

Participant Information Sheet

**Guidance note: All guidance information (in blue) should be deleted after reading. The final text should be in black font.**

**Study title**

[Insert title]

The title should explain the study in plain English. You should ensure that your study title is the same on all participant documents (i.e. advertisement; Participant Information Sheet; Consent Form) and includes the type of study. The title on participant-facing documents such as this and the Consent Form, may be a lay version of the scientific title given on the application form and not necessarily the full title, but both titles should be given in the research ethics application form.

**Version number and date**

[Insert version number and date into the header, for example Version 1.0: 01.12.2020].

The versions of the supporting documents to your original application should be labelled ‘Version 0.1’ (or anything up to ‘Version 0.9’). Version 1.0 will be the final QMERC-approved version.

**Researcher’s name**

[Insert name; and that of educational supervisor if a student project]

**Queen Mary Ethics of Research Committee reference number:**

[Insert reference number allocated to your study by the Research Ethics Facilitators]

**Invitation paragraph**

Clarify that you are inviting potential participants to consider taking part in your research and that participation is entirely voluntary. Refusal to participate requires no reason and will not affect the individual or their rights.

For example,

*You are being invited to participate in a research study. Before you decide whether or not you wish to participate in this study, 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 discuss it with others if you wish. Ask us questions if there is anything that is not clear or if you would like more information.*

**What is the purpose of the study and what would taking part involve?**

Provide a brief but complete description of the purpose of the study and what participants should expect to happen if they decide to participate in your research. Your description should be written at a level of language that someone without prior knowledge of your study could understand. Consider your sampled population; with the default target reading age being 12-14 years.

You may find some of the following resources useful when considering accessibility and readability of participant documents:

* [Microsoft 365 - Get your document's readability and level statistics](https://support.microsoft.com/en-gb/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2?ui=en-us&rs=en-gb&ad=gb).
* [Microsoft 365 - Make your Word documents accessible to people with disabilities](https://support.microsoft.com/en-gb/office/make-your-word-documents-accessible-to-people-with-disabilities-d9bf3683-87ac-47ea-b91a-78dcacb3c66d?ui=en-us&rs=en-gb&ad=gb)
* [Hemingway App](http://www.hemingwayapp.com/)
* [Readability Formulas](https://www.readabilityformulas.com/free-readability-formula-tests.php)
* [QMUL Disability and Dyslexia Service & Institute of Dentistry - Assessing inclusively Guidelines for inclusive writing and formatting of print and digital assessments](http://www.dds.qmul.ac.uk/media/disability-and-dyslexia-service-/documents/Guidelines-for-inclusive-writing-and-formatting-of-written-assessments-v9-07-11-2019.pdf)

Information to include here:

* Length of the participant’s involvement in the research
* How often they will need to meet the researcher, in-person or otherwise, and how long each research session will last
* Are there any plans for follow up?
* What types of information will you be collecting?
* What methods will you be using to collect data?

Where it is not appropriate to fully inform participants of the research purpose at this stage, you should ensure that participants are fully debriefed at the end of the research. A debriefing form should be included to your research ethics application form.

The potential impact of research success should be cautiously stated, with care taken not to use language or content that is overly persuasive.

**Why am I being invited?**

Describe why the individual has been identified as an eligible potential participant and invited to take part.

For example,

*You are being invited to participate in this research study because [insert main inclusion criteria here].*

and

*You should not take part in this study if you [insert main exclusion criteria here].*

**Do I have to take part?**

Potential participants should be informed that it is up to them to decide whether or not to take part in your research. It should be made clear to them that if they do decide to take part, they are still free to withdraw at any time without giving a reason. Refusal to participate requires no reason and will not affect the individual or their rights.

For example,

*This participant information sheet has been written to help you decide if you would like to take part. It is up to you whether you wish to take part. If you do decide to take part you will be free to withdraw at any time without needing to provide a reason, and with no penalties or detrimental effects.*

**What are the possible benefits of taking part?**

You should state any potential benefits that may be gained by the research participant through taking part in the research, either now or in the future.

Research outcomes can benefit the individual participant directly (for example, by having access to new interventions or treatments that are not currently available or by providing a voice for vulnerable groups of participants). Research can also benefit the community in which the individual resides and the society as a result of finding an answer to the research.

Once again, the potential impact of benefits to the individual or other parties should be cautiously stated, with care taken not to use language or content that is overly persuasive.

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

However unlikely the possibility, it is important to disclose potential disadvantages and risks of taking part in the research for potential participants to consider. These might include physical harm; risks to confidentiality; risks to anonymity; psychological risk etc. Where potential disadvantages are identified you should also describe the procedures in place to minimise or mitigate risks, and provide referral to relevant support services for those in distress.

**Expenses and payments**

Detail any expenses that might be incurred by the participants (for example travel, refreshments etc.) and any reimbursement the participants may be eligible for and a simple process for how these can be accessed.

**What information about me will you be collecting?**

Describe what personal data you will be collecting. Take guidance from the research ethics application form about what details to include.

**How will my data be stored and who will have access to it?**

Describe the measures to protect security and confidentiality of data. Provide a lay summary description of the anonymisation and data management plans as described in section 12 (Anonymity and Confidentiality) and section 13 (Data management plan) of your research ethics application form.

Please refer to relevant University data policies when writing this section:

* [Data Protection Policy](http://www.arcs.qmul.ac.uk/media/arcs/policyzone/Data-Protection-Policy-v03.0.pdf)
* [Information/Data Governance Policy – DG14 – Storage of information](https://www.its.qmul.ac.uk/media/its/documents/governance/sops/SOP-DG14-Storage-of-Information-Policy---V2.0.pdf)

Example text;

* *Your data will be stored in fully anonymised format in [insert location], and only [insert individual] will be able to access it.*

or

* *Your data will be stored in de-identified format. Your name and other identifiers will be replaced by a unique code. To reduce the risk of disclosure, personal identifiers will be stored separately from the research data in [insert location] and will only be accessible to [insert individual]. There will be a key document which will link your unique code to your real identity. This will be kept in [insert location] and only [insert individual] will be able to access this and link your data to you.*

or

* *Your data will be stored in identifiable format in [insert location], and only [insert individual] will be able to access it.*

**When and how will my data be destroyed?**

Provide a lay language summary of your retention and data destruction plans which are described in section 13 (Data management plan) of your research ethics application form.

Please refer to key University data policies and guidelines for writing this section:

* [Queen Mary Records Retention Schedule](http://www.arcs.qmul.ac.uk/governance/information-governance/records-management/records-retention-schedule/)
* [Information/Data Governance Policy – DG16 – Disposal of information](https://www.its.qmul.ac.uk/media/its/documents/governance/sops/SOP-DG16-Disposal-of-Information-Policy--V2.0doc.pdf)

**How will my data be used and shared?**

Explain how participants’ data will be used and published (i.e. dissertation report/ thesis/ peer reviewed journals/ conferences) and in what format (anonymised/ pseudonymised/ identifiable). Also clarify if data will be stored in a database accessible by others (open access).

Provide a lay summary of what is described in section 13 (Data management plan) of your research ethics application form.

Please refer to key University data policies for writing this section:

* [Research Data Access and Management Policy](http://www.arcs.qmul.ac.uk/media/arcs/policyzone/Research_Data_Management_policy_for_publication_Dec13.pdf#:~:text=Queen%20Mary%20University%20of%20London%20%28QMUL%29%20is%20committed,requirements%2C%20and%20following%20QMUL%20policies%2C%20guidelines%20and%20standards.)

**Under what legal basis are you collecting this information?**

Do not amend or delete the following text as this is required to comply with Queen Mary’s legal obligations.

Queen Mary University of London processes personal data for research purposes in accordance with the lawful basis of ‘public task’.

Please read [Queen Mary’s privacy notice for research participants](http://www.arcs.qmul.ac.uk/media/arcs/policyzone/Privacy-Notice-for-Research-Participants.pdf) containing important information about your personal data and your rights in this respect. If you have any questions relating to data protection, please contact Queen Mary’s Data Protection Officer, Queens’ Building, Mile End Road, London, E1 4NS or [data-protection@qmul.ac.uk](mailto:data-protection@qmul.ac.uk) or 020 7882 7596.

**What will happen if I want to withdraw from this study?**

Participants should be informed that they can withdraw their participation in the study at any time without providing a reason.

Explain what will happen to the data in the event that a participant wishes to stop taking part in the study. Clarify if you will retain and analyse already-collected data relating to the participant up to the time of participant withdrawal or if you will confidentially destroy the participant’s data. Be realistic about stages at which complete, or only partial withdrawal of information is possible.

For example, participants can ask for access to the information they provide and can request the destruction of that information if they wish at any time prior to [specified point: i.e. anonymisation/submission of dissertation/a time frame, i.e. - 1 month] following which they will not be able to request access to or withdrawal of the information they have provided.

**What should I do if I have any concerns about this study?**

You must include a way for the participants to contact someone if they have any complaints. Do not amend or delete the following text.

If you have any concerns about the manner in which the study was conducted, in the first instance, please contact the researcher(s) responsible for the study [Principal Investigator or Supervisor if you are a student]. If you have a complaint which you feel you cannot discuss with the researchers then you should contact the Research Ethics Facilitators by e-mail: [research-ethics@qmul.ac.uk](mailto:research-ethics@qmul.ac.uk). When contacting the Research Ethics Facilitators, please provide details of the study title, description of the study and QMERC reference number (where possible), the researcher(s) involved, and details of the complaint you wish to make.

**Who can I contact if I have any questions about this study?**

[insert Investigator’s name]

[insert Investigator’s Queen Mary email address]

[insert Investigator’s Queen Mary telephone number]