

Informed consent protocol

This protocol is designed to give guidance to researchers about the informed consent procedures and informed consent forms that they should use in their research. It should be used alongside the Privacy Notice for Research, available at <https://dataprotection.leeds.ac.uk/information-for-researchers>.

Principles of informed consent

1. Informed consent, also known as valid consent, means giving sufficient information about the research and ensuring that there is no explicit or implicit coercion so that prospective participants can make an informed and free decision on their involvement. The change in data protection law means that individuals still need to provide their consent to participate in research, but that researchers do not always need the individual's consent to process their data as part of that research (this could include repurposing data, or sharing data with other parties). The primary objective in all cases is to be open with the participant about the realities, and potential risks, of their involvement.
2. Researchers should take the steps necessary to ensure that all participants in the research:
 - (a) understand the process in which they are to be engaged, including why their participation is necessary and;
 - (b) understand the purpose of the research and how and to whom its research findings will be reported.
3. Researchers should make clear to participants what their rights are regarding their withdrawal of consent, as well as the right not to answer particular questions. Researchers should indicate the point at which withdrawal will no longer be possible because data will have been anonymised and/or amalgamated and cannot be excluded. If data are to be archived and shared participants should, where possible, give specific consent to this. For further information see the protocol on Data Protection, Anonymisation and Sharing Research Data.
4. Typically information to participants should be provided in written form, time should be allowed for the participants to consider their choices, and an informed consent form should be signed. However, research is a dynamic process and consent, similarly, is not simply resolved through the formal signing of a consent document at the start of research. Instead it is continually open to revision and questioning, and should be revisited regularly as the project evolves. Researchers should aim to foster relationships in which ongoing regard for participants' consent is sustained, even after the study itself has been completed.
5. There should be no coercion of research participants to take part in the research. Adult research participants, however, may be given small monetary reimbursement for their time and expenses involved. For further information see the protocol Reimbursement for Participants.
6. It is recognised that there are occasions when the use of covert research methods is necessary and justifiable. However deception (i.e. research without consent) should only be used as a last resort.

Information sheet

7. An information sheet should help a person to make an informed choice regarding whether or not to participate in a research project. Potential participants may take more care when reading a concise information sheet and, thereby, be better informed than if s/he has to read an information sheet that runs into several pages. It should contain information which is clear and accessible to potential participants about:
 - The people conducting the research, their institutional affiliations and the funding body if relevant.
 - The purpose of the research.
 - What participation will involve, including the right to withdraw.
 - How the information provided will be used (and where it might be repurposed and shared if known).
 - How confidentiality and anonymity will be preserved.
 - The risks and benefits of participation.
8. The information sheet should normally be given to potential participants in advance of their participation, giving them sufficient time to reflect on the information provided, ask questions, and come to a decision about participation. Ideally it should not be provided at the same time as the informed consent form to enable sufficient time for decision making.
9. It is good practice to reiterate verbally the contents of the information sheet before participants sign consent forms. This is important because some participants may have undisclosed literacy problems. In addition, such a discussion would help clarify any misunderstandings, for example over limits to withdrawal of data and the rights of researchers to repurpose and share data. In situations where the provision of written information prior to the commencement of the research is inappropriate researchers should always give the information listed above verbally allowing potential participants to take sufficient time for discussion and consideration before making a decision about participation. Potential participants should always be given the opportunity to ask questions about the research before signing the consent form.

Informed consent

10. Written informed consent should be obtained from participants where possible. In cases where consent is to be obtained verbally this should be recorded. For further information see the [Protocol on Verbal Consent](#)¹. In all cases the purpose is to verify that participants:
 - have understood the information provided on the information sheet (or its verbal equivalent);
 - have been able to discuss this information with the researcher;
 - are participating voluntarily;
 - recognise that they are free to withdraw (up to the point at which their data is anonymised and amalgamated);
 - recognise that they can decline to answer particular questions without negative consequences;
 - understand how their personal data will be protected; and
 - understand that their data might be used in other research and might be shared with other researchers (with as much specific details as possible).

¹ http://ris.leeds.ac.uk/ris/downloads/file/557/verbal_consent_protocol

11. Where written or verbal consent is not to be recorded a full statement justifying this should be submitted to the Ethics Committee for review and approved.
12. Note that in longitudinal research it may be necessary to explain the need for (and limitations of) enduring consent. This is where there is no time limit on consent given and participants do not need to be re-contacted should any of their personal data be reused for further research. This may also be important for data that is placed in an archive. Principles of preserving confidentiality apply. It may also be necessary to re-negotiate consent during the lifetime of the research.
13. Where participants are not legally responsible, their legal representatives or guardians should be consulted as well as the individual. Additional safeguards also need to be put in place if participants are vulnerable due to their age, health and any other factors. It must be clear that participants fully understand the research and what they are being asked to do.
14. Further guidance is available on the [Research and Innovation Service website](#).
15. All participant-facing material is reviewed by the Faculty or School Research Ethics Committee during the [ethical review process](#).

Model Information Sheet

The [Privacy Notice for Research](#) should be provided alongside the Information Sheet.

Below are examples of the main points an information sheet should include:

The title of the research project

If the title could be difficult to understand then it should be explained in lay terms.

Invitation paragraph

Explain that the prospective participant is being asked to take part in a research project. For example you could say:

'You are being invited to take part in a research project. Before you decide 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 and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.'

What is the purpose of the project?

The background, aim and duration of the project should be given here. Remember to be brief and don't use overly complicated language that a lay person wouldn't understand.

Why have I been chosen?

You should explain how the participant was chosen and say how many other participants will be recruited.

Do I have to take part?

You should explain that taking part in the research is entirely voluntary and that refusal to agree to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. For example:

'It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form) and you can still withdraw at any time without it affecting any benefits that you are entitled to in any way. You do not have to give a reason.'

What do I have to do?/ What will happen to me if I take part?

You should state how long the participant will be involved in the research, how long the research will last (if this is different), how often they will need to participate and for how long each time. You should explain if travel expenses are available.

You should explain what exactly will happen (e.g. blood tests, interviews?)

Where a participant is to be interviewed, it might be helpful to explain the questioning style (e.g. clarify if questions will enable open as well as closed answers to be given in relation to a particular topic; e.g. clarify which aspects of the topic participants should be able to discuss in-depth and which not in-depth).

You should explain the participant's responsibilities, setting down clearly what you expect of them.

You should set out simply the research methods you intend to use. State if there are any lifestyle restrictions as a result of participating.

What are the possible disadvantages and risks of taking part?

Any reasonably foreseeable discomforts, disadvantages and risks need to be stated.

What are the possible benefits of taking part?

Any benefits to the participants that can reasonably be expected should be stated. However, where there is no intended benefit to the participant from taking part in the project this should be stated clearly. It is important not to exaggerate the possible benefits to the particular participant during the course of the project, this could be seen as coercive.

For example you could say:

‘Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will ...’

Use, dissemination and storage of research data

This should be explained. Also explain your plans for future publishing, archiving and re-use of the data where known, or be explicit about the potential for this to happen.

What will happen to my personal information?

Clarify any limits to confidentiality and anonymisation. Explain how identifiable participants will be. Explain what will, and what could happen to the data.

What will happen to the results of the research project?

You should state that all information collected about them will be kept secure and explain how information will be kept confidential. Example paragraph: ‘All the contact information that we collect about you during the course of the research will be kept strictly confidential and will be stored separately from the research data. We will take steps wherever possible to anonymise the research data so that you will not be identified in any reports or publications’.

Sometimes it is not possible to keep everything confidential, for example if the participant discloses an intention to harm themselves or others. If you feel that your research data collection methods may well solicit information about potential harm or abuse or other situations that require reporting, then potential participants should be informed about this possibility/obligation in the consent process. Where, due to the nature of the research, it may not be possible to guarantee the anonymity of the data then the reasons for this should be stated here and any limits to anonymisation made clear to participants before they consent to take part. Furthermore, the consequences to the participant from data not remaining confidential should be provided here.

If a focus group is being used as a method of data collection, full anonymity cannot be guaranteed on behalf of the other focus group participants. The consent form should clearly note this limitation.

You should be able to tell the participants what will happen to the results of the research (i.e. when the results are likely to be published, whether they can obtain a copy of the published results) and add that they will not be identified in any report or publication.

Given the importance of research data for the future you need to include a statement indicating that the data collected during the course of the project might be used for additional or subsequent research (this should be explicit on the participant consent form).

What type of information will be sought from me and why is the collection of this information relevant for achieving the research project’s objectives?

Please explain here.

Who is organising/ funding the research?

You should state the organisation or company that is sponsoring or funding the research.

Contact for further information

You should give the participant a contact point for further information.

This can be your name, address and telephone number or that of another researcher in the project. If this is a supervised-student project, the address and telephone number of the student's supervisor should be included as well. The use of personal phone numbers and email addresses should be avoided.

Finally ...

The information sheet should state that the participant will be given a copy of the information sheet and, if appropriate, a signed consent form to keep.

Remember to thank the participants for taking the time to read through the information.

Version control is important. For example use a table like the one below to keep track of the various versions of your documents:

<i>Project title</i>	<i>Document type</i>	<i>Version #</i>	<i>Date</i>
	Eg consent form for...		

Additional question to include in an information sheet if the research involves producing recorded media:

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

You need to obtain the participants' permission to record their activities on audio or video media. You must ensure that there is a clear understanding as to how these recorded media will be used. For instance, if you record a music or theatre performance, you must not publish or broadcast the recording, show it in public, or deposit it in an archive without the performers' permission. Storage (and eventual disposal) of interview recordings which contain sensitive material can also be an issue to address. For example:

'The audio and/or video recordings of your activities made during this research will be used only for analysis and for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.'

If you plan to use the recording in a publication or broadcast or deposit it in an archive, it is often better to prepare and sign a separate release form for each item used. You must ensure that all appropriate boxes have been agreed to, to avoid any future complications. For example, if an individual is not happy for data to be used in the future (even in an anonymised form) you should not consent them to the project.

Example participant consent form – the highlighted parts need to be adapted to your project – to be printed on headed paper

Consent to take part in [title of research project]	Add your initials next to the statement if you agree
I confirm that I have read and understand the information sheet/letter [delete as applicable] dated [insert date] explaining the above research project and I have had the opportunity to ask questions about the project.	
I understand that my participation is voluntary and that I am free to withdraw [at any time without giving any reason/ until [date]] and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline. Insert contact number here of lead researcher/ member of research team (as appropriate). [Include a statement about what will happen to data already provided following withdrawal from the study.]	
I understand that members of the research team may have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research. I understand that my responses will be kept strictly confidential [only if true].	
I understand that the data collected from me may be stored and used in relevant future research [in an anonymised form] or I understand that the data I provide may be archived at [name of archive]. [If applicable]	
I understand that relevant sections of the data collected during the study, may be looked at by individuals from the University of Leeds or from regulatory authorities where it is relevant to my taking part in this research. [If applicable]	
I agree to take part in the above research project and will inform the lead researcher should my contact details change.	

Name of participant	
Participant's signature	
Date	
Name of lead researcher [or person taking consent]	
Signature	
Date*	

*To be signed and dated in the presence of the participant.

Once this has been signed by all parties the participant should receive a copy of the signed and dated participant consent form, the letter/ pre-written script/ information sheet and any other written information provided to the participants. A copy of the signed and dated consent form should be kept with the project's main documents which must be kept in a secure location.