

Participant Information Sheet

This version has been approved by the Queen Mary Disability & Dyslexia Service

**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 simple English**.
* You should ensure that **your study title is the same on all participant documents** i.e.:
  + advertisement.
  + Participant Information Sheet.
  + Consent Form.
* The title should **include 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.
* **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]

QME24.XXXX If the Project ID is 0001 then the reference number will be QME24.0001

**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 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](file:///C:\Users\Mantalena\Desktop\Website%20review\Dyslexia%20versions\o%09http:\www.dds.qmul.ac.uk\media\disability-and-dyslexia-service-\documents\Guidelines-for-inclusive-writing-and-formatting-of-documents-and-presentations-v7-12-12-2019.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 during the data collection phase without giving a reason**. Make sure to **include a final withdrawal date or timeframe** after which participants can no longer withdraw (e.g. within a month of data collection, or 1st January 2024)
* Refusal to participate **requires no reason** and will not affect the individual or their rights.
* For studies involving questionnaires/ surveys/ interviews, it is expected that the participant **can choose not to answer** any individual question(s) and move on to the next with impunity, without question and without explanation. If **the researcher believes that forced answers are necessary**, this will need to be **justified** to the Ethics Committee via application (with a clear indication of how any potential harms would be mitigated) and to the participant in the PIS.

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 during your participation** 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 e.g.:
  + 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.).
  + Any **reimbursement** the participants may be eligible for.
  + 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 your research ethics application form:
  + Section 12 (Anonymity and Confidentiality)
  + Section 13 (Data management plan)
* 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)

For examples,

* 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 such as a time frame or specific date, i.e. - 1 month, or 1 January 2024] 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 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 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]