# University guidance on designing a participant information sheet

*This guidance document has been adapted specifically for veterinary studies involving human participants, such as animal owners, animal carers, farmers or vets.*

Text with a coloured background in this document is for guidance only, and should be deleted from the final ‘Participant Information Sheet’ that is provided to participants.

*The informed consent process*

The informed consent process in animal-based research requires that human participants (including owners of pets, farmers, Vets and any other relevant human participants) are provided with as much information as possible about a research study in order that they and / or their legal guardians / advocates can make an **informed decision** about whether or not they want their animal(s), Vet practices etc. or themselves as participants to take part in the study.

Information sheets, which are normally provided in written format but can also be spoken, are an important part of the informed consent process. This document has been produced as guidance for staff and students designing their information sheets to be used for the human participation element of their Veterinary research.

If you have any questions, please contact the Research Ethics and Integrity team on 0151 794 8290 or at ethics@liverpool.ac.uk.

## Guidelines for creating your participant information sheets

*Designing your participant information sheets*

The design of your information sheet should reflect the nature of the research study.

**Wherever possible, it is important to seek input from your participant pool, who can help design your form with you for best practice.** For example, for a study which involves children, you may consult the [Young Person’s Advisory Group](https://www.liverpool.ac.uk/humanities-and-social-sciences/research/research-themes/children-childhood/ypag/).

Some information sheets may need to be more detailed than others, or may use graphics as well as text. You may decide that a word-processed document is not the best or only way to communicate with your participants – **you should** **consider exploring other formats such as video, audio, or leaflets.**

*Important rules relating to your information sheets*

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, as in the template provided later in this 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 aid 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.
* **You must ensure that the information you provide in this document is consistent with the statements in your consent form and the information listed in your data management plan.** For example, if your data management plan states anonymised data will be archived, the consent form must also have a statement mirroring this, and so on.

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/brand-guidelines/> at the top in the centre.

*Specific considerations for different research populations*

**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; and you will need to consider appropriate ways to record the participant’s consent.

**Information should be displayed in an appropriate format for the population involved in the research**, for example, pictorial / diagram / oral / video format 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.

Checklist for your participant information sheet

Before finalising your information sheet using the template on the following page, please use the checklist below to ensure your information sheet conforms with good research practice.

| **Consideration**  | **Response** |
| --- | --- |
| Have you worked with, consulted with, or at least considered the needs of, the research population when designing your information sheets?(*Information should be displayed in an appropriate format for the population involved in the research*) |[ ]
| Have you considered different ways to provide information to your participants? (*For example: explanatory videos, leaflets and visual media, audio recordings, diagrams etc.*) |[ ]
| Do your information sheets have version numbers and dates? |[ ]
| Is the information in your participant information sheet consistent with information in other documentation? (*For example, have you described the data management practices consistently in your information sheet, consent form, and research ethics application?*) |[ ]
| Have you included clear and consistent contact details for: * the research study team?

(*So that participants can ask any questions about the study – these should be work phone numbers and email addresses; you must not include personal contact details*)* the research ethics team, ethics@liverpool.ac.uk and 0151 794 8290?

(*So that participants can raise any complaints or issues that they do not feel comfortable discussing with the research study team*)* The Information Commissioner's Office, 0303 123 1113; or an equivalent body

(*So that participants can raise any concerns about the way their personal data have been processed*)* Any relevant procedures for safeguarding

(*So that participants have contact details if they wish to raise safeguarding issues*) |[ ]

**Please see the below pages for the template for the University of Liverpool participant information sheet**, which consists of sections that 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.

## **University Participant information sheet template**

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 (usually recorded in the document footer) as a way of determining which version of the documentation participants have received should any queries arise.

1. **Invitation Paragraph**

Invite the human participant to take part in the study, and 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 Veterinary Surgeon [if relevant] 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 plain language that can be understood by a non-expert, and with all technical terms and acronyms defined, you should explain why the study is being done - the background, what is already known, aims and objectives etc.

If it is not appropriate to inform human participants of the purpose of the research at this stage - for example in the case where this may affect their behaviour - please ensure that human 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 the human participants or include their animals, Veterinary practices etc. State how many other human participants or animals, Veterinary practices etc. will be taking part.

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

It should be made clear that participation is voluntary and that owners, carers, farmers, Vets and other human participants are free to withdraw 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 human participant / how their animal(s) are to be involved 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, including time for checking processes or taking part in follow up interviews or multiple processes - a flow chart may be helpful, particularly for longitudinal studies;
* what the human 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.

Human 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 animal’s vet may need to be contacted, this should also be made clear in the information sheet and consent form.

IMPORTANT - Research requiring a Home office licence

If a Home Office project licence is required for your study it should be made clear to the owner of the animal(s) that the study will involve the application of procedures to their animal conducted under the Animals (Scientific Procedures) Act 1986.

This is to ensure that animals are not re-used in another procedure without specific authorisation from the Secretary of State [Section 14(3) and 14(4) of the Act], either by the owner, in a further clinical study involving Home Office authorisation, or inadvertently, if the animal(s) is sold on.

The fact that the animal has been used under the Animals (Scientific Procedures) Act 1986 must also be communicated to any subsequent owner and this should be made clear to the current owner in the accompanying owner consent form, and if possible in a debriefing note / session at the end of the study.

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

Please explain any potential disadvantages or risks. Explain that if the human participant should experience any concerns about their own or their animal’s 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 participants or to others. 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 professional recommendation on diagnosis and / or treatment.
2. if you are studying consumer behaviour or spending behaviour, you might include contact details of the Citizens Advice Bureau so that participants may contact them if they want further advice on debt.
3. If your research involves studying smoking or alcohol use, you could offer details of local or national agencies, e.g., Drinkline or Go Smoke Free

In the case of sensitive online studies that are anonymous, if there is a risk of participant distress you should provide a statement ensuring participants that the researchers will not be able to identify them, and you should signpost participants to a list of relevant support services.

If the nature of the study means that individuals outside of the research team may need to be provided with details about the participant’s involvement in the study, this should be stated and included in the consent form.

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; but remember that research can provide benefits in advancing knowledge and understanding.

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

You must inform the human 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/research-support-office/research-ethics/research-ethics-data-management/) for further guidance on the lawful basis for processing). Describe the data you will be collecting - example wording could be: “specifically we will collect information about your ethnicity and occupation”. You should also state who will be transcribing the data, if using audio / video recordings.

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[[1]](#footnote-1)

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 human participants may be eligible for.

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

Detail how the results will be made available to the human 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 the human participants that they will not be identifiable from the results unless they have consented to being so.

If participants are asked to consent to being identifiable through use of their real names or identifiable quotations, then they should be given the opportunity to review their transcripts and redact them, or decline to take part after a defined timescale.

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

Human participants should be informed that they can withdraw their participation or participation of their animal(s), Veterinary practice, etc. in the study at any time, without explanation.

Results up to the period of withdrawal may be used, if the human 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; and it is good practice to provide participant with an estimated time for when the anonymisation will take place.

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, or if you plan to use the data for future studies).

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**. 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 state which bodies have given approval to the research (including any reference numbers for the study) – this should also include any local ethics committees if the research is taking place outside the UK.

1. **Who has reviewed this research?**

You should give the work name, address, and contact telephone number of the **Principal Investigator.** Personal contact details and telephone numbers must not be provided.

**Principal Investigator** **Student Investigator**

[**Name**] [**Name**]

[**Work address**] [**Work address**]

[**Work telephone**] [**Work telephone**]

[**Work email**] [**Work email**]

**Accessibility**: To request this document in an alternative format, please contact the Principal Investigator listed above.

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

*Who is organising and funding the research?*

If the research is externally funded, you should state the organisation or company that is sponsoring or funding the research.

*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 are 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 (best practice is to copy in the participant). 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/health-and-life-sciences/research/liverpool-shared-research-facilities/bio-imaging/liverpool-magnetic-resonance-imaging-centre/).

*Disclosure of criminal activity and duty to disclose*

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 and / or prisoners) **you should inform participants that confidentiality may not always be assured.** Example wording could be as follows: “if during the study, you disclose information about any current or future illegal activities, we have a legal obligation to report this and will therefore need to inform the relevant authorities.”

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**.**

If the nature of the study means that individuals outside of the research team may need to be provided with details about the participant’s involvement in the study, this should be stated and included in the consent form. Examples include:

If, during the study, we have concerns about your safety or the safety of others, we will inform your GP/care team/family member.

If, during the study, you disclose information about misconduct/poor practice, we have a professional obligation to report this and will therefore need to inform your employer/professional body.

Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident.

A court can in exceptional circumstances order researchers to disclose confidential information that they have collected as part of research projects. If a court orders disclosure of information collected from you, confidentiality can no longer be maintained.

*Audio/Visual activities*

For audio/video recordings you must explicitly state 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 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)

Example: Recordings of your voice during the focus group discussion

Example: Pictures that you take of your local community including the residents, buildings and any community events that are taking place.

*Projects involving Human Tissue*

For projects where the researchers are collecting Human Tissue the participant should be informed of: the samples to be collected; how, when and by whom; where samples will be stored and for how long; and whether they are able to ask for the samples to be destroyed at any point.

They should be informed whether there will be DNA analysis; whether you are seeking generic consent, i.e., to retain the samples (including DNA) for use in future, ethically approved, research studies, which may include DNA analysis; how you will dispose of the samples; whether any samples in this study or future studies will be used in other countries such as the U.S.A; whether it will involve commercial organizations or the use of laboratory animals.

## Appendix 2: Other 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://ukdataservice.ac.uk/learning-hub/research-data-management/ethical-issues/consent-for-data-sharing/)

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/)

Utilising different PIS formats may be helpful participants for whom a traditional participant information sheet may be inaccessible. An example would be researchers providing some information on their study via YouTube. The study advertisement can provide a link to the video and this may supplement the paper version of the participant information sheet provided. Video link provided courtesy of Ms Tsai Ping-Chen.

 [https://www.youtube.com/watch?v=hAeNhA8oRAk](https://www.youtube.com/watch?v=hAeNhA8oRAk%20%20)

When presenting an alternative participant information sheet, captions or alt-text and other appropriate accessible alternative should be used for images or graphics. Where video is proposed, a transcript should be provided with the research ethics application. All videos should be subtitled.

## Appendix 3: University of Liverpool example child participant information sheet

“Breakfast, lunch and feeling full”

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.

Information sheet for you!

**What is the study about?**

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

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

**Why have I been chosen?**

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?**

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

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

**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.**

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

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



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

**![C:\Users\eboyland\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\F9AMR3TF\MC900423171[1].wmf]()**

## Appendix 4: Example of a project poster used as a child appropriate participant information sheet used in a University of Liverpool approved study (courtesy of Dr Ataa Alsalloum, School of the Arts).

Utilising different formats for the PIS might be appropriate. Leaflets or posters for children can accompany a parental/guardian PIS. An example of this is shown below used for a workshop involving children:



1. Please note: for the purposes of data protection, the UK is classed as “adequate” and is free to transfer data within the EU with no additional obligations. [↑](#footnote-ref-1)