*[All text that is* ***dark blue, bold, italicised and in square brackets*** *is guidance and should be deleted from your final draft. Text in black (without highlights) should not be deleted or modified.*

***It is recognised that research projects are diverse and some of the guidance presented here may not apply to you; if in doubt, seek advice from supervisors, principal investigators, or ethics advisors. Avoid the use of acronyms and specialised language or scientific jargon. Text must be accessible and suitable for the reading comprehension level of your target audience. Please consult*** [*the Plain English Website*](https://www.plainenglish.co.uk/) ***for further information.***

***When the participants are children or adults who lack the capacity to consent, two PIS forms should be created: one for the participant and one for the guardian that consents in their name. Children’s PIS forms should match the comprehension level of their age group. When several age groups are targeted, a separate PIS should be made for each age group.]***

Participant Information Sheet

# [Research Project Title\*]

***[\*title must match exactly across all your documents and ethics application]***

## Invitation to research

***[Describe who you are and what you are doing. You MUST clearly indicate all the organisations and individuals who are organising and funding the research.]***

## Why have I been invited?

***[Explain why and how the participant was chosen and how many others will be in the study.]***

## Do I have to take part?

***[Explain that participation is voluntary. If this is not the case, provide a full explanation.]***

## What will I be asked to do?

***[Provide full details of everything that you are asking a participant to do for your project.]***

## Are there any risks if I participate?

***[You MUST disclose any potential risks to the participant and how likely these are to occur.]***

## Are there any advantages if I participate?

***[Provide details describing any rewards or recompense for taking part in the project.]***

## Informed consent

***[Explain the details of the consent process. If you intend to use recordings/photographs as part of a publication, in broadcast, or upload them to an archive, it is MANDATORY that you: explain this clearly in the PIS, AND include this on the Consent Form, AND sign a separate release form for each type of item that you are collecting and intend to use.]***

**What will happen with the samples I give?\***

***\*[This section is for research involving human tissue - delete if not applicable]***

***You should outline what you intend to do with any samples they give, including any tests which may be undertaken (use language easily understood by potential participants)***

***You should give potential participants more information on your medium to long-term plans for any samples remaining after your specific piece of research has ended. This should include consideration of the following:***

***Will participants' samples be destroyed at the end of this study, or do you intend to keep them for future use?***

***How will you ensure confidentiality is maintained during medium to long-term storage?***

***Do you intend to share samples with others, including transferring samples elsewhere, maybe even outside the UK?***

***Could this future use include genetic testing, the use of animals, commercial involvement?***

***How will you manage access to samples in the future? Will all future use require additional ethical approval?***

***Is it possible that you might share anonymous information with others? Potential participants should be informed of the importance of data sharing; to ensure your research is open to peer scrutiny, to optimise the use of good quality research data and to support policy and other decision-making.***

***Could any future use produce health related findings that might be significant to individual participants? If so, how will this be handled, what should potential participants expect?***

***Are you making any specific provision for destruction of any remaining samples?***

***There are a number of options to consider when asking potential participants for consent to collect samples. These include obtaining:***

***Generic consentˣ – is non-specific consent, where potential participants are informed of the possible breadth of potential uses any donated samples might be put to in the future. This might include some studies that are already planned, but also some future research that cannot yet be described in detail.***

***Suggested text for retaining samples for future use: We would also like to seek your consent so that any remaining samples may be stored and used in possible future research – this is optional (please indicate you agree to this on the consent form). The samples will be stored with a code unique to you and securely at the Manchester Metropolitan University under the University’s Human Tissue Research Licence (no 12402)***

***Some of these future studies may be carried out by researchers other than the current team, who ran the first study, which may include researchers working for commercial companies. Any samples or data used will be anonymised, and you will not be identified in anyway. If you do not agree to this any remaining samples will be disposed of in accordance with the Human Tissue Authority’s codes of practice.***

***Tiered consentˣ – is where you describe a number of discrete research activities that the donated tissue could be used for, and enable potential donors to agree to some but not necessarily all. Some of these elements may be well defined, whilst others could be relatively undefined as yet. You should only offer tiered consent if you are confident that you can deliver all aspects of consent in any combination the donor specifies.***

***Specific consentˣ – is when donors are asked only to give consent to specific use(s) of their samples, and when no future, as yet unspecified research is likely. You should think about offering this option only if you are sure that you have no intention of any further storage or use of the donated samples.***

***ˣ [The consent form will need amending accordingly]***

## What information about me will you collect and why?

***[Explain what information (data) you will be collecting, including when/ how you will collect the data. Explain why the data is required for the study]***

## How will my information be stored and how will you look after it?

***[Explain if the data that is collected will be anonymised/ pseudonymised/ identifiable, and what this means. Explain where the data will be kept and what will happen to recordings, bio-samples or any participant-made artefacts.]***

## How will you use my information?

***[Explain how you intend to process the data. Inform participants if they will be anonymous or identifiable in any publications or other outputs.]***

## Will my data be sent anywhere else, or shared with other people or organisations?

***[Explain whether the data will be shared or not, and if it will leave the country (contact dataprotection@mmu.ac.uk if you plan on exporting personal data from the UK to any country outside of the European Union). If the data is going to be shared, then you should explain if it will be anonymous/ pseudonymised/ identifiable. Inform the participant if you intend to use third party processors (translators, transcribers, app processing, cloud storage, etc.) and how you will ensure their services are secure.]***

## When will you destroy my information?

***[Provide details of how long you intend to retain both personal and non-personal data.]***

## Data Protection Law

***[You must provide the information set out in this section by law. If you wish to alter or adapt the text to better suit a specific audience, please contact dataprotection@mmu.ac.uk with your proposed revisions.***

***You can use either the full or the simplified version of the information set out below, according to your target audience. For adults, the full version is usually appropriate. The simplified version is usually appropriate for children or adults with restricted understanding. Retain either the full or simplified version and delete the other.]***

***[Full version:]***

Data protection legislation requires that we state the ‘legal basis’ for processing information about you. In the case of research, this is ‘a task in the public interest.’ If we use more sensitive information about you, such as information about your health, religion, or ethnicity (called ‘special category’ information), our basis lies in research in the public interest. Manchester Metropolitan is the Controller for this information and is responsible for looking after your data and using it in line with the requirements of the data protection legislation applicable in the UK.

***[DELETE IF NOT APPROPRIATE: This project also includes the use of filming and/or photography. Please refer to the additional consent form for further information about this aspect of the project, including our lawful basis for using your data in this way.]***

You have the right to make choices about your information under the data protection legislation, such as the right of access and the right to object, although in some circumstances these rights are not absolute. If you have any questions, or would like to exercise these rights, please contact the researcher or the University Data Protection Officer using the details below.

You can stop being a part of the study at any time, without giving a reason. You can ask us to delete your data at any time, but it might not always be possible. If you ask us to delete information ***[before/within] [SPECIFIC DATE/TIME LIMIT],*** we will make sure this is done. If you ask us to delete data after this point, we might not be able to. If your data is anonymised, we will not be able to withdraw it, because we will not know which data is yours.

***[Simplified version:]***

The way we look after your information is ruled by UK law. Under UK law, we need to have a very good reason for using your information (this is called a ‘lawful basis’). Sometimes, we might also want to use sensitive information about you, like information about your health, religion and ethnic background. This is called ‘special category information’. We collect all this information from you to help with our research, which aims to benefit everyone (this means that it is in the ‘public interest’).

***[DELETE IF NOT APPROPRIATE: We would also like to film you or take photographs for this project. It is up to you if you would like us to do this. You will be given a separate consent form for this aspect of the project.]***

You have the right to make choices about your information under UK law. If you have any questions or would like to ask us to do something with your information, you can ask the researcher or a parent or guardian, or someone else at the University. Contact details are shown towards the bottom of this document.

You can stop being a part of the study at any time, without giving a reason. You can ask us to delete your data at any time, but it might not always be possible. If you ask us to delete information ***[before/within] [SPECIFIC DATE/TIME LIMIT],*** we will make sure this is done. If you ask us to delete data after this point, we might not be able to. If your data is anonymised (where we take out your name and any other information that lets us know the information is about you), we will not be able to delete it, because we will not know which data is yours.

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

***[Explain how you will disseminate and / or publish the results of the study. Provide details if you intend to acknowledge their contribution in an open access publication or output.]***

## Who has reviewed this research project?

***[Provide details of the institution/body/committee that is responsible for reviewing and approving the research.]***

## Who do I contact if I have concerns about this study or I wish to complain?

***[Five contacts are usually provided, as follows:***

***Provide name, role in the project, email, and work telephone number (if available. do not use personal numbers) for the researcher and the researcher’s supervisor/line manager.***

***Contact details for the Committee that approved the project (role, email and phone number; name optional). For projects approved by Manchester Metropolitan University this will usually be the contact details for the relevant Faculty Head of Research Ethics and Governance.]***

**Manchester Metropolitan Data Protection Officer** dataprotection@mmu.ac.uk

Tel: 0161 247 3331Legal Services, All Saints Building, Manchester Metropolitan University, Manchester, M15 6BH

**UK Information Commissioner’s Office**

You have the right to complain directly to the Information Commissioner’s Office if you would like to complain about how we process your personal data:

<https://ico.org.uk/global/contact-us/>

**THANK YOU FOR CONSIDERING PARTICIPATING IN THIS PROJECT**