

QUB FACULTY REC ACKNOWLEDGMENT OF EXISTING ETHICAL APPROVAL

Where possible, the University seeks to avoid duplication of an ethical review. If you are involved in a project that received an ethical approval from another organisation, a request can be submitted to the MHLS/EPS Faculty RECs for acknowledgement of the existing ethical approval. It is important to note that the Faculty RECs will not conduct an additional ethical review. The Faculty RECs are only recognising the existing approval through the QUB Faculty REC Acknowledgement process.

When is the Acknowledgment of Existing Ethical Approval appropriate?

The Acknowledgement of Existing Ethical approval is generally considered **appropriate** for studies where the external organisation is:

- another UK university;
- an international university with equivalent ethical standards and that has defined ethical review procedures;
- an international organisation with equivalent ethical standards and that has defined ethical review procedures (e.g. healthcare body, national research ethics committee).

QUB researchers should be included in the external ethics application (or added as an amendment) and the researcher will need to confirm that the application covers the work they are to undertake. It is the responsibility of the QUB lead (staff member/supervisor in the case of student projects) to ensure the study documentation is of a similar standard to that expected by QUB.¹

The Acknowledgement of Existing Ethical Approval is generally **not appropriate** for studies where:

- The funder has mandated a dual review (i.e. an ethical review in the UK by the lead institution and an ethical review in the country where the research will take place);
- a collaborating institution issues an 'exempt from ethical review' decision for the research but under QUB's policies and procedures an ethical review is required.

Acknowledgment of Existing Ethical Approval Process

The following documents must be submitted to the Faculty REC:

- Acknowledgement of Existing Ethical Form
- Ethical approval letter/email from the external institution
- All study documents approved as part of the external ethical approval which are to be used by QUB researchers in the study (e.g. ethics application form, protocol, information sheets and consent forms).

The Research Ethics Officer will inform the applicant of the outcome of the Acknowledgement process within 10 working days of receipt of a valid submission.

Research Conducted Outside UK

It is the responsibility of researchers to ensure they are familiar with the relevant legislative and regulatory requirements, customs and practices in the countries in which they are undertaking the research. Researchers are also responsible for ensuring appropriate translations are available if required.

¹ See [QUB Policy on the Ethical Approval of Research, Section 7](#)

Data Protection

Where research is conducted outside of the UK it is the responsibility of the researcher to ensure that processing of personal data complies with the legislative requirements of that country. The researcher must also ensure that any transfer of data from the UK complies with UK data protection legislation and University policy, including putting in place data sharing/processing agreements where necessary. Please contact the Information Compliance Unit to discuss requirements prior to any transfer of data - info.compliance@qub.ac.uk

Indemnity

Where research is being conducted outside of QUB for a '*Medicinal Purpose*' and QUB are the Sponsor/entity legally responsible then consideration will need to be given to indemnity arrangements. Under the University's Clinical Trial Policy **Medicinal Purpose** is defined as:

- a) *treating or preventing disease or diagnosing disease or*
- b) *ascertaining the existence degree of or extent of a physiological condition or*
- c) *assisting with or altering in any way the process of conception or*
- d) *investigating or participating in methods of contraception or*
- e) *inducing anaesthesia or*
- f) *otherwise preventing or interfering with the normal operation of a physiological function*

A referral may be required to the University Insurers and there may be additional costs involved. Any additional insurance costs must be met by the research team. Please contact Research Governance if you have any queries: researchgovernance@qub.ac.uk

FREQUENTLY ASKED QUESTIONS

How will I know if my research is suitable?

If the lead institution on a collaborative research project has obtained, or will obtain, ethical approval, then the Acknowledgement of Existing Ethical Approval may be appropriate. Or, if you are conducting research in another country and that country has a requirement for REC review by one of its own institutional committees then the Acknowledgement of Existing Ethical Approval may be appropriate.

How will I know if the other institution's ethical review and approval is suitable?

To be suitable for the Faculty REC Acknowledgment process, the ethical review from the other institution must be as robust as that of QUB. It is the responsibility of the QUB lead (staff member/supervisor in the case of student projects) to ensure the study documentation is of a similar standard expected by QUB.

Whether a study is suitable for the Acknowledgement process is considered on a case by case basis, depending on the Institution that conducted the ethics review.

What is required for the Acknowledgement process?

The Acknowledgement of Existing Ethical Approval Form, completed and signed by the QUB Chief Investigator/Supervisor, the Approval/Decision letter and all supporting documents that were reviewed by the approving institution such as:

- Ethics Application Form;
- Research Protocol;

- Recruitment Material;
- Participant Information Sheet(s);
- Consent Form(s);
- All methodology documents e.g. for surveys, interviews, focus groups etc;
- Any other documents reviewed, as applicable.

All relevant documentation must be submitted to your Faculty REC for scrutiny. The Research Ethics Officer will inform the applicant of the outcome of the process within 10 working days of receipt of the complete submission.

When would a study not be appropriate for the Faculty REC Acknowledgement process?

- If your project is funded research, please check the terms and conditions of the funder as they may require a dual ethical review or ethical review by each party collaborating in the research. If an ethical review is required by all parties you must also seek an ethical review and approval by your Faculty REC.
- If the collaborating institution issues an 'exempt from ethical review' decision for the research but under QUB's policies and procedures an ethical review is required. Some examples include: use of human tissue, which even if de-identified requires an ethical review under the University's policy; any research involving human participants, such as questionnaires or interviews, which may be considered low risk by another institution but under QUB's policy requires ethical review.
- If your involvement in the research, which has been reviewed and approved by another institution, means you would only be receiving anonymous/aggregated data you are not required to complete the Acknowledgement of Existing Approval process. Appropriate contractual arrangements should be in place to allow for the transfer/sharing of such data.
- Similarly, if your involvement in the research is limited to analysis of samples under a protocol ethically approved by another institution you will not need to complete the Acknowledgement of Existing Approval process. There must however been appropriate contractual agreements in place which cover the use of the samples and confirm that ethical approval is in place for the intended use (eg Material Transfer Agreement).
- Finally if your involvement is only in a consultative capacity e.g. for your particular expertise, with no participant involvement, an acknowledgement would not be required. If in any doubt please contact the Research Ethics Officer.

It is funded research, would this be suitable for Acknowledgement?

In this instance it is important you review the terms and conditions of the funder as they may mandate a dual ethical review or stipulate ethical review is required by all parties conducting the research. If this is the case the QUB Acknowledgement process would not be suitable as an ethical review would be required by all research partners.

My research is being conducted outside the UK, does this have any implications for the type of review?

A collaborator or governmental body in the country the research is being conducted may mandate an ethical review and approval in their country. If this is the case QUB may acknowledge the existing approval as long as the external organisation issuing it has equivalent ethical standards and defined ethical review procedures.