

**RESEARCH ETHICS POLICY**

**September 2024**

**Version: Phase 1**

1. **Introduction**
	1. Associated Research Policies
2. **Ethical Principles**
	1. Respect for people’s autonomy
		1. Dignity
		2. Informed consent
		3. Who can consent?
		4. The Informed Consent Process
		5. The Participant Information Sheet (PIS)
	2. Do no harm (Non-Maleficence)
		1. Researcher Competence
		2. Risk Assessment and Risk Management
	3. Justice
		1. Confidentiality
		2. Data Management
		3. Data Storage and Destruction
		4. Data storage for Undergraduate and Postgraduate dissertations
		5. Academic freedom and restrictions on publication
	4. Do good (beneficence).
	5. Conclusion
3. **Researcher Misconduct**
	1. Researcher Misconduct
	2. Data Breach.
4. **Process for Ethical Approval**
	1. University Level (UREC) Ethics Application
	2. Divisional Level (DivREC) Ethics Application
	3. Appeals at DivREC or UREC level

1. Introduction

Research Ethics and related data protection regulations are everyone’s responsibility. Rather than thinking of the ethical approval process as extra bureaucracy, it is more useful to use this process as '*a way to think throug*h' potential problems and issues that may arise in such a way that will ensure researchers and research participants are protected and safe, as well as ensure the legal duty to appropriately manage, store and dispose of data. Research ethics should be considered throughout the whole natural history of a project.

1.1 Associated Research Policies

Researchers should also be aware of:

* [QMU’s Data Management Policy](https://qmu.sharepoint.com/%3Ab%3A/s/QMUResearchEthics/EZfNPVsitZxFt_pqSamSzSEB77WamZTr8CulaJMVlZw5Ng?e=hNVRpa) (due for review).
* QMU’s Code of Practice for Research and Knowledge Exchange (under development) guidance, as these outline research conduct standards across the sector, as based on [UKRIO Code of Practice for Research](https://ukrio.org/ukrio-resources/publications/code-of-practice-for-research/).
* QMU ’Safeguarding in Research and Knowledge Exchange guidance, available [here](https://www.qmu.ac.uk/research-and-knowledge-exchange/strategy-and-culture/concordats-and-sector-good-practice/safeguarding-and-research-and-innovation). This guidance is part of the overarching QMU Safeguarding Policy, Procedure and Framework (currently under development)
* QMU’s participation in ‘Trusted Research’ – a UK Government [initiative](https://www.npsa.gov.uk/trusted-research) to ensure that international collaboration in research and innovation is safe from potential theft, manipulation and exploitation, including as a result of interference by hostile actors. Support available at QMU is available [here.](https://www.qmu.ac.uk/research-and-knowledge-exchange/strategy-and-culture/concordats-and-sector-good-practice/trusted-research/)
* QMU is committed to support the Integrity of Research and providing associated online training to all researchers where possible. Please contact rkedu@qmu.ac.uk for more information.

[The UK Research Integrity Office](http://www.ukrio.org/) is an independent advisory body, offering support to the public, researchers, and organisations to further good practice in research. It works to enhance good research practice, address mistakes, questionable practices, and fraud, and improve the culture and systems of UK research. **Research integrity refers to all of the factors that underpin good research practice and promote trust and confidence in the research process.** Research integrity covers all disciplines of research and all sectors where research is carried out. Research integrity covers all research and the whole lifecycle, from the initial idea and design of the project through the conduct of the research and its dissemination. It also covers making sure that environments and systems for research safeguard and enhance good research practice, rather than hinder it – often described as ‘**research culture**. See [here](https://ukrio.org/about-us/what-is-research-integrity/) for more about research integrity.

**2. Ethical Principles**

Ethics permeates all research, but in practice, ethical research is often complex, and it is less a rule-governed process or a set of tick box barriers, but rather an art that needs to take into consideration the context, the research domain, and specific responsibilities, such as those of data management. There is no ‘*one-size fits all*’ approach to ethical research, and in order for research to have social and cultural impact, ethical research requires a balance to be struck between minimising probable harm and advancing academic knowledge.

Where research falls in the category of health and social care, researchers should read and ensure their applications are consistent with the [UK Policy Framework for Health and Social Care Research - Health Research Authority](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/#:~:text=These%20principles%20protect%20and%20promote%20the%20interests%20of,confidence%20of%20patients%2C%20service%20users%20and%20the%20public.). This includes the statement that research projects should be "*scientifically sound and guided by ethical principles in all their aspects*." It is similarly advisable to refer to the Declaration of Helsinki, in particular the section on “[Ethical Principles For Medical Research Involving Human Subjects](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)”

To help guide researchers on how to conduct research, how to treat their research participants, and how to handle the data gathered. QMU has developed the following ethical principles (derived from Beauchamp and Childress, 2001) for researchers to consider and embed into their work:

* **Respect for people’s autonomy** – including Dignity, Informed Consent.
	+ **Do no harm** (non-maleficence) – including Competence and Risk Assessments.
	+ **Justice** – including Confidentiality and the legal duties of Data Management/Storage.
	+ **Do good** (beneficence).

2.1 Respect for Autonomy

2.1.1 Dignity

Participants in research should be treated with appropriate dignity. A helpful test for researchers is to ask whether they would consider their proposed research appropriate for a beloved family member. Unfortunately, there are many historical cases of research participants being treated in undignified, even brutal, ways that are clearly unethical. Nonetheless, sometimes research requires intrusive, invasive, tedious or unpleasant treatment of participants, and participating in research can be stressful, challenging, boring, upsetting or even painful. Researchers need to justify the potential benefits of the knowledge gained, whilst still ensuring to treat people as persons rather than a means to a research end. It is essential to consider also the social impact of the research results, independently of the scientific or social impact.

**2.1.2 Informed Consent**

Any research that collects identifiable human data requires serious consideration of informed consent. Collecting human data can include taking tissue samples, interviewing someone, or gathering data from a specific social media account. This is not simply about getting a signature on a consent form, but instead ensuring that the research participants have been appropriately informed about the research study, and they are aware how their data - their name, or their demographic information, or their tissue samples - will be used. This also includes informing them of their right to exit the study at any time without needing to give an explanation, and of their ‘right to be forgotten’ (if applicable to the data gathered, and if it possible to identify their data). Participants need to be informed of the risks, benefits and consequences of their participation in the study and ensure they have of their own free will - without coercion, undue inducement or manipulation of any kind - chosen to be part of the research.

Researchers who are working with potentially vulnerable people (such as children, those with mental illness, or the very sick or old) will need to pay particular attention to the way in which they gain informed consent. **If researchers are aiming to work with any NHS Patients, NHS Staff, those in custody, or those in a condition which may affect ability to consent, they will need to submit an application through IRAS in addition to seeking QMU Ethical Approval.** It is also advisable for anyone wishing to enact audit or R&D purposes within the NHS to review [this guidance](https://qmu.sharepoint.com/%3Af%3A/s/QMUResearchEthics/EqTZ7Ctqh9FIneR6ixt-KUIBE8uZ6gar4-5DobSpsze3uA?e=9LuYlx). Please also see Section 5.1 of the [general guidance](https://www.qmu.ac.uk/research-and-knowledge-exchange/qmu-research-ethics/qmu-research-ethics-supplementary-forms) documentation. for more information about criminal record checks and working with vulnerable groups. Lastly, if researchers are planning research in schools or educational settings run by Local Authorities, Local Authority Approval is needed in addition to QMU Ethical Approval.

2.1.3 Who Can Consent?

Only persons able to freely understand, question and refuse without fear of sanction or reprisal can give informed consent. Please see Section 5 of the [general guidance](https://www.qmu.ac.uk/research-and-knowledge-exchange/qmu-research-ethics/qmu-research-ethics-supplementary-forms) documentation for more information about consent.

For research involving participants who may lack the capacity for understanding and questioning, such as children under 16 years (in Scotland), people with mental or intellectual difficulties, or people severely ill or heavily medicated, consent should be obtained from a parent, carer or other person serving in a responsible capacity AND from participants themselves, to the extent that they are capable of understanding and offering (or refusing) consent. It is important to remind researchers that in Scots law, children are often able to assent to take part in research and are often considered sufficiently mature to form a view, even if they are not considered fully competent to give consent[[1]](#footnote-2). Ingenuity needs to be exercised in providing satisfactory consent procedures in such cases. Consent from the parent or carer alone is rarely adequate.

The freedom to refuse to participate in research is potentially threatened where there is a power imbalance between the prospective participant and the researcher, along with their perceived allies. For example, students may believe that refusing to participate in staff research might impact their assessments or education. This type of power dynamic can also occur whenever there are gatekeepers involved in facilitating access to participants. The two key methods of ensuring true refusal are:

* To ensure whenever possible that the research team is completely independent of anybody in a position of power over the potential participants; and
* That the procedures to ensure independence are explicit during the informed consent process. For example, a patient might be asked to participate in a study in which their medical consultant is part of the research team: in this instance, it should be clear to the patient that the consultant will have no knowledge of whether any individual patient has participated or not, and so participation cannot impact their treatment or care. Where this is impossible, other means of enabling true refusal or ensuring the voluntary nature of participation should be actively written into the research protocol.

It is also important to remember that research on groups, societies, organisations, institutions and their members – including closed social media groups – also ‘involves human beings’ who should be involved in the consent process. This does not necessarily mean obtaining consent from everybody, but appropriate procedures should be in place for collective consent and treating the organisation as the ‘participant’.

**2.1.4 The Informed Consent Process**

The Consent From must always be accompanied by a Participant Information Sheet – see below – that provides specific details about the project. Researchers may also include other information – such as indicative questions, or a timeline, etc – as part of gaining consent. Researchers should ensure all these materials are accessible and give appropriate time for any participant to review them all, before agreeing to the statements on the consent form, including those seeking consent obtained online. Remember, consent forms will also contain data and should be stored securely for the agreed duration of the project. Often, researchers will scan consent forms to keep them with all other digital data – if doing so, remember to safely destroy any paper copies.

**2.1.5 The Participant Information Sheet (PIS)**

How to provide information as part of the consent process is a critical part of ethical research, and key to this is providing information to the potential participant about the study. This is usually – though not always – done via a Participant Information Sheet (PIS). Two general questions should be answered on the information sheet:

* What are the likely benefits of the research for science, for society and for the research participants? This should enable potential participants to make an informed choice regarding their participation (or not) and understand how their data may be used, even if there are risks involved. Researchers should avoid the temptation to exaggerate benefits and/or underplay risks.
* How will participants and the data about them be protected? This should include explanation of how confidentiality and/or anonymity will be ensured and what data will be retained, where, and in what format. For example, if making a film as part of research that will be put online, participants must know that once the film is published, it would be almost impossible to retract consent.

When reviewing an informed consent form, participants are rarely able to recall every single detail of the proposed research and so it is essential to provide a copy of a Participant Information Sheet, so they can refer back to the details of the project. An example Information Sheet and Consent Form can be found [here](https://www.qmu.ac.uk/research-and-knowledge-exchange/qmu-research-ethics/qmu-research-ethics-supplementary-forms/).

Two common dilemmas about the consent process relate to how researchers might need to navigate ethically around the consent process for the benefit of the participant, for example:

* A researcher may incidentally discover signs of disease or abnormality. In most cases the appropriate procedure is to notify the participant and refer to appropriate health care professionals. In some cases, it is appropriate for the participant to choose to not be informed, or be informed, as part of the consent procedure. Genetic screening research is one example of such risks.
* When research incidentally discovers a significant risk of harm to the participant by others, or by the participant to others. With children under 16 years, researchers are legally obliged to disclose such risks to appropriate guardians/adults and this is a legal limit on confidentiality clauses.

Researchers should also be clear that all data produced will only be used for purposes for which the participants have consented. For example, if images are produced as part of the research, they cannot later be used for promotional purposes unless this this was made clear as part of the informed consent process.

**2.2 Do no harm** (**Non-Maleficence)**

Researchers must not harm their study participants. However, even taking blood samples might be felt to be ‘*harmful’* so it is important that the research team approach this ethical principle with nuance and weigh up the potential for harm against the benefits of the study and to come to a justifiable conclusion. It is also the team’s duty to ensure that research which carries a risk of any sort of harm should only be conducted by competent research teams.  Many potential ethical issues can be resolved by ensuring that the research team has sufficient competence to manage problems appropriately. For example, a badly designed survey may waste participants’ time, and ask problematic and time-consuming questions: it is the role of the entire research team to ensure such potential harm is minimised.

**2.2.1 Researcher Competence**

Competence is a function of relevant skills, experience, training and commitment of appropriate time and effort to the research project. Competence is also contextual and a highly trained and specialised researcher/researcher team conducting new research in a different domain might lack the competencies to conduct such research ethically. For example, a health scientist may lack the appropriate skills to deliver ethical humanities research as it requires different sort of competencies. As such, a good researcher or research team should have an appropriate mix of competencies in the appropriate domain. Part of the ethics review process is therefore to establish if there is sufficient competence to:

* Minimise harm.
* Conduct research that is likely to be of sufficient quality to be worth any related risks of harm.
* Manage any issues of harm should they arise, even if it is very unlikely.

When researchers are less competent or less experienced, then supervisors should be in place to ensure the appropriate level of support and competence to ensure safety and the research project’s success. Within the context of supervisors working on undergraduate, postgraduate or PhD research teams, particular care should be exercised in decisions about what types of research can be conducted, and that complexity of the research is suitably aligned with the level of study. It is important to remember that staff teaching loads can sometimes make close supervision difficult, so unless a student has special demonstrable competencies, caution should always be exercised in developing supervised-research projects which may present major ethical issues.

There are also specialised competencies that need to be considered when working with children or participants from vulnerable groups. Dependent on the type of study and the participants involved, criminal record checks such as the Protecting Vulnerable Groups (PVG) scheme may be required prior to ethical approval being granted. These checks are a legal requirement and any researchers who intend to work with these groups should consider this when planning the timescale of their research. Further details can be found [here](https://www.qmu.ac.uk/about-the-university/quality/forms-and-guidance/qmu-disclosure-and-pvg-membership-guidance-version/).

**2.2.2 Risk Assessment and Risk Management**

In order to address the issue of ‘risk of harm’, researchers must demonstrate that they have exercised a standard of due care. As well as being competent, this involves *identifying* the likely risks, *assessing the probability* that they will occur, assessing their *magnitude* if they do occur, *evaluating* the risks to determine their acceptability in relation to the objectives of the research, and finally *managing* the risks, which involves the steps that can be taken to minimise them (Beauchamp and Childress, 2001:199).  Common examples of managing risk of harm include:

* Screening procedures that identify participants more likely to come to harm through the research.
* Competence to work with participants who become distressed, including being able to listen and communicate appropriately about the distress and being able to refer to further counselling should this be required.
* Sufficient knowledge to provide advice about services or help as a result of discussing needs which are not being met.
* Sufficient knowledge to discuss the benefits of appropriate interventions.
* Adequate post-research debriefing, including offering explanations of any necessary deception or withholding of information.
* Appropriate research training on the proposed research techniques: For example, appropriate specialist interview skills; specific experimental methods; specialist biological sampling.
* Appropriate risk assessment, monitoring and management (i.e., reporting and supporting mechanisms) for the conduct of the research, including any physical, psychological or biological risks faced by researchers and participants.
* Adequate supervisory procedures to address researchers’ difficult thoughts and feelings about the research and the participants, to reduce harm to researchers.
* Consideration of the environment in which research is taking place such that the need for privacy is balanced with the risk of accusations of harm or of physical harm.

**All research should therefore assess risk appropriately and thoroughly, and if required, complete a QMU Risk Assessment, and/or develop a comprehensive risk mitigation protocol**. As a reminder, researchers should be aware of the QMU Safeguarding in Research and Knowledge Exchange guidance, available [here](https://www.qmu.ac.uk/research-and-knowledge-exchange/strategy-and-culture/concordats-and-sector-good-practice/safeguarding-and-research-and-innovation/). This guidance is part of the overarching QMU Safeguarding Policy, Procedure and Framework (in development). Researchers can also seek insight from the [UKCDR Guidance on Safeguarding in International Development Research](https://ukcdr.org.uk/publication/ukcdr-guidance-on-safeguarding-in-international-development-research/)

Not all research requires significant risk management – for example: surveys about purchasing habits, or interviewing someone online on a subject is unlikely to cause distress will unlikely require a Risk Assessment form. However, researchers should always reflect honestly if including a Risk Assessment may be beneficial to their research ethics application.

**2.3 Justice**

The Informed Consent process (Section 2.1.2) should ideally ensure a participant’s full rights are being respected, and they are being treated equally and fairly. However, there are often considerations of Justice that are outwith of the informed consent process – for example, excluding entire groups of people. There are often legitimate reasons for restricting a study to exclude specific groups (for example, including non-native speakers of the predominant language). However, sometimes these choices are made mainly for convenience: such choices are ethically debatable and would require justification. Any inclusion or exclusion criteria should therefore be clearly outlined and justified in the ethical approval application. Indeed, participant involvement in research design is good practice, and it is now widely recognised that research participants are entitled to help form the research agenda. Such concerns for equity are certainly considerations when undertaking ethical research, however, due to legal considerations, the bulk of the ethical principle of Justice concerns issues of confidentially and data management and/or storage.

**2.3.1 Confidentiality**

Confidentiality is the subject of considerable literature and a key feature of current Data Protection legislation. This means there are legal ramifications to data collection.

It is important to keep confidentiality distinct from anonymity. Anonymity involves ensuring a participant’s identity is not revealed or otherwise linked to the data/information gathered in a study. This not only requires the avoidance of names, but also other identifying information such as postcodes or job titles. Moreover, particularly in small-scale more qualitative studies, some participants may be identifiable solely by the data they provide – for example, the director of a company can be discovered by a simple internet search. Consequently, true anonymity from start to finish is relatively rare in all research and should not be offered unless it is truly provided. It is certainly good practice to aim for anonymity, however, if participant consents to being identifiable, anonymity is not a requirement.

Confidentiality, in contrast, involves the *prevention of disclosure* of identity and/or relevant data other than to authorised people and for authorised purposes. For example, in the NHS, patient records are confidential, but may be accessed by any NHS staff for appropriate purposes but not for any other reason. Using data for anything other than the intended purposes would be a serious breach of confidentiality and could potentially result in legal proceedings.

If data gathered are to be retained for further research, researchers need to ensure that the informed consent form explains and justifies this. Applicants should describe the measures taken to encode or anonymise stored data. Generally, it is advisable that data should be anonymised as soon as it is reasonable to do so, even if this requires the loss of potentially useful information. Indeed, current legislation suggests it is illegal to store confidential data for longer than consent was granted. Even where only anonymised data are used, adequate security for storage and handling of such data must still be demonstrated. This is a legal duty. It includes avoiding the unnecessary duplication of electronic data sets, which increases the chances of their being misused.

In most research projects, confidentiality is a process, rather than a condition. It is important to make clear to participants what confidentiality involves and what measures will be in place to protect participants from unwanted violations of confidentiality.  For example, ensuring data are stored on a compliant platform, or in locked cupboards on campus is a way to ensure data confidentiality is not breached. Confidentially is also therefore deeply intertwined with data management, as explored below.

**2.3.2. Data Management**

Data management is a key pillar of ethical research, and researchers should familiarise themselves with the current advice on data collection, storage and deletion of data. Researchers should be aware of data protection legislation (Data Protection Act 2018 – also often referred to as ‘GDPR’). This legislation sets out mandatory rules for how personal information is to be processed. Personal information should be processed in line with the principles, including storing information securely and keeping it for no longer than necessary. Knowing what data researchers have and managing it appropriately throughout its lifecycle can ensure they are meeting these legal requirements. Researchers need to indicate how they will comply with the above legislation.

There are legal as well as ethical responsibilities to data management, as per Data Protection legislation**.** This is the same for both Personally Identifiable Data “P.I.D.” (which might be collected on consent forms or in recruitment lists) and Research Data (which might collected as part of our research activities.)'Personal data’ means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural 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 natural person. Truly anonymised data means that there is no longer any link to an identifiable natural person.

QMU also has a [Data Management Policy](https://qmu.sharepoint.com/%3Ab%3A/s/QMUResearchEthics/EZfNPVsitZxFt_pqSamSzSEB77WamZTr8CulaJMVlZw5Ng?e=b2g0FK) (due for review) and researchers should be familiar with this, as it includes a reminder that research data (raw or processed) **must** be:

* Accurate, complete, authentic and reliable.
* Identifiable, retrievable, and available, with as few restrictions as possible in a timely and responsible manner.
* Kept in a manner that is compliant with legal obligations, University policy and, where applicable, the requirements of funding bodies.
* Where necessary, adhere to NHS and NIHR data guidelines as a minimum.

The policy also provides a link to a free online Data Management Plan that helps researchers to create, review, and share data management plans that meet institutional and funder requirements.

For more specific practical concerns about Data Management, please see Section 7 of the General Guidance for Completing the Research Ethics Approval Process (REAP). Very broadly, data management will be different for each project, but all researchers should avoid using personal devices to record (e.g., Smartphones) any data as these are often unencrypted and can be lost. Similarly, it is advisable that researchers should generally not use personal computers to store data, but if they are, these should be encrypted, password protected devices. The use of portable drives such as USB sticks or external hard drives is generally not permitted, but this is complicated by research that might use video files, which are often too large to store on cloud drives. Researchers should justify the use of such data storage devices and pay extra attention to how these are kept secure and how the data is kept confidential. It is important to remember that data breaches have occurred when researchers have accidentally left computers on trains or misplaced a USB drive resulting in significant monetary penalties. As such, compliance with safe data storage - especially raw data - is very important.   Further advice on how to avoid a personal data breach and report one should it happen can be found via the intranet link here: [Personal Data Breach – Guidance for Staff.](https://myshare.qmu.ac.uk/governance/infogov/_layouts/15/WopiFrame2.aspx?sourcedoc=%7bD051486B-7AAA-4FFC-AC69-ED043632C115%7d&file=Personal%20Data%20Breaches-%20Guidance%20for%20Staff.docx&action=default)

Once data is ready to be analysed, researchers should be aware of the use of AI in data analysis – See Section 7.6 of General Guidance Document – as this will also have implications of confidentially and data protection.

**2.3.3 Data Storage and Destruction**

Identifiable data should not be stored for any length of time identified beyond the terms of the consent process. Ideally, any data retained electronically should have all personal identifying information removed (i.e., it should be fully anonymised) and where this is not possible researchers may wish to consider how to pseudonymise the data. It is advisable for researchers to justify the storage of any data stored for long periods of time (i.e., beyond a year). This especially concerns creative practice research, archivable oral history or testimony, or contributions to speech corpora, etc. in which identifiable data (such as videos, audio recordings, documents or photographs) might be kept indefinitely and shared widely

It is the responsibility of the principal researcher to store data securely for the appropriate length of time, and to ensure it is appropriately destroyed when required. Destruction can include using on-site confidential waste bins, or safe-deleting documents. Moving files to the recycle bin on computers is rarely sufficient. Deleting unused data minimises the risk of data breaches and is compliant with data management and data destruction.

In the event of staff leaving University employment, researchers should ensure to pass on ownership or transferral of data, if appropriate. This is less about the University claiming ownership of staff IP (see below for link to QMU’s IP policy), but rather about ensuring data is securely managed.

**2.3.4 Data storage for Undergraduate and Postgraduate dissertations**

Generally, as above, it is recommended that all data gathered for undergraduate or postgraduate research projects is stored on OneDrive (Microsoft) folders, via QMU login.  Additionally, as supervisors are considered the competent researcher, it is good practice that the supervisor should set-up and ‘own’ these folders and make them accessible to the student for the duration of the research. Once the student research projects have been assessed (i.e., once Board of Examiners meet), supervisors should destroy this data.

Supervisors and students should also be aware of QMU’s [Intellectual Property Policy](https://www.qmu.ac.uk/about-the-university/quality/committees-regulations-policies-and-procedures/regulations-policies-and-procedures/intellectual-property) which indicates that "All IP generated by students during the course of their studies at the University and/or using University resources (“Student IP”) will be owned by the inventor (the student who created the IP), except:

* Where, as a condition of support an external funder providing funding or other support requires that Student IP is assigned to them (for example projects involving 3rd parties and work requiring use of pre-existing University-owned IP); or
* Where the Student IP has been developed in the production of an MSc or PhD thesis or in the production of course or teaching materials, in which cases the Student IP will be owned by the University.

As such, students would not be able to access research data once graduated, and any outputs intended for public consumption should be co-authored with the supervisor who has access to the data. These outputs should be negotiated with the student and take into consideration if such work necessitates a new research ethics application – for example, if the original application did not include publication. This may include a new process of informed consent with the original participants.

**2.3.5 Academic freedom and restrictions on publication**

Whilst not within the remit of the Ethical Approval process, it is important to note that QMU policy is opposed to research that has restrictions placed on the publication of findings. These restrictions are usually placed by some funders, including some NHS, government and industry sources. Sometimes there are legitimate ethical reasons for restricting publication - for example to protect commercial interests. However, QMU’s commitment to Open Access would mean we support research that errs on the side of access, and generally the University would not support research contracts with strong clauses restricting publication. Please see the various [Concordats and Sector Good Practice,](https://www.qmu.ac.uk/research-and-knowledge-exchange/strategy-and-culture/concordats-and-sector-good-practice/concordat-to-support-research-integrity)the [Concordat on Open Research Data](https://www.qmu.ac.uk/research-and-knowledge-exchange/strategy-and-culture/concordats-and-sector-good-practice/concordat-on-open-research-data/).

Researchers should also be aware of the QMU Code of Practice for Research and KE and to Procedure for Handling Issues of Misconduct in Research and KE

**2.4 Do good (Beneficence)**

Will the research truly benefit the individual participants, or those like them? Will the research truly benefit some wider or more abstract entity such as science, knowledge, or society? Naturally, researchers generally hope the answer to at least some of these questions is ‘yes’. However, in justifying research it is important to reflect upon and respect conflicting notions of ‘benefit'. It is incorrect to assume that benefit to participants, to science, or to society is an automatic and absolute good. Contemporary disagreements abound: for example, over animal rights, over the age at which the foetus becomes a person, or the appropriate balance between eroding individual liberties and promoting safety. Goodness is therefore contextual; however, QMU aims to support research that contributes positively to the world.

Reflections around ‘beneficence’ and what constitutes ‘goodness’ can help develop and extend research objectives and when research can genuinely indicate a positive contribution to a specific domain, then this is important, and such work may justify research that might pose a risk of harm that would otherwise seem unacceptable.

**2.5 QMU’s Ethical Research Framework**

Considering the above considerations on Respecting autonomy (Dignity, Informed Consent), Non-Maleficence (Competence, Risk Assessments); Justice (Confidentiality; Data Storage); and Beneficence, all research at QMU should operate with the following framework:

* **A clear and informed participant consent process.**
* **The safety of researchers and participants.**
* **Alignment with legal frameworks for appropriate data management & storage**



The flexibility of this framework that should allow research from multiple different research domains within the University to operate effectively whilst still ensuring alignment to QMU’s Research Ethics Policy

**3. Misconduct and Data Breach**

**3.1 Researcher Misconduct**

Researcher misconduct is taken very seriously. Misconduct can consist of both negligence and accidents (for example, a data breach stemming from a stolen, unencrypted laptop). It can also consist of intentional misconduct (for example, lying to participants about how their data will be used, or stealing other researcher’s proprietary data).The UK Research Integrity Office has also provided a comprehensive definition of researcher misconduct (see pp.27-28 of this [UKRIO guidance document](https://ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf)) that researchers should review. Researchers should be aware of QMU’s Research Misconduct Management Procedure and its connection to QMU’s Code of Practice in Research and KE.

Any person can report misconduct of any sort to researchintegrity@qmu.ac.uk. The misconduct complaint will then be investigated and proceed in accordance with the appropriate University policies and principles. For staff, this may be via HR policies and/the Concordat to Support Research Integrity, of which we are a signatory. For students, the appropriate policies may relate to Academic Integrity and/or Discipline. As soon as a complaint is made, a research project will be paused whilst an investigation takes place.

If anyone thinks Research Ethics misconduct *might* be occurring, you can also contact the UREC secretariat to discuss concerns: researchethics@qmu.ac.uk

**3.2 Data Breach**

Whilst a Data Breach is considered Ethical Research misconduct, it is understood that this can also be accidental. In the event of any data breach, the research team **must** contact the Data Protection Officer (DPO) within 24-48 hours of identifying the breach. The DPO can be reached at: dataprotection@qmu.ac.uk.

It is important to note that Data Breaches can have legal and cost ramifications, so it is vital that researchers seek rapid support from the University in the event of a data breach.

**4. Process for Ethical Approval**

The ethics review process at QMU aims to be collaborative and constructive. In considering ethical issues from the conceptual stage of a proposal it is intended to enhance the quality of research and - where appropriate - increases the chances of productive funding and publication outcomes. In cases where ethical approval is not granted at the first stage, the aim is to provide feedback and a chance for resubmission to facilitate positive research outcomes for students and staff.

There are two tiers of Ethical Approval: University Level (UREC) and Divisional Level (DivREC). The reason for these tiers is to ensure each division is working within the epistemological frameworks of their domains. For example, in scientific research, anonymity might be considered essential in order to ensure that the data is not influenced by personal knowledge; however, in humanities research, demographic and personal data may be considered essential to understand the context of the domain being studied. As such, DivRECs are considered the appropriate place for each researcher within that division to seek out ethical approval.

It is important to note that whilst methodology will inevitably impact data collection, the aim of an ethical approval panel is not to critique methodology. Reviewers on both panels can provide advice, comments or suggestions on methodological concerns, but their remit is only to ensure the University’s ethical principles are being upheld.

**4.1 University Level (UREC) Ethics Application**

UREC is made up from representatives from each division. Representatives from UREC also sit within the DivRECs and the aim is for these representatives to filter down developments and learning from UREC to these panels.

UREC’s remit is to both enhance and develop ethical research at the University, as well as to review any ‘high level’ applications, such as those that engages with extremism/terrorism, participants that lack capacity to consent and overseas travel with a Crisis24 score of 3.5 and above. Further details about these areas can be found on the QMU [website.](https://www.qmu.ac.uk/research-and-knowledge-exchange/qmu-research-ethics/)

With the online ethics application process, submission to the UREC panel will be automatically triggered dependent upon the proposed research activities. Researchers may with wish to check with the Research Ethics secretariat – researchethics@qmu.ac.uk – to see if their submission would necessitate UREC review before submitting to the online portal:

**4.2 Divisional Level (DivREC) Ethics Application**

Each Division has a DivREC which is made up of members from across the subject areas and their remit is to review ethical approval applications from staff, students, PhD candidates and/or external research consultants, ensuring that research projects adhere to the Research Ethics Policy set out above, such as informed consent, ensuring PVGs are valid, checking proper data storage, etc. Information about which DivREC a researcher may submit to is available on the QMU [website.](https://www.qmu.ac.uk/research-and-knowledge-exchange/qmu-research-ethics/) See [DivREC guidance](https://qmu.sharepoint.com/%3Aw%3A/s/QMUResearchEthics/ETtWENfRzb5LvZqgRHyuzLEBnkXObnkLZt5xWCUV_V6mZA?e=nMZvK0) here for more information about suggested structure and process for DivRECs.

Membership of DivREC should be discussed and confirmed with Heads of Division and every DivREC members should all have completed training on the reviewing of REAP applications – available on the self-enrol Canvas [here](https://canvas.qmu.ac.uk/enroll/YKMKCR). Heads of Department (HoDs) and/or Research Centre Directors (RCDs) should also sit on the relevant DivREC in order to review staff applications. This would ensure good governance but also avoid conflicts of interest within the division, or a situation where a junior or less experienced staff feeling pressured to approve more senior/advanced staff applications.

DivRECs should keep an annual record of approved and rejected applications, and more information about DivRECs and their operation is available via the Guidance Document [available here](https://qmu.sharepoint.com/%3Aw%3A/s/QMUResearchEthics/EYZBYTykzOVPvMZa0KePsmwBQOyw6kChk05gOWUwqvE1Aw?e=lbKiQe).

**4.3 Appeals at DivREC or UREC level**

For local-level appeals (i.e. DivRECs) or disagreements with decisions of DivREC panel members, the DivREC administrator should forward the application to 2 (two) other DivREC panel members who will be tasked to jointly come to a decision, and this would be the final research ethics application decision at DivREC level. This decision may mean flat out rejection, and/or suggestions to resubmit. If the applicant appeals or disagrees with this final DivREC decision, the application can be recommended for review by UREC and the Convener - along with discussion with the committee – will make a final decision on the application that is final and cannot be appealed.

For appeals or disagreements with decisions at UREC level, the application will be reviewed by 2 (two) different UREC panel members who will be tasked to jointly come to a decision, and this would be the final UREC decision that cannot be appealed. This decision may mean flat out rejection, and/or suggestions to resubmit.

In both UREC or DivREC cases, an applicant that has previously been rejected from an appeal process would not be able to resubmit an application for the same project.

1. ‘Consent’ is defined as “permission for something to happen” whereas ‘assent’ is an “agreement with an opinion.” It is important the researchers are aware of this distinction, especially when working with young people in Scotland. [↑](#footnote-ref-2)