participant should 'opt in' to your research; who they should contact, and whether there is a deadline for doing so.

# What will happen to the results of the research study?

You should tell the potential participant what will happen to the results of the research. Will they be published as a journal article or used as a conference paper / presentation? You do not need to be specific about the type of publication but you do need to be clear that the results will be published and so in the public domain. It would also be helpful to remind them at this point that any results will be anonymised and that they will not be identifiable if that is what you have guaranteed earlier in your PIS. Will the results be used in your dissertation or thesis and, if so, where will this be deposited and in what format? It is good practice to make a copy of the findings of the study available to each participant and you should advise potential participants about how this will be done, i.e. will this be automatic or will they have to apply for a copy.

# Who is funding the research?

You should provide full details of any and all organisations that are funding the research, if appropriate, e.g. the Economic and Social Research Council; UK Department of Health; European Commission. It is not sufficient to state ‘a commercial company.

# Who has reviewed the study?

You should provide details of which ethics review body has reviewed and approved your application for ethical approval. If approval has been granted internally this would either be the Ethics Sub Committee 1, or Ethics Sub Committee 2, or Ethics Sub Committee 3 at the University of Essex or the University of Essex Ethics Committee. However, it may be that

you have sought and obtained ethical approval from elsewhere. If this is the case then you need to include the name of that committee and the reference number of the approval.

# Concerns and Complaints

Participants should be provided with details of who can be contacted if they have any concerns or wish to make a complaint. The list should include the principal investigator, the departmental Director of Research and the University’s Research Governance and Planning Manager. An example of this would be:

‘If you have any concerns about any aspect of the study or you have a complaint, in the first instance please contact the principal investigator of the project, [name], using the contact details below. If are still concerned, you think your complaint has not been addressed to your satisfaction or you feel that you cannot approach the principal investigator, please contact the departmental Director of Research in the department responsible for this project, [name and e-mail address]. If you are still not satisfied, please contact the University of Essex Research Integrity Manager, Mantalena Sotiriadou (email: [ms21994@essex.ac.uk](mailto:ms21994@essex.ac.uk)). Please include the ERAMS reference which can be found at the foot of this page.

# Name of the Researcher/Research Team Members

The name(s), status(es) and departments of all the researchers involved should be provided, together with details of how to contact them.