**Participant information sheet guidelines**

The informed consent process requires that prospective participants are provided with as much information as possible about a research project in order that they and / or their legal guardians / advocates can make an “informed decision” about whether or not they want to take part in the project.

Information sheets - normally provided in written format but can also be spoken - are an important part of the informed consent process. With this in mind, this document has been produced to act as guidance for staff and students when designing their information sheets. If you have any questions about this document please contact the Research Ethics and Integrity team on 0151 794 8290 or at [ethics@liverpool.ac.uk](mailto:ethics@liverpool.ac.uk).

**General Information**

The design of your information sheet should reflect the nature of the research study. Some information sheets may therefore need to be more detailed than others; or may use graphics rather than just text.

It is important to make sure that even after the information sheet has been read and consent has been obtained, the participant has the right to ask any further questions and they should be provided with details on where to find further appropriate information on the specific research area.

All protocols, research proposals, and supporting documents (including information sheets and consent forms) should state the version number and date of the document. This date indicates when the documentation was finalised. Version numbers and dates show how a document was developed, help to identify earlier versions if required, and act as an aid to monitoring and audit.

*Please note****:***

* If an amendment to a document is made, the version number and date must also be amended.
* Failure to include version dates will slow up the approval process as they will be sent back to the researcher for amendment.

It is essential that any logos, project titles, contact details, etc. are consistent across all documents, and that a record of the changes to documents is logged through version numbers and dates for each document.

The first page of the information sheet (and all corresponding documents) should have the University Crest (found at: <https://www.liverpool.ac.uk/intranet/brand-identity/brand-toolkit/>) at the top in the centre.

You may need to make provision for participants who are not fluent in the language used in the information sheet and should consider how to deal with challenges such as illiteracy. For example, you may choose to have an interpreter / translator to hand for participants who may not be fluent in the language used.

Information should be displayed in an appropriate format for the population involved in the research, for example, pictorial / diagram / oral format rather than text may be more suitable for some participant groups.

**Studies involving children / vulnerable adults**: 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 (e.g. parent / guardian/ caregiver etc.). This alternative version should, however, conform to the same purpose as other information sheets in that its aim is to provide enough information and in appropriate detail so that informed consent can be obtained.

Please see below the University of Liverpool participant information sheet template which consist sections which apply to each research project. There are also some optional statements which apply only to specific studies. Please read these carefully and add any that are appropriate to your research project.

The information on the blue pages of this document is intended as guidance; whereas the information on the white page represents the University template.

*Please see the University of Liverpool Template participant information sheet on the pages below*

1. **Title of Study**

Your study title should be the same on all related documents and should explain the study in simple English. If you have used a short title, make sure that you quote this as well as the full title on your ethics application form.

1. **Version Number and Date**

All information sheets should have a version number and date is recorded as a way of determining which version of the documentation participants have received should any queries arise.

1. **Invitation Paragraph**

Invite the participant to take part in the study and be careful to make sure that it does not sound as if they are being pressured or coerced. For example:

*You are being invited to participate in a research study. Before you decide whether to participate, 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 feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your friends, relatives and GP if you wish. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.*

*Thank you for reading this.*

1. **What is the purpose of the study?**

In lay terms, with all technical terms and acronyms defined, you should explain why the study is being done - the background, aims and objectives etc.

If it is not appropriate to inform participants of the purpose of the research at this stage - for example in the case where this may affect the behaviour of participants - please ensure that participants are fully debriefed at the end of the research. Please also enclose a debriefing form with your application for research ethics review.

1. **Why have I been chosen to take part?**

Briefly explain the reasons why and how you have chosen to invite participants and also how many others will be taking part.

1. **Do I have to take part?**

It should be made clear that participation is voluntary and that participants are free to withdraw their participation at any time, without explanation, and without incurring a disadvantage.

1. **What will happen if I take part?**

In language that can be understood by a lay reader, you should provide an explanation of exactly what will be asked of the participant and what will happen during the research. For example, you should explain clearly:

* what the methods are
* who the researchers are
* who will be carrying out the procedure
* what the duration / frequency of the procedure is
* what the participant’s responsibilities are

When writing this section, think about what details you would want to know if you were to take part in a research study.

Participants should be made aware if research involves any audio / visual recording and this should be made clear in both the information sheet and consent form.

Please note that if there is a possibility that the participant’s GP may need to be contacted, this should also be made clear in the information sheet and consent form.

1. **How will my data be used?**

You must inform the participant of the lawful basis for processing their personal data – and if special category data or criminal offence data will be collected, you will need to outline the condition of processing as well as the lawful basis (please see the [GDPR and research note](https://www.liverpool.ac.uk/intranet/media/intranet/staff-intranet/images/gdpr/GDPR,and,Research,Notice.pdf) for further guidance on the lawful basis for processing).

You should use the following wording to inform participants of the lawful basis on which the University processes personal data in research; and to inform them of how their data will be used:

“*The University processes personal data as part of its research and teaching activities in accordance with the lawful basis of ‘public task’, and in accordance with the University’s purpose of “advancing education, learning and research for the public benefit.*

*Under UK data protection legislation, the University acts as the Data Controller for personal data collected as part of the University’s research. The [Principal Investigator / Supervisor] acts as the Data Processor for this study, and any queries relating to the handling of your personal data can be sent to [****Principal Investigator / Supervisor contact details****].*

*Further information on how your data will be used can be found in the table below*”.

|  |  |
| --- | --- |
| How will my data be collected? |  |
| How will my data be stored? |  |
| How long will my data be stored for? |  |
| What measures are in place to protect the security and confidentiality of my data? |  |
| Will my data be anonymised? |  |
| How will my data be used? |  |
| Who will have access to my data? |  |
| Will my data be archived for use in other research projects in the future? |  |
| How will my data be destroyed? |  |

Transferring data outside the EU

If personal data will be transferred outside the European Union, you must explain how this will be conducted, why this is necessary, and outline the safeguards in place to protect the data.

1. **Expenses and / or payments**

Detail any expenses that might be available (for travel, refreshments etc.) and any **reimbursement** that participants may be eligible for.

1. **Are there any risks in taking part?**

Please explain whether there are any perceived disadvantages or risks involved. Explain that if the participant should experience any discomfort or disadvantage as part of the research that this should be made known to the researcher(s) immediately.

Certain areas of research may have the potential for identifying a serious risk to the participant or to others. For example, this might relate to the identification of a medical condition, financial concerns (e.g. severe debt), legal concerns, etc. **If you believe your research could identify such risks you should provide details in your information sheet of advice and resources; and details of any procedures that will be followed.**

For example:

1. in the event of discovering a medical risk, you may advise that information collected may be referred to an appropriate medical practitioner for examination
2. if you are studying consumer behaviour / spending behaviour might include a section in the information sheet which gives the details of the Citizens Advice Bureau so that participants may contact them if they want further advice on debt.

If your research involves studying smoking or alcohol use, you could offer details of local / national agencies, e.g. Drinkline or Go Smoke Free

1. **Are there any benefits in taking part?**

Any benefits (at the time of participation or in the future) should be explained. If there is no intended benefit this should be made clear.

1. **What will happen to the results of the study?**

Detail how the results will be made available to the participants and whether the results are to be published. If the results are to be published, detail how and where they will be accessible. Tell participants that they will not be identifiable from the results unless they have consented to being so.

1. **What will happen if I want to stop taking part?**

Participants should be informed that they can withdraw their participation in the study at any time, without explanation.

Results up to the period of withdrawal may be used, if participants are happy for this to be done. Otherwise participants may request that the results are destroyed and no further use is made of them. If results are anonymised you should make clear that results 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).

1. **What if I am unhappy or if there is a problem?**

All complaints should be handled through the Committee on Research Ethics complaints procedure. You should use something similar to the following to explain how complaints will be handled:

*“If you are unhappy, or if there is a problem, please feel free to let us know by contacting [****Principal Investigator name and number****] and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the Research Ethics and Integrity Office at* [*ethics@liv.ac.uk*](mailto:ethics@liv.ac.uk)*. When contacting the Research Ethics and Integrity Office, please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make.*

*The University strives to maintain the highest standards of rigour in the processing of your data. However, if you have any concerns about the way in which the University processes your personal data, it is important that you are aware of your right to lodge a complaint with the Information Commissioner's Office by calling 0303 123 1113.””*

1. **Who can I contact if I have further questions?**

You should give the name, address and contact telephone number of the **Principal Investigator.**

**Contact details of investigatory team**

**Appendix 1: Optional sections (choose as appropriate)**

*Disclosure Barring Service check (DBS)*

If the research involves vulnerable people (e.g. children, the elderly, those with learning disabilities etc.) you will usually need to obtain a Disclosure Barring Service (DBS) check. You may therefore want to make a short statement to explain that the researchers involved have obtained a DBS check and that research participants may request evidence of the DBS from the Principal Investigator.

*Discussing sensitive or distressing topics*

If the research involves the potential disclosure of personal and sensitive information, you should explain 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 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).

*Health related findings in research*

Some health related studies may involve the collection of data which can reveal significant unexpected abnormalities, which require medical follow-up, either for further investigation or (more rarely) treatment.

You should explain to participants that the data is being collected for research purposes, and state whether you propose to review the data for potential health related findings in research. If so, you should explain 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. It should be emphasised that participation in the study is not a substitute for a ‘health check’.

**Please note:** for studies taking place at Liverpool Magnetic Resonance Imaging Centre (LiMRIC), please follow the [Policy on Incidental Findings](https://www.liverpool.ac.uk/limric/contacts/).

*Disclosure of criminal activity*

If you are carrying out research where you may collect information with the potential for disclosure of serious criminal activity (e.g. research with young offenders / prisoners) **you should inform participants that confidentiality may not always be assured.** Please also ensure that you have discussed with the Prison or Young Offender Institution an appropriate reporting procedure to follow if such information is disclosed**.**

**Appendix 2: Example participant information sheets**

Examples of participant information sheets can be accessed through the following links:

* [Health Research Authority](http://www.hra-decisiontools.org.uk/consent/examples.html)
* [UK Data Service](https://www.ukdataservice.ac.uk/manage-data/legal-ethical/consent-data-sharing/consent-forms)

Examples of age appropriate information sheets for children can be found using the below resources:

* [Health Research Authority](http://www.hra-decisiontools.org.uk/consent/examples.html)
* [Global Kids Online](http://globalkidsonline.net/tools/qualitative/)

*University of Liverpool example child participant information sheet*

“Breakfast, lunch and feeling full”

Information sheet for you!

Hello, my name is [A] and I’m from the University of Liverpool. I am visiting your school today and I am interested in finding out what kind of breakfast, snack and lunch makes you feel more full. Please have a look at this leaflet which tells you about this study.

**This study is to find out what kind of breakfast, snack and lunch makes you feel more full!**

**What is the study about?**

**Why have I been chosen?**

**You are very important and with your help I can learn more about this!**

1. **I will visit you four times at school. Each time I will ask you to eat a different kind of breakfast, snack and lunch and I will ask you how full you feel and if you liked what you ate.**
2. **I’ll also ask you to fill in a few short questionnaires (I will explain what to do before each one and can help if you get stuck).**
3. **The last time I visit I will see how tall you are and what you weigh (no-one else will see this).**

**What will happen if I take part?**

**Yes, you can stop at any point if you don’t want to take part anymore. You don’t have to say why.**

**Can I stop if I don’t want to do the study anymore?**

**Will the things I write be kept secret?**

**Yes, we will put a number on it but not your name. No-one will know who you are when we write about this study.**



**If you have any questions, please ask me!**

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**Thank you for reading about my study ☺**