Participant Information Guidance

1. Important rules

The informed consent process requires that prospective participants are provided with information about a study in order to make an “informed decision” about whether or not they want to take part in the study.

The information provided to participants is important for various reasons: it explains to individuals everything that will happen to them, if they consent to participate; it allows them to weigh up the risks and beneﬁts of taking part; and it ensures that the information provided to them is fully documented.

The University’s Participant Information Sheet (PIS) template is a guide to help you as the researcher design study information sheets. Depending on your participants, it may be appropriate to:

* Translate the template into another language.
* Adapt it to account for cultural context or literacy level.
* Create a ‘script’ or presentation to relay this information verbally (for example, for participants who are unable to read).

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 you application.

The PIS should be printed on University of Essex headed paper when a study is undertaken by University staff or students. If a study involves more than one organisation, for example research involving an NHS Trust, it might be necessary to include other logos.

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

* 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.
* 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.
* The date of the document: As with the version number, this assists with maintaining an accurate record of the current version
* The ERAMS reference: This provides a link between the PIS and the application for ethical approval.

Failure to follow these rules will delay the approval process as the documents will be returned for amendments.

2. Specific guidance

2.1. Children and young people

For children and young people the information should be given in an appropriate language and format and at an appropriate pace for the age or stage of development. You may need to consider producing an alternative version of the information sheet which is more accessible, and which can be discussed with the legal guardian (i.e., parent/guardian/caregiver etc.). For example, use simple section headings in the PIS such as “What will happen?”, “What will I have to do?”, “Why is this project being done?”, “Why me?”, “When will this happen?”, “Will I have a choice?” and “What if I don’t want to do this anymore?”. This alternative version should, however, provide enough information and in appropriate detail so that informed consent can still be obtained.

It may be necessary to produce several versions of a PIS, for example when the research involves children and young people with a wide variety of ages or cognitive abilities.

A child who is incapable of providing valid consent on their own behalf may nonetheless be capable of expressing their assent (agreement) or dissent (disagreement) about participation. The assent of the child should be obtained where possible. When seeking assent from a child, your assent document should include any information that can affect a child’s decision to participate - an explanation of the proposed research procedures, the research purpose, and any discomforts. You should use language that is geared to the cognitive level of participating children. It might be more appropriate to obtain assent orally for younger children. For younger participants you could consider the careful use of pictures, if you believe they will support understanding.

There are several professional bodies that have published guidance, including the [Health Research Authority (HRA)](https://www.hra-decisiontools.org.uk/consent/examples.html) and [Ethical Research Involving Children (ERIC).](https://childethics.com/blog/supporting-children-to-make-informed-decisions-about-research-participation/)

A PIS for the parents/guardian/caregiver should inform them about the nature of the study and the option to include their child in the study if they so wish. Information sheets should indicate how the study will affect the child at home, school or other activities. You should tailor the section headings (i.e. “Why has my child been invited to take part”, “Does my child have to take part”, “Will my child’s data be shared or used in future research?”. In the information sheet, it is important to reassure parents/guardians/carers that the researcher is trained appropriately to conduct research with children. Researchers working directly and unsupervised with children may require a DBS disclosure. If a [DBS check](https://www1.essex.ac.uk/dbs/) is required, provide a statement in the information sheet declaring that the researcher has undergone an appropriate level of DBS check.

2.2. Working with potentially vulnerable participants

There are research types, contexts, or participants where there may be a greater likelihood of risk. Special consideration must be taken for research with potentially vulnerable participants. Examples include those with a learning disability or cognitive impairment; those in dependent or unequal relationships; those suffering bereavement; refugees, asylum seekers or displaced people; individuals having had an adverse experience like sexual or psychological abuse, crime, war, natural disasters; individuals in custody or long-term medical or psychiatric care.

You should tailor the information sheet taking into consideration whether the participant has a learning difficulty or lack of capacity due to cognition or another factor. You may need to consider using the most appropriate media for communication, including larger fonts, double spacing and clear visual aids, verbal explanations and diagrams or photographs as appropriate.

If the research involves the potential disclosure of personal and sensitive information, you should explain the risk of potential emotional distress in the information sheet, and you should emphasise that participants can abstain from answering any questions they may be uncomfortable with.

You should explain 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). Where there is a risk of distress or re-traumatisation, you should consider providing in you information sheet details of support resources, processes and contact points.

Reassurance should be given in the PIS for participants who are in dependent relationship with the researcher that they are free to participate or withdraw from the study. For example, should you wish to invite your University students to participate in a project, you need to clarify in the information sheet that their participation, non-participation or withdrawal will not affect their academic assessment in any way.

Researchers working with vulnerable adults may require a DBS check. If a [DBS check](https://www1.essex.ac.uk/dbs/) is required, provide a statement in the information sheet declaring that the researcher has undergone an appropriate level of DBS check.

If you might collect information with the potential for disclosure of illegal activities where there is a legal obligation, or a long-standing 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 the information sheet that confidentiality may not be assured.

2.3. Language and translation

Careful consideration should be given to accessibility and readability guidelines when you are preparing information documents for your participants. Implementing successfully the following guidelines will make your materials more accessible, not only to a visually impaired audience but to everyone: [University of Essex Diversity and Inclusion website](https://www.essex.ac.uk/staff/diversity-and-inclusion/accessibility); [Microsoft 365 - Get your document's readability and level statistics](https://support.microsoft.com/en-gb/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2?ui=en-us&rs=en-gb&ad=gb); [Microsoft 365 - Make your Word documents accessible to people with disabilities; Readability Formulas.](https://support.microsoft.com/en-gb/office/make-your-word-documents-accessible-to-people-with-disabilities-d9bf3683-87ac-47ea-b91a-78dcacb3c66d?ui=en-us&rs=en-gb&ad=gb)

You should include in your ethics application any information sheets to be used for the proposed project in the language in which it will be distributed, as well as an English translation. If your information sheets will be translated into another language, it is important to ensure that essential information is not lost in translation. If you are translating the participant information sheets yourself, you may want to consider asking another fluent speaker of the language to check what you have written. If your documents are in English, but English is not your participants’ first language, you should think how this might affect the language you use, i.e. avoiding idioms. If English is not your first language, you might also like to ask a fluent or native speaker to check your documents.

2.4. Human tissue

If your project will involve collecting human tissue, the participants should be informed in the PIS of the samples to be collected; how, when and by whom these samples will be collected; where samples will be stored and for how long; and whether the participants will be able to ask for the samples to be destroyed at any point.

2.5. Health related findings

Some health-related studies may involve the collection of data which can reveal significant unexpected abnormalities, which require medical follow-up. If there is a likelihood of discovering health related findings about a participant during your study which may affect their well-being, you should explain in the information sheet the procedure in the event that a significant health related abnormality is found, including whether you will send a report to the participant’s GP/Consultant. Permission to contact their GP/Consultant should be sought prior to study participation and consent obtained for information to be shared.

2.6. Audio/video recordings

You need to obtain the participant’s permission to record their activities on audio or video media. In your information sheet, you must ensure that there is a clear understanding as to how these recordings will be used. For example, if you are planning to record an interview, you must not publish or broadcast the recording, show it in public, or deposit it in an archive without the participants’ permission. Storage, retention and destruction of interview recordings which contain sensitive material should also be covered in your information sheet.

For audio/video recordings you must explicitly state in your information sheet whether participants are free to decline the recording or whether it is essential to their participation in the study. You must also state that participants should be comfortable with the recording process at all times, and they are free to stop recording at any time.

For audio/video recordings you should tell participants in the information sheet what the recordings/photographs will consist of (e.g., voice only, facial features, full body, surrounding environment, other individuals, etc.) and how they are obtained (e.g., during a focus group discussion, asking participants to take images or recordings of their lives).

2.7. Online surveys

## When using online surveys, you should ensure that the first page before the survey starts provides a summary of the study, the information from the participant information sheet ([found on the staff directory here](https://www.essex.ac.uk/staff/research-governance/research-participant-information-and-consent)) and the researcher(s)’ contact information.

Participants should be given a copy of what they have consented to. Participants can be offered options to download the information sheet or to enter an email address to which a copy of this information will be sent. It is important that participants read and retain a copy of the information sheet so that they are aware of how and why you are using their information and what their rights are under the data protection legislation. A clear statement should be provided on the survey that indicates that the participant is consenting to participate in your study by completing and submitting the online survey. The statement could be repeated at the end of the survey before submission takes place.