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UoM Template for Research Participant Information Sheets

This is a template Participant Information Sheet which includes all essential information that you are obliged to provide to participants**.** **Important note:** the information described in this template **should be adapted, where necessary**, where the participant is a child, adult with learning difficulties or a non-English speaker.

We have provided guidance notes in **red** for you to consider, please ensure you replace these with your own text or delete sections if not appropriate to your project (e.g. DBS checks). In all example text provided below you **must change the wording in red** to reflect the details of your specific project. **You should also delete this guidance section**.

Please ensure you also **adjust the footer to the correct version number and date for your project**.

**Title of Research**

**Participant Information Sheet (PIS)**

This PIS should be read in conjunction with [The University privacy notice](http://documents.manchester.ac.uk/display.aspx?DocID=37095)

You are being invited to take part in a research study [as part of a student project – **participants should be told about the overall aim of the research and whether it will be for a degree**]. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask 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 taking the time to read this.

**Who will conduct the research?**

Insert the name of the researcher(s), the School/Academic unit address, University of Manchester and name any other collaborating institutions.

**What is the purpose of the research?**

Provide a brief and simple to understand explanation of what you, the researcher, are hoping to achieve by the research

**Why have I been chosen?**

Provide a statement explaining how and why the participant was chosen and how many other participants will be involved.

**What would I be asked to do if I took part?**

Provide an explanation of what is going to be done by you, the researcher, to the participant and a clear explanation of what the participant is expected to do during the research. Also include an explanation of the risks, if any, that the participant may experience.

**What will happen to my personal information?**

In order to undertake the research project we will need to collect the following personal information/data about you:

List the personal information you will be collecting about the participant in bullet point format.

For audio/video recordings you must state:

* how the recordings/photographs will be obtained (e.g. during a focus group discussion or interview session, asking participants to take images or recordings of their lives, etc)
* what the recordings/photographs will consist of (e.g. voice only, facial features, full body, surrounding environment, other individuals, etc)
* how the recordings/photographs will be used in the research, if they will be used for other purposes or if they will be reused in future for other purposes, other purposes must be compatible with your initial research.

[Only] the research team will have access to this information. If others will have access to this information then you must say who.

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is “public interest task” and “for research purposes” if sensitive information is collected. For more information about the way we process your personal information and comply with data protection law please see our [Privacy Notice for Research Participants](http://documents.manchester.ac.uk/display.aspx?DocID=37095).

The University of Manchester, as Data Controller for this project, [If UoM is not the sole Data Controller this will need to be revised and the other data controller added. An explanation provided in the ethics application] takes responsibility for the protection of the personal information that this study is collecting about you. In order to comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained and your data will be looked after in the following way:

You must tell participants exactly who will have access to their identifiable information, if, and when, you will be anonymising the data, if you will be sharing the data with any other organisation and if you will be retaining the data (or their contact details) for use in future studies. You must adjust the example to match the specifics of your research project. Please note we require identifiable data to be anonymised as soon as the objectives of the project allow. The standard retention period for data once anonymised is 5 years unless funders or regulators have specified longer retention requirements.

**Example:** The **study team** at the University of Manchester will have access to your personal identifiable information, that is data which could identify you, but they will anonymise it **after X amount of time/as soon as practical**. However your **consent form, contact details, etc** will be retained for **X** years **(describe where and how)**.

In this section you must inform participants where their data will be held (including how it will be transferred to the University from the site it was obtained), if you are using third party software like an app, for how long it will be stored, whether it will be transferred outside of the University and how, including the involvement of transcription services. It must be noted if the data are to be transferred outside the EU (or to any cloud services) and what will happen to the data at the end of the study.

You must include the following information regarding participant’s rights.

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings or photographs. This is known as a Subject Access Request. If you would like to know more about your different rights, please consult our [privacy notice for research](http://documents.manchester.ac.uk/display.aspx?DocID=37095) and if you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL. at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner’s Office](https://ico.org.uk/concerns), Tel 0303 123 1113

**Will my participation in the study be confidential?**

Your participation in the study will be kept confidential to the study team and those with access to your personal information as listed above.

For audio/video recordings or photographs you must state the following:

* if the recordings will be used to create transcripts, who will be performing the transcribing (including if they are a member of the research team, another UoM employee or a third party who is a UoM approved supplier. If they are another UoM employee, ensure they are reminded of the guidelines regarding confidentiality and ask them to sign a copy of the Confidentiality Agreement). <<link to be inserted for Confidentiality Agreement>>
* whether the personal information will be removed in the final transcript
* how the audio/video/photographs will be protected and kept secure
* how long they will be kept in accordance with the UoM retention schedule if different to the retention for the personal information listed above
* when and how the recordings/photographs will be destroyed or digitally altered to remove personal information (Pixellation / voice masking software)
* who will have access to the recordings/photographs (if different to the rest of the personal information)
* **REMINDER**: you are **not permitted** to use personal devices (e.g. iPhones, iPads, tablets, other personal, portable devices) to capture audio/video recordings or photographs. Any devices used must be encrypted by UoM and be exclusively for research use.

If there are circumstances where you need to inform/disclose information to individuals outside of the research team this should be made clear and **ethical consent** sought.

You need to consider who will need to be informed of their participation or need to review their information as part of the routine management of the study. For example:

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.

There may be other circumstances that mean that you need to inform participants the circumstances which may lead to disclosure and to whom it would be disclosed, for example:

in the event that there are concerns about the participant’s safety or the safety of others you may need to contact their GP/care team/family member

where there is a professional obligation to report misconduct/poor practice you may need to inform their employer/professional body

reporting of current/future illegal activities to the authorities

There should be a description of the steps taken to ensure confidentiality e.g. de-identifying the data and linking to the individual via an assigned participant ID only known to research team (also referred to pseudonymised or coded data). Ensuring the reporting of the data is done in such a way that individuals cannot be readily identified.

**What happens if I do not want to take part or if I change my mind?**

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. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised and forms part of the dataset as we will not be able to identify your specific data. This does not affect your data protection rights.

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.

**Will my data be used for future research?**

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation. The future research should not be incompatible with this research project and will concern <<insert research field>>. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)**.**

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you regarding any other matter or to affect your care. It will not be used to make decisions about future services available to you.

Reminder: If you are intending to add their contact details to a database for newsletters or about other research etc., you must provide a mechanism for them to opt out of this in each communication. Also consider how long you will keep contacting participants to take part in other research, if they have not responded. Document when you have told the participant that they will be on the database and the purpose, what they are expecting to receive.

Reminder: Social group: tell them the use of the group and you should not contact them directly (DM or tagging), writing on the “wall” / newsfeed is fine). Ensure that the messages are in line with original purpose and not about other research if they have not been informed of this.

**Will I be paid for participating in the research?**

Provide a clear statement of payment arrangements for compensation for the participant’s time and inconvenience and any out-of-pocket expenses, course credits, if applicable.

**What is the duration of the research?**

Provide details on the duration of the study (e.g. 3x ½ hour interviews; 1x 30 minute questionnaire etc) including how long in total the participant will be involved in the study (from consent to final visit). Remember to also include time for checking processes or taking part in follow up interviews or multiple processes.

**Where will the research be conducted?**

Provide details of the location and venue.

**Will the outcomes of the research be published?**

Provide details of anticipated outcomes and if participants will be informed of the findings or if they will be published.

**Disclosure and Barring Service (DBS) Check (if applicable)**

Provide a statement declaring that the researcher who may have access to children or vulnerable adults has undergone a satisfactory DBS check. If this paragraph is not relevant to your research delete it.

**Who has reviewed the research project?**

Indicate that the project has been reviewed by the University of Manchester Research Ethics Committee 1/2/3/4/5/University of Manchester Proportionate Research Ethics Committee or the name of the Division/School Ethics Committee.

**What if I want to make a complaint?**

You must include a way for the participants to contact someone if they have any complaints. The first point of contact should be yourself or **your supervisor if you are a student**, and the PI and then the University using the paragraphs below:

**Minor complaints**

If you have a minor complaint then you need to contact the researcher(s) in the first instance.  **PROVIDE CONTACT DETAILS IN LARGE BOLD PRINT contact details must include email and telephone numbers these contact points should be professional or project specific email and phone numbers not personal ones. Please ensure they are live and that phone numbers have voicemail that is regularly checked.**

**Formal Complaints**

**If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact**

TheResearch Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk  or by telephoning 0161 275 2674.

**What Do I Do Now?**

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s) **PROVIDE CONTACT DETAILS IN LARGE BOLD PRINT contact details must include email and telephone numbers these contact points should be professional or project specific email and phone numbers not personal ones. Please ensure they are live and that phone numbers have voicemail that is regularly checked.**

**This Project Has Been Approved by the University of Manchester’s Research Ethics Committee [ERM reference number]**