Participant information sheet template

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This document provides a framework to help you create a participant information sheet specific to your project. You should write it in language that would be easy for a layperson to understand and therefore be able to grant you informed consent should they wish to participate in the study. It is the responsibility of research participants to act in accordance with Edge Hill University Policies.

The text provided here is not intended for the participant but is provided as a guide for you as the researcher.

**Please note:** If you are doing work under the HTA Licence, you must use the participant information sheet and consent form templates in the [Quality manual for governance in the acquisition, use, storage and disposal of human tissue](https://www.edgehill.ac.uk/documents/human-tissue-quality-manual/), informed by HRA/NHS guidance on this topic.

# Study title

*The title of the research project.*

# Principal researcher

*The name and contact details of the person responsible for the research project. If the researcher is a student, also include the supervisor’s details.*

# Invitation

Invite the participant to take part in the research study. Explain that, before they decide whether to take part, it is important that they understand why the research is being done and what it will involve. Advise the participant to take time to read the information that follows carefully and discuss it with others if they wish. Advise them to inform the researcher (the person who gave them the information sheet) if they would like more information or if anything is unclear.

The numbered points below are items that the research team should address when writing the information sheet. Please give sufficient information so that the participant can make an informed decision.

# What is the purpose of the study?

Briefly explain the background and aim of the study; you may briefly cover reasons why the study is important. Make it clear if the study is a student research project, along with details of the level of study being undertaken.

# Why have I been invited?

Explain why and how the participant was chosen or recruited (i.e. their suitability and eligibility for the study) and how many others will be in the study.

# Consent

Explain that they do not have to take part; it is up to the participant to decide after reading the information sheet. Explain how you are seeking consent (e.g. signed, verbal or, where appropriate, assumed). [Consent must be informed, unambiguously and freely given, unconditional, and be a positive indication of agreement](https://www.edgehill.ac.uk/research/governance/?tab=gdpr) – not inferred from silence or inactivity. Your information sheet should make it clear:

* exactly what information is being collected,
* what it will be used for,
* to whom it may be released, and
* whether and in what form the data will be published or otherwise shared (for re-use).

Parental consent is required for children under the age of 16.

You should keep a record of how and when consent was given, should you need to demonstrate this at some point.

While not a substitute for a participant information sheet, you should include a ‘just in time’ notice on your information sheet and consent form that signposts to the University’s Privacy Policy. For example:

*At Edge Hill, we are committed to respecting and protecting your personal information. To find ways in which we use your data, please see* [*edgehill.ac.uk/about/legal/privacy*](https://www.edgehill.ac.uk/about/legal/privacy)*.*

## Data protection legislation & the lawful basis for processing personal data

The General Data Protection Regulation (GDPR) operates in parallel to various other pieces of data protection legislation and updates, and expands people’s rights to see, correct and, normally, delete their *personal* data that is held by an organisation. It therefore places additional legal responsibility on to the researcher.

You will need to understand the [lawful basis](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/) on which you are seeking the participant’s data:

* Academic research is a public good for current and future generations, so **the lawful basis for research data collection is *normally* that of ‘public task’** i.e. the collection of personal data is ‘necessary for the performance of a task (research) carried out for reasons of public interest’.
* The nature of the personal data you will be collecting may require you to cite a lawful basis other than public task. If in doubt, please contact the University’s Data Protection Officer.
* **You do not need to specify the lawful basis on your participant information sheet** – there are limited circumstances in which you would rely on something other than public task – but you will need to be able to explain the reasons for your chosen lawful basis if asked.
* Instead of specifying the lawful basis on your information sheet, the University’s Data Protection Officer suggests reassuring your participants by **including the following text**:
	+ The University is committed to ensuring compliance with current data protection legislation and confirms that all data collected is used fairly, stored safely, and not disclosed to any other person unlawfully. The University is a data controller and, in some instances, may be a data processor of this data.

Special category data brings additional responsibilities. Such data covers race, ethnicity, health, politics, religion, trade union membership, genetics, biometrics, sex life, and sexual orientation. Please contact the University’s Data Protection Officer for advice.

While you need to obtain consent for reasons of research ethics, you should not use this as the lawful basis for the purpose of GDPR. Doing so would pose a significant risk to the future of the research because you would have to be prepared to remove an individual’s data from your dataset at any point, should they ever withdraw consent.

While some research activity may be exempt from some aspects of the legislation, provided it meets certain criteria such as safeguarding and transparency, you will need to demonstrate why this should apply to the processing of your research data.

Furthermore, if your research falls under the NHS Health Research Authority (HRA), [there are additional GDPR requirements for your participant information sheet](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/).

# Can I withdraw consent?

Explain how the participant can withdraw from the study (e.g. it may be wise to use a dedicated form for withdrawal) and what you will do with any data collected from the person upon receiving such a request.

Clarify what the rules are regarding withdrawal from the study, bearing in mind that anonymous data cannot be withdrawn as the participant cannot be identified. In addition, given the nature of focus group data collection, while the participant may retract consent and not participate further, it is unlikely that any data collected up to the point of withdrawal will be able to be deleted.

Because research is conducted in the public interest, participants will not have open-ended rights over their personal data under GDPR, although they retain the right to object. Despite this, you should not hold identifiable data any longer than is necessary for the purpose of your research – you should anonymise or delete personal data as soon as possible where practical.

Separate from GDPR, as an ethical researcher your participants may still have a right to withdraw their participation from the study. As best practice, it is recommended that you specify a period in which people can withdraw their data from one-to-one interviews (normally between 7 and 30 days after the interview): clarity is important.

# Will my participation be confidential?

The answer here should explain exactly how you will protect participants’ data to comply with data protection legislation. You must ensure that any identifiable data (e.g. names, contact details, non-anonymised questionnaires or interview transcripts) are stored safely with limited access and are encrypted/password protected (if they are being transferred electronically, etc.).

You need to explain what the limits of confidentiality are. You have an obligation to act if a disclosure is made that suggests, either directly or indirectly, harm to the participant or to others, or criminal activity or bad practice (especially if you have a professional responsibility) – you will need to explain what this process will entail.

For queries regarding your legal obligations with the storage of data, please contact the University’s Data Protection Officer. Please also refer to the University’s [Research Data Management Policy (RO-GOV-04)](https://www.edgehill.ac.uk/documents/research-data-management-policy/) and [Research Data Management Guidance (RO-GOV-14)](https://www.edgehill.ac.uk/research/files/2018/06/RDM-Guidance-RO-GOV-14.pdf). It is increasingly expected that researchers will share data through open access although this will be done in a way that respects confidentiality and the law.

# What will happen to the results of the research study?

Explain what will happen to the results. Will they be published? In what format (journal, book, etc.)? Will anonymity be preserved in publications? Avoid giving unrealistic guarantees of confidentiality and anonymity, and be aware that in a legal challenge you may be compelled to disclose certain information to the authorities.

Explain the retention period(s) you will apply to the data and how it will change as your process it (e.g. for how long will data be identifiable; how long will anonymous data be held?). If you are intending to keep data indefinitely, you should make that clear and explain why. Your data management plan should help you with this.

# Who has reviewed the study?

Explain that the study has been reviewed by the relevant research ethics committee at Edge Hill University (name the one responsible) and any other review undertaken (e.g. NHS ethics committee if appropriate).

# What will I be asked to do?

Explain what the process will be if they consent to take part: e.g. how many trials, interviews, focus groups or questionnaires, etc. will they have to complete? If a focus group is proposed, explain what it is for those who might not know. How long will the participant’s involvement last?

# What are the possible disadvantages and risks of taking part?

Explain any possible side effects/adverse effects of taking part. This could include physical or psychological effects (if the subject matter is sensitive, embarrassing, or potentially upsetting). How will you respond should any adverse effects occur? What support systems will you have in place should it be a sensitive or upsetting topic, etc.? Are any safety measures on standby? How quickly will the participants be able to access the support (e.g. if you are referring people to a third party agency)?

## Health-related findings

You should inform the participant if participation could result in a finding that has potential health or reproductive importance to the individual. You will need to establish whether you have a duty of care as a researcher to inform the participant when these health-related findings (HRF) are identified and, if so, whether your duty of care overrides a participant’s wishes not to know potentially upsetting information about their own health.

[Edge Hill guidance on HRFs is available](https://www.edgehill.ac.uk/research/files/2018/06/Governance-Guidance-Health-related-findings-RO-GOV-18.pdf) but, if you have any other questions, please consult [this advice from the Medical Research Council](https://mrc.ukri.org/documents/pdf/mrc-wellcome-trust-framework-on-the-feedback-of-health-related-findings-in-researchpdf/) or contact the Biological Safety Officer.

Please remember that your specific discipline or area of study may have additional governance and best practice guidelines, so please consult your local research lead.

# What are the possible benefits of taking part?

It may be unlikely that individual participants will benefit personally from participation, but they may feel better from having the opportunity to share their experiences or helping to potentially improve services. In some cases, you may have resources in place to reward participation e.g. a small financial reward or vouchers. If so, you should provide details but please keep consent in mind (any payment will have to have been explained in your ethics application).

# Is there someone independent I can talk to about the research?

In addition to the researcher’s contact details at the start, it is important to provide the contact details of someone independent of the study should the research participants have any feedback or queries that they do not wish to share with the research team, or should they have concerns or a complaint.

Such independent contacts are generally the departmental director of research, faculty associate dean for research (or equivalent), or the secretary of URESC.

# Support

There should also be aftercare support agencies identified for those research projects that carry risk to the participant. The research team should have made contact with such organisations before recommending them wherever feasible. If the research participants are not UK-based, an alternative, local provider of support services should be identified – you should have written confirmation from the organisations that they are willing to provide such a service.