

Creating a Participant Information Sheet

Potential recruits to a research study must be given sufficient information to allow them to decide whether or not they want to take part. The purpose of the project, and the fact that it is a research project, should be explained concisely in plain English. Technical terms, acronyms and abbreviations should be avoided or clearly explained.

An Information Sheet must contain information under all the headings given below, and in the order specified. Additional headings may be included if the study has exceptional aspects to be clarified. The document should be written in simple, non-technical language which can be easily understood by a person outside the field of expertise. Use short words, sentences and paragraphs, and remember that the Information Sheet should not be too long.

Please note that this sheet along with a consent form (where relevant) will be provided to each participant to keep. If you are carrying out an online survey/questionnaire, this sheet should be included at the beginning of your questionnaire/survey.

How much information?

There are no specific criteria as to how much information is required, except to say that a reasonable person could be expected to understand enough to properly weigh up the risks, disadvantages and benefits of taking part. If invasive procedures are being used, the person should understand in broad terms the nature and purpose of the procedure and the material risks involved.

When providing the above information, care should be taken to:

- give the prospective participant full opportunity and encouragement to ask questions;
- exclude the possibility of unjustified deception, undue influence and intimidation;
- seek consent only after a sufficient opportunity has been given to the prospective participant to consider whether or not to participate;
- as a general rule, but subject to exceptions (e.g. anonymous online surveys/questionnaires), obtain from each prospective participant a signed form as evidence of consent;
- renew the consent if there are material changes in the conditions or procedures of the research, or if it is a longitudinal study.

Where participants may have any difficulties with communication, the Information Sheet must be adequately adapted. This may involve providing a translation, or if participants are children, providing a version using age-appropriate language.

Participant Information Sheets must appear on headed paper bearing the Brunel University London logo, and must always contain Brunel (not personal) contact details for the researcher and for student applications, the supervisor.

The headings

- **Study title**

Is the title self-explanatory to a lay person? If not, a simplified title should be included.

- **Invitation paragraph**

This should explain that the person is being asked to take part in a research study. The following is a suitable example:

'You are being asked to take part in a research study. 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 me/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. Thank you for reading this.'

- **What is the purpose of the study?**

The background and aim of the study should be given here. Also mention the duration of the study. If the study is being undertaken in the course of a degree, you should state this here.

- **Why have I been invited to participate?**

You should explain why and how the person was selected to be invited and approximately how many other participants will be taking part in the study. You should include the age range of the participants here, along with any other inclusion criteria relevant to the study.

- **Do I have to take part?**

You should explain that taking part in the research is entirely voluntary. You could use the following paragraph:

'As participation is entirely voluntary, 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 you may be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time up until [a date] and without having to give a reason.'

You should also state whether participants can withdraw their data after their involvement has ended and if so, by which date (i.e. submission date of a dissertation or the point at which your data is anonymised). If you are carrying out an anonymous questionnaire, you should remind the participants that once they have submitted their results, they will be unable to withdraw.

It should be clearly stated that the right to decline or withdraw from the project will in no way adversely affect the participant. A 'no detriment' statement may need to be included in the case of student participants or those who may be vulnerable by context.

- **What will happen to me if I take part?**

You should state:

- how long the person will be involved in the research; ○ how long the research will last (if this is different);
- (where relevant) how often they will need to visit University premises/laboratory/hospital/school etc. and how long these visits will take;
- whether reasonable travelling expenses will be paid; ○ what exactly will happen during your participant's involvement, e.g. interviews, tests, scans, Xray, etc.;
- what the participant's responsibilities are; ○ what you expect of them.

You should set out in simple terms, understandable by a non-expert, the research methods you intend to use. If interviews are involved, and will be recorded, you need to ensure this is specified on the consent form.

- **Are there any lifestyle restrictions?**

In most low risk studies, there are not any life style restrictions. You should clearly state this.

If there are restrictions, you should inform the participants of these. This may include pre-restrictions such as abstaining from alcohol, or post restrictions such as being unable to drive after the study.

You should also consider the following: Are there any dietary restrictions? Can the person take part in sport? Will there be any effect on regular medication? Should the participant refrain from giving blood? What happens if the participant is or becomes pregnant? This list is not exhaustive.

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

Here, a simple statement of risk should be included. Remember, you cannot be certain that there will be 'no risks' involved in a study.

Any material risks, side effects or discomforts should be clearly indicated. If there is any possibility of psychological distress or discomfort, this should be clearly stated, along with proposed mitigation.

If conducting your research with participants in person, you should also set out risks relating to Covid-19 and appropriate safety measures.

- **What are the possible benefits of taking part?**

Where there is no intended benefit to the person from taking part in the study, this should be stated clearly. It is important not to exaggerate the possible benefits to a particular person during the course of the study, e.g. by saying they will be given extra attention. This could be seen as coercive.

- **What if something goes wrong?**

You should inform participants of what to do should something go wrong during the study. You should also include how complaints will be handled and what redress may be available.

Is there a procedure in place? In relation to NHS projects, you will need to distinguish between complaints concerning treatment by members of staff (doctors, nurses etc.) and something serious happening during or after participation in the research, i.e. a reportable serious adverse event.

Where the study carries risk of physical or psychological harm, the following is a good example:

'If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.'

The person to be contacted if the participant wishes to complain about the experience should be the Chair of the relevant Research Ethics Committee (relevant contact details should be provided – see details at the end of this document).

- **Will my taking part in this study be kept confidential?**

Explain what will happen to the participant's data. This should be in line with University policies and take into account any additional requirements from an external funding agency.

You should state how long you will keep the data (if you are a taught student, this is usually up until your graduation date), where you will store it (in a secure password protected Brunel server or locked file) and whether the participant can withdraw it at a later date. In most cases, you should ensure anonymised data can be used in future research with permission from the participant.

You may need to obtain the person's permission to allow restricted access to their records/files/notes and to all information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. The following form of words may be appropriate:

'All information which is collected about you during the course of the research will be kept strictly confidential [include how long for]. Any information about you which leaves the University will have all your identifying information removed. With your permission, anonymised data will be stored and may be used in future research – you can indicate whether or not you give permission for this by way of the Consent Form.'

You should always bear in mind that you, as the researcher, are responsible for the security of the data you collect. You must comply with the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) and remember – you may be personally liable if you contravene them. This is particularly important if you are collecting special category (sensitive) personal data.

It may sometimes be necessary to break confidentiality if, for example, you witness harm or a disclosure of harm to a participant or someone else. If this is a possibility (however remote) within the context of your research, you must ensure you are aware of your responsibilities and are ready to take action should this occur. You should add a statement to your Participant Information Sheet indicating what you will do if this happens. The following is a suitable example:

'If during the course of the research evidence of harm or misconduct come to light, then it may be necessary to break confidentiality. We will tell you at the time if we think we need to do this, and let you know what will happen next.'

- **Will I be recorded, and how will the recording be used?**

If you intend to audio or video record participants, you must set out in detail when and how they will be recorded and what will happen to the recordings. Ensure you have an explicit statement relating to this on the Consent Form. Please ensure you consider how you will record research activity and make sure the recording device/app/platform is GDPR compliant. You must also consider how you will store the recordings securely and when you will destroy them.

- **What will happen to the results of the research study?**

You should be able to tell participants what will happen to the results of the research. Will the results be written up as part of a dissertation? Will they be published, and if so, where and when? Where can they obtain a copy of the published results? You should add that they will not be identified in any report or publication unless they specifically request it.

- **Who is organising and funding the research?**

The answer should include the organisation or company sponsoring or funding the research (e.g. funding council, company, charity, academic institution).

If the research is not funded, please state that the research is being organised by yourself [state full name] in conjunction with Brunel University London.

If the research is funded and the funder demands that they remain anonymous, then you must clearly state that there is an external, anonymous funder. The participant can then make an informed decision as to whether they wish to take part under those circumstances.

- **What are the indemnity arrangements?**

As long as research ethics approval has been obtained, Brunel normally provides insurance cover for research projects. The following is suggested:

'Brunel University London provides appropriate insurance cover for research which has received ethical approval.' Participants

should be informed if participation in a study might affect health-related insurance.

- **Who has reviewed the study?**

You must give the name of the Research Ethics Committee which has reviewed the study (see the end of this document). This is the Research Ethics Committee for the College you belong to.

- **Research Integrity**

A suggested insert should read:

Brunel University London is committed to compliance with the Universities UK [Research Integrity Concordat](#). You are entitled to expect the highest level of integrity from our researchers during the course of their research.

- **Contact for further information and complaints**

You should give participants a contact point for further information – this should be official Brunel contact information and not personal telephone numbers or email addresses.

If the researcher is a student please also include the contact details of your supervisor.

You should also include contact details for the Chair of your relevant Research Ethics Committee (see below) so that participants can contact the University if they wish. The Research Ethics Committee you list should be the one of the College you belong to. These are listed below.

The Participant Information Sheet should state that the individual will be given a copy of the information sheet and signed consent form to keep.

Remember to thank the individual for reading the document.

Brunel University London Research Ethics Committees:

University Research Ethics Committee

Chair – Prof Christina Victor (Christina.Victor@brunel.ac.uk)

College of Business, Arts and Social Sciences Research Ethics Committee Chair – Professor Nigar Hashimzade (Nigar.Hashimzade@brunel.ac.uk)

College of Health, Medicine and Life Sciences Research Ethics Committee Chair – Professor Louise Mansfield (Louise.Mansfield@brunel.ac.uk)

College of Engineering, Design and Physical Sciences Research Ethics Committee Chair – Professor Simon Taylor (Simon.Taylor@brunel.ac.uk)