Participant Information Sheet for [insert group]

**Important note**

Please see the below pages for the University of Essex Participant Information Sheet (PIS) template. This consists of sections that apply to every study. There are also some optional statements which apply only to specific studies in Appendix 1. Please read the optional statements carefully and choose any that are relevant and appropriate for your study. If you need to adjust the sections in your PIS, you must provide details and justification in your ethics application form. It is essential that the information you provide in the PIS matches with the statements in your consent form and the information listed in your ethics application form. Variations may result in delays to your application. [Access the University’s Participant Information Sheet Guidance on the Staff Directory](https://www.essex.ac.uk/staff/research-governance/research-participant-information-and-consent). This provides further information about preparing participant facing documents, including guidance for preparing information materials for children and young people; potentially vulnerable participants; online surveys and recommendations for the design and style of the participant facing documents. This note and all guidance information should be deleted after reading.

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. Acronyms should be avoided.
* In some cases, the title on a PIS might not match for justifiable reasons. If this is 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.
* You should ensure that the project title is the same on all participant documents (i.e. advertisement, Participant Information Sheet, Consent Form).

Invitation paragraph

You should provide details of who you are and your affiliation i.e., your status, your department, and your institution.

* You should explain that the potential participant is being asked to take part in a study and that participation is entirely voluntary. Refusal to participate requires no reason and will not affect the individual or their rights.

**Example statement:**

“My name is [insert 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 study. Before you decide whether you wish to participate in this study, it is important for you to understand why the study 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. Ask me questions if there is anything that is not clear or if you would like more information”.

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 situations 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 identified as an eligible participant and invited to take part and how many other people will be invited to participate.

**Example statement:**

“You are being invited to participate in this research study because [insert main inclusion criteria here]”.

and/or

“You should not take part in this study if you [insert main exclusion criteria here]”.

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.

**Example statement:**

“It is up to you to decide whether or not you wish to take part in this 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”.

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

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. Provide a brief summary that is consistent with what you described in your ethics application form.

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 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. This should include risks at the time of their participation and any that may come later. Examples of typical risks that need to be considered as part of research ethics can be found on the [Research risk assessment](https://www.essex.ac.uk/staff/research-governance/research-risk-assessment) webpage. Try to describe the likelihood of any adverse events in language that all potential participants are likely to understand.

How will my data be stored and who will have access to it?

* 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 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. Appropriate storage must be used as per the information security classification of the data captured. Further advice about information storage can be found in the [Information security policy](https://www.essex.ac.uk/records_management/documents/information-security-policy.pdf).
* You will need to provide potential participants with details of who will have access to their data, both during a project and after it has been completed. Note that, if your study includes interviews or discussion groups, this could involve a transcriber or a transcription service and participants need to be advised accordingly.

**Example statements:**

“Your data will be stored in fully anonymised form[[1]](#footnote-1) in [insert location], and only [insert individual] will be able to access it”.

or

“Your data will be stored in pseudonymised form[[2]](#footnote-2). Your name and other identifiers will be replaced by a unique code. To reduce the risk of disclosure, identifiers will be stored separately from the research data in [insert location] and will only be accessible to [insert individual]. There will be a key document which will link your unique code to your real identity. This will be kept in [insert location] and only [insert individual] will be able to access this and link your data to you”.

or

“Your data will be stored in identifiable form in [insert location], and only [insert individual] will be able to access it”.

**How long will my data be stored for?**

* You should include a statement about the period for which you intend to retain the research data generated by the study. A suggested minimum period of retention is three years from the end of the project, however requirements by funders and data providers, as well as disciplinary guidance should be observed, as this it may be substantially greater. Please see more information about data storage and retention in the [Research Data Management Policy](https://www.essex.ac.uk/-/media/documents/directories/reo/rdm-policy.pdf). 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.

Will my participation be kept confidential?

* If you will be publishing/sharing fully anonymised or pseudonymised data,

Example statement:

“Your participation will only be known to [name here the individuals who will have access to the participant’s identifiable data, consent forms or contact details]”.

* If you will be publishing/sharing fully identifiable data,

Example statements:

“Information that identifies you will be used in reports, publications, and other study outputs so that anything you have contributed to this study can be recognised”; or “Your real name will be quoted in study outputs”.

How will my data be used and in what form will it be shared further?

* It is important that your participant information sheet describes your future data sharing and/or publication requirements and that you ensure that you obtain the participants’ consent to do this. This is a requirement of many research funders and the University encourages data sharing in a suitable form so it is important that you have planned for this. Provide a lay summary of what is described in sections “Data” and “Data sharing” of your ethics application form.

Example statements:

“Your data will be analysed as part of the study. It may then be published in [my dissertation/my thesis/ research publication(s)]. Data used in publications will be in [fully anonymised/pseudonymised/fully identifiable] form”.

or

“Your data will be made publicly available in [anonymised/pseudonymised/fully identifiable] form by sharing it in a data repository for the purpose of further research. All users, including the public, will have access”.

or

“Your data will be made available in [anonymised/pseudonymised/fully identifiable] form to other bona fide researchers by sharing it in an access-controlled data repository. Users will need to request access to the data and satisfy the repository’s access requirements”.

or

“Your data will be made available to [specific researchers/specific institutions who will have access to your data in [anonymised/pseudonymised/fully identifiable] form”.

Withdrawing my data

* Data collected up to the period of withdrawal may be used, if participants are happy for this to be done. Otherwise participants may request that their data are destroyed and no further use is made of them. If results are anonymised you should make it clear to participants that their data may only be withdrawn prior to anonymisation.
* You should provide details of how participants can withdraw their information, explain who should be contacted, and explain any limitations on the withdrawal of information (for example, if the data have been fully anonymised).
* Withdrawing data may adversely impact the reliability of the data for the entire focus group. If you will be undertaking focus groups, you may want to consider this matter when forming the ‘Withdrawing my data’ section in your PIS.

Example statement:

“Participants can ask for access to the information they provide and can request the destruction of that information if they wish at any time prior to [specified point: i.e. anonymisation/submission of dissertation/a time frame, i.e. - 1 month] following which they will not be able to request access to or withdrawal of the information they have provided”.

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

* The Data Controller will normally be the University of Essex and the contact will be the University Information Assurance Manager (dpo@essex.ac.uk). 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.
* You must inform the participant of the legal basis(es) for processing their personal data which is shown in the statement below. Do not amend the statement as this is required to comply with the University’s legal obligations.

Statement:

“The University processes personal data for the primary purpose of research under the lawful basis of processing set out in Article 6 (1)(e) of the UK GDPR, ‘processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller’. The University’s lawful basis for processing Special Category data is Article 9 (2), (j) ‘processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1)’. Using this lawful basis requires the University to also meet a substantial public interest condition as set out in Schedule 1, Part 1 of the Data Protection Act 2018. The condition that the University will use is 4. Research, etc. Under UK data protection legislation, the University acts as the Data Controller for personal data collected as part of the University’s research. For more information on data protection legislation and your rights visit the University’s [Data protection and research activity](https://www.essex.ac.uk/staff/freedom-of-information/data-protection-and-research#:~:text=Under%20Data%20Protection%20law%20individuals,to%20erasure%20of%20personal%20information) webpage. For any queries, email dpo@essex.ac.uk”.

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, include a statement indicating that the project has been granted a favourable ethical opinion by 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 must be provided with details of who can be contacted if they have any concerns or wish to make a complaint.

**Example statement:**

“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, [insert name], using the contact details below. If are still concerned, if 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, [insert name and e-mail address]. If you are still not satisfied, please contact the University of Essex REO Research Integrity Manager (reo-integrity@essex.ac.uk). Please include the ERAMS reference which can be found at the footer of this page so that the study can be identified, details of the name or description of the study, the researcher(s) involved, and the details of the complaint you wish to make”.

Contact details

* The name(s), status(es) and departments of all the researchers involved should be provided, together with details of how to contact them (email address/telephone number).
* Avoid using personal email addresses or phone numbers if possible.

Appendix 1 - Optional sections (choose if appropriate for your study)

Will I be compensated for taking part?

* Detail any expenses that might be available (for travel, refreshments etc.) and any reimbursement that participants may be eligible for.
* Detail when and how payment is made, including for what should happen if a participant withdraws.

**Example statements:**

“You will be offered a £15 shopping voucher for participation in a 2-hour focus group” (or financial and cultural equivalent outside the UK);

or

“You will be offered refreshments while you are taking part in an interview”;

or

(For young children) “You will be provided with a pack of stickers/a certificate for participation in the activities”;

or

(For schools/colleges) “Your school will be rewarded in books for recruiting students into the study”.

Who is funding the study?

* 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’.

Will I be recorded and how will the recorded media be used?

* You must inform the participant if you intend to use video or audio recording or photography. If you record activities (i.e. interviews, focus groups, theatre performance) you must not publish the recordings without the participants’ consent.
* You should inform participants what their recordings will consist of (i.e., voice only, facial features, full body, surrounding environment, other individuals, etc.) and how they are obtained (i.e., during a focus group discussion, asking participants to take images or recordings of their lives).
* You should explain that you will transfer the recordings from the recording device to secure storage. When it is checked that the recordings are transferred, you should delete the recordings from the recording device. Inform the participants that transcripts will also be securely stored.
* Appropriate storage must be used as per the information security classification of the data captured. Further advice about information storage can be found in the [Information security policy](https://www.essex.ac.uk/-/media/documents/directories/records-management/information-security-policy.pdf).
* You should consider informing the participants that the transcription of their recordings will be done in a secure environment where the participant cannot be seen or heard by another person outside the approved researcher/team.

**Disclosure Barring Service (DBS) check**

* If your study involves vulnerable people (i.e., children, the elderly, individuals with learning disabilities etc.), it may need a [Disclosure Barring Service (DBS) check](https://www1.essex.ac.uk/dbs/). If your study requires DBS check, you should consider making a short statement to explain that you have obtained a DBS check and that participants may request evidence of the DBS from you.

Dependent relationships

* A dependent relationship in the context of research can be defined as a pre-existing relationship between individuals who are prospective participants and the researcher that carries the potential to compromise the ability of the participant to provide free consent to participate or withdraw from a project. Examples include: employees recruited through their workplace; students of the University invited to participate in a research project. Participants in a dependent relationship with the researcher might feel obliged to participate or might believe that they will be disadvantaged if they decline to participate.
* If your study involves recruitment of students or pupils you must explicitly explain in your PIS 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, you must highlight in your PIS that a decision to participate or not will have no impact on their current or future employment or on their access to the service.

What if we find something unexpected? (for health related research)

* Consider whether analysis of images, samples, or questionnaire responses might produce findings of clinical significance for participants. If so, specify in your PIS the management pathway of these incidental findings, for example referral to the participant’s GP.

What will happen to the tissue samples I give?

* State in your PIS how the samples will be collected, when and by whom; how the samples will be used in the study (where they will be transferred or held, what analysis will take place) and in what form (i.e. fully anonymised, pseudonymised). Give potential participants information on your plans for any samples remaining after your specific piece of study has ended, such as whether they will be destroyed or stored, with consent, for future use.

**Sensitive or distressing topics**

* For studies involving discussing sensitive or distressing topics, you should explain in your PIS the risk of potential emotional distress, and you should emphasise that participants can abstain from answering any questions they may be uncomfortable with. You should explain in your PIS the procedure in place to manage a situation where participant distress occurs (for example, pausing the interview to provide time for participants to consider whether to continue or withdraw from the study).

**Potential for disclosure of illegal activities**

* If there is a possibility that you may collect information with the potential for disclosure of illegal activities where there is a legal obligation, or a strong convention to report these activities i.e., an act of terrorism or suspected financial offences related to terrorism; suspected instances of money laundering; or information about the neglect or abuse of a child, you should inform participants in your PIS that confidentiality may not be assured.
1. Fully anonymised data: All identifiers from the data have been irreversibly removed and participants are no identifiable in any way. [↑](#footnote-ref-1)
2. Pseudonymised data: Data that is not completely anonymous nor directly identifying. With pseudonymisation you separate direct identifiers from data so that linkage to a participant is no possible without the additional information that is held separately. [↑](#footnote-ref-2)