

**Queen Mary Ethics of Research Committee**

Joint Research Management Office (JRMO)

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Research Ethics Facilitators

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**RESEARCH ETHICS APPLICATION FORM**

This version has been approved by the Queen Mary Disability & Dyslexia Service (DDS) & Institute of Dentistry

Guidance notes

Research ethics is a **fundamental part of research design and conduct**. Research ethics principles **underpin every aspect** of a research study, from design to dissemination of findings and beyond, such as storage and use of data for future research. Addressing ethical issues **requires researchers to reflect upon** the design, recruitment method, eligibility criteria, consent process, and the study information they provide to participants. Keeping ethical issues at the forefront leads to a high-quality application, which is a key component of the Queen Mary Ethics of Research Committee (QMERC) review and approval process and, ultimately, **optimises the effectiveness** of the research design.

**What should be included in this application form?**

Members of the Queen Mary Ethics of Research Committee and Research Ethics Facilitators:

* **Identify and minimise the risks** of a research study.
* Evaluate the **recruitment process** of research participants.
* **Prevent discrimination** against participants on the basis of factors such as race, gender, etc.
* Assess the process for **seeking participants’ informed consent**.
* Ensure that a study is **responsible and honest**.
* Protect participants’ **privacy and confidentiality**.
* Recognise **any interests that may inappropriately affect** a study.

To support this essential work, the Research Ethics team request that you ensure the research ethics application form and any supporting documents are **complete and correct**, and that efforts have been made to **identify and mitigate any risks** that may arise in planning and conducting your study.

* **Participant Information Sheets** and **Consent Forms** must be submitted along with the application form.
* Where there are **different participant groups**, separate Participant Information Sheets and Consent Forms must be supplied.
* Any **relevant research tools** (e.g. surveys, interview schedule, etc) **should be attached** to the application form.
* If appropriate, a **health and safety risk assessment** for the study should be enclosed.
* **Advertising materials** such as posters, email texts and social media recruitment material should be included.

Applications with **incomplete sections** or submitted **without the requisite supporting documents** will be returned to applicants for modifications before being processed for further review.

**Who should complete this** **application form?**

This application form is intended for all Queen Mary University of London staff, students and visiting, honorary or emeritus researchers who are planning research studies involving human participants, personal data or the collection of human tissue as per the [University’s Policy on Research with Human Participants.](http://www.arcs.qmul.ac.uk/media/arcs/policyzone/QMUL-Research-with-Human-Participants-Dec-14-final.pdf) This includes pilot studies and international studies.

For **student studies**, it is expected that the **academic supervisor(s) will discuss** the application with their students prior to submission, and that they will be fully familiar with the ethical considerations arising from the research methodologies proposed.

For all studies, it is expected there is **evidence of departmental oversight** (ideally peer review) prior to submission and that this continues after approval until completion.

**Exemptions to QMERC review requirement**

A few investigative activities involving human participants would not require Queen Mary Ethics of Research Committee review and approval:

**Secondary data analysis (unless the following apply):**the data is personal or sensitive and confidential in nature; or if data or confidential information is linked or shared beyond the initial consent (for example, if the research topic or data gathering or re-use involves a risk of information disclosure that would require the researchers to breach confidentiality conditions agreed with participants). Information freely available in the public domain (i.e. published biographies), whilst still personal data, would not require ethics review.

**Service evaluation (where the following apply):** the ‘service provider’ or someone acting on their behalf aims primarily to monitor or improve a service being delivered by collecting information from a ‘service user’; the conclusions are primarily applicable to the ‘service provider’; the conclusions are only internally published (i.e. a module coordinator seeking feedback on a module from their students. This exemption does not apply if your study explores a sensitive topic which involves vulnerable groups of participants, and if your study creates generalisable new knowledge and you intend to publish its outcomes externally (peer reviewed journals; conferences etc.).

**Audit** work which aims to find out whether the quality of a service meets a defined standard.

**If there is a legal requirement for NHS REC review.** For example, studies involving NHS patients or intrusive procedures with adults who lack the capacity to consent for themselves fall outside the remit of QMERC.   For confirmation of whether or not your study requires an application to an NHS REC, you are advised to use the decision tool ‘[Do I need NHS REC review’](http://www.hra-decisiontools.org.uk/ethics/) on the Health Research Authority website.

**What guidance is available to support with completing this form?**

The **Notes to Applicants** provide question-specific guidance within the form below.

Applicants are advised to **explore the Joint Research Management Office website** which provides links to the Queen Mary Ethics of Research Committee (QMERC), the University’s research ethics policy, guidance notes, and Participant Information Sheet and Consent Form templates to support your application.

For additional support please contact the Research Ethics Facilitators by e-mail: [research-ethics@qmul.ac.uk](mailto:research-ethics@qmul.ac.uk)

**How should the form be submitted?**

The **completed application form** and any supporting documents should be **returned to the Research Ethics Facilitators** ([research-ethics@qmul.ac.uk](mailto:research-ethics@qmul.ac.uk)).

In the **subject title of your email** please indicate the **type of approval sought** (low risk review or panel review – more information in Section 17), **followed by investigator name** and **date of submission** (date of original email sent): for example,‘Application form for low risk review; Dr A. Person; 01 December 2020’.

* Examples of research that may involve **more than minimal risk** and require panel review can be found [here](https://esrc.ukri.org/funding/guidance-for-applicants/research-ethics/research-that-may-require-full-ethics-review/).
* Most research that does not fall into one of these examples of research is assumed to be low risk.
* The low risk review is appropriate for research in which the probability of possible harms by participation in the research is not significantly higher than those encountered in other aspects of the participants’ everyday life.
* Some examples of research that may qualify for low risk review include studies which can demonstrably evidence that participants are at no additional risk of harm, stigma or prosecution or studies which will not induce undue psychological stress or anxiety to the participants.

**When should a research ethics application be submitted and how long does it take?**

The ethics review is a potentially **time-consuming process** which should be fully engaged with and **not left to the last minute**. A high-quality research ethics application requires **time and careful planning**. Researchers are strongly advised to allow sufficient time to develop a well-designed ethics application that addresses all relevant ethical issues. It is recommended that you **allow at least 6-8 weeks during term time for the ethics review process** at Panel meetings to be completed and **3-4 working weeks for the low risk review** process. These timeframes apply to ‘review ready’ applications, namely applications that have been submitted to a high-quality standard and are well-documented and well-completed.

**Research must not start until QMERC ethical approval letter is received.**

**Failure to comply with this requirement may result in a research misconduct investigation.**

**Section 1 – Basic study details**

**1a. Full study title**

Click or tap here to enter text.

**1b. Participant documents study title**

**Note to applicant:** Provide an alternative study title that will appear in your participant documents (i.e. participant information sheet; consent form; research tools; advertising material etc) if the official full study title would be difficult for participants to understand. The title should be written in plain language so that it is easily understood to a lay person.

Click or tap here to enter text.

**1c. Study type**

This is a:

Queen Mary University of London staff research study

**Note to applicant:** Queen Mary University of London staff includes visiting, honorary or emeritus researchers who conduct research under the auspices of the University.

Queen Mary University of London Postgraduate Research student study (for example, PhD)

Queen Mary University of London Taught Postgraduate student study (for example, MA, MRes, MSc, LLM)

Queen Mary University of London Undergraduate student study

Queen Mary University of London group of sufficiently similar low-risk studies

**Note to applicant:** For example, Supervisors and Module leaders should select this option if they are applying for approval to a group of sufficiently similar low-risk student research projects e.g. for successive cohorts of UG/PGT students. See more information [here](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/applications-and-approval/#d.en.849154).

**1d. Details of the Queen Mary Principal Investigator (or Supervisor for student studies)**

**Note to applicant:** Named Principal Investigators and Supervisors must hold an employment contract with

Queen Mary University of London.

**Note to applicant:** Duplicate box for multiple supervisors

|  |
| --- |
| Title and full name:  School or Institute:  Email:  Telephone: |

**1e. Details of the Queen Mary Student Investigator(s) *(if applicable)***

|  |
| --- |
| Title and full name:  School or Institute:  Email:  Telephone:  Programme of study:  Module and course: |

**1f. If this is a student study, please describe what supervisory arrangements are in place for monitoring the conduct of the research.**

**Note to applicant:** For example, has a meeting schedule been arranged to monitor progress and review of the student research work Has the supervisor provided appropriate research ethics advice and guidance? Has the supervisor assisted the student in identifying training needs and relevant [QMUL](https://www.esdcourses.org.uk/userlistcourse.php) or external training opportunities? Has the supervisor reviewed the student’s ethics application to ensure it is of appropriate quality and completeness before permitting the student to apply for Queen Mary Ethics of Research Committee review? Has the student been advised on Queen Mary policies on [research ethics](http://www.arcs.qmul.ac.uk/media/arcs/policyzone/QMUL-Research-with-Human-Participants-Dec-14-final.pdf) and [integrity](http://www.arcs.qmul.ac.uk/media/arcs/policyzone/QMUL-Research-Integrity-policy-Dec14-final.pdf), a [Disclosure and Barring Check (DBS)](https://www.qmul.ac.uk/prospective/termsandconditions/criminalconvictions/dbs/) or carrying out a [risk assessment](http://www.hsd.qmul.ac.uk/risk-assessment/) before the research work is undertaken? Note supervisors will be expected to ethics meetings with students.

Click or tap here to enter text.

**1g. Details of other Queen Mary Co-Investigator(s) *(if applicable)***

**Note to applicant:** Duplicate box for multiple co-investigators

|  |
| --- |
| Title and full name:  School or Institute:  Email:  Telephone: |

**1h. Details of other external collaborator(s) who will be contributing to the study *(if applicable)***

**Note to applicant:** Duplicate box for multiple collaborators

|  |
| --- |
| Title and full name:  Position held:  Organisation, postal address and website if available:  Email:  Telephone:  Role in study: |

**1i. Estimated study start date**

Click or tap here to enter text.

**1j. Estimated study end date**

Click or tap here to enter text.

**Note to applicant:** Before providing the estimated study dates, please ensure that the research has been adequately planned so it will be completed in a timely manner and in line with funding milestones. Include milestones and planning with regard to recruitment and testing phase. Please note that the Queen Mary ethics approval is valid for 3 years.

**1k. Provide details of the funding of the research, including funding organisation(s), amount secured (or pending approval), duration, and Queen Mary University of London reference code *(if applicable)***

Click or tap here to enter text.

**Section 2: Review routes**

**2a. Does your study involve any of the following? (please select all that apply)**

Human participants

Human tissue

**Note to applicant:** Queen Mary Ethics of Research Committee will only review the proposal if the research is conducted by University staff outside the NHS, for example where human tissue samples are obtained from healthy volunteers and there is no legal requirement for NHS REC review (see Section 2b below).

Personal data

**Note to applicant:** ‘Personal data’ means any information relating to an identified or identifiable person (‘data subject’). An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person [(Art.4 GDPR).](https://gdpr.eu/article-4-definitions/) Please note that pseudonymised data can make it more difficult to identify individuals, but it remains personal data under GDPR.

None of the above

**Note to applicant: If answered ‘None of the above’**, your study does not require review by the Queen Mary Ethics of Research Committee.

**2b. Does your study require NHS Research Ethics Committee review?**

**Note to applicant****:** Please use the [HRA decision tool](http://www.hra-decisiontools.org.uk/ethics/) tohelp you determine if your study requires review by an NHS Research Ethics Committee.

Yes  No

**Note to applicant: If answered ‘Yes’**, your study does not require review by the Queen Mary Ethics of Research Committee but you will require the approval of an NHS REC instead.

**If answered ‘No’,** ensure that you check the guidelines carefully as research with some groups of participants may require approval from other ethics committees, i.e. [Social Care Research Ethics Committee](http://www.scie.org.uk/research/ethics-committee/) or [Ministry of Defence Research Ethics Committee](https://www.gov.uk/government/groups/ministry-of-defence-research-ethics-committees) or [HMPPS](https://www.gov.uk/government/organisations/her-majestys-prison-and-probation-service/about/research). Your research may also require ethics review from an external research ethics committee if it is based in a different Institution or in a context outside the UK.

If still undecided, please seek clarification on whether any level of QMERC review is required by contacting [research-ethics@qmul.ac.uk](mailto:research-ethics@qmul.ac.uk).

**Section 3: Research outside the UK**

**3a. Does the study involve data collection outside the UK?**

\* Yes  No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘Yes’, will local research ethical approval in the host country be obtained?**

**Note to applicant:** To determine if local ethics approval is needed for your research, it would be useful to consult the [International Compilation of Human Research Standards](https://www.hhs.gov/ohrp/sites/default/files/2020-international-compilation-of-human-research-standards.pdf) which lists laws, regulations, ethics review bodies and guidelines on human participants protections in 133 countries.

For studies involving international fieldwork you will also need to complete a health and safety risk assessment form. Consult Queen Mary’s [Fieldwork Safety Policy, Guidance and Risk Assessment](http://www.hsd.qmul.ac.uk/media/hsd/documents/QMUL_HS_123_Off-site-and-Fieldwork-H&S-Policy-Guidance-Risk-Assessment_Feb-2017.pdf) and enclose the [relevant fieldwork risk assessment form](http://www.hsd.qmul.ac.uk/a-z/fieldwork-and-off_site/) with your research ethics application.

Yes  \* No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**3b. If answered ‘Yes’, please provide details below about the location of the research and the external Research Ethics Committee from which approval will be sought.**

Click or tap here to enter text.

**If answered ‘No’,** **please** **demonstrate why local research ethical approval is not being obtained, specify the location(s) of the study, and explain how the proposed research meets the cultural, ethical and legal requirements of the country where the research is being undertaken.**

**Note to applicant**: For international studies, it is expected that the research should be approved by a relevant research ethics committee in the host country. Demonstrate that this option is not available to the researcher or that Research Ethics Committee approval exemption is justified.

Click or tap here to enter text.

**3c. Has this study received any other approval from any other regulatory bodies in the country of the intended research site?**

Yes  No

**If answered ‘Yes’, please attach any relevant documents to your research ethics application form.**

**Section 4: Existing ethical approval**

**4a. Has this study already received ethical approval from another Institution?**

Yes  No

**If answered ‘Yes’**, **please provide the name of Institution which provided ethical approval, and the name of the Institution’s Research Ethics Committee**.

Click or tap here to enter text.

**Note to applicant:**

If the study has existing ethics approval from a Research Ethics Committee at another institution, please complete **ONLY** Section 5 (Research Design) and Section 18 (Declarations) of this form and submit your application to [research-ethics@qmul.ac.uk](mailto:research-ethics@qmul.ac.uk). You are required to enclose the following additional documentation in your research ethics application:

1. a copy of the approval letter from the other institution’s Research Ethics Committee

2. the approved application and any supporting documentation reviewed by the other institution’s Research Ethics Committee

3. the terms of reference of the other institution’s Research Ethics Committee or summary of the external ethics review body process (such as; are applications peer reviewed and evaluated by Committee? Does the external Research Ethics Committee refer to standardised or nationally accepted values and principle statements that are equivalent to Queen Mary Ethics of Research Committee’s policy on research with human participants?)

For international institutions where the original documentation is written in a language other than English, please provide a copy of the documents listed above translated into English. Applications will not be processed without this information.

After submission to QMERC, your application will be processed by a Panel of Chairs and you will receive confirmation from the Research Ethics team as to whether or not QMERC ethics review and approval is also required. Notwithstanding the principle of avoiding duplication, if deemed appropriate the QMERC will consider the ethical implications of the research and will provide an additional opinion.

**Section 5: Research design**

**5a. Describe the research aim(s) of your study.**

**Note to applicant:** Describe in lay language free from technical terms the research aims and the research questions to be examined.

Click or tap here to enter text.

**5b. Outline the background and rationale for the study.**

**Note to applicant:** Explain here how the research aims have been formulated, considering scientific justification and existing knowledge. Please write between a minimum of 200 words and a maximum of 500 words.

Click or tap here to enter text.

**5c. Will stakeholders be involved in the study?**

**Note to applicant:** Stakeholders are people or organisations who have an interest in your study; or who affect or are affected by its outcomes (i.e. government agencies, professional societies and the members they represent, people affected by the condition, healthcare and academic centres, quality improvement organisations).

Yes  No

**If answered ‘Yes’, explain how you have involved stakeholders in the design of the study and how they will continue to be involved at each stage from design to dissemination.**

Click or tap here to enter text.

**5d. Does your study examine a topic that may be considered sensitive**?

**Note to applicant:** The [Economic and Social Research Council](https://esrc.ukri.org/funding/guidance-for-applicants/research-ethics/research-that-may-require-full-ethics-review/) suggests that the following may be considered sensitive topics: participants’ sexual behaviour, their illegal or political behaviour, their experience of violence, abuse or exploitation, their mental health, or their gender, ethnicity or immigration status.

\* Yes  No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘Yes’, explain what the potential risks might be as a consequence of the study and outline what precautions will be in place to minimise these risks.**

Click or tap here to enter text.

**If answered ‘Yes’, demonstrate how the potential and actual benefits of conducting this study outweigh the possible harm to participants.**

Click or tap here to enter text.

**5e. Will the study involve any of the following interventions? (please select all that apply)**

\* Administration of licensed medicinal products

\* Use of medical devices ***(Note to applicant****: For example,* [*Magnetic Resonance Imaging*](https://www.webmd.com/a-to-z-guides/magnetic-resonance-imaging-mri)*(MRI)*

\* Ingestion of any substance by participants *(****Note to applicant:*** *For example, food substances, nutritional supplements or vitamins)*

\* Physical interventions *(****Note to applicant:*** *For example, exercise or hypnotherapy)*

\* Collection of human tissue samples

None of the above

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**5f. Summary of the research design**

**Note to applicant:** Outline the method(s) that will be employed to collect data, and describe how each method will be utilized. Describe what will be required of the participants, including time commitments, data collection settings and data analysis methods. The content here should be written in terms easily comprehensible by a non-specialist and containing no complex technical terms. Any relevant documents, such as study protocol, interview or survey questions, should be attached to the application form. To help the reviewers understand your study, please write a minimum of 300 words and a maximum of 600 words.

Click or tap here to enter text.

**Section 6: Human participants**

**6a. Does your study involve the collection of new data from human participants?**

Yes  No

**6b. Does the study involve any of the following participant groups? (please select all that apply)**

**\*** Children and young people under 18

**\*** Potentially vulnerable people or groups (**Note to applicant:** For example, people with a learning disability or cognitive impairment, older adults or individuals in a dependent or unequal relationship).

**\*** Participants who may be identifiable in the material used or generated (**Note to applicant:** For example, visual or vocal methods producing images or sound recordings, or interviews with people holding high office (elite interviews) who may be identifiable).

**\*** Participants recruited or identified through the internet or social media where the understanding of privacy in these settings is ambiguous (**Note to applicant:** For example, in ‘closed’ discussion groups where there is potential for quotes and visual images to be identifiable).

None of the above

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**6c.** **Describe the key characteristics of your participants (for example, age, gender). State and briefly justify the inclusion and exclusion criteria that will be used for both identification and recruitment of participants.**

Click or tap here to enter text.

**6d. State the number of participants to be recruited and explain how the sample size was decided.**

Click or tap here to enter text.

**6e. Site(s) of the research study**

**Note to applicant:** Specify exactly where the research will be conducted within the chosen research site(s). Clarify if any approvals are required to conduct the research in the chosen site(s), i.e. approval to conduct interviews on private or institutional premises.

Click or tap here to enter text.

**6f. How will potential participants be identified, approached and recruited?**

**Note to applicant:** Attach a copy of any poster(s), advertisement(s) or letter(s) to be used for recruitment.

Click or tap here to enter text.

**6g. Will participants receive reimbursements of expenses, compensation for time or other incentives (financial or not financial) for participation?**

\* Yes  No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘Yes’, please provide further information and justification.**

Click or tap here to enter text.

**6h. Will you be seeking informed consent from participants?**

**Note to applicant:** If your study requires informed consent, please attach a copy of the participant information sheet and the consent form or other material that will be used in the consent process. The [University’s Participant Information Sheet and Consent Form templates](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/#Guidance) must be followed, unless there is a requirement to modify the documentation to ensure that the content is more accessible to the research participants (for example, children) or justification given for using an alternative format.

Yes  \* No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘No’, please justify below why informed consent will not be obtained.**

Click or tap here to enter text.

**If answered ‘Yes’, please explain how you will obtain consent; who will seek it; what information is to be provided to potential participants about the study and how you will document consent.**

Click or tap here to enter text.

**6i. Will your study design involve deliberately deceiving participants in any way?**

**Note to applicant:** Deception occurs when a researcher offers false information to participants or intentionally misleads them about key aspects of the research.

\* Yes  No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘Yes’, please explain how and when deception will be employed and why the use of this strategy is necessary.**

Click or tap here to enter text.

**6j. Will you debrief your participants?**

**Note to applicant:** The debriefing provides participants with a full explanation of the hypothesis being tested, procedures to deceive participants and the reason(s) why it was necessary to deceive them. It can also be used to answer participants’ questions; or if participants may need referral to support services.

Yes  \* No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘Yes’, please provide further details below.**

**Note to applicant:** A copy of the debriefing document should be attached in your research ethics application form.

Click or tap here to enter text.

**If answered ‘No’, please explain why below.**

Click or tap here to enter text.

**6k. Will the study involve individuals or groups where permission of a gatekeeper is normally required for initial conduct or continued access to participants?**

**Note to applicant:** For example, employees recruited through the workplace; adult professionals working with children or the elderly; or research in communities (in the UK or international locations) where access to research participants is not possible without the permission of another adult, such as another family member (e.g. the parent; next of kin) or a community leader.

Note this is not the same as seeking the assent of a person on behalf of another who does not have capacity to consent for themselves ([Mental Capacity Act and research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/)).

\* Yes  No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘Yes’, provide details of the procedures for obtaining permission from the gatekeeper to access your participants.**

**Note to applicant:** Attach any relevant documents for obtaining permission from the gatekeeper with your research ethics application, i.e. invitation email / letter; Participant Information Sheet; Consent Form.

Click or tap here to enter text.

**If answered 'Yes’, please describe any anticipated ethical constraints relating to power imbalances or dependent relationships and the steps you will take to ensure that participants are not subjected to any form of coercion.**

Click or tap here to enter text.

**Section 7: Use of new human tissue samples**

**7a. Does your study involve the collection of new samples?**

\* Yes  No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**7b. Specify the amount and types of human tissue that will be collected as part of the study.**

Click or tap here to enter text.

**7c. Who will collect the samples?**

Click or tap here to enter text.

**7d. Describe the methods that will be employed to analyse the samples.**

Click or tap here to enter text.

**7e. Could findings of clinical significance be produced that would need to be reported to the participants?**

\* Yes  No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘Yes’, describe the arrangements for reporting the findings to the participants.**

Click or tap here to enter text.

**7f. Where will samples be stored during the study and who will have access to them?**

Click or tap here to enter text.

**7g. What will happen to the samples at the end of the study?**

Click or tap here to enter text.

**Section 8: Use of existing human tissue samples**

**8a. Does your study involve the use of existing human tissue samples?**

Yes  No

**If answered ‘Yes’, who is current holder of the samples from whom samples will be released to the researcher?**

Click or tap here to enter text.

**8b. Specify the amount and the types of human tissue samples that will be used as part of the study.**

Click or tap here to enter text.

**8c. Will you receive the samples in:**

Fully anonymised form (there is no link between stored tissue and personal data)

Linked anonymised form (data is linked to stored tissue but individual who has provided the samples is not identifiable to researchers)

Identifiable form

**8d. Has consent been obtained for the use of human tissue samples for research?**

Yes  \* No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘Yes’,** **please describe in detail what consents are already in place.**

**Note to applicant:** Enclose with your research ethics application a statement from the laboratory or institution that informed consent has been obtained and attach evidence of Research Ethics Committee approval.

Click or tap here to enter text.

**If answered ‘No’, will you seek consent to use the human tissue samples?**

Yes  \* No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘No, please justify why.**

Click or tap here to enter text.

**8e. Will any of the samples be imported from outside the UK?**

Yes  No

**If answered ‘Yes’, provide details of the holder of the samples and sufficient information to assure the Queen Mary Ethics of Research Committee that the collection of samples complies with ethical requirements in the exporting country.**

**Note to applicant:** Enclose with your research ethics application form copies of import licence (if relevant).

Click or tap here to enter text.

**8f. Where will samples be stored during the study and who will have access to them?**

Click or tap here to enter text.

**8g. What will happen to the samples at the end of the study?**

Click or tap here to enter text.

**Section 9: Personal data**

**Note to applicant:** ‘Personal data’ means any information relating to an identified or identifiable person (‘data subject’). An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person [(Art.4 GDPR).](https://gdpr.eu/article-4-definitions/) Please note that pseudonymised data can make it more difficult to identify individuals, but it remains personal data under GDPR.

**9a. Does your study involve processing of personal data?**

Yes  No

**If answered ‘Yes’, are you collecting any of the following categories of data? (please select all that apply)**

\* personal data revealing racial or ethnic origin

\* personal data revealing political opinions

\* personal data revealing religious or philosophical beliefs

\* personal data revealing trade union membership

\* genetic data

\* biometric data (where used for identification purposes)

\* data concerning health

\* data concerning a person’s sex life

\* data concerning a person’s sexual orientation

\* data relating to criminal convictions and offences

None of the above

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**Note to applicant:** Personal data that falls into the above categories is defined by [GDPR](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/special-category-data/) as special category data and may require extra safeguards to be met if your research is likely to result in a high risk to individuals. You can use [ICO’s screening checklist](http://www.arcs.qmul.ac.uk/governance/information-governance/data-protection/data-protection-impact-assessments/) to help you decide when you must conduct a Data Protection Impact Assessment (DPIA). If a DPIA is needed; or if you are uncertain whether a DPIA is required, contact [Queen Mary Data Protection Office](http://www.arcs.qmul.ac.uk/governance/information-governance/data-protection/data-protection-impact-assessments/) for more guidance.

**If you have selected ‘None of the above’, but you are collecting data revealing information that individuals would not otherwise disclose in the course of everyday life please provide more details below.**

Click or tap here to enter text.

**9b. Does your research involve further processing of previously collected personal data (including use of pre-existing datasets or sources, secondary analysis of data, merging existing data sets)?**

Yes  No

**If answered ‘Yes’, please provide details about the source of data (i.e. name of owner or datasets etc.).**

Click or tap here to enter text.

**Is the data publicly available?**

Yes  No

**If answered ‘No’, have you obtained the owner’s permission to use these datasets?**

\* Yes  No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**Is the data anonymised?**

Yes  No

**Will you be conducting subsequent analysis within the remit of the original consent the data was collected for?**

Yes  No

**If answered ‘No’, was consent obtained from participants for future analysis?**

Yes  \* No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**Section 10: Security sensitive material**

**10a. Does the study involve research that may be security sensitive?**

**Note to applicant:** Research commissioned by the military; or commissioned under an EU security call; or research concerning terrorist or extremist group can be classified as security sensitive.

\* Yes No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**10b. Does your research involve visits to websites, storage or transmission of documents that might be associated with extremist, or terrorist, organisations?**

\* Yes  No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**Note to applicant: If answered ‘Yes’**, you are advised to store the relevant records or statements electronically on a secure university file store. The same applies to paper documents with similar content. These should be scanned and uploaded. Access to this file store will be protected by a unique password. Please also be advised that websites associated with extremist groups may be subject to surveillance by the police. Accessing those sites from university IP addresses might lead to police enquiries. By submitting to the ethics process, you accept that Queen Mary Research Ethics Office will have access to a list of titles of documents (but not the contents of documents) in your file store. These titles will only be available to the Research Ethics Office.

**Section 11: Benefits and risks**

**11a. Outline the potential benefits of the study.**

**Note to applicant:** Research can benefit the individual participant directly (for example, by having access to new interventions or treatments that are not currently available or by giving a voice to 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 question.

Click or tap here to enter text.

**11b. Describe any risks to the participants that are possible and/or anticipated and the measures that will be taken to mitigate the identified risks.**

**Note to applicant**: Outline any potential risks to participants (i.e. physical, emotional or social harm; invasion of privacy; personal expenses for travel; findings impacting the physical or mental health of the individual).

Click or tap here to enter text.

**11c. Provide details about any risks to the researcher(s) and state any precautions being taken to protect your safety and wellbeing.**

**Note to applicant:** For example, if you are travelling abroad, have you read and acted upon [FCO travel advice](https://www.gov.uk/foreign-travel-advice)? If your study involves work with minors, have you completed your [DBS check](https://www.qmul.ac.uk/prospective/termsandconditions/criminalconvictions/dbs/)? If your study involves visiting participants’ homes or working overseas have you completed a [risk assessment](http://www.hsd.qmul.ac.uk/risk-assessment/index.html)? If you are working alone/ out of hours on QMUL premises have you familiarised yourself with the [Lone Working and Out of Hours Working Health and Safety Policy and Guidance](http://www.hsd.qmul.ac.uk/a-z/lone-working/)? If you are working alone/ out of hours but not on QMUL premises have you read the guidance on the [Health and Safety Executive website?](https://www.hse.gov.uk/pubns/indg73.pdf) [If you are conducting in-person face-to-face research with human participants what steps will you be taking to protect your participants and yourself from coronavirus during your encounter?](http://www.hsd.qmul.ac.uk/covid-19-secure-procedures/)

Click or tap here to enter text.

**11d. Provide details about any reputational risks and mechanisms that will be put into place to control these risks.**

**Note to applicant:** Potential risk factors include for example, loss of participant information; complaints made by participants; inappropriate disclosure of participant information.

Click or tap here to enter text.

**Section 12: Anonymity and Confidentiality**

**12a. Will data collected be stored in:**

fully anonymised form

**Note to applicant:** Data are fully anonymised if no one, including the researcher, can connect the data to the individual who provided it. No direct personal identifiers are collected, for example names, addresses or student identification numbers.

pseudonymised form

**Note to applicant:** Pseudonymised data has a link between the data and the individual who provided it. To reduce the risk of disclosure, the researcher uses methods such as storing the participant’s name or other identifiers separately from the research data; or replacing the participant's name and other identifiers with a unique code and using this code to refer to the participant data. Please note that coding the data does not make that data anonymous. As noted above, pseudonymised data is considered personal data under the GDPR.

**\*** identifiable form

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**12b. Please describe in more detail the process of anonymising data.**

**Note to applicant:** Please see [ICO guidance](https://ico.org.uk/media/1061/anonymisation-code.pdf) for anonymising data.

Click or tap here to enter text.

**12c. Will data be treated as confidential (meaning participants’ identities will not be revealed in any outputs or disclosed to a third party)?**

**Note to applicant:** It is of paramount importance that researchers respect the confidentiality of, and data provided by, their participants. Details that would allow individuals to be identified must not be published or made available to anybody not directly involved in the research unless explicit consent is given by the individuals concerned.If there are any circumstances where the duty to protect confidentiality of participants’ information may be compromised (i.e. if a participant discloses information which suggests that they or someone else may be at risk of harm) please describe these below and make explicitly clear in the Participant Information Sheet(s).

Yes  \* No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**If answered ‘No’, please provide further information and justification for this.**

Click or tap here to enter text.

**Section 13: Data management plan**

**Note to applicant:** Describe below in detail your plans for managing your data, i.e., Consent Forms, surveys and questionnaires, interview transcripts, audio and video recordings, films and photo images etc.

**13a. Confirm that all personal data will be stored and processed in compliance with data protection legislation. See** [**Information Governance guidance**](http://www.arcs.qmul.ac.uk/governance/information-governance/data-protection/dp-glossary/) **for more details.**

Yes

**13b. Will you transfer personal data outside the EEA?**

\* Yes  No

\* Discuss any potential ethical issues in Section 15: Other Ethical Issues

**Note to applicant:** If answered ‘Yes’, you must ensure compliance with guidance provided in [Queen Mary Data Protection Policy](http://www.arcs.qmul.ac.uk/media/arcs/policyzone/Data-Protection-Policy-v03.0.pdf), confirm compliance with data protection legislation and state that in your Participant Information Sheet(s).

**13c. Where will you store the data?**

**Note to applicant:** You should consider the [Queen Mary Storage of Information policy](https://www.its.qmul.ac.uk/media/its/documents/governance/sops/SOP-DG14-Storage-of-Information-Policy---V2.0.pdf) to ensure that the data storage plans for your study abide by Queen Mary University policy.

Click or tap here to enter text.

**13d. Will mobile devices or media (i.e. phones, laptops or USB sticks) be used?**

Yes  No

**If answered ‘Yes’, will these devices be encrypted?**

Yes  No

**13e. Who will have access to the data?**

Click or tap here to enter text.

**13f. Explain how the security of the data will be maintained.**

Click or tap here to enter text.

**13g. Explain how long data will be retained for and data disposal plans.**

**Note to applicant:** You should consider the [Queen Mary Records Retention Schedule](http://www.arcs.qmul.ac.uk/governance/information-governance/records-management/records-retention-schedule/) and the [Disposal of Information policy](https://www.its.qmul.ac.uk/media/its/documents/governance/sops/SOP-DG16-Disposal-of-Information-Policy--V2.0doc.pdf) to ensure that the data retention and disposal plans for your study abide by the Queen Mary University policies.

Click or tap here to enter text.

**13h. Will data be made available for re-use by other researchers (i.e. open access)?**

Yes  No

**If answered ‘Yes’, please describe your plans for making your data available for re-use.**

**Note to applicant**: Please consider [Queen Mary 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.).

Click or tap here to enter text.

**13i. How will the results of the study be reported and disseminated?**

**Note to applicant:** Dissemination plans may include conference presentations, journal publication, dissertation/PhD thesis, presentations or feedback to participants.

Click or tap here to enter text.

**13j. Describe any ethical considerations relevant to the dissemination of findings.**

Click or tap here to enter text.

**Section 14: Peer Review**

**14a. Has your study received peer review?**

Yes  No

**If answered ‘Yes’, please provide more details about the source of the review (for example, peer review as part of the grant application process, from internal departmental colleagues, from companies or collaborators or from supervisors of student studies).**

**Note to applicant:** Confirm whether the reviewer is independent of the study, and whether internal or external to Queen Mary University of London. Attach any relevant documentation. Evidence of IHSE peer review outcome should be attached in the form if the research study recruits Queen Mary medical students.

Click or tap here to enter text.

**Section 15: Other ethical issues**

**15a. Are there any other ethical issues that should be taken into consideration?**

Yes  No

**If answered ‘Yes’, please provide below details, mitigations and justification in relation to these issues and attach any relevant documentation to your research ethics application.**

Click or tap here to enter text.

**Section 16: Conflict of interest**

**16a. Please declare any real or perceived conflicts of interest that are relevant to this research study and provide details of the process that has been agreed to manage these.**

**Note to applicant:** Please see situations where a conflict of interest might arise in the [Queen Mary Standards of Business Conduct (Appendix E)](http://www.arcs.qmul.ac.uk/media/arcs/policyzone/ARC2017-34ii-Standards-of-Business-Conduct-updated-22.2.18-v1.pdf#:~:text=Notwithstanding%20the%20principles%20of%20conduct%20which%20staff%2C%20students,interest%20is%3A%20%E2%80%98A%20conflict%20between%20the%20private%20interests).

Click or tap here to enter text.

**Section 17: Level of Ethics Review**

**17a. BEFORE SUBMITTING YOUR APPLICATION PLEASE CONFIRM IF YOU ARE SEEKING (please check with “x” one of the following options):**

Panel Review

**Note to applicant:** Examples of studies that may require Panel review can be found [here](https://esrc.ukri.org/funding/guidance-for-applicants/research-ethics/research-that-may-require-full-ethics-review/). Most studies that do not fall into one of these examples is assumed to be low risk. Please see [here](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/qmerc-meetings/) Panel review meeting dates and submission deadlines.

Low Risk Review

**Note to applicant:** The low risk review is appropriate for research in which the probability of possible harms by participation in the research is not significantly higher than those encountered in other aspects of the participants’ everyday life. Some examples of research that may qualify for low risk review include studies which can demonstrably evidence that participants are at no additional risk of harm, stigma or prosecution or studies which will not induce undue psychological stress or anxiety to the participants.

Generic Review

**Note to applicant:** Generic review and approval is appropriate for a group of sufficiently similar low-risk studies (i.e. cohorts of UG and PGT students). See more information [here](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/applications-and-approval/#d.en.849154). For specific guidance on completing a QMERC research ethics application for generic approval and for more information about this review route, please contact the Research Ethics Facilitators ([research-ethics@qmul.ac.uk](mailto:research-ethics@qmul.ac.uk)).The form should be submitted to [research-ethics@qmul.ac.uk](mailto:research-ethics@qmul.ac.uk), along with examples of supporting documents that the students will be expected to use (i.e. Participant Information Sheet template; Consent Form template, an appendix detailing the procedures to be used etc.

QMERC Main Committee Review

**Note to applicant:** Select this option if your study is security sensitive (i.e. research commissioned by the military, commissioned under an EU security call, research concerning terrorism or extremist groups etc.); or if a Panel Chair or a Research Ethics Facilitator has recommended that review by QMERC Main Committee is required.

**Section 18: Declarations**

**18a. By checking this box,** **I confirm that the information in this research ethics application, including any supporting documentation is, to the best of my knowledge, complete and correct. I have attempted to identify and mitigate all risks that may arise in conducting this research and acknowledge my obligations as investigator and the rights of the participants.**

**18b. By checking this box, I confirm that I am responsible for notifying the Queen Mary Ethics of Research Committee (**[**research-ethics@qmul.ac.uk**](mailto:research-ethics@qmul.ac.uk)**) of any amendments, minor or major, to the study and therefore the terms of the ethical approval through the** [**amendments procedure**](http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/#Amendments)**.**

**18c. By checking this box, I confirm that all personal data will be stored and processed in compliance with data protection legislation. See** [**Information Governance guidance**](http://www.arcs.qmul.ac.uk/governance/information-governance/data-protection/dp-glossary/) **for more details.**

☐

**18d. By checking this box, I confirm that I have read and understood the** [**Queen Mary Policy on Research with Human Participants**](http://www.arcs.qmul.ac.uk/media/arcs/policyzone/QMUL-Research-with-Human-Participants-Dec-14-final.pdf) **and the** [**Concordat to Support Research Integrity**](https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2019/the-concordat-to-support-research-integrity.pdf)

**18e. By checking this box, I confirm that I am responsible for reporting any unexpected deviations to study protocol or unexpected events which occur, to the Queen Mary Ethics of Research Committee (**[**research-ethics@qmul.ac.uk**](mailto:research-ethics@qmul.ac.uk)**).**

**18f. By checking this box, I confirm that if invited to an Ethics Committee Panel review meeting, I will make every effort to be available in person or by phone or video-conference at the time of the review to clarify points of uncertainty. I understand that if no member of the research or supervisory team is available to attend the panel meeting, the Queen Mary Ethics of Research Committee reserves the right to refer my research ethics application to the next available meeting that a member of the research or supervisory team can attend.**

**Note to applicant:** Electronic signatures and/or scanned versions accepted

Signature of Principal Investigator

or Supervisor (for student study): ………………………………………………………….

Print name: ……………………………………………………………………………..……

Date: ………………………………………………………………………….......................

Signature of Student Investigator: ………………………………………………………...........................................................

Print name: …………………………………………………………………………………………………..

Date: …………………………………………………………………………………………...

**Note to applicant:** Head of Department signature only required for research studies reviewed at Panel meeting (not applicable for low risk applications).

Signature of Head of Department: ……………………………………………………….........................................................

Print name: ………………………………………………………………………………………………...

Date: ………………………………………………………………………………………….

**THANK YOU FOR COMPLETING THIS APPLICATION FORM.**

**Section 19: Feedback on the research ethics application form**

**Note to applicant:** This section is voluntary.

**19a. This is a new version of the research ethics application form, revised in response to feedback, suggested improvements and in order for committee members to get a more complete picture of your research study, thus reducing the need for further information requests. The application form will be reviewed regularly with a view to ensuring it meets the needs of the applicants and Committee members. As part of the review process, applicants are invited to give feedback on the content and format of the application form, including any suggestions to resolve the issues identified. If you would like to leave feedback here, please provide more information below. Alternatively if you would prefer to submit anonymous feedback, please access the questionnaire here** [**https://www.surveymonkey.co.uk/r/WJMLYTS**](https://www.surveymonkey.co.uk/r/WJMLYTS)

Click or tap here to enter text.