Template for New Trust Policies: In the template provided here, items in red are for completion by the author. Items in black show the structure of the document.

TRUST CORPORATE POLICY

JOINT RESEARCH MANGEMENT POLICIES

APPROVING COMMITTEE(S)	Trust Policy Committee	Date approved:	7 March 2022
EFFECTIVE FROM	Immediate		
DISTRIBUTION	All those undertaking research activities and responsible for those undertaking research activities.		
RELATED DOCUMENTS	Trust policies on data protection, risk, financial probity and HR policies on investigating misconduct.		
STANDARDS	National and international, including UK and EU legislation, MHRA, HRA and NIHR regulations and guidance. Specifics are set out in policies as applicable.		
OWNER	Director of Research Development		
AUTHOR/FURTHER INFORMATION	This paper was put together by Nick Good, R&D Projects Manager, but the original authors of the individual policies are various managers within the Joint Research Management Office (JRMO) and experts is departments across the Trust– www.jrmo.org.uk These policies have also been agreed where indicated by Queen Mary University of London (Queen Mary) on 20 October 2022 to cover joint and partnership working between Barts Health and Queen Mary.		
SUPERCEDED DOCUMENTS	Previous set of Joint Research Management Policies		
REVIEW DUE	October 2025		
KEYWORDS	Joint Research Management Policies		
INTRANET LOCATION(S)	https://weshare.bartshealth.nhs.uk/trust-wide-policies Plus: http://www.jrmo.org.uk/about-us/research-policies/		

CONSULTATION	*Barts Health*	This set of policies has been subject to a full consultation, taking up the latter six months of 2021 with individual researchers and internal business partners. It been discussed and approved by both the Barts Health Research Board and the Joint Clinical Research Board.

	External Partner(s)	This set of policies is going, parallel to this Barts Health review, through the Queen Mary University of London approval process.

SCOPE OF APPLICATION AND EXEMPTIONS	**Included in policy:**
	All Trust staff, working in whatever capacity on research
	Other staff, students and contractors working within the Trust on research
	Exempted from policy: Staff not involved in research activities

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INTRODUCTION

These core policies have been constructed to enable Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary), to develop coherent and collaborative approaches to managing their research activities and the Joint Research Management Office (JRMO). They are designed to ensure there is a clear policy framework to address regulatory and legal requirements for research managers and research-active staff.

Queen Mary and Barts Health are partners in research involving human subjects and are supported in this through a single set of policies, systems and processes via the JRMO. The UK policy framework for health and social care research, 2017 and all other related regulations and laws require all research-active organisations to have systems in place to meet their requirements. Establishing a common set of principles provides a sound basis for collaboration in research across the NHS and academic boundary, ensuring that the researchers who are often active in both organisations can work to a clear and largely consistent set of standards and policies.

These Policies have existed since 2003 and have been constructed to meet the requirements of the National Institute for Health Research, Research Support Services Framework and have been reviewed and revised as and when needed. The Policies are either individual organisational policies (where a joint policy is not appropriate or feasible) or were drafted by working groups drawn from managers in the Joint Research Management Office (JRMO), Professional Services Managers within Queen Mary and/or Group Support Services within Barts Health.

Regulatory guidelines change routinely so these policies are reviewed routinely to ensure they remain consistent with legal and regulatory requirements.

These policies should be read in conjunction with associated related institutional policies including HR, Financial Regulations and other policies relating to the governance of both Queen Mary and Barts Health.

This policy set was approved by the Trust's Policy Committee on 7 March 2022 and by Queen Mary Senate on 20 October 2022.

JRMO, October 2022.

Policy 2(a), (Queen Mary only) amended June 2024
Policy 22, (Queen Mary only) amended January 2025

STANDARD FOR RESEARCH

1: Study Set-up and Regulatory Approvals

1.1 Background

The UK Policy Framework for Health and Social Care Research (2017), sets out principles of good practice in the management and conduct of health and social care research in the UK. It is the responsibility of all researchers to ensure that all research, is conducted to the highest ethical standards and with integrity, in line with current guidance and UK legislation[1]. This Policy is applicable to research projects involving NHS staff, NHS premises, NHS data and Social Care research that come under the UK policy Framework for health and social care. For Queen Mary Research of Ethics Committee research please refer to Policy 2b (not involving the NHS).

1.2 Study Set-up

1.2.1 Research Integrity

Research integrity is at the core of the UK policy framework as described in Principle 5 Integrity, Quality and Transparency "Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency" and Principle 18, Integrity of the Care Record, "All information about treatment, care or other services provided as part of the research project and their outcomes is recorded, handled and stored appropriately and in such a way and for such time that it can be understood, where relevant, by others involved in the participant's care and accurately reported, interpreted and verified, while the confidentiality of records of the participants remains protected"

Barts Health and Queen Mary researchers must uphold the highest standards of rigour and integrity when conducting their research work ensuring that they:

- Honestly report data, results, methods and procedures, and publication status;
- Do not fabricate, falsify, or misrepresent data (See JRMO policy 7 on Dissemination and publication; and Policy 8 on Citation);
- Avoid bias in research design, data analysis, data interpretation, and other aspects of research (See JRMO Policy 24 on Misconduct);
- Arrange data management plans from the outset of the research project and throughout the work, within the framework set out by the University data management policy (Policy 11) and Trust data sharing policy (Policy 16);
- Make research findings and methods widely available to other researchers and the public in line with the JRMO dissemination and publication policy (Policy 7); and
- Declare any actual, potential or perceived conflicts of interest relating to research. and seek advice and/or to take steps to resolve them.

[1] The Royal College of Physicians (1997, updated 2007) Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects;
The Declaration of Helsinki (2000, amended 2013) Ethical Principles for Medical Research involving Human Subjects;
Governance Arrangements for NHS Research Ethics Committees, (updated 2020);
General Medical Council (1999, updated 2019) Good Medical Practice;
General Data Protection Regulation (2016);
The UK Policy Framework for Health and Social Care Research (2017, updated 2020);
The Medicines for Human Use (Clinical Trials) Regulations (2004).

1.2.2 Project registration

Research carried out by Barts Health or Queen Mary, either singly or together with external collaborating organisations, must be reviewed and recorded at project registration and arrangements put in place to ensure that oversight is maintained throughout the study. Accurate registration and well-maintained records are an essential enabler of sponsor oversight. Barts Health and Queen Mary are also host sites for research led by other partners including pharmaceutical companies, other NHS Trusts and Universities and have responsibilities to these external sponsors in this regard. Furthermore, it is a requirement of the UK policy framework for health and social care research that organisations maintain an accurate database of all clinical trial activity that involves NHS staff, patients, premises, equipment or facilities.

Accurate registration along with appropriate, proportionate review of all studies and precise record-keeping enables the following:

- Sharing of information across organisations involved in collaborative research or where a researcher holds more than one contract.
- Maintenance of confidentiality and appropriate handling of sensitive information and personal data.
- Monitoring compliance of research with the UK policy framework for health and social care research (2017), Good Clinical Practices standards and all applicable research regulations.

The overall responsibility for maintaining an accurate database of all research studies sponsored by and conducted at either Barts Health or Queen Mary sits with the JRMO. This will include research projects awarded through a successful grant application, projects submitted via the Queen Mary Faculty of Medicine and Dentistry (FMD) and all Barts Health research projects. In some instances, such as research databases and tissue banks, registration of sub-projects falling within a generic approval is delegated to the study teams for record-keeping. Database management includes data entry, verification and data cleansing.

The JRMO will share activity data with Queen Mary and Barts Health and other collaborating organisations to promote accurate recording and reporting of research activity across all research projects. The JRMO, on behalf of the sponsor, Barts Health or Queen Mary, may use information recorded on the database as a mechanism for undertaking monitoring and/or audits of GCP standards and/or research governance compliance.

It is the responsibility of all researchers to undertake the following steps to ensure that projects are properly registered:

- Comprehensive scientific peer review and institutional review are undertaken (See policy 4);
- Costing is undertaken by the JRMO (see policies 18 & 19);
- Barts Health indemnity or Queen Mary insurance is arranged (see policy 15);
- No disclosure of valuable Intellectual Property has been made (see policy 17);
- Ethical approval is sought from the appropriate Research Ethics Committee, as appropriate;
- HRA approval is obtained, as appropriate;
- MHRA approval is obtained, as appropriate;
- Any further additional regulatory approvals are obtained as required;
- Arrangements for tissue sample consent, storage, transfer and analysis are in place;
- Data storage and data security arrangements are in place (see policies 11 and 16); and
- All project documentation, as per appropriate submission SOPs, is provided to the JRMO.

1.2.3 The Sponsor Organisation

The UK Policy Framework for Health and Social Care Research states that the sponsor is "the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a "sponsor". The sponsor is normally expected to be the employer of the Chief Investigator in the case of non-commercial research, or the funder in the case of commercial research.

For health and social care research conducted by researchers at Queen Mary and/ or Barts Health, the following principles apply:

A. The sponsor organisation will, normally, be the Chief Investigator's substantive employer. However, there are some exceptions to this rule, which may relate to funding sources, the grant holder, and the intention to conduct international research. The JRMO can issue sponsorship on behalf of either Queen Mary or Barts Health, as the two institutions share a joint research misconduct policy, but the Chief Investigator must have substantive employment with either Queen Mary or Bart Health, and hold an honorary contract with the other.

B. The sponsor organisation will be either Barts Health or Queen Mary, not joint sponsorship. Additionally, neither Barts Health nor Queen Mary will agree to be a joint sponsor with any external organisation.

C. For prospective Chief Investigators not employed by Barts Health or Queen Mary, sponsorship by Barts Health or Queen Mary will *only* be considered if all of the following apply:

    (a) If the funding has been directly awarded to Barts Health or Queen Mary; and
    (b) An honorary contract is in place with the prospective sponsor organisation (Barts Health or Queen Mary); and
    (c) Written confirmation is obtained from the Chief Investigator's substantive employer's Research & Development department, confirming they have no objections to their staff member acting as Chief Investigator for the study; and
    (d) Written confirmation is obtained from the Chief Investigator's substantive employer's Human Resources department, confirming that any future research misconduct allegation will be investigated as a partnership and that the sponsor's (Barts Health or Queen Mary) recommendations will be actioned; and
    (e) Chief Investigators agree to follow all Queen Mary and Barts Health policies and SOPs regarding research, including the requirement to attend JRMO face-to-face or virtual GCP training.

D. Barts Health and Queen Mary can, under certain circumstances, act as legal representatives within the UK. If this is agreed the study will undergo and adhere to the same policy and procedures that would apply if either Barts Health or Queen Mary were the sponsor.

1.3 Ethics and Other Regulatory Approvals

Before any research activity can commence at Barts Health or Queen Mary, all applicable national and local permissions and approvals must be in place. Researchers must follow national, local and sponsor guidelines and JRMO and local SOPs to ensure appropriate applications are made to the necessary regulatory bodies.

Where a researcher is unclear whether their research requires NHS Research Ethics Committee (REC) or Queen Mary Ethics of Research Committee (QMERC) and/or other local approvals, they must seek clarification from the JRMO. Contact details can be obtained through the JRMO website.

All applications for Sponsorship and external approvals should be applied for following JRMO Procedures. Advice and guidance should be sought from the JRMO, before completion of the required form.

The Chief Investigator has overall responsibility for ensuring that the research meets the standards stipulated by the HRA, REC and the sponsor. For Barts Health and Queen Mary sponsored studies the Chief Investigator will be asked to sign a Sponsor to Chief Investigator agreement outlining their duties and responsibilities, as Chief Investigator. This includes (but is not limited to):

- Compliance with requirements to protect the rights, health & safety, privacy and dignity of research participants;
- Notification of changes to the protocol or supporting documentation to regulatory bodies and other interested parties;
- Maintaining high standards of record keeping;
- Ensuring participants have given fully informed consent (see JRMO Consent Policy 3);
- Ensuring that research is assessed following the JRMO Peer Review Policy 4;
- Ensuring full accountability for all study supplies (including trial medication, clinical equipment and devices);
- Ensuring the investigator and study team are appropriately trained in the protocol and the applicable regulations (for example, GCP and UK Policy Framework for Health and Social Care Research);
- Notification of annual reports to required bodies; and
- Agreement to register the clinical trial on a public website and to disseminate results.

For Barts Health and Queen Mary MHRA regulated sponsored studies where Barts Health or Queen Mary is the only site the Chief Investigator and Principle Investigator will be the same person. This will apply unless clear justification is given for a deviation from this policy.

1.3.1 Training

All staff engaged in delivering Barts Health and Queen Mary led studies must complete mandatory GCP training, regardless of the type of study or sponsor. The Chief Investigator and lead team (See SOP 34a Researcher training for full definitions) working on Barts Health/Queen Mary sponsored studies are required to attend JRMO training.

Staff delivering studies that are sponsored by external parties' such as commercial companies or NHS Trusts or Universities other than Barts Health or Queen Mary, may complete any GCP training that meets the sponsor's requirements (NIHR training provision is advised).

A 2 yearly GCP refresher course is mandated for all staff working on MHRA regulated studies and is recommended as best practice for all other study types.

1.3.2 Monitoring Progress

Investigators must update the JRMO during the active stage of a project ensuring that the office is provided with annual reports and safety reports, and is notified of project delays and halts, changes in project details such as amendments to protocols or other study documentation, changes to vendors or suppliers or when additional contracts with third parties are required. as directed by the relevant JRMO SOPs.

Official documents relating to a project, such as amendments to a protocol or study documentation must be sent to the JRMO as soon as possible and following sponsor and/ or JRMO procedures. Investigators must notify the JRMO at the close of a project and provide all the required closure documentation, (for example, end of trial notifications, publications and archiving arrangements) as set out in the relevant JRMO SOPs

1.3.3 Externally Sponsored Studies

Principal Investigators leading studies at Barts Health or Queen Mary, where the Sponsor and study Chief Investigator are external, must ensure that they obtain a complete study pack from the Sponsor that contains the appropriate regulatory approvals and study information. Local confirmation of capacity and capability issued by the JRMO must also be in place before commencing any study.

For all externally sponsored studies one of the following must be in place:

- A Site agreement between Barts Health or Queen Mary and the study Sponsor, using the UK model template agreement where possible is mandatory; or
- Organisational Information document (or current HRA equivalent)

These agreements will cover data protection and confidentiality, material transfer agreements and intellectual property management arrangements.

REC/ HRA approval should not be viewed as an automatic license to begin a research project. Investigators must ensure they have all the appropriate contractual agreements in place, any additional regulatory approvals and any local Barts Health or Queen Mary approvals, in particular, final JRMO confirmation of sponsorship and local confirmation of capacity and capability (as applicable) before a study can commence.

Failure to obtain the appropriate regulatory approvals and JRMO approval constitutes research misconduct and may result in formal disciplinary action being taken.

The JRMO retains the right to monitor and audit studies to ensure that all research conducted at Barts Health and Queen Mary has JRMO and the required regulatory approvals and is being delivered according to the approved protocol.

This policy applies to Barts Health and Queen Mary as indicated.

2(a): Queen Mary Policy on Research Integrity

2(a).1 Introduction

Queen Mary is committed to the highest standards of integrity and probity in the conduct of research and our procedures are aligned to those established by the United Kingdom Research Integrity Office (UKRIO). The policy covers allegations of research misconduct brought against any present member of staff of Queen Mary in respect of research undertaken while employed by the University.

2(a).2 Scope

This policy is designed to cover staff (academic and professional services supporting research) and honorary staff. It is intended to support other members of Queen Mary and those external to the organisation, to raise concerns or make complaints where the individual has a genuine and reasonable belief of research misconduct, which is in the interest of Queen Mary or of the public to be investigated.

The University uses the definition of research misconduct specified in the Universities UK *Concordat to Support Research Integrity*. This conceives of research misconduct as '*behaviours or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld'*. The forms these might take might be summarised as follows:

(i) Fabrication: the making up of results, data, or any other information presented on documentation.
(ii) Falsification: the inappropriate manipulation of research data, processes, and other materials.
(iii) Plagiarism: the appropriation of the intellectual property or work of others without their knowledge or permission.
(iv) Failure to meet legal, ethical, and professional obligations: This might be deviation from the formal protocols and regulations governing research, leading to risks of harm to people or the environment. Examples include ethics approvals and disciplinary codes of conduct. Other examples include misuse of personal data and improper conduct in peer review.
(v) Misrepresentation: This is applicable to research data, authorship, and declarations of conflicts of interests by researchers and funders.
(vi) Improper dealing with allegations of misconduct: This includes failure to investigate alleged research misconduct and reprisals against whistle-blowers.

Honest errors, which are clearly unintended and acknowledged, and differences in interpretation do not amount to research misconduct.

Allegations of research misconduct involving visiting staff will be referred to the institution that employs them.

Matters, unrelated to research conduct, pertaining to individual staff circumstances or concerns should be addressed through Queen Mary's Grievance Resolution Policy and Procedure. (https://hr.qmul.ac.uk/procedures/policies/grieve/)

It is the responsibility of the Research Integrity Committee to determine whether research misconduct has taken place. To this end, it will delegate competence to a Research Integrity

Panel. The Research Integrity Panel, following investigation, may recommend a case for consideration under University disciplinary procedures once it has made its final determination on behalf of the Committee: https://hr.qmul.ac.uk/media/hr/policies/Discipline-Policy-Updated-2021.pdf. This will be directed to the head of school and the line manager of the respondent, or another appropriate management contact. The Director of Human Resources will be informed.

Decisions about subsequent disciplinary action are a matter for the relevant disciplinary panel. However, these do not have any bearing on the final determination of the Committee or the Panel as to whether research misconduct has occurred.

2(a).3 Making a Complaint of Research Misconduct

Any person becoming aware of an allegation of potential research misconduct should immediately inform the Research Integrity Office in writing, either directly using the dedicated email address, at research-integrity@qmul.ac.uk, or through their Faculty Research Integrity lead, who are contactable through faculty research managers. The Research Integrity and Assurance Officer will ensure that the Named Person (http://www.jrmo.org.uk/performing-research/research-integrity/) is made aware and initiates the actions outlined in this procedure.

1. Where an allegation has been made orally or briefly, the Named Person will request that the complainant provides a substantive written outline of the allegation along with any supporting evidence. The complainant will be issued with a dedicated proforma. They will be asked to ensure that their complaint, in its entirety, is presented on this document.

2. Upon submission of the complaint, the Named Person, with support from the Research Integrity and Assurance Officer, will make an initial assessment of its substance. This will be based entirely on the information presented to them on the dedicated proforma.

3. If there are major concerns about immediate risk to safety, suffering to animals, negative environmental consequences (where this might contravene the law or fall below good practice), or that experimental results will be destroyed, the Named Person will take urgent action to ensure that any such potential or actual detriment, danger, illegal activity, or risk is prevented as much as possible. To ensure legal and governance compliance, appropriate advice will be obtained. On instruction, the Research Integrity Office will take steps to secure all relevant information and evidence so that it can be available to those undertaking any consequential investigation. This may include, but is not limited to:

    (i) Liaising with ITS securing all relevant electronic and physical information and records, materials and locations associated with the work.
    (ii) Liaising with Human Resources and relevant line manager(s) to:
    (iii) Request the temporary suspension of the respondent in accordance with the relevant provisions of the Queen Mary disciplinary policy.
    (iv) Request the temporary barring of the respondent from part, or all, of the premises of QMUL and any of the sites of any partner organisation(s), such as Barts Health; and/ or
    (v) Request a temporary restriction be placed on the respondent requiring him/her not to have contact with some or all the staff of QMUL and/or and those of any partner organisation(s), such as Barts Health.
    (vi) Liaising with Faculty, or clinical board, managers, review the risk that evidence could be destroyed, risk to individuals and any respondents' responsibilities for supervision, teaching and management.

4. On receipt of a substantive written allegation, accompanied by any supporting evidence, the Research Integrity Office, on behalf of the Named Person, will formally acknowledge receipt of the allegations by letter to the Complainant, with a copy of any relevant information about how their complaint will be considered. The complainant will be reminded that the information they have provided in writing, on the dedicated proforma, will define the scope of any subsequent investigation.

5. A meeting of the Research Integrity Committee will be arranged to consider the complaint and appropriate route in accordance with the UKRIO procedure. This is essentially a triaging stage before an investigation and should consider whether the complaint(s) are:

   (i) mistaken, frivolous, vexatious and/or malicious.
   (ii) should be referred directly to the organisation's disciplinary process or other internal process.
   (iii) are sufficiently serious and have sufficient substance to justify a formal Investigation.

6. The Research Integrity Committee will decide whether to convene a panel to investigate the complaint. An important consideration will be the intentionality of the alleged misconduct.

7. The Named person will, on behalf of the Committee, inform the Director of Human Resources and the Chief Governance Officer and University Secretary of all disclosures they determine an investigation is required. They will request any evidence of further, distinct instances of proven misconduct in research by the respondent, unconnected to the allegations under investigation.

2(a).4 Investigating a Complaint

Where the matter is to be investigated, the Research Integrity Committee will then determine:

- who should undertake the investigation – the Named Investigator.
- the composition of the Panel convened to investigate.
- the policy to be followed.
- the scope of the concluding report.

In deciding who should undertake the investigation, the Research Integrity Committee will check with the proposed investigator that they:

- do not have a potential conflict of interest, as defined by this policy.
- are able and willing to conduct the investigation in a timely way.
- are adequately experienced or knowledgeable about conducting investigations of this nature and are confident they have received adequate training.
- do not believe themselves conflicted in any other respect.

The Named Investigator may need to contact the respondent's substantive (primary) employer, where an honorary contract is held and the Research Integrity Office may need to contact external sponsors, funding organisations and/or collaborators, as dictated by their policies. The Named Investigator shall liaise with the Employee Relations Advisory Service relevant to the School/Institute of the respondent, to ensure that the rights of the respondent and the integrity of the investigation are not compromised by any such actions.

2(a).5 Remit and composition of a panel convened by the Research Integrity Committee to investigate a complaint of research misconduct.

The Panel will investigate complaints of research misconduct, in accordance with the University standard operating procedures, including interviews with complainants and respondents where applicable, and recommend a course of action to the Named Person. The investigative process will be led by the Named Investigator.

The Panel will be appointed for the purpose of investigating a specific complaint and will make its final determination on behalf of the Research Integrity Committee from whom its authority is delegated.

The Panel will be comprised as follows:

- At least one member of the Research Integrity Committee, who shall chair the Panel. Other members may be appointed to ensure the Panel is comprised of an odd number.
- A research integrity champion within the University with disciplinary knowledge relevant to the specific case.
- An external expert with disciplinary knowledge relevant to the specific case, if applicable.
- A representative from the partner organisation, if applicable.

The Panel should always be comprised of an odd number of members. The exact number may vary according to the expertise required for a specific case.

Administrative support will be provided to the Named Investigator and to the Panel by the Research Integrity and Assurance Officer.

The Named Investigator will be responsible for the collection of evidence, which usually should involve the conducting of interviews with relevant parties such as the respondent.

Using the evidence collected, the Named Investigator will write a draft report, with recommendations. They will present this to the Panel and take questions. The respondent will have been given the NI's report before the panel meeting and be allowed to submit comments in response for their consideration.

The Panel will formally consider the draft report presented to them by the Named Investigator. They may request revisions to it or for the collection of additional evidence.

Once the Panel has agreed a final version of the report, it will be presented to the Named Person. The report will:

- Summarise the conduct of the investigation.
- State whether the allegations of misconduct in research have been upheld in whole or in part, giving the reasons for its decision and recording any differing views.
- Make recommendations in relation to any matters relating to any other misconduct identified during the investigation; and
- Address any procedural matters that the investigation has brought to light within QMUL and/ or BHT and relevant partner organisations and/ or funding bodies.
- Ensure compliance with the scope agreed at the outset of the investigation.

In addition to reaching a conclusion over the nature of the allegations, the Panel should also, in the report, make recommendations with respect to:

- Whether the allegation(s) should be referred to the relevant organisation's disciplinary process.
- Whether any action will be required to correct the record of research (e.g., informing publishers, correcting, or retracting publications etc.).
- Whether action will be required to inform external organisations such as funders, collaborators, business partners, regulators (such as MHRA, HRA, GMC, NMC as applicable), professional bodies etc.
- Whether organisational matters should be addressed by QMUL and/or BHT through a review of the management of research; or
- Other matters that should be investigated e.g., clinical trials the respondent may have been involved in, in case of any subsequent regulatory inspection.

The Named Person will make the Panel report available to the respondent and to the complainant(s) for comment solely on the factual accuracy of the report. This is unless there are proven reasons not to arising from legal or safety concerns. Comments are to be returned within 10 working days. Modifications will only be made to the draft report where it is found to contain errors of fact. No other information will be shared with the complainant or respondent.

Once initiated the investigation will progress to the natural endpoint irrespective of:

- The complainant withdrawing the allegations at any stage.
- The respondent admitting, or having admitted, the alleged misconduct, in full or in part; and
- The respondent or the complainant resigning or having already resigned their post(s).

It might form the basis of a separate investigation, as in some instances it may be necessary to refer the matter to an external authority for further investigation.

2(a).6 Appeals by respondents

The respondent has the option of appealing against the report of the Panel. This is distinct from the outcome of its deliberations and subsequent recommendations. The grounds for appeal and the process will be explained in the outcome letter resulting from the investigation.

The grounds for appeal are as follows:

(i) Procedural irregularity in the investigation.
(ii) The emergence of new evidence that was not available during the investigation.

Appeals should be made in writing to the Named Person. The respondent should specify which of the grounds for appeal they wish to cite. They should then explain the reasons for this, providing evidence if applicable.

The appeal will be considered by an independent panel that will decide whether further action or investigation is required. If so, they will reinitiate the investigation process as described in this policy. Their decision will be based on the written information provided to them. The Panel will be appointed by the Named Person. They will not have had any previous involvement in the investigation.

2(a).7 Right of response by complainants

Complainants will have the right to provide a written response to the Named Person at the following stages of the investigation:

(i) After the initial assessment by the Named Person if a decision is taken to dismiss the complaint.
(ii) After triage by the Committee if a decision is taken to dismiss the complaint.
(iii) At the conclusion of an investigation after being notified of the outcome.

2(a).8 Reporting of Outcomes

If all or part of the allegations are upheld, the Named Person, in consultation with the Director of Human Resources, shall determine whether the matter should be referred to the QMUL disciplinary process. At this point, research misconduct will have been proven. If the allegations proceed to disciplinary processes, the report of the Panel shall form the basis of the evidence that the Disciplinary Panel receives. All the information collected and brought to light through this policy will be transferred to the disciplinary process.

The Named Person will inform the following of the outcome of their report if the allegations are upheld in full or in part:

- The respondent
- As relevant to their employment status, the Principal (QMUL), Chief Executive (BHT)
- The Director of the School, Institute or Clinical Body
- As relevant to their employer, the Research/Clinical Director
- The Academic Secretary
- If the respondent has left the University and moved on to alternative employment by another university or in a research role, the Director of Research or nearest equivalent
- The complainant(s)

When the allegations were found to have some substance, but due to a lack of clear intent to deceive or due to their relatively minor nature, the Research Integrity Committee can decide that the matter should be addressed through QMUL competency, education and training mechanisms, or other non-disciplinary processes. The Research Integrity Committee can agree remedial actions who will ensure that relevant remedial actions are taken through management structures with support from relevant School/Institute Human Resources. Any such recommendations are actioned via the Head of School, Institute, or Clinical Board if applicable. This may include:

(i) Retraction/correction of articles in journals.
(ii) Notifying other organisations involved in the research, such as funding bodies, research collaborators, industry collaborators, Queen Mary Innovations etc.
(iii) Discussion with funders about withdrawal/repayment of funding.
(iv) Notifying participants/participants' doctors of any potential medical issues that may arise, ensuring due diligence in line with reporting duties of all clinical professionals' duty of candour and duty of care.
(v) Notification of misconduct to regulatory bodies (such as the MHRA, the Healthcare Commission, the Home Office (for research involving animals), other professional bodies, etc.).
(vi) A review internal management, training, supervisory procedures for research as appropriate; and/ or
(vii) Undertaking further investigations of other projects, the Respondent was involved in (especially Clinical Trials of Investigational Medicinal Products) to assure the organisation that the data are robust and there is no evidence of research misconduct with respect to these other projects.

If the allegation is not upheld following an investigation, both the respondent and complainant will be informed of the reason for this normally within 10 working days. The final report will be shared.

Where allegations have not been upheld, the Named Person will take steps as are appropriate based on the seriousness of the allegations, to protect the reputation of the respondent and any relevant research project(s). Where the case has received any publicity, the respondent shall be offered the possibility of having an official statement released for internal and/ or external purposes.

The Research Director will submit a report of all disclosures and any subsequent actions taken to the Audit and Compliance Committee. Where the issue falls within the purview of the Committee, a detailed report will be submitted, in other cases a summary report, to allow the Committee to monitor the effectiveness of the policy. Copies of the report will be retained for a minimum of three years by the Integrity office.

2(a).9 Timescales

The investigation will be conducted to the following timescales:

- Upon submission of their proforma, the complainant will be notified of the outcome of the initial assessment of their complaint, by the Named Person, within 10 working days.
- The Research Integrity Committee will meet to triage the complaint and, if required, appoint a Named Investigator and Panel within 21 working days.
- The Named Investigator and Panel will seek to complete their work within 60 working days.
- Following the submission of the Panel report, the Named Person and the Research Integrity Committee will deliberate and notify the relevant parties of the outcome within 15 working days.

Should the Research Integrity Committee or the investigating Panel require more time for their deliberations, they will seek agreement for an extension from the Named Person. This may be necessary in cases that are particularly complex or involve external parties. The complainant and respondent will be notified accordingly.

2(a).10 Guidance on implementation of the policy

2(a).10.1 Confidentiality

Queen Mary will treat all disclosures in a confidential and sensitive manner. The identity of the individual making the allegation will be kept confidential so long as it does not hinder or frustrate any investigation. However, the investigation process may reveal the source of the information and the individual making the complaint may need to provide a statement as part of the evidence required. The individual making the complaint will be informed if it is felt that their identity needs to be disclosed or is likely to become apparent in the progress of an investigation.

Queen Mary expects the individual making the complaint and all others involved in any subsequent investigation to observe strict confidentiality in relation to the nature of the complaint, the identity of those involved and any other information relating to the investigation.
During an investigation, identifiable complainants will be provided with the following information:

- Acknowledgement of the complaint.
- Notification of the different stages of the investigation, such as the referral of the complaint to the Research Ethics Committee and the appointment of a Named Investigator and panel.
- Notification of the outcome of the investigation.

At the discretion of the Named Person, the complainant may be provided with a full or redacted version of the final report arising from the investigation. This will be determined by considerations of confidentiality and legality.

During an investigation, the respondent will be provided with the following information:

- Notification of the complaint being submitted.
- Notification of the different stages of the investigation, such as the referral of the complaint to the Research Ethics Committee and the appointment of a Named Investigator and panel.
- Notification of the outcome of the investigation.

The respondent will be entitled to a copy of the final report arising from the investigation. However, redactions may be made at the discretion of the Named Person. These will be determined by considerations of confidentiality and legality.

2(a).10.2 Support for respondents and internal complainants

Respondents and internal complainants will be made aware of the support provided by their School/Faculty management and other organisational support, such as the Employee Assistance Programme, during the investigative process. However, they will also be allocated a local Research Integrity champion unconnected to the investigation.

2(a).10.3 Suspension

The Named Person or the Research Integrity Committee may consider, in the early stages of the investigation, whether the respondent could jeopardise the progress of an investigation, for example by destroying records. If so, they can recommend that the individual should be suspended from duty. Any such suspension will be governed by policies outlined at paragraph 12 of this policy.

If necessary, the funders and other stakeholders should be notified that the respondent has been suspended.

2(a).11 Anonymous allegations

The University will examine anonymous allegations of research misconduct at its discretion, in accordance with its Whistleblowing Procedure. This will be on a case-by-case basis. In exercising this discretion, the relevant considerations include the seriousness of the issues raised, the credibility of the concern and the likelihood of confirming the allegation from attributable sources. The following approach will be used if a claim is investigated following triage:

(i) Should they provide an email address, anonymous complainants will be issued with a summary, rather than a full report, after an investigation has concluded.
(ii) Anonymous complainants will not be provided with updates during the process.

The University reserves the right not to engage with anonymous complainants, particularly if their claims are found to be vexatious, malicious or have been repeated persistently.

2(a).12 Good faith

Those making allegations of research misconduct in good faith will be afforded appropriate protections in accordance with the University policy on whistleblowing: https://hr.qmul.ac.uk/procedures/policies/pid/#. This is irrespective of the outcome of any investigation. However, the policy stipulates that those found to be making vexatious or malicious allegations may be subject to disciplinary action.

2(a).13 Conflicts of interest

All involved in the investigative process, at any stage, should declare potential conflicts of interest to the Named Person. On the basis of the information provided, the Named Person will decide whether further participation in the process is appropriate.

Conflicts of interest, in the context of a research misconduct investigation, are defined as the following:

- A close personal relationship with either the respondent or the complainant.
- A professional relationship with either the respondent or the complainant. This might include supervision or co-authorship
- A financial interest that might be affected by the outcome of the investigation.
- A professional interest that might be affected by the outcome of the investigation. This might relate to publication or funding.

Conflicts of interest do not necessary include being acquainted with a respondent or complainant or being employed in the same department or faculty.

2(a).14 Role of other professional services teams in the investigation

The role of other professional services teams is advisory only. Determining whether research misconduct has taken place is the entirely the responsibility of the Research Integrity Committee

The investigative process will be undertaken by the Named Investigator with support from the Research Integrity and Assurance Officer. However, advice may be sought from other professional services teams, such as the Academic Registry and Human Resources, on relevant matters. This is to ensure compliance with regulatory and governance requirements.

The Human Resources team will be regularly updated on the progress of any investigation in case of referral for consideration under disciplinary procedures.

The Named Person will ensure that other professional services teams are appraised of new information, that becomes apparent during the investigation, relevant to their remits.

2(a).15 Learning lessons from an investigation

Following the conclusion of an investigation, the final report will be considered by a meeting of the Research Integrity Committee. The Committee will reflect on whether the specific case has implications for research integrity best practice within the University, or for the investigative process. Subsequently, the Committee may undertake or initiate the following:

- The formulation and promulgation of new policies and procedures within the University.
- The provision of confidential high-level briefings.
- The development of appropriate training programmes.
- The sharing of anonymised information within, and beyond, the University to promote best practice and compliance.

The Research Ethics Committee will endeavour to ensure that those involved in the investigative process are provided with an appropriate programme of training.

2(a).16 Review

The Secretary to Council and Director of Research may review this policy following the conclusion of an investigation if any procedural or other problems were experienced during an investigation, or if there is a change to best practice or national guidance in respect of public interest disclosures.

The policy should be reviewed every 3 years as a matter of course.

Further information: Please see the JRMO Research Integrity webpage.

Contact: For further advice please contact: research-integrity@qmul.ac.uk

This policy applies only to Queen Mary
Revised June 2024

2(b): Queen Mary Policy on Research with Human Participants

2(b).1 Scope

All research involving human participants (including personal data or human tissue) using Queen Mary premises or facilities or conducted at external sites but led by Queen Mary staff, requires ethical approval before it commences. Queen Mary University of London regards a failure to meet this responsibility as a serious matter, which may constitute research misconduct.

Research is defined as 'the attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies." (Source: HRA).

2(b).2 Exemptions

The Queen Mary Ethics of Research Committee (QMERC) is responsible, under authority delegated by Senate, for approving the ethical standards of research involving human participants or materials derived from human participants. All such projects throughout Queen Mary should be submitted to the Committee for approval, except those research studies which fall within the remit of the NHS Research Ethics Committee, or other such recognised bodies.

2(b).3 External ethics review approval

QMERC may accept ethical approvals granted by external ethics review bodies when certain criteria are met. Reliance solely on external ethical approval must be explicitly authorised by QMERC.

2(b).4 Ethical principles underpinning the ethical conduct of research

This policy aims to ensure that Queen Mary research is conducted with honesty, integrity, and due care for the rights of participants and researchers.

Researchers must abide by the following principles:

- Participants must be treated with care, dignity, and compassion at all times;
- The design of research should provide benefits that outweigh potential risk or harm. Risks to those involved in the research must be minimised. Participants should be warned about any potential risks of harm;
- Research should not be intrusive nor otherwise compromise the integrity of the participants or those related to them, or their physical or emotional environment;
- Any incentives offered should not be such as to influence a potential participant to do anything which would be contrary to their best interests;
- Full informed consent should normally be obtained from participants to enable participants to take part voluntarily unless it would be unreasonable to do so or there is a justifiable scientific reason for deception. Informed consent should cover the research aims, research methodology and risks, and the approach to data management and the handling of the research data or findings. Consent should be given freely without force or coercion;
- Confidentiality must be safeguarded at all times: if the research requires that responses will not be confidential the participant's agreement to this must be specifically and explicitly recorded;
- Research data should be managed in compliance with the relevant Queen Mary

Data Management Policies, Queen Mary Research Data Access and Management Policy and the GDPR;

- Proposed use of the research material must be clearly stated, including possible publication and the form such publication might take;
- The research must conform to all relevant regulatory or organisational requirements in the country and institution within which the research is undertaken.
- Any actual, potential or perceived conflicts of interest relating to research must be recognised and declared. Researchers should seek advice and/or take steps to resolve them. Reference should be made to the Queen Mary Standards of Business Conduct Policy asapplicable;
- Research with children and young people:
    (i) Research with children and young people under the age of 18, and those who may not be able to give informed consent, should only be carried out with the explicit consent of a parent or guardian and with the consent or assent of a child / young person unless there are exceptional circumstances which must be approved by the QMERC;
    (ii) Research with children or any vulnerable groups must be conducted with the guidance and supervision of expert intermediaries and should be conducted in line with relevant external safe-guarding policies.

For research undertaken by students, the Supervisor is ultimately responsible for ensuring that the above responsibilities are met.

2(b).5 Process and Procedure

The Senate has granted authority to the QMERC to establish criteria, independent processes, and procedures that are proportionate to the potential risks to enact this policy and to grant approval to research according to its terms. More information about the QMERC approval routes can be found on the JRMO research ethics webpage or by contacting the Research Ethics Facilitators (research-ethics@qmul.ac.uk).

2(B).6 Review of the Policy

The QMERC is responsible for reviewing and updating this policy regularly to ensure it takes into account current guidelines and relevant legislation.

2(b).7 Oversight and Reporting

The present policy is subject to oversight by the QMERC, which reports to the Senate of Queen Mary University of London and routinely submits minutes of its meetings. This policy was approved by the Queen Mary Senate on 5th March 2020.

Contact: For further advice please contact: research-ethics@qmul.ac.uk

This policy applies only to Queen Mary.

2 (c) Queen Mary Ethical Partnerships Policy

Purpose and scope

1. This policy outlines the principles through which we ensure that our educational partnerships are consistent with Queen Mary's Purpose and charitable aims, support the achievement of the Queen Mary Strategy and embody the Queen Mary Values that underpin them. It applies to all of our partnerships that support the delivery of teaching and postgraduate research, including:

- collaborative programmes of study, research and training;
- individual modules that are delivered collaboratively;
- articulation and progression arrangements with partner institutions;
- study abroad, exchange and other mobility arrangements for students;
- placement learning, work experience and internships; and
- agreements with student recruitment agencies.

Authority

2. Senate holds responsibility, subject to the general superintendence of Council, for the academic activities of Queen Mary, including for safeguarding academic standards and the quality of the student experience, and for supporting and fostering academic freedom. Senate delegates its responsibilities in respect of educational partnerships as follows:

- Partnerships Board determines the suitability of potential partners, making reports on issues of strategic significance to Senate and the Queen Mary Senior Executive as appropriate (in practice, Partnerships Board delegates responsibility for the approval and management of agreements with student recruitment agencies to the International Office);
- Taught Programmes Board considers detailed academic proposals for taught programmes and modules that are delivered through collaborative arrangements;
- Ethics of Research Committee oversees the criteria and procedures for granting ethical approval for research.

3. Partnerships with long-term strategic significance for Queen Mary require the approval of Council, consistent with its responsibility for:

- approving the mission and strategy, as well as securing the financial sustainability, of QueenMary;
- safeguarding the reputation and Values of Queen Mary.
- providing for the general welfare of students, in consultation with Senate.

Principle 1: Integrity and ethical standards

4. Queen Mary is committed to operating ethically across the full range of its activities, thereby safeguarding its reputation, as well as that of the UK higher education sector. In addition to operating ethically ourselves, we will undertake due diligence checks and risk assessments on all potential partners, giving appropriate emphasis to the principles of:

- good governance;
- financial probity and sustainability;
- freedom from undue influence and conflicts of interest;
- compliance with legal obligations and professional standards; and

- capacity to enter into the proposed partnership.

5. The same ethical standards apply to bodies that provide sponsorship to our students, although Queen Mary's contractual relationship will be with the student in the majority of cases, rather than with the sponsor. In order to ensure that the principles outlined in this policy are put into practice, all partnerships will be governed by an appropriate written agreement and reviewed on a periodic basis. These agreements will prohibit partners from transferring or sub-contracting their obligations to others without Queen Mary's approval.

Relevant policies:

- Anti-Bribery and Corruption Policy
- Anti-Money Laundering Policy
- Environmental Sustainability Policy
- Ethical Investment Policy
- Gift Acceptance Policy
- Health and Safety Policies
- Modern Slavery Statement
- Research Integrity Policy
- Joint Research Management Policies with Barts Health NHS Trust
- Standards of Business Conduct

Principle 2: Academic standards

7. Queen Mary adheres unequivocally to its fundamental academic mission, which is to pursue the creation and dissemination of knowledge to the highest international standards, thereby transforming wider society and the lives of students and staff. To this end, we will only enter into educational partnerships that:

- support the achievement of the Queen Mary Strategy;
- contribute to and enhance the reputation of Queen Mary; and
- embody our Values and commitment to freedom of speech within the law.

8. Queen Mary holds ultimate responsibility for the academic standards of its awards and the quality of the learning opportunities of its students. The same standards apply to all our educational activities, including partnerships. In order to safeguard Queen Mary's academic standards and reputation, we will not:

- delegate final decisions on the admission of students to our programmes, or take account of factors other than academic merit and potential in admission decisions;
- delegate final decisions on the assessment of students, or take account of factors other than academic and relevant professional attainment when conferring academic credit and awards;
- enter into validation or franchise arrangements.

Relevant policies:

- Academic Regulations
- Admissions Policy
- Code of Practice on Assessment and Feedback
- Freedom of Speech Policy
- Guidelines on the Right to Privacy and the Monitoring of Data
- Intellectual Property Policy
- Quality Framework

Principle 3: Equality and diversity

9. Queen Mary is diverse and inclusive, with a proud record of nurturing and supporting the best and brightest of students, and the most talented staff, regardless of their social or economic background. We are committed to creating and maintaining a community in which all people can learn, work and interact freely without fear of discrimination, prejudice or harassment. A continued adherence to this tradition will inform our educational partnerships. To this end, we will take account of information about the commitment of potential partners to equality and diversity, as well as information about the local context and legislation, in our due diligence and risk assessment processes.

Relevant policies:

- Equal Opportunities Policy Statement
- Dignity at Work Policy Statement
- Harassment Policy

Principle 4: Engagement with local, national and international communities

10. Queen Mary is equally committed to the achievement of the highest international standards in education and to the service of its local communities through public engagement and the promotion of opportunity to individuals less favoured by financial or social background. This defining and differentiating characteristic of Queen Mary will inform the development of our educational partnerships, whether they are to embed an international dimension in our activities, to further enhance our stature as a leading global university, or to achieve maximum impact from our academic work through public engagement and partnerships. We will be respectful of local and cultural differences of approach in all our interactions with partners, nationally and internationally.

All Queen Mary policies cited above e can be found in the Queen Mary Policy Zone.

Academic Registrar and Council Secretary
October 2016

This policy applies only to Queen Mary.

ASSURING THE QUALITY OF RESEARCH

3. Consent to participate in research

The primary purpose of the policy is to ensure that for any participant taking part in research consent is considered both legal and ethical. Researchers should be able to demonstrate that the consent process is:

- Given by a person with capacity;
- Voluntarily given, with no undue influence;
- Given by someone who has been adequately informed;
- A fair choice.

This Policy should be read and acted upon in conjunction with the Trust's policy on Consent to Examination and Treatment[2] and JRMO SOP 25 Informed Consent.

Throughout this policy, the use of 'participants' means someone taking part in research, such as healthy volunteers, patients, consultees on behalf of patients etc.

3.1 Standards for 'All' types of research

Before applying to the Barts Health or Queen Mary for Sponsorship or QMERC, all researchers should:

- Ensure that template information, such as a participant information sheet, is in an accessible form (for example, that it responds appropriately to language, literacy and capacity needs). The cost of producing information in these formats should be included in the overall project costing;
- Consider the specific language and cultural needs of the study population. Queen Mary and Barts Health would particularly encourage researchers to seek advice from local community groups and Barts Health Advocacy Service. Failure to engage local ethnic minority groups may have implications for the validity of the research sample;
- Read and adhere to the current National Research Ethics Service (NRES) guidelines and templates on writing a participant information sheet and consent form;
- Read the HRA and MHRA joint statement on seeking and documenting consent using electronic methods (e-consent), if applicable.
- Should it not be feasible to contact individual participants to obtain consent, the REC must confirm that it is acceptable for the research to proceed without it. This may require SECTION 251 exemption from the Confidentiality Advisory Group (CAG).

3.2 Procedures for obtaining consent to participate in clinical research

The Health Research Authority (HRA) website and the Information Commissioner's Office (ICO) contains a range of guidelines on obtaining an individual's consent to participate in health and social care-related research which Barts Health and Queen Mary researchers must adhere to.
They include but are not limited to, ensuring that:

- Protocol(s) for research involving participants, human tissue, participant data or healthy volunteers are submitted for Research Ethics approval.
- Templates (such as participant information sheets and consent forms) satisfy standards set by the National Research Ethics Service.

[2] Barts Health Policy on Consent to Examination and Treatment, 26 March 2012: https://weshare.bartshealth.nhs.uk/trust-wide-policies

- Research is conducted openly and transparently, by:
  - (i) Informing participants of, and clearly identifying, any conflict of interest and/ or personal benefit to be gained from the research (including financial) and/ or any involvement with a commercial entity that might constitute a conflict of interest
  - (ii) Ensuring that consent covers 'consent to participate', 'consent to process personal data', 'consent to transfer personal data outside the Sponsor organisation' and 'consent to use images and tissues gathered during research', where relevant.
  - (iii) Seeking approval for the study from the sponsor and having local confirmation of capacity and capability before any participant being informed of the study or approached.

Chief Investigators and Principal Investigators leading health and social care-related research at our sites are required to ensure that all research staff working on a research project abide by the standards set by the HRA.

The following applies to all research where it is assumed that the potential participant has the legal capacity to consent.

- Consent for research should always be obtained in writing, be signed and dated by the person taking consent, the participant/ their representative and, for health and social care-related research, a witness. The same principles would apply for e-consenting but any platform/system used would need to be validated using SOP 38a first.
- The participant should receive one copy of the signed consent form, a second copy should go on the site file and, where relevant (i.e., where the research is health and social care related), a third copy should be kept in the medical notes.
- The researcher should ensure that the original consent form is stored securely.
- Written consent should be sought from the participant at the earliest opportunity.
- The best practice procedures for written consent and records storage should be followed.

More information concerning groups requiring Special Consideration is contained in Section 3.5 below).

To be able to demonstrate compliance with Good Clinical Practice & UK Policy Framework requirements the researcher must be able to show that:

- Consent was sought by someone fully trained and able to explain the nature of the research, the risks and benefits of taking part and capable of answering any questions the participant may have;
- The version of the consent form and participant information sheet used to obtain consent is the same version approved by the REC;
- The participant had ample time to consider whether to take part in the research. Time allocated should be proportionate to the level of complexity and risk of taking part in the study;
- Appropriate advocacy or interpretation arrangements or translated documents are made available during the consent process and clearly documented. Ideally, all participants requiring advocacy or interpretation should have this provided in person;
- The participant has been made aware that they may withdraw at any time without their routine care being affected;
- The participant has a contact point for further information about the study;
- Participants have not been offered inducements (financial or otherwise).

Reimbursement of expenses and moderate inconvenience allowances are permitted if declared and approved by the REC.

3.3 Research on Human Tissue

The Human Tissue Act (HTA) 2004 regulates the storage and use of human organs and tissues from the living and the removal, storage and use of organs and tissue from the deceased. Certain uses (scheduled purposes) require appropriate consent. Please refer to the separate policy on consent under the HTA held within the Trust/University HTA designated Individual policies.

3.4 Groups for special consideration

There are several groups of potential participants whose inclusion in research requires special consideration. These include but are not limited to:

- Children
- Adults lacking the capacity to consent
- Participants in emergency situations
- frail elderly people,
- those living in institutions
- pregnant women

When planning research involving these populations, researchers should seek advice from the Governance section, JRMO and JRMO SOPs, all applicable regulations and guidelines and ensure the use of guardians, parents, personal, legal and professional representatives, as appropriate.

Individuals lacking the capacity to consent may be included in research only if it relates to their condition and the relevant knowledge could not be gained through research on persons able to consent. Please see the Mental Capacity Act (2006), for further information. Where possible and appropriate if a participant regains capacity their consent should be sought and wishes respected.

Where participants lack the legal capacity to consent, REC-approved procedures for seeking consent from professional/personal consultees should be followed.

Further Information may be obtained from:
1) JRMO Governance Section via research.governance@qmul.ac.uk
2) HRA website: www.hra.nhs.uk/
3) Medicines & Healthcare Products Regulatory Agency: www.mhra.gov.uk

This policy applies to both Queen Mary and Barts Health.

4. Review of research including peer review

4.1 Purpose

The purpose of this Policy is to ensure that Barts Health and Queen Mary have a peer review process that is robust and rigorous, but also appropriate and proportionate to the type, scope and nature of any given clinical research study. The UK Policy Framework for Health and Social Care states that it is the sponsor's responsibility to have adequate peer review systems in place, proportionate to the research activity.

Scientific peer review is the process of assessing the quality of a research proposal or study protocol for its academic and clinical relevance, appropriate design and methodologies and scientific rigour. Research conducted under the auspices of, or on the premises of, Queen Mary and Barts Health should always strive to be of the highest quality and integrity.

In addition to scientific review, Review Committees must be established by Clinical Boards (Barts Health) and Institutes (Queen Mary) and they are responsible for conducting several other components of a review (see below). These reviews should be initiated before, or alongside, the submission of an application to the Joint Research Management Office (JRMO) for sponsorship, regulatory approvals or research site approval. The Review Committee that leads the review of any given study should be appointed by the Clinical Board or Institute within which the Chief Investigator holds substantive employment, though this may not necessarily be the place where the research is proposed to take place (the research site).

Accountability for and oversight of the scientific peer-review process and resource and capacity assessment will remain with the Institute Director (Queen Mary) or the Clinical Board Director of Research /or delegated Specialty Clinical Leads (Barts Health).

Responsibility to obtain the approval from the appropriate Review Committee lies with the Chief Investigator and failure to so do, or falsely claiming that this is in place, may constitute research misconduct (see *Policy 24: Research Misconduct*).

4.2 Scope

This policy applies to all staff and students at Queen Mary (primarily School of Medicine & Dentistry) and Barts Health, who are conducting clinical research, and external staff using Barts Health or Queen Mary as a research site for their clinical research. Note: for students of Universities other than Queen Mary, primary responsibility for the quality of the research lies with the educational institution issuing the qualification.

For the purposes of this policy, the term 'review' can refer to various aspects of the review process, including scientific peer review of the quality of the research protocol, the relative merits of the research, feasibility and likelihood of successful delivery, resource and capacity assessment.

4.3 Aspects of Review

For clinical research involving human participants, each Clinical Board, Institute or School must ensure that the following aspects are reviewed for every study before confirming approval or support to conduct the research within their jurisdiction. (Note: this is not an exhaustive list and more information is given in SOP 14 and Associated Documents):

- Departmental approval of funding – should include details of the grant application; availability of sufficient funds and confirmation of departmental capacity to underwrite any unexpected costs or shortfalls.

- Confirmation of appropriateness of the scientific peer review – if a scientific review has occurred as part of the grant application to a funder listed as a member of the *Association of Medical Research Charities (*AMRC), this is sufficient. If scientific peer reviewers have been identified through other means, the Review Committee should confirm the suitability of the chosen reviewer(s) to appraise the study, taking into consideration their degree of independence.[1] Subsequently, the Review Committee needs to consider the reviewers' comments and whether, if necessary, they have been suitably addressed by the Chief Investigator. The amount and independence of the scientific peer review should comply with JRMO SOP 14.

- Reputational risk to the organisation – assess perceived risks to the sponsor organisation, and if appropriate the proposed research sites delivering the study, with regards to:
  (i) highly sensitive, controversial or security-sensitive topics;
  (ii) Chief Investigator and study team experience and expertise (specifically concerning institutional risk, as opposed to the appropriateness of the team to deliver the study);
  (iii) the likelihood of successful delivery and completion (considering previous audits if applicable);
  (iv) past performance of Chief Investigator and study team, including registration and reporting of previous studies; and
  (v) potential conflicts of interest and mitigations.

- Protocol review – assess the risks and benefits, departmental strategic fit, practicalities and feasibility.

- Training and expertise of the researchers – assess the appropriateness of the Chief Investigator and study team to coordinate, deliver, monitor and oversee the research study.

- Capacity and Capability departmental approval – this is a resource and capacity review by the department conducted when Queen Mary and/or Barts Health is also a research site in the study. To assess the availability of adequate resources, including departmental capacity and infrastructure to ensure the research is conducted and completed.

4.4 Establishing Review Committees

The Institute Director (Queen Mary) or the Clinical Board Director of Research /or delegated Specialty Clinical Leads (Barts Health) should:

- Identify individuals that will be responsible for reviewing research proposals for studies to be conducted in their areas;
- Adopt specific terms of reference (advice on the content of these and a template guide can be obtained from the JRMO);
- Ensure that the responsibilities of researchers and the Review Committee are explicitly recorded;
- Outline appropriate appeals, complaints and escalation process; and
- Ensure the procedures of the Review Committee align with the standard operating procedures of the JRMO, and publicise relevant JRMO SOPs to researchers in their area.

In establishing the Review Committee, a Chair (and Deputy) should be appointed, with consideration given to that individual's experience, expertise and capacity. Adequate administrative support is essential to the success, function and effectiveness of a Review Committee and so it is advised that specific work time allocation for the position of Secretary is given in a suitable role.

Additional guidance on establishing Review Committees is available from the JRMO in SOP 14 and Associated Documents.

4.5 Review Committee Composition

The Review Committee must be comprised of individuals that have a sufficient range of knowledge, expertise and experience to address all the relevant criteria being reviewed.

In undertaking reviews regarding resource and capacity, reviewers should be able to address the practicalities of conducting a specific study within the organisation, its cost, impact and the capacity of the department or research group to deliver the project. Furthermore, it should consider the impact on routine clinical caseloads for research-related services and clinical departments inputting to the research such as Radiology, Pathology, Pharmacy, Lung Function and Clinical Physics.

The Review Committee should assess the scientific peer-review process and the suitability of the selected scientific peer reviewers. Scientific peer review should be carried out by individuals who are independent of the research;[3] qualified to make a judgment about the scientific quality, relevance and probity of the research; and the clarity of the protocol.

4.6 Review Committee Process

The Chair of each local Review Committee, or their designated deputy, should ensure that staff and students are aware of the following: a) how to submit research for approval, including contact details for queries and assistance; b) the frequency and dates of meetings; c) the expected review time for applications; d) outcome dissemination procedure; e) appeals, complaints and escalation procedure; and f) any other special arrangements that may apply.

4.7 Review Committee Reporting

The Review Committee is expected to keep up-to-date and accurate records of the applications submitted for approval. The JRMO reserve the right to request access to records and reports at any given stage, including the option to audit.

This policy applies to both Queen Mary and Barts Health.

[3] A guide on who can act as an 'independent' scientific peer reviewer, as proportionate to the type and nature of a research study can be found in the SOP 14 AD1 Review of Research Guidance document.

5. Public involvement in research

5.1 Background

> "Every day, hundreds if not thousands of patients and the public go the extra mile to help make research happen in the UK. Their contribution is many and varied. One of the most important ways in which they make a difference to what we do is by improving the quality of research, how it is designed, conducted and delivered. Within the NIHR, such is the extent to which the public has become involved that research is increasingly becoming a joint venture between patients and the public, researchers, clinicians and health professionals. If we are to meet the health and social challenges of the future then these partners must be empowered, encouraged and supported to work even closer together."[4]

5.2 Definitions

Public Involvement (also known as **Patient and Public Involvement [PPI]** or **Patient and Public Involvement and Engagement [PPIE]**)

The NIHR defines 'public involvement in health and social care research' as research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. This includes, for example, working with research funders to prioritise research, offering advice as members of a project steering group, commenting on and developing research materials, undertaking interviews with research participants.

When using the term 'public' we include patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. Whilst all of us are actual, former or indeed potential users of health and social care services, there is an important distinction to be made between the perspectives of the public and the perspectives of people who have a professional role in health and social care services[5].

Public Engagement

Within NHS research, public involvement is viewed as being different to public engagement, which is when information and knowledge about research is shared with the public[6]. Read the HRA's Transparency Agenda for further information.

It is important to note that 'public engagement' is a term that is widely used in a variety of sectors, from arts and heritage to science policy and local government, as well as universities and research funders like UKRI and Wellcome. In these contexts, it "describes the myriad of ways in which the activity and benefits of higher education and research can be shared with the public. Engagement is by definition a two-way process, involving interaction and listening, with the goal of generating mutual benefit."[7]

Additionally, Queen Mary University of London uses the term 'public engagement' to encompass all other terms referred to here.

[4] NIHR Going the Extra Mile 2014
[5] NIHR (2021) Briefing Notes for Researchers
[6] NIHR (2021) Briefing Notes for Researchers
[7] National Coordinating Centre for Public Engagement

For the purpose of this policy, the term 'public involvement' also broadly encompasses 'public engagement', 'co-production', 'user or patient-led research' and 'participatory research' although it is acknowledged that variations in practice exist.

5.3 Why is public involvement in research important?

Public involvement can influence research in many positive ways:

- In the identification and selection of research topics
- Informing project design and research methods
- Improving recruitment and data collection
- In the analysis and dissemination of results
- Informing the translation of research into real-life benefits
- Increasing the likelihood of securing research funding

Other benefits for people who get involved:

- Learning about research and health conditions
- Having more informed control over their health
- Developing new skills and gaining new perspectives

Benefits for the public more broadly:

- Improved trust in science, research and healthcare
- Ensures different ethical issues have been considered
- Ensures research is carried out for the public benefit

Public involvement ensures all communities are included in the research process, helping innovations in healthcare to be meaningful and ethical. The involvement of the public in research can empower individuals, give the research greater credibility and help bring about developments that will lead to more sustainable change. Staff, participants in research, and the public, in general, can help to ensure that standards are understood and met[8].

The purpose of this policy is to ensure that staff undertaking research, at Barts Health and Queen Mary:

- Are aware of their responsibilities in involving the public in their research.
- Are suitably trained and supported to effectively engage and involve the public in their research.
- Aspire to best practice in the different ways they involve the public in their research.

5.4 Policy

This policy applies to all research that is led by or involves significant input from Queen Mary or Barts Health staff, honorary employees, short term appointees, volunteers and visiting staff using Barts Health patients or the staff, premises or facilities of the two organisations, for their research.

- Research, and those pursuing it, should uphold the principles[9] and standards[10] underpinning public involvement to ensure research is representative of the diversity of human society and conditions and the multicultural nature of society. It should take account of age, disability, gender, sexual orientation, race, culture and religion in its

[8] UK Policy Framework for Health and Social Care, 2017
[9] NIHR Going the Extra Mile, 2014; p13
[10] UK Standards for Public Involvement

design, undertaking, and reporting. The body of research evidence available to policymakers should reflect the diversity of the population.

- Healthcare research should be pursued with the active and meaningful involvement of patients, service users, families, carers and the public, including where appropriate those from under-served groups. There is no single definition for an under-served group; it will depend on the population, the condition under study, the question being asked by research teams, and the intervention being tested. No single, simple definition can encompass all under-served groups.[11]

- Those undertaking public involvement in research should be suitably trained and supported to engage in meaningful ways with patients, service users, families, carers, community groups and the public.[12] Further information about PPIE training opportunities is available via local PPIE leads (see below for contact details).

- Patients, service users, families, carers, participants and the public should be involved, where possible, in the design, conduct, analysis and dissemination of research and also in the strategic direction and setting of research priorities.

- Members of the public involved in research should be recompensed or rewarded in line with established good practice. Public involvement activities should be appropriately costed and funding must be secured to ensure that out of expenses and payment for involvement can be met.[13]

- Once established, the results of research should be disseminated to the research community, study participants and the general public. Special arrangements should be made to ensure access to information for those with a low level of literacy, English as a second language, or a disability. Members of the public involved in your research will want to ensure that the findings are widely disseminated so they can influence and change practice for the better[14]. Public involvement can help to identify how research outcomes could be communicated. Public contributors can assist with the production of plain English summaries and facilitate the dissemination of these by providing access to patient and community groups. The results of the study or clinical trial can, therefore, be shared appropriately to ensure that the right people and organisations have been involved.[15] For further information, see Section 7 Dissemination Policy.

Queen Mary and Barts Health researchers should seek input from local Patient and Public Involvement and Engagement (PPIE) leads, patient or interest groups, as well as regional and national advisory bodies. Current guidance should be sought and followed on recruitment, training and involvement of the public in the activities of individual research groups as well as in Queen Mary and Barts Health corporate activities, such as Clinical Governance or Modernisation groups.

Further advice and guidance can be obtained from:

Research Engagement Unit, Research Development, Barts Health NHS Trust,
Education Centre, Newham University Hospital, Glen Road, London E13 8SL
T: 020 7363 8923/ 07901 009069

[11] NIHR CRN INCLUDE Guidance, July 2020
[12] NIHR Learning for Involvement
[13] NIHR Payment guidance for researchers, Jul 2021
[14] NIHR (2021) Briefing Notes for Researchers
[15] Health Research Authority, Research Transparency

E: patientsinresearch.bartshealth@nhs.net
W: jrmo.org.uk/public-involvement/

Centre for Public Engagement, Queen Mary University of London
CB100, Queens' Building, Mile End Road, London, E1 4NS
T: 020 7882 6115
E: publicengagement@qmul.ac.uk
W: www.qmul.ac.uk/publicengagement/

NIHR Research Design Service, London
E: ppi@rdslondon.co.uk
W: www.rds-london.nihr.ac.uk/patient-public-involvement/

NIHR Centre for Engagement and Dissemination:
E: ced@nihr.ac.uk
T: 020 8843 7117

NIHR website: www.nihr.ac.uk/health-and-care-professionals/engagement-and-participation-in-research/involve-patients.htm

HRA website: www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/

This policy applies to both Barts Health and Queen Mary.

RESEARCH INFORMATION

7. Dissemination and publication

This policy remains subject to review by Queen Mary Library Services.

7.1 Background

The Research Councils UK (RCUK) and the Higher Education Funding Council for England (HEFCE) have issued a joint statement to set out the principles regarding greater open access to published research. This included outlining their shared commitment to maintaining and improving the capacity of the UK research base to undertake research activity of world-leading quality and to ensure that significant outputs from this activity are made available as widely as possible both within and beyond the research community. [16]

The UK policy framework for health and social care research, 2017 requires public sector organisations to actively disseminate the findings of their work to appropriate public sector, academic and public audiences. Effective dissemination is also an important means of raising the profile of an organisation, enhancing the recruiting and retention of staff and improving academic and clinical practice.

This policy should be read in conjunction with Policy 11, Research data management. Its purpose is to ensure that staff undertaking research at Queen Mary and Barts Health are:

- Aware of their responsibilities in publishing and promoting their research activity
- Suitably trained to effectively transmit information to other public sector bodies, academic professionals, the public in general as well as patients and their advocates; and
- Supported to identify suitable mechanisms for dissemination by relevant Queen Mary and Barts Health departments.

7.2 The Policy

This policy applies to all research which is led by or involves significant input from Queen Mary or Barts Health staff, honorary employees, short term appointees and visiting staff using Barts Health patients or the staff, premises or facilities of the two organisations, for their research.

All research-active staff are required to abide by the principles of this policy and guidance on publishing research set out in UK and EU Regulations[17] by professional and funding bodies[18].

Before research is initiated:

- Bids for research funds from income streams held by Queen Mary, Barts Health or associated charitable, government or commercial organisations, should include a broad dissemination strategy, encouraging quality research to be widely

[16] For detailed information regarding this please see the RCUK website www.rcuk.ac.uk

[17] Medicines for Human Use (Clinical Trials) Regulations, 2004 (and all its amendments) and EU Directive 2001/20/EC & GCP Directive 2005/28/EC and data protection laws.

[18] GMC Good practice in research and Consent to research (2010)

Committee on Publication Ethics (COPE) Guidelines on Good Publication Practice

disseminated and freely accessed.

- During a research project, investigators should maintain a list of peer-reviewed publications, presentations and other dissemination outlets e.g. briefing papers for commissioners or service managers and make this available to the JRMO in an appropriate electronic format if required; and
- To avoid disputes over attribution of academic credit, it is suggested that, at an early stage, it should be agreed who will be credited as authors, contributors or otherwise acknowledged in the publication. This should where possible, be documented in the project protocol or outline. Special attention should be given to external collaborators and any funder acknowledgements.

Upon completion of the project:

- Investigators should report results in a way that is transparent and open to audit. Researchers will normally produce publications in academic journals. However, Queen Mary and Barts Health seek to encourage a broader approach to dissemination that includes dissemination:
    - Within the organisations
    - To professional audiences
    - Of appropriate findings to commissioners and / or service managers
    - To patients, carers or members of the public taking part in the research
    - Of information to the wider general public
- Investigators may seek advice from Queen Mary or Barts Health Communication Departments on the most effective media to use including language, format and style. Information for patients, in particular, must take account of the language and literacy needs of the local population. It is important to ensure that participants are informed according to plans described in regulatory approved documentation. Advice may also be sought from the Patient Advice and Liaison Service on these issues.
- For clinical results, particular consideration should be given to the dissemination of adverse findings to participants, those responsible for their care, the research sponsor, funding agencies and other organisations with a remit for public safety such as the Medicines and Healthcare Products Regulatory Agency. All efforts should be made to ensure that patients are informed of results before dissemination to the popular media, particularly where there are clinical implications.
- Dissemination strategies must not breach confidentiality agreements and contractual terms where research is externally funded. However, Queen Mary and Barts Health would normally expect that external contracts do not unnecessarily restrict the organisation's publication rights. Contracts and Costings officers and investigators should also ensure that the potential to protect and exploit intellectual property is not compromised by dissemination plans. Such plans must allow for publication to be delayed allowing time for the filing of patent applications or for other forms of protection to be put in place. For advice on Intellectual Property issues, investigators should contact the Innovation and Enterprise Unit at Queen Mary.
- When disseminating research findings researchers should ensure that details of individual participants are not disclosed, unless the participant has given explicit prior consent.
- Research active staff should ensure that claims of authorship are justified. Where publications involve more than one author, the list of authors must conform to accepted good practice: authorship should be in line with the degree of input to the paper and the project upon which it is based. Conflicts of interest (that is, those which, when revealed later, would make a reasonable reader feel misled or deceived) must be declared to editors by researchers, authors and reviewers.[19]

[19] GMC Conflicts of interest - guidance for doctors September 2008, Queen Mary - Standards of Business Conduct, Barts Health NHS Trust - Standards of Business Conduct (Including declaration

- In citations, researchers should ensure that they appropriately reference their employer in any publication. Queen Mary and Barts Health staff must adhere to the Instructional Citation policies (see 8 below).
- Participants expect that they will be given access to the results of a study and sponsors or investigators should normally provide them. Sponsors or chief investigators are expected to explain how participants will be able to access this information when it does become available and when to expect this. This information can be communicated to participants in many different ways and this is a decision for the sponsor or the chief investigator. Study results could be communicated by:
    - post in a letter or newsletter
    - email
    - DVD
    - Website

Source: HRA Guidance

7.3 Publication

The JRMO should be notified of any outputs of the research such as guidelines, publications, presentation, changes in service delivery etc. before external submission or presentation.

If research misconduct or data integrity concerns have been raised, the JRMO, as sponsor, with senior management of the affected organisation, reserves the right to review, request a hold on publication submission or to refuse permission to publish.

Further information can be obtained from:
Committee on Publication Ethics
BMJ Publishing Group
BMA House, Tavistock Square, WC1H 7JR

Tel:	020 7383 6602
Website:	www.publicationethics.org.uk
Email enquiries:	cope@bmjgroup.com

This policy applies to both Queen Mary and Barts Health.

of interest)

8. Citation (open access)

This policy has been developed in response to the need to develop a standard citation policy for research publications and grant applications as well as the dissemination of research findings. It builds on a policy first adopted by Queen Mary for RAE 2008. This was reinforced in October 2011 for REF 2014, with updates in August 2013, when Queen Mary University of London was adopted as the institution's legal name, and in December 2013 to amend the arrangements for monitoring and follow-up action. It is equally relevant that Barts Health employees adopt a standard citation policy in the light of Barts Health's merger in 2012 and subsequent legacy and identity issues.

It is important for our continuing success that the use of the relevant organisation's correct name is consistently used, so that all citations to the work of our researchers are recognised, and more generally so that all of the contributions to the reputation of the institution by our researchers combine effectively.

8.1 Acknowledging Queen Mary and Barts Health

In all public events, presentations and debates involving staff discussing work undertaken as an employee of Queen Mary or Barts Health, participants must make clear that they work for either:

Queen Mary University of London
Or:
Barts Health NHS Trust

Such activities might include attendance at conferences and seminars, TV and radio interviews, articles and quotes for newspapers, posters and event notices, online communications and debates etc. All research and academic debate in whatever form undertaken by staff must be associated with the name Queen Mary University of London or Barts Health NHS Trust, as applicable. In all correspondence, email or otherwise, concerning media appearances, public engagement or associated activities, staff must use a signature that makes it clear that they work for either Queen Mary University of London or Barts Health NHS Trust, as applicable. This includes ensuring that Queen Mary University of London and/ or Barts Health NHS Trust is clearly visible on websites, email addresses and signatures and business cards.

While other affiliations (schools, faculties, research institutes, centres, etc.) may be included, Queen Mary or Barts Health must appear in a prominent position.

8.2 Queen Mary -specific policy

8.2.1 Citing Queen Mary for research purposes

Similarly, all research publications and outputs by Queen Mary employees must make it clear that they work for Queen Mary.

The policy for citing the name of the university in research publications and grant applications applies to all academic and research staff (including honorary staff) and to students whose research outputs are the result of research undertaken and funded through grants awarded to Queen Mary, and via the use of Queen Mary resources and facilities. It is not acceptable to drop the Queen Mary name because the affiliation is considered too long.

How to cite Queen Mary University of London for research purposes

Research outputs by Queen Mary authors are indexed in Web of Science under more than thirty different institutional names. Thomson Reuters, the publisher of Web of Science, reported that the comma previously used in the name of the university (Queen Mary, University of London) added to the problem by splitting the name into two parts. It states unequivocally: “authors must present their addresses as Queen Mary University of London without the comma. “

The use of impact case studies for REF makes it similarly crucial that the University's name is associated with the work of its academic staff in the public arena. The consistent use of the name is essential if all relevant research outputs and grants are to be credited to our Units of Assessment. This will, in turn, ensure that Queen Mary can maximise its academic reputation as well as the financial rewards of REF and other forms of success.

For the purposes of research publications, therefore, researchers must ensure that you do not use a comma after Queen Mary. The name must be cited as:

Queen Mary University of London

This title must be used as the institutional address on all forms of research outputs and grant applications, irrespective of where the affiliation appears.

It should be recorded as near the beginning of the affiliation as possible to maximise citation impact. It will be the responsibility of each researcher to ensure that the affiliation details are correctly recorded.

Examples of acceptable citations:

- Researcher name, Queen Mary University of London
- Researcher name, Barts Cancer Institute, Queen Mary University of London
- Researcher name, School of Physics and Astronomy, Queen Mary University of London, Mile End Road, London E1 4NS
- Researcher name, Blizard Institute, Barts & The London School of Medicine and Dentistry, Queen Mary University of London, Turner Street, London E1 2AD

It is recognised that for some publications, for example, those produced by large consortia governed by contracts, this change may involve external negotiation: those affected should contact Emma Bull, Director of Library Services, and give details of the expected timescale for the change.

Researchers should recognise that not following this policy will damage our ability to maximise our return to the REF and other monitoring exercises.

8.2.2 Monitoring

Because there are significant costs to the university (both in terms of REF results, reputation and financial outcomes) of staff failing to follow this policy, QMSE has asked the Director of Library Services to monitor ‘pub lists’ and other sources to ensure that staff use the appropriate citation format. The Joint Research Management Office will not allow grants to be processed if they do not follow this policy. The Communication team will be monitoring the online and press environment to note how Queen Mary academics are identifying their affiliation.

Staff who do not consistently identify themselves as working for Queen Mary University of London in public presentations or use the citation policy described above will be reminded of this policy in a letter, copied to their Head of Institute or School and the faculty Vice-Principal and Executive Dean. In the case of persistent non-compliance, the faculty VP and Executive Deans may impose a financial penalty on the relevant school or institute.

There are potentially significant costs to Queen Mary if research appears under a range of different institution names, as this affects citation data and hence potentially REF results, reputation etc. Given the exceptional importance of this policy, we expect all schools, institutes and professional services to take the necessary steps to support staff in promoting their affiliation with their employer.

Contact for questions about this policy

Please contact the Library Research Support team at
scholarlycommunications@qmul.ac.uk

8.3 Barts Health -specific policy

8.3.1 Citing Barts Health for research purposes

Similarly, all research activities undertaken by Barts Health employees must make it clear that they work for Barts Health NHS Trust.

The policy for citing the name of Barts Health NHS Trust in research publications and grant applications applies to all Barts Health staff (including honorary staff). It is not acceptable to drop the Barts Health NHS Trust name because the affiliation is considered too long.

How to cite Barts Health NHS Trust for research purposes

The consistent use of the name is essential if all relevant research outputs and grants are to be credited to Barts Health which will ensure that it can maximise its reputation for research and clinical excellence.

For the purposes of research publications the name must be cited as:

Barts Health NHS Trust

This title must be used as the institutional address on all forms of research outputs and grant applications, irrespective of where the affiliation appears.

It should be recorded as near the beginning of the affiliation as possible to maximise citation impact. It will be the responsibility of each researcher to ensure that the affiliation details are correctly recorded.

Examples of acceptable affiliation:

- Joe Bloggs, Barts Health NHS Trust
- Jane Bloggs, Communications Manager, Barts Health NHS Trust
- Bo Wang, Cardiovascular Services, Barts Health NHS Trust

It is recognised that for some publications, for example, those produced by large consortia governed by contracts, our preferred citation format may involve some negotiation with

external bodies, both funders of research, particularly the National Institute for Health Research and other partners.

8.3.2 Monitoring

Staff who do not consistently identify themselves as working for Barts Health NHS Trust in public presentations or use the citation policy described above will be reminded of this policy in a letter, copied to their Clinical Board Group Director and Barts Health's Medical Director. Persistent non-compliance may result in further action being taken by Barts Health.

This policy applies to Queen Mary and Barts Health as indicated.

9. Use of participant information for research

9.1 Background

The UK General Data Protection Regulation (GDPR)[20], Data Protection Act 2018[21], Caldicott Report[22], UK policy framework for health and social care research, 2017[23], ICH-GCP[24], funding and professional bodies[25] have all issued guidance on how patient information for research should be gathered, handled, stored and disclosed.

The purpose of this policy is to ensure that Barts Health and Queen Mary staff undertaking research that uses research participant information are aware of their responsibilities concerning the use of existing medical records, as well as the creation of a new hard copy or electronic patient records for research.

9.2 The Policy

This policy covers the following areas:

(i) Use of existing records to identify or enrol participants in a study.
(ii) Obtaining and storing participant data for research, or retrospective note-based studies.
(iii) The compilation, handling, audit and storage of research documentation utilised for research.
(iv) New or existing electronic files of research participant information for research.

General Guidelines

- Data must be kept and shared in keeping with the details supplied in the original ethics application.

- Organisations outside Barts Health, including Queen Mary, wishing to access personally identifiable data for research must comply with Barts Health Information Governance, confidentiality and information security policies.

- Only members of the patient's care team should have access to patient records and make first contact with patients before any consent being taken (except for section 251 exemption).

- Participant information used for research whether it is existing records or records created purely for research must conform to accepted standards laid out by the Health Research Authority (HRA), EU and UK law, professional bodies and funding organisations regulations. All staff must make sure that they are aware of these standards before commencing a research project.

[20] UK GDPR
[21] Data protection laws.
[22] Caldicott Committee (2013) Report on the Review of Patient - Identifiable Information
[23] Department of Health (2004) Research Governance Framework for Health & Social Care, 2017 and The Department of Health (2003) Code of Confidentiality.
[24] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996.
[25] MRC Guidelines for Good Clinical Practice in Clinical Trials, 1998. Safeguarding Good Scientific Practice (1998) Joint Statement by the Director General of the Research.

- Costs of providing a Medical Records and Archiving Service must be included in the research project costing for externally funded research.

- The confidentiality of records that could identify individual participants should be protected. Where data is needed for research investigators should comply with data protection principles, specifically the principles of:

    - Lawfulness, fairness and transparency.
    - Purpose limitation.
    - Data minimisation.
    - Accuracy.
    - Storage limitation.
    - Integrity and confidentiality (security)
    - Accountability.

- Records made for one purpose, such as the provision of care, should not usually be disclosed for another purpose without the patient's consent. Investigators asked to supply participant information for research should assure themselves that the patient has given explicit consent wherever this is practicable.

- Where it is not practical for the person that holds the records to obtain consent or to de-identify records, data may be supplied for research. However, participants must be informed that:

    - Their records may be disclosed to persons outside the team which provided their care.
    - The purpose and extent of the disclosure.
    - That the person given access to the records is bound by confidentiality.
    - That they have a right to object and their objection will be respected unless there is a significant public interest to be served.
    - They can opt-out from the use of their data for research or planning purposes, in line with the recommendations of the National Data Guardian. They can view or change their national data opt-out choice at any time.

- Where the intention is to access confidential patient information without consent or by staff who are not members of the patient's care team in England and Wales, Confidentiality Advisory Group (CAG) approval must be in place before records are accessed. CAG application forms will also require Caldicott authorisation.

- Where a clinician or an academic controls access to personal information on research participants they must not allow access to any staff member unless they are members of the patient's care team and:

    - The person has been properly trained.
    - Appropriate ethical and Barts Health/ Queen Mary approval has been obtained.

- The person is subject to a duty of confidentiality Records used for research are NOT the property of the Investigator or researcher but the property of the sponsor or institution. They must, therefore, be stored, handled and reported in a way that means they are accessible to:

    - Other clinicians responsible for the care of the patient.

- Monitors from approved regulatory, funding and sponsor organisations.
- Other academics or academic organisations who, under funding body rules, have a use for the base data collated by Queen Mary or Barts Health researchers for future research projects[26].

- All records used for research must conform to The National Health Service Litigation Agency (NHSLA) Risk Management Standards[27], Barts Health and Queen Mary Information Security and Management Policies.

- All research projects submitted to JRMO will be reviewed to ensure consistency with data protection laws and local policy requirements[28]. They will also receive a review by the Health Research Authority who check for compliance against all data protection laws.

- Researchers must conform to Barts Health and Queen Mary data protection policies and should seek guidance, when required, from the JRMO and Barts Health and Queen Mary Information Governance teams.

Patient's care team

- For the purposes of this policy, the definition of "care team" is that used by the Health and Research Authority and come from The Information Governance Review in 2013 by the National Data Guardian which stated that 'direct care is provided by health and social care staff working in 'care teams', which may include doctors, nurses and a wide range of staff on regulated professional registers, including social workers, care teams may also contain members of staff, who are not registered with a regulatory authority, but who may need access to a proportion of someone's personal data to provide care safely'.
- To ensure compliance with this definition, individuals may be required to evidence all the following criteria:
  - Staff members must have a contract (which could be honorary) with Barts Health;
  - Line manager determines the level of Barts Health statutory and mandatory training that must be completed commensurate to the type of access required
  - Oversight by a line manager, who holds a contract with Barts Health, to ensure all appropriate training/supervision is in place to deliver the role;
  - An appropriate level of competency in their role as determined by line manager; and
  - Line manager's confirmation that the individual meets the above criteria.
- For clarity, the line manager has the ultimate responsibility for ensuring staff members fall within a patiet's care team. The line manager ideally should be substantively employed by Barts Health but a clinical honorary contract will suffice.
- If the above criteria cannot be met then CAG Approval must be sought before any patient approach is made or patient data is accessed.
- A DPIA for this approach to the role of the patient's direct care team in research (outlining the above) have been approved by the Information Governance Committee and Trust Data Protection Officer in December 2020.

Use of Barts Health Medical Records Service

[26] UK Research Councils (UKRC) policy on Research data-sharing – information can be found at https://www.ukri.org/funding/information-for-award-holders/data-policy/ . An example of a specific policy is the MRC policy on Data Sharing September 2011

[27] NHSLA Risk Management Standards 2012-13, Organisational Policies and Procedures.

[28] Barts Health NHS Trust Data Protection Policy Queen Mary Data Protection Policy

- Medical Records will only be supplied for research that has appropriate ethical and Barts Health/ Queen Mary approval, following completion of the Request for Access to Patient records form.

- All research that uses Barts Health patient records or includes volunteers must be formally registered with the JRMO for internal review and the subsequent approvals process.

- All requests for records for research should supply the name and contact details of a person who will be responsible for their safekeeping.

- Research staff must give adequate notice of the need for records to be traced and pulled, particularly where large numbers of records are involved. Records should then be viewed in a secure area.

- Where a large number of records are required, they should be requested in batches to avoid compromising access to patient data for the purposes of service or audit.

- Records must be returned to the Health Records Department as soon as possible and NOT passed onto other staff or departments without appropriate documentation being completed which will allow onward tracing.

- Patients have the right to expect that staff will adhere to approved standards for maintaining confidentiality. Records must be stored securely during their use in research and not left in areas where there is public access.

This policy applies to both Barts Health and Queen Mary.

MINIMISING RISK IN RESEARCH

10. Minimising Risk

10.1 Background

All studies carry a definable level of risk and must be adequately managed to ensure that these risks are minimised.

The main risk categories are as follows:

- Regulatory Compliance
- Clinical risk
- Product risk
- Employment risk
- Contractual risk
- Asset risk
- Financial risk
- Reputational risk
- Investigator risk
- Data breach/loss risk

Detailed policies on each of the areas set out below are contained in various sections of this core research management policy document. Reference will be made to each relevant policy.

10.2 Policy

Staff undertaking research in Queen Mary and Barts Health will adhere to national legislation and regulatory frameworks and the relevant Queen Mary and Barts Health research management policies, to ensure that the risks associated with undertaking research are identified, minimised and mitigated.

10.3 Regulatory Compliance

Staff will comply with local and national regulations before commencing any research activity in Queen Mary and Barts Health, ensuring also that their managerial procedures are adhered to. This will include:

- Obtaining external or internal Ethical Approval – See policy number 1
- Obtaining any regulatory approval from the appropriate regulatory body e.g. The Medicinal and Healthcare products Regulatory Agency and Health Research Authority.
- Adherence to Good Clinical Practice and the Declaration of Helsinki when undertaking research.
- Adherence to the published UK policy framework for health and social care research, 2017 for Health and Social Care.
- Compliance with the Human Tissue Act.
- Compliance with GDPR (General Data Protection Regulations)
- Information Governance policies and procedures of Queen Mary and Barts Health and other relevant regulations.
- Adherence to Queen Mary and Barts Health policy and procedures concerning the management of research and development activities in the organisations.

10.4 Clinical Risk

Clinical risk is a generic term that covers a wide range of clinical and related activities. Investigators are required, when undertaking clinical activities as part of their research, to adhere to the appropriate Barts Health and Queen Mary policies and relevant national and local clinical guidelines. Access to these policies is via the Barts Health or Queen Mary's websites. Particular attention should be paid to the following core policies:

- Health and Safety policies of Barts Health and Queen Mary
- Complaints policies of the Barts Health and Queen Mary
- Policies and SOP's relating to specific clinical areas
- Risk Management Strategy & Policy
  Adverse Incidents Policy

10.5 Product Risk

Staff will ensure that the risks associated with the use of experimental products in research are minimised by:

- Adhering to the Indemnity Policy
- Complying with MHRA regulations and adhering to the Safe and secure handling of Medicines (including Advanced Therapies) in clinical trials Policy and the Use of medical devices in research policy.

Ensuring that the value to any patients or volunteer subjects participating in research projects outweighs the personal risks surrounding such participation. This issue should be addressed during the Peer Review Process.

10.6 Employment Risk

Investigators leading research projects, together with other staff who may be involved in the appointment of other staff with a research remit, must adhere to the respective organisational policies on HR arrangements for research-active staff.

10.7 Contractual Risks

To control the risks associated with entering research contracts with external research sponsors and collaborating partner organisations, staff involved in research shall pass the responsibility for all contractual matters relating to research to the Joint Research Management Office or Business Development (QMUL), who will negotiate contract terms, indemnity or insurance, price and arrange for contracts to be signed by an authorised signatory. Failure by staff to adhere to the policies covering agreement with external sponsors of research could be regarded as research misconduct.

10.8 Asset Risk

Queen Mary and Barts Health have, over many years, built up considerable expertise, knowledge and know-how in many scientific fields. This resource, together with the facilities they have at their disposal, constitutes a valuable asset base upon which the organisation's research strategies and plans are developed. All employees involved in research must ensure that the assets of Queen Mary and Barts Health are protected, in particular those Intellectual Property assets that may have future commercial value. To minimise the risk of external organisations taking unfair advantage of the communication and dissemination activities that are necessary facets of the research process, investigators are required to

adhere to the policies set out in Policy 16, Identification and protection of Intellectual Property.

Investigators must contact the Joint Research Management Office before entering any arrangement with external research collaborators or funders.

10.9 Financial risk

Queen Mary and Barts Health must ensure that research is not conducted which could lead to unfunded, unreasonable costs being incurred by either organisation. Commercially funded research must be fully funded and not subsidised in any way by Barts Health or Queen Mary. To minimise financial risks Investigators must ensure that their research is costed and agreed by the JRMO, and adhere to the following policies: Policy 18, Costing research, Policy 19, on externally supported R&D Pricing, and Policy 20, Distribution of research project funds.

10.10 Investigator risk

The investigator and all staff working on a research project must adhere to the approved protocol or agreed schedule of activity to ensure that they are compliant with all regulations concerning research and to ensure that they are fully indemnified. Chief Investigators of CTIMPs are required to attend the mandatory Chief Investigator training courses run by the JRMO and all Chief investigators are required to ensure that their knowledge of the regulatory framework for research is adequate, by undertaking regular training updates in GCP. Where an investigator is made aware of any breaches in compliance with the protocol they must inform the JRMO as per the relevant published JRMO SOPs.

Where a clinical study takes place on a single site, the Chief Investigator and Principle Investigator will be the same person unless there are agreed exceptional circumstances. Chief Investigator and Principle Investigator s must be experienced in the therapeutic area of the study and clinical research. Chief Investigators or Principle Investigators who lack relevant experience in clinical research may still be selected to perform the role of Chief Investigator or Principle Investigator; however, this must be agreed, in writing, by the sponsor, who may appoint an experienced individual to support or mentor the Chief Investigator or Principle Investigator for the duration of the study. This will facilitate the development of the research workforce.

10.11 Reputational risk

The investigator and all staff working on a research project should ensure that their activities do not lead to reputational damage for the Barts Health, Queen Mary or the sponsor organisation. This should be addressed during the internal peer review and any organisational approval process. This risk is mitigated by ensuring that the study is compliant with the UK regulations governing research, the protocol or schedule of activity, policies of each organisation and the JRMO SOPs.

10.12 Responsibility for Minimising Risk concerning Research Activities

The Investigator and all staff working on a research project or programme of research have both individual and collective duties to ensure that studies are conducted in accordance with good academic practice in research, Good Clinical Practice, national regulations and Queen Mary and Barts Health standing orders and corporate policies. Clinical Board Directors, Faculty Deans of Research, Institute Directors, Heads of Schools, and the Joint Research Management Office are charged with a duty to ensure that staff adhere to this regulatory framework.

10.13 Data breach/loss Risk

The investigator and all staff working on a research project must adhere to Policy 9 Use of Research Participant Information for Research and Policy 16 Barts Health Research Data Sharing to ensure mitigations are in place to reduce any risk of data loss or data accessed by inappropriate staff. Any data leaving the organisation should have a data sharing/transfer agreement in place even if data is fully anonymised. Failure to comply with these policies could amount to Research Misconduct (see Policy 24) which would be investigated as a potential failure to comply with GDPR.

This policy applies to both Barts Health and Queen Mary.

11. Research data management at Queen Mary

11.1 Background

Data management, including planning for processing, long-term storage, sharing and integrity, is an increasingly important aspect of the UK Research environment. Most grant applications for research that will generate digital data sets require a data management plan that meets the UK Research Council (UKRC) policy; this states that: 'Publicly funded research data are a public good, produced in the public interest, which should be made openly available with as few restrictions as possible in a timely and responsible manner that does not harm intellectual property': https://www.ukri.org/.

As of May 2012, UKRI required all funded universities to have a data management policy and road map in place that will be fully implemented by 2015 to meet their expectations for data sharing, as follows:

- Publicly funded research data should be made openly available in a timely manner;
- Data with acknowledged long term value should be made accessible;
- UKRI recognises that there are legal, ethical and commercial constraints on the release of research data. To ensure that the research process is not damaged by the inappropriate release of data, research organisation policies and practices should ensure that these are considered at all stages in the research process; and
- Research Council funded work may be entitled to a limited period of privileged use of the data.

A summary of funder data management/sharing requirements can be found here: http://www.dcc.ac.uk/resources/data-management-plans/funders-requirements

Barts Health supports this stance and works with Queen Mary to manage its research data in ways that accord with the external policy recommendations and uphold data sharing expectations. Policy 16 on Barts Health Research Data Sharing outlines data transfer/sharing requirements and expectations from any organisation using Barts Health patient data.

11.2 Research Data Access and Management Policy

(i) Queen Mary and Barts Health are committed to the general principle of Open Access to research, including to research data[29] within the necessary constraints of any funder, legal and ethical requirements, and following Queen Mary policies, guidelines and standards.

(ii) Any Barts Health patient identifiable data can only be stored in in Faculty of Medicine and Dentistry's safe haven and not on any personal or shared Queen Mary drives.

(iii) Due to the particular concerns around access to medical-related data, access to data that is associated with medical research will be governed by the relevant funder's

[29] Queen Mary and Barts Health research data here refers to the final forms of information which are essential to the understanding of the published or otherwise publicly available final research output that represents the completion of a well-defined research project. This information is generated by QM and Barts Health researchers for the purposes of the research project, for example via experimentation, observation or interview. It may include samples and related material used or created in the course of the research. Published materials, bibliographies, and data acquired from third parties (generated outside QM and/ or Barts Health) are not included in this definition.

policies on data sharing. If a funder does not have such a policy, then the MRC's policy on data-sharing should be the default policy[30].

(iv) Where reasonably practicable, publicly funded research data should be made available for access, subject to such conditions as are necessary to ensure compliance with legal, data protection, ethical, confidentiality, IP protection, and security or funder obligations.

(v) Data identified for open access will be offered for deposit either in a Queen Mary or an appropriate external repository, following relevant standards and community best practices, which may be determined by the area of research activity.

(vi) Data must be retained intact in an appropriate format and storage facility according to funder requirements and consonant with any data management plans approved as part of any funding.

(vii) The rights of researchers to the exclusive use of research data that they generate as part of a well-defined research project will be protected up until the point of publication or public availability.

(viii) Where data is made available on request rather than via straightforward open access the rationale for this must be made public and such availability should not be unreasonably withheld.

(ix) Data arising from research involving human participants can only be made accessible if those participants give their informed consent in advance for the future public release of their data, with clear and study-specific explanations of how the data will be anonymised/de-identified so that it will not be possible for those in receipt of the data to identify any individuals. Where it has been determined that it would be inappropriate to make such data accessible, for example, because it might lead to the identification of research subjects or because seeking consent would make it unlikely that subjects would participate in the research, then the data will remain confidential.

(x) For research collaborations, any open access arrangements can only take place with the agreement of all research partners.

(xi) Where retention is not specified as a condition of funding, data storage and disposal will be determined by the nature of the research activity and would normally be retained for at least 5 years for non-clinical and at least 20 years for all clinically-based activities from the date of any publication which is based upon it, as specified in the Queen Mary and Barts Health Records Retention schedules.

(xii) Protocols for research in which data will be generated or reused should include data management plans that explicitly address data capture, management, integrity, confidentiality, retention, sharing and publication. These plans will be retained by Queen Mary and Barts Health, as appropriate, to guide future management of the data.

(xiii) The Investigator, or most senior Queen Mary researcher, in a research project, has responsibility for ensuring that research data management requirements are observed during a research project or programme that they are undertaking.

[30] https://mrc.ukri.org/funding/guidance-for-applicants/5-ethics-and-approvals/

(xiv) Those responsible for research staff and students should ensure that researchers in their areas are aware of this policy and any associated guidelines and procedures. Supervisors should always have access to their student's data. No data should be stored outside the organisation (unless explicit consent from participants is in place).

(xv) All researchers are expected to familiarise themselves with and act in accordance with this and other Queen Mary and Barts Health policies relating to research practice. This information will be made accessible from the Queen Mary and/ or Barts Health research webpages, both external and internal.

(xvi) Queen Mary will provide their staff with advice, training and support regarding research data management.

(xvii) Any queries on the application of this policy should be directed to the Records and Information Compliance officer or the JRMO Governance Section.

(xviii) Appeals against the withholding of data may be made in writing to the JRMO Governance Section or the Records and Information Compliance Officer who will review the case from the researcher or their representative for withholding data. The case will then be submitted to the Vice Principal (Research) and on review will make a final decision.

11.3 Further information

For information about open access please see the Queen Mary Library research webpages http://www.library.qmul.ac.uk/openaccess

The *Queen Mary Guidelines on Open Access* are available at http://www.library.qmul.ac.uk/sites/www.library.qmul.ac.uk/files/users/user15/OA__Principles%20&%20Guidance.pdf

For information about IT Services support for IT resourcing and data management requirements please see the ITS webpages at http://www.itstrategy.its.qmul.ac.uk/research/researchdatamanagement/

This policy applies to Queen Mary.

12. Clinical trial compensation

12.1 Background

Clinical trials and other research studies undertaken by employees of Queen Mary or Barts Health may be undertaken at the instigation of commercial organisations or non-commercial external funders, or they may be unfunded. Where trials are funded by a company, it is accepted practice for the company to offer compensation to patients or healthy subjects who participate, if they are harmed through some fault of the manufacturer or for other reasons not attributable to the negligence of the investigator. In such circumstances, the offer of compensation will be made according to a standard procedure of independent evaluation.

At present, a trial subject who suffers harm as a result of participation in a non-company-funded (e.g. charity-supported) or unfunded study will only be entitled to compensation if they can prove negligence on the part of the investigator or the clinical staff or the manufacturer of a product used. They must, therefore, prove not only the existence of fault but who or what was at fault.

It is generally thought that where a subject is harmed as a result of participation in a trial, the prospect of compensation should not depend on whether the trial happens to be company-sponsored or if there is evidence of negligence.

This document sets out Queen Mary and Barts Health's policy concerning compensation payments. It sets out applicable criteria and procedures for making compensation payments to those subjects injured in non-company sponsored trials for which there is no alternative equivalent compensation available, or in company-sponsored trials where an injury results from the negligence or other fault of the investigators.

12.2 The Policy

For the purpose of this policy, Trial Subject means:

a) A patient, that is, an individual, whose participation in a piece of research derives from either:
   - Having sought or accepted medical care within Barts Health primarily for the treatment of a condition, the investigation of which is the subject of the clinical trial.
   - Having been selected from the general population because of known or suspected abnormality

b) A healthy volunteer, i.e. an individual, who is generally healthy and does not suffer from the condition expected to be modified by the trial intervention.

c) A child in utero - a child subsequently born alive whose mother was a trial subject while the child was in utero.

All research studies must first be submitted to and approved by an appropriate ethics committee or other relevant ethics committee and the JRMO. Failure to obtain such approval, or disregard of any conditions for approval, would be a breach of the investigator's terms of employment within Queen Mary or Barts Health. Further, the investigator could bear personal responsibility for any harm resulting to a patient.

12.3 Coverage

Queen Mary or Barts Health will pay compensation to trial subjects suffering a bodily injury in accordance with this policy.

Compensation will be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product or device under trial, or any clinical trial intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.

Where a trial design includes pregnant women, the principles of compensation under these Guidelines will apply to injuries caused to a mother or her child in utero. However, since strict criteria are laid down by the Health Research Authority (HRA) for the exclusion of pregnant women from clinical trials in general, compensation will be paid in the event of injury to a child in utero only where the mother's participation in such an excluding trial has been non-negligent on her part.

Compensation will not be paid for temporary minor pain or discomfort.

Where there is an adverse reaction to a medicinal product or device under trial and injury is caused by a procedure adopted to deal with the adverse reaction, compensation will be paid for such injury as if it was caused directly by the medicinal product or device under trial.

Neither the fact that the adverse reaction causing the injury was foreseeable or predictable nor the fact that the trial subject has freely consented (whether in writing or otherwise) to participate in the trial, should exclude a trial subject from consideration for compensation under this policy although compensation may be abated or excluded in the light of the factors described below in section 12.4.

This policy applies to injury caused to patients and healthy volunteers partaking in clinical trials involving unlicensed medicinal products or devices who are not protected by a similar policy offered by any external sponsor of the trial.

Compensation will also be paid for an injury caused by licensed or non-licensed products administered to the trial subject for the purpose of comparison with the product under trial.

12.4 Limitations

Compensation will not be paid:

- For the failure of a medicinal product, device, technique or procedure to benefit a patient
- To patient receiving placebo in consideration of its failure to provide a therapeutic benefit
- To the extent that the injury has arisen (or it should be abated as the case may be):
    - Through the wrongful act of default or a third party for whom Queen Mary or Barts Health is not responsible (for example, a patient's own doctor); or
    - Through contributory negligence by the trial subject.

The maximum amount of compensation payable under this policy will be the maximum ex gratia payment permitted by Queen Mary's insurance policy or, in the case of Barts Health, The Department of Health national insurance provisions.

The undertaking given by Queen Mary and Barts Health extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the trial but not to treatment extended beyond the end of the trial at the instigation of the investigator. The use of unlicensed products beyond the trial period or on a named patient basis is wholly the responsibility of the treating doctor. Doctors should notify their protection society of their use of unlicensed products.

12.5 Investigators Liability

Where the cause of an adverse reaction or injury is attributed wholly or partly to a significant departure from the protocol as approved by the HRA and Queen Mary or Barts Health, either organisation, in respect of its liability to compensate the trial subject, shall be entitled to claim indemnity to the appropriate extent from the investigator(s) responsible. For this reason, investigators are required to maintain appropriate professional indemnity insurance.

12.6 Assessment of Compensation

Subject always to any overriding financial limitations imposed on Queen Mary or Barts Health, the amount of compensation should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by an English court in cases where legal liability is admitted.

Compensation may be abated, or in certain circumstances excluded, in the light of the following factors:

a) The seriousness of the disease or condition being treated.
b) The risks and benefits of established treatments.
c) The known or suspected risks and benefits of the trial medicine or device.
d) The information and warning given to the patient as to (a) – (c) above, in the knowledge of which he or she has given consent.

Where Queen Mary or Barts Health have agreed in principle to compensation being paid but the amount offered under clause 12.4 is not acceptable to the trial subject, the question may, if the trial subject agrees, be submitted for the decision of an independent arbitrator accepted by both parties, and failing such appointment, to be appointed by the President of the Law Society.

12.7 Procedure and Claims

An investigator undertaking a non-company sponsored trial should make it clear to participating trial subjects that the trial is being conducted in accordance with either Barts Health or Queen Mary policy.

The management of claims will be decided on a case by case basis, between Queen Mary and Barts Health, with due regard to the employment status of the investigator, any contractual arrangements with external funders, honorary contract considerations and insurance coverage. Once an agreement has been reached, and where it is possible, one organisation will conduct the procedures involved in examining and settling claims.

Claims under this policy should be made by the trial subject to Barts Health for patient-based studies, or the most appropriate organisation in the case of patient volunteer studies, setting out details of the nature and background of the claim and are conditional upon the trial subject providing, on request, an authority for Barts Health or Queen Mary to review any

medical records relevant to the claim. Queen Mary or Barts Health should consider the claim expeditiously.

Trial subjects should be required to accept that any payment made under the policy is in full settlement of their claims.

The fact that Queen Mary or Barts Health has agreed to abide by this policy does not affect the right of a trial subject to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, it is hoped that by adopting this policy the organisations will be seen to deal fairly with trial subjects and will avoid litigation with its attendant expense, publicity and uncertain outcome.

Where relevant, the basic principles and procedures described in Barts Health's Policy for the handling of Clinical Negligence and Personal Injury Claims will apply to this clinical trials compensation policy except where the procedures conflict, in which case the wording of this clinical trials compensation policy will take precedence.

In providing financial compensation in accordance with this policy Queen Mary and Barts Health accept the need for an expeditious settlement and will make every effort to complete the necessary investigations as a matter of urgency.

This policy applies to both Barts Health and Queen Mary.

13. Safe and secure handling of Medicines (including Advanced Therapies) in clinical trials

13.1 Background

The purpose of this policy is to ensure that Barts Health and Queen Mary comply with the relevant guidelines for the safe and secure handling of clinical trial medication (including advanced therapies).[31]

This policy applies to all drug trials that involve Barts Health patients and or Barts Health or Queen Mary healthy volunteer studies.

The ordering, storage and handling of clinical trial medication and advanced therapies must comply with Barts Health policies on the safe and secure handling of medicines. Barts Health's Pharmacy Department must be involved at an early stage of all clinical trials that involve the use of medicines or advanced therapies

Where a clinical trial does not use regular systems of purchasing, storage or administration the proposed alternative must be agreed with the Pharmacy Department. These local systems and facilities will be subject to audit by the Pharmacy department.

13.2 Scope

This Policy applies to all trials falling within the scope of The Medicines for Human Use (Clinical Trials) Regulations 2004 regardless of licensing status, indication, funder, sponsor or source. Researchers should always seek JRMO confirmation of study status. The JRMO will, if required, contact the MHRA helpline for a final decision on whether or not a trial falls under the scope of The Medicines for Human Use (Clinical Trials) Regulations 2004. The final decision will remain with the JRMO Sponsor Oversight Group.

13.2 Policy

(a) Regulatory and local approvals

In addition to HRA, NHS ethics and local NHS Capability and capacity confirmation, trials involving an investigational medicinal product (IMP) should follow current submission guidelines and the processes required to apply the Medicines and Healthcare products Regulatory Agency (MHRA) as per current UK processes.

. Before prescribing clinical trial material the Principal Investigator or pharmaceutical company trial co-ordinator should discuss with Barts Health's Pharmacy (the clinical trials pharmacist) the exact procedure and necessary information for prescribing the trial material. For clinical trials involving in-patients, it is the Principal Investigator's responsibility to ensure that all staff involved in the study are well informed and given reasonable notice of pending clinical trials. As well as local confirmation of capacity and capability approval, written local pharmacy approval must be in place before any prescribing takes place.

(b) Prescribing and Administration

All prescribers and persons administering IMP must be suitably trained and delegated to do so

[31] The Declaration of Helsinki (2013); Good Clinical Practice (2017); The Medicines for Human Use (Clinical Trials) Regulations 2004 (and all its amendments); Data protection laws; UK Policy Framework for Health and Social Care Research 2017

by the principal investigator.

IMP must be prescribed using a trial-specific prescription form approved by a trial pharmacist. In some circumstances, a standard non-trial prescribing process can be used, and this must be agreed upon in advance with a trial pharmacist

(c) Patient Safeguards

Informed consent must be obtained as per local and national policies. The Principal Investigator or delegate is responsible for informing patients about trial medication and the potential for any harmful effects. Arrangements must be in place to indemnify Barts Health or Queen Mary for any claims against them relating to a medicine-induced injury.

All patients and volunteers must be given study information that, where applicable, contains the name of the trial and a named 24-hour contact with a telephone number. This may then be passed to Barts Health's Pharmacy in the event of a query.

(d) Supply and storage

All medication and advanced therapies intended for clinical trial use should be delivered either to the Pharmacy Departments or to a location audited and advised by the Barts Health Pharmacy Department and stored under its direction.

It is normally inappropriate for stock to be stored in an office environment, and special arrangements will be needed for out of pharmacy storage. Where normal arrangements would seriously affect the running of the trial, the pharmacist may consider authorising an alternative for out of pharmacy storage arrangements. This must be documented, and an audit of the procedures and conditions must be carried out. The trial will be subject to an ongoing audit by the pharmacist in these circumstances. Any significant breaches of GCP, or the safe and secure handling of medicines policy, may result in the suspension of the trial whilst satisfactory arrangements are put in place.

(e) Dispensing

Barts Health's Pharmacy should have a clear dispensing procedure for each clinical trial and must ensure correct labelling of trial material, as per the clinical trial application and Sponsor instructions.

(f) Information

The pharmacy should hold within its Pharmacy Trial File information relevant to each clinical trial, including a protocol, MHRA, ethics and JRMO approval letters, an investigator's brochure or summary of product characteristics, and randomisation codes, where appropriate.

(g) Pharmacy role in Queen Mary and Barts Health Sponsored C and A TIMPS
(h) Pharmacy specific software and oversight of prescribing systems
(i) Barts health Pharmacy oversight of sub-contractors (for example, Lloyds)

This policy applies to both Barts Health and Queen Mary

14. Use of medical devices in research

14.1 Background

Devices are used in research to either:

- **Support a study:** CE-marked medical equipment used as intended by the manufacturer as part of routine standard of care or used above the standard of care.
- **Be the focus of a study, that is a device-centred study,** which includes:
  - Clinical evaluations of CE-marked equipment, which is used as intended by the manufacturer to gather more data on, for example, the device's performance;
  - MHRA clinical investigations for commercialisation purposes; and
  - Pre-CE marking or for proof of concept (POC) studies to assess feasibility or intent – this may include using or altering CE-marked devices for a purpose not intended by the manufacturer outside its CE-mark indications. In these studies, there is no commercialisation intent, hence no MHRA involvement.

Medical Devices are utilised in research in several ways:

- Clinical Investigations and Clinical Evaluations may be conducted to test novel medical devices.
- Devices may be purchased or introduced on loan to enable research to be carried out.
- Existing devices may be altered for use in research or may be tested for a new purpose.
- Commercial devices may be tested for safety and efficacy as a potential means of improving practice.

The purpose of this policy is to ensure that:

- Devices used for research have undergone clinical physics governance and basic safety checks.
- Appropriate departments within Barts Health and Queen Mary are aware of and have approved the use of the device and the study.
- The risk associated with the use of experimental devices is minimised.
- Any incidents or near misses relating to experimental devices are reported using Barts Health incident reporting procedure.

This policy needs to be read in conjunction with the Trust's Decontamination of Medical Devices Policy[32]. Full details of Barts Health management of medical equipment can be found at: https://weshare.bartshealth.nhs.uk/trust-wide-policies

14.2 Background for Using Devices in a Clinical Setting

The Medical Devices Directive 93/42/EEC, the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Active Implantable Medical Devices Directive 0/385/EEC have been implemented in the United Kingdom by the Medical Devices Regulations 2002 (SI 2002 No 618). [33]

[32] Barts Health Environmental Cleaning and Decontamination of Medical and Non-Medical Devices Policy, December 2017: https://weshare.bartshealth.nhs.uk/trust-wide-policies

[33] EU Directive 93/42/E of 14 June 1993 concerning medical devices In Vitro Diagnostic Medical Devices Directive 98/79/EC The Medical Devices Regulations 2002 No. 618

The purpose of the medical devices directives is the harmonisation of technical standards and essential safety requirements to enable medical devices to be marketed freely throughout the European Economic Area.

Note: The current directives will continue to have effect in Great Britain after the transition period up until 2023, by which time a new regulatory system for medical devices (currently under development) will apply. For Northern Ireland and the EU, the new Medical Device Regulations 2017/745 (MDR) will apply from 26th May 2021. For further information, see https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk.

Medical Device means "an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which:

a) Is intended by the manufacturer to be used for human beings for the purpose of:
- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- The investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception.

b) Does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means."

Scope of regulations

If a device is made by one legal entity for use on or by the patients of that same entity, there is no placing on the market and the Regulations do not apply.

When a health care establishment or other body manufactures devices intending to market them to another legal entity, as opposed to treating their own patients, MHRA would regard such manufacture as being covered by the Regulations.[34] This would include a transfer between Queen Mary and Barts Health. However, there are examples of medical devices being transferred between healthcare establishments where, although there is a transfer between legal entities, the product is not placed on the market.

Products manufactured in-house, in a healthcare establishment and undergoing testing for proof of concept, are considered medical devices. They are, therefore, subject to the provisions of the Medical Device Regulations. In circumstances where the in-house manufacture intends to commercialise the device, an application must be made (irrespective of whether the manufacturer and subjects are part of the same legal entity).

If a clinical investigation is to be carried out, the investigator must ensure the Competent Authority is notified of a proposed clinical investigation. MHRA guidance notes [35] clearly set out procedures. Advice and guidance should always be sought from the JRMO.

The full details of Barts Health management of medical equipment can be found at:

[34] The Medical Devices Regulations: Implications on Healthcare and other Related Establishments, Bulletin No. 18 Competent Authority (UK), February 2011.
[35] MHRA-EC Medical Devices Directives Guidance Note 1 (Guidance for Manufacturers in Clinical Investigations to be Carried out in the UK, February 2012).

https://weshare.bartshealth.nhs.uk/trust-wide-policies

Barts Health and Queen Mary (through the JRMO) will review the Medical Device production and research activities to decide whether or not they are covered by the Regulations.

The JRMO in conjunction with the Clinical Physics Department will decide whether regulations apply. The following should be considered:

- Whether the product falls within the definition of "device".
- Whether the product is at such an early stage of development that the scope of its application and therefore its intended purpose has yet to be precisely defined.
- Whether the body making or developing the device falls within the definition of "manufacturer" in relation to that particular product.
- Whether the device is being "placed on the market".

For any activity that is identified as subject to the provisions of the Regulations, all relevant obligations must be identified and complied with. Even if it is decided that the activities in question are not subject to the Regulations on medical devices, there are Institutional responsibilities under the general law (including consumer protection legislation) and a responsibility to ensure the safety of patients, users and any relevant third party.

14.3 Policy

This policy is designed to ensure that Barts Health and Queen Mary meet their legal obligations concerning the use of medical devices in Clinical Research.

This policy follows Barts Health's existing guidance in the context of devices used in research. This policy applies to Barts Health and Queen Mary personnel using medical devices in research, regardless of the type of participant or setting.

It should also be noted that any devices that are developed 'in house' for research and are not on the market are not covered by any Medical device regulations and therefore, it is the responsibility of Barts Health or Queen Mary researchers to ensure that their use is safe and appropriate.

14.4 General Points

- All research that intends to use human subjects must have appropriate sponsorship, ethical and HRA approvals.
- MHRA regulated research must have the appropriate MHRA approval.
- All medical devices, whether used to carry out the research or developed as the subject of research, must be registered with Barts Health Clinical Physics Department and JRMO.
- All medical equipment used in Clinical Trials of Medicinal Investigational Products (CTIMPs) must be registered with Barts Health Clinical Physics Department and JRMO to ensure that the equipment used is appropriately recorded and maintained.
- Any research involving Barts Health patients or staff using medical devices must seek advice and guidance from the JRMO and Barts Health Clinical Physics Department, who will on a case-by-case basis provide risk management and safety reviews.
- The Clinical physics department will keep a log of all medical equipment they test.
- Clinical Boards and Faculties must ensure that Clinical Physics are notified if the equipment is re-located.
- All experimental equipment intended for clinical investigations must be clearly labelled and registered as "Exclusively for clinical investigation" or 'For research only.'

- Medical equipment intended for research must not be used in routine clinical practice without the written approval of Clinical Physics.

14.5 Purchasing Equipment for Research

All equipment purchased for use in research, either by Barts Health or Queen Mary must go through the approved Barts Health or Queen Mary Procurement Process. This is designed to ensure that consideration of installation, consumables, training, staffing, maintenance and disposal costs are considered before a device is purchased. The selection process should also consider any risks associated with the use of the equipment. Additional risks could be introduced by equipment diversity i.e. where users are not trained to operate the range of equipment in use. Purchasers should aim to standardise the number and range of equipment in use. Decontamination processes and cross infection risks must also be considered. Researchers should always seek advice from Clinical Physics and Clinical Risk Departments before introducing a new piece of equipment.

Where a tendering process is required, Clinical Physics should be informed, and a tender specification approved. The department should also be involved in the final selection process.

Before any order is made, the Supplies Manager must ensure that a completed Pre-Purchase Questionnaire has been obtained from the Supplier and has been approved by Clinical Physics.

14.6 Equipment Loaned for Research

Although there is no prohibition on accepting loans, it is important that the arrangements are transparent and do not carry a longer-term commitment by Barts Health or Queen Mary or to the organisation making the loan. It is also important to understand and be clear about any expectations from the company that accompany the loan. Therefore, before entering into any agreement, researchers must consult the JRMO and Clinical Physics Department and:

(i) Ensure there is no commitment to buy or pay rental at the end of a specific period and that the company is aware that Queen Mary or Barts Health undertakes no commitment to purchase, even if the equipment proves itself in use.
(ii) Be clear about whether or not Barts Health or Queen Mary must pay for wear and tear. If expected, the amount should be specified in advance
(iii) Be clear about whether Queen Mary or Barts Health is expected to pay for any damage to the equipment whilst on loan and the maximum liability
(iv) Consider the cost of consumables and or maintenance etc. If revenue costs are how they will be funded must be clarified
(v) Be clear about other commitments from the loan, including time spent in talking/demonstrating the “product” to other potential purchasers and also the medico-legal, confidentiality and insurance issues associated with such practice.
(vi) Consider the overall value for money.
(vii) Follow Barts Health or Queen Mary Standing Orders on tendering and quotations for any purchases of consumables or associated items.
(viii) Clarify the position at the end of the loan period.
(ix) Be clear about the medico-legal position particularly on any additional risks to individuals, Barts Health or Queen Mary.
(x) Discuss and secure the agreement for the loan with the relevant Clinical Director and General or Institute Manager.
(xi) Ensure the equipment is clearly labelled as “on loan & from whom” and does not become confused with Barts Health assets. It must not be included on the Barts Health or Queen Mary asset register.

(xii) Ensure appropriate indemnity cover is in place for any loan devices. Loan indemnity cover can be obtained via two routes:

a. Master Indemnity Agreement (MIA) – this has been set up by the Department of Health who maintains a register of approved suppliers. For further details, see https://www.gov.uk/government/publications/master-indemnity-agreement-mia. A copy of any completed forms should be sent to Clinical Physics (research.clinicalphysics@nhs.net).
b. Model Clinical Trial Agreement (mCTA) - If a supplier is not on the MIA register and does not want to join it but still wants to supply the Trust with loan equipment, contact the JRMO office to check if the equipment used is covered within appendix 7 of the mCTA.

If there is no indemnity cover (either via the MIA or Appendix 7 of the mCTA), contact the JRMO for advice.

(xiii) Any loan items **must** be returned to the supplier at the end of the study and Clinical Physics informed so records can be updated.

Finally, it is important to undertake a full evaluation of the equipment to assess its effectiveness and suitability. A report should be compiled for the benefit of other staff both in the directorate/ institute and other directorates/institutes that might be interested.

If subsequently the decision is taken to purchase the equipment or enter into some other financial arrangement, then Barts Health or Queen Mary's business case rules apply.

14.7 Safety Testing for clinical research in a hospital setting

Any requests for safety testing should first be sent to Clinical Physics who will first review the study. Once the review has been performed and safety testing is indicated, any new portable devices for use in Barts Health or on Barts Health patients or staff must be delivered to the relevant Clinical Engineering Workshop. Non-portable equipment should be delivered to the user site and Clinical Physics informed. Electrical safety testing will be performed on any new medical equipment that is electrically powered and the device(s) will be registered on the service's equipment database. Depending on capacity and capability, any relevant function testing may be performed. This will be carried out in-house. If Clinical Physics is unable to perform any functional testing, researchers are expected to contact the Supplier/Manufacturer to carry out the appropriate tests. Any tests and checks performed by Clinical Physics will be documented and held by Clinical Physics.

14.8 User Training

Before equipment is used the Investigator must ensure that all staff are adequately trained in its use and this training is documented. They must also ensure that user manuals and operating instructions are available locally. No member of staff should use the equipment until they are declared competent to do so. If user instructions are produced by the Clinical Board or Faculty rather than the manufacturer, their adequacy must be checked by Clinical Physics (depending on capacity and capability).

14.9 Maintenance

Researchers must be clear who provides maintenance for any equipment used in research. Costs of maintenance of equipment should be sought from the funder. Maintenance will normally be carried out to the manufacturer's recommendations. Where maintenance is carried out to a lower level than specified by the manufacturer, the reasons for the change should be documented and a risk assessment carried out. All external organisations providing maintenance services must be accredited to a recognised quality assurance

standard by an appropriate accreditation body. Details of all maintenance should be recorded, and records kept for a minimum of 11 years after the disposal of the equipment or 25 years after the end of the research, depending on which period is longer.

14.10 Risk Management

All equipment to be used in clinical interventions must be capable of disinfection unless it is designated as single use. No single-use item may be re-used under any circumstances. Researchers are advised to seek advice from Sterile Services in this respect.

All experimental devices, that is, new products or amended existing products, must be subject to a review by Clinical Physics, who will, on a case-by-case basis perform risk management and safety reviews. It is strongly recommended that investigators/researchers involve Clinical Physics from the concept forming phase of research to minimise delays (and the risk of rejection).

In the event of an incident or near-miss involving research equipment, the Clinical Risk Department must be notified through the normal channels. Where the device is the subject of the research, the Ethics Committee and the JRMO should also be informed. Barts Health and Queen Mary incident reporting policies should be followed.

14.11 Storage of Devices

Custodians of equipment and investigators should ensure that medical devices are stored according to the manufacturer's instructions. Where a device is experimental, advice on storage should be sought from the Clinical Physics Department. No experimental devices should be stored in a way that may lead staff to believe they are for routine clinical use, i.e. they should be clearly identified as being for research purposes only and be stored separately.

14.12 Disposal of Devices

Medical Equipment that is no longer in use or has been replaced should be disposed of through Clinical Physics / Equipment. It should also be removed from the equipment inventory. Any radioactive substances should be disposed of according to the Radioactive Substances Act, 1993 and the Radiation Protection Officer advised.

14.13 Requirements for Clinical Investigations and Clinical Evaluations

- All research studies which may be Clinical Investigations or Clinical Evaluations must be notified to the JRMO GCP team.

  Note: As defined in the EU Medical Device Regulations (MDR 2017/745):
  - 'Clinical evaluation' means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data on a device to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;

  - 'Clinical investigation' means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device.

  Such studies apply to:
  - a medical device that does not have a CE-mark or UKCA-mark.
  - a medical device for a novel purpose not covered by its existing CE-mark or UKCA-mark.

    - the generation proof-of-concept data about a medical device that will be used to commercialise the device or obtain a CE/UKCA-mark for the device.

- When setting up a research study involving a medical device, the Chief Investigator must provide sufficient documentation to evidence that MHRA approval is not required, or else set up the study as a Clinical Investigation/ Clinical Evaluation.

- The JRMO GCP team must be notified of grant applications for proposed Clinical Investigations and Clinical Evaluations before the grant is submitted. This is to ensure that all of the costs required for regulatory compliance can be included in the grant budget.

- Before initiating a Clinical Investigation or Clinical Evaluation, the Chief Investigator or device manufacturer must maintain a technical file with all of the necessary pre-clinical development and testing and other documentation necessary for the device to obtain a CE/UKCA-mark after the Clinical Investigation has been completed.

- All Clinical Investigations must have a statistician and a non-academic study coordinator on the study team for the duration of the study.

- All Clinical Investigations must have a named device manufacturer. Neither Barts Health nor Queen Mary may act as a device manufacturer, so an external collaborator must be contracted to take on the role of the device manufacturer.

- Clinical Investigations must be run in compliance with ISO 14155 GCP. All staff working on Clinical Investigations must complete ISO 14155 GCP training before commencing work. All staff must refresh their training every two years while working on a Clinical Investigation.

- All relevant JRMO SOPs must be followed to set up and manage the Clinical Investigation or Clinical Evaluation.

This policy applies to both Barts Health and Queen Mary.

15. Indemnity

15.1 Background

Clinical Trials and other research studies undertaken by Barts Health NHS Trust or Queen Mary University of London carry an element of risk for research subjects. The principal objective of the Joint Clinical Trial Compensation Policy (12 above) is to ensure that where subjects suffer harm as a result of participation in a study, they will be compensated – if, of course, the circumstances under which the subject was harmed, meets the criteria set out in the policy. The objective of this policy is to set out the indemnities that are required to be in place for the Compensation Policy to come into force.

15.2 Policy

(a) Commercially Sponsored Trials

All organisations in the UK are required to ensure that before any trial sponsored by a commercial organisation (pharmaceutical company, devices company) commences, confirmation of Indemnity is reviewed and accepted by the JRMO. This is captured within the Liabilities and Indemnity clause of the appropriate standard ABPI Agreement which is Section 5 of the mCTA (Model Clinical Trial Agreement) and is submitted with the Research Ethics Application by the Study Sponsor. This legally binding agreement provides indemnity for both trial subjects, and Barts Health NHS Trust or Queen Mary University of London, ensuring that if harm is caused by the product under investigation, or because of deficiencies in the trial protocol, the subject will be compensated (see Policy 12 above) and Barts Health NHS Trust or Queen Mary University of London indemnified from liability to pay the claim.

(b) Non-commercially Sponsored Trials

Where a trial is sponsored by either Queen Mary University of London or Barts Health NHS Trust they, as the sponsor, will be responsible for the design of the study protocol and the conduct of the study and will provide the following indemnities dependant on the scope of the study. These include but are not limited to the following:

- A commercial company that is providing support, such as finance, contributing free drugs or devices etc. will be indemnified by the sponsor against any claims made by a participant in the study.

- Where an unlicensed product is used beyond the trial period, on a named patient basis, or for humanitarian purposes, the sponsor is not liable, and the responsibility is wholly that of the treating doctor. Doctors are required to maintain adequate and appropriate professional Indemnity Insurance and notify their protection society and the appropriate regulatory body if they intend to use unlicensed products.

- A company supplying products for a research study will reciprocate with its own indemnity to the sponsor for any manufacturing defect of the product it supplies ensuring that adequate insurance is in place to cover this liability, evidence of which should be provided on request from the sponsor (product liability cover).

15.3 Negligence

Organisations are required to indemnify research subjects and some funding organisations from claims arising from the negligent acts of their employees. Where an ethics application is required and before submission to the NHS or Queen Mary Ethics Committee, investigators

are required to submit the Ethics Application Form and Protocol/Project Specification to the JRMO for review. The Office will issue a Provisional Letter of Sponsorship, which includes terms under which indemnity would be issued. Once Ethics Approval has been given for a study, the Office will issue a Final Letter of Sponsorship, which incorporates confirmation of Indemnity.

Where Queen Mary University of London is the legal sponsor, they offer “no-fault” Indemnity to the subject for any harm caused by participation in a trial. “No-fault” indemnification means the subject does not need to seek legal redress in court to prove harm. The claim would be made directly to the sponsor who will submit it to their insurer to settle. Queen Mary would indemnity any partner organisations against claims made against the study by any subject. The partner organisation will reciprocate by indemnifying the sponsor against negligence.

Where Barts Health NHS Trust is the legal sponsor, their indemnity is covered through NHS Resolution and that only covers Barts Health staff and patients. Where Investigators from other organisations are conducting a study on Queen Mary or Barts Health premises, a letter of Indemnity from the sponsoring organisation must be submitted to the JRMO and Ethics Committee. Investigators must continue to inform the Office and Ethics Committee(s) of changes to the Protocol/Project Specification so that Indemnity cover is maintained. Failure to inform the Office and/or the Ethics Committee(s) of the intention to conduct a study will be viewed as a breach of an Investigator’s contract of employment and investigators could have personal liability for any harm resulting to a patient or claims made by a funder (see Policy 12 above).

15.4 Health and Safety

Staff involved in Research and Development activities are bound by all published Health and Safety Regulations, as set out in Queen Mary or Barts Health policies on Health and Safety at work.

15.5 Insurance

Queen Mary secures insurance for its research liabilities from a commercial insurance company. Whilst most of its liabilities are covered, exclusions within the policy may require additional insurance cover to be purchased. Expert reviews of individual cases, plus annual audits undertaken by the JRMO, enable the JRMO to bring to the attention of Queen Mary’s Insurance Purchasing Officer any instances where additional coverage may need to be purchased from an external insurer.

Barts Health insures its liabilities through the NHS Litigation Authority’s liabilities to third parties’ scheme.

This policy applies to both Barts Health NHS Trust and Queen Mary University of London.

16. Research data sharing

16.1 Introduction

This policy sets out the Trust's position on sharing data gathered for research studies set up within the scope of the UK Policy Framework for Health and Social Care research. That includes any database or registry generated from such studies that are shared either internally with other individuals or groups, or externally with other organisations. The policy defines those organisations with which the Trust is prepared to share such identifiable, pseudo-anonymised and anonymised datasets as it controls. It also defines the type of data the Trust is prepared to share and how we share that data. The policy also states that all such research databases must be reviewed by the JRMO.

The context for this policy is the Trust's commitment to improving patient care through the careful use of data collected for research purposes. The Trust will not share or disclose such data on an exclusive basis, nor will it enter into arrangements that grant third parties (commercial or non-commercial) exclusive access to the raw data that it holds (healthcare, research or operational) or include conditions limiting any benefits relating to that data that belongs to the Trust. The Trust will always endeavour to grant access only to anonymised or pseudo-anonymised data sets. The Trust already shares patient data with a range of external organisations and partners and internally amongst different parts of the organisation, applying a range of managed governance processes and procedures to do so

The Policy should be read in conjunction with the policies referenced above that deal with data protection and the standards all staff must adopt in the handling and management of information (data) about people, to ensure compliance with the General Data Protection Regulation and Data Protection Act, 2018, and in a research context, the UK policy framework for health and social care research 2017. It should also be read in conjunction with the Department of Health & Social Care Guidance, 'Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation', published on 15th July 2019. This guidance can be found on the UK Government website and its Guiding Principles are included at Appendix 1.

For clarity, this policy applies only to data for which Barts Health NHS Trust is the data controller. Where others are the data controller their policies will apply.

16.2. Scope

16.2.1 Data covered by this policy

This policy includes, but is not limited to, personal data in any form, including anonymised or pseudo-anonymised data and special category data (for example, race, health, genetics, ethnic origin, etc), that is collected during a research project, or during an activity that is ancillary to a research project or any associated activity that is conducted with or without ethical approval.

Appendix 2 sets out some examples where research data is already collected and stored in line with a variety of data management processes.

16.2.2 Data Sharing Partners

The Trust is committed to sharing data with external partners and amongst internal groups to provide an increased understanding of the conditions that our patients suffer from,

acknowledging the potential benefits that accrue to our care systems from research conducted under required regulatory and security controls.

Specific partners the Trust is prepared to share data with include:

- Internal speciality groups at all Barts Health Sites
- Other NHS Trusts
- Primary Care organisations
- Higher Education Institutions
- Charities
- Government Departments
- Social and Community Services
- Commercial Entities
- Research Funders

Other institutional policies may preclude the sharing of data with several organisations, including, for example, companies engaged in the supply of tobacco products, certain market survey organisations, political lobbyists, etc. It is expected that the Trust's research project approval process, which includes approval at Speciality level and approval from Joint Management Research Office (JRMO), Health Research Authority (HRA) and/ or NHS regulated Ethics Committee, as applicable, will determine whether or not an entity is a suitable partner with which the Trust is prepared to share its patients' data.

16.3 Data Sharing

16.3.1 Data Sharing Modalities

How the Trust shares its data with external research partners will, to a degree, depend on the partner's organisational purpose and the kind of activity they are engaged in. For most research activities, data may only be shared when a clear purpose has been defined for data use and HRA/NHS Ethics approval obtained for the activity. This applies to data collections or registries for which the Trust is data controller, whether this is data collected during a wide range of research activities and held on a database, or data collected specifically for formulating a registry, under a specific NHS Ethics approval, or clinical service data that is collected for identifying new areas of research.

16.3.2 Data Sharing Formats

The Trust maintains the right to share its data either internally or with external organisations in a format that is acceptable to the Trust. It may decide that it is acceptable to share patient identifiable data with some partners but may wish to restrict data sharing arrangements to anonymised or pseudo-anonymised formats with certain categories of partners.

The following table sets out examples of the parameters within which the Trust is prepared to share data with research partners and the modality that must be employed to secure our patient data:

Partner Organisation	Data Format	Designated Purpose	Transfer/ access requirements
Internal speciality groups at all Barts Health Sites.	Open access to all contemporary patient records accessible on the Electronic Patient Record system or paper files.	Used solely for research purposes for a specific research project with JRMO Sponsorship review and HRA/ NHS ethics approval (as applicable) or transfer to registries with similar approvals in place.	Only the patient's direct care team can access patient records unless there is a Section 251 approval in place.
Other NHS Trusts and Primary Care Organisations	• Patient identifiable data • Pseudo-anonymised data • Anonymised data	Used solely for research purposes for specific research projects with NHS Ethics and/ or HRA approvals or transfer to registries with similar approvals.	Research referrals must be made by the direct care team and must have the written consent of the patient unless there is a Section 251 approval in place. The process is normally covered by the Sponsor's research project protocol or under research site Patient Identification Centre (PIC) arrangements. All data transfers must be covered by appropriate research or data sharing contract.

Partner Organisation	Data Format	Designated Purpose	Transfer/ access requirements
Higher Education Institutions	• Pseudo-anonymised data • Anonymised data	Patient data must only be used for specific research projects with HRA/ NHS ethics approvals or transfer to registries with appropriate ethics approval, to be used solely for research purposes.	Unless anonymised, the patient must have consented to possible non-specific data transfer taking place. Anonymisation must take place before data is transferred to HEI storage. Data must be kept for the duration of the research project and deleted on completion as set out in n accordance with the Trust's Records Retention and Disposal Policy. Data collected for inclusion in registries can only be transferred or shared with third-party organisations for research purposes. All data transfers to HEIs must be covered by appropriate research or data sharing contract. All data sharing contracts with Barts Health must be reviewed by the Trust's Information Governance team or the JRMO as applicable.

Partner Organisation	Data Format	Designated Purpose	Transfer/ access requirements
Charities; Social and Community services; and other non-commercial research Funders	• Pseudonymised/ Anonymised data	Patient data must only be used for specific research projects with HRA/ NHS ethics approvals or transfer to registries with appropriate ethics approval, to be used solely for research purposes.	Unless anonymised, the patient must have consented to possible data transfer taking place (non-specific). Anonymisation or Pseudonymisation must take place before data is transferred to the partner organisation. Data must be kept for the duration of the research project and deleted on completion in accordance with the Trust's Records Retention and Disposal Policy. Data collected for inclusion in registries can only be transferred or shared with third-party organisations for research purposes. All data transfers must be covered by an appropriate research or data-sharing contract. All data-sharing contracts with Barts Health must be reviewed by the Trust's Information Governance team or the JRMO as applicable.

Partner Organisation	Data Format	Designated Purpose	Transfer/ access requirements
Commercial Entities including pharmaceutical and devices companies, private research establishments and hospitals, data analyst organisations. (A list of potential commercial research partners is attached at Appendix 3)	• Pseudo-anonymised data • Anonymised data	Patient data must only be used for specific research projects with NHS ethics approvals or transfer to registries with ethics approval, to be used solely for research purposes.	As above for Charities; Social and Community services; and other non-commercial research Funders'. In addition, access to the Trust's patient records must be managed according to the protocols agreed between the Trust and Sponsor, which will be laid down in the research contract between the parties. It is acknowledged that sponsor representatives will be granted access to source data for monitoring and auditing purposes.
Government Departments	• Patient identifiable data • Pseudo-anonymised data • Anonymised data	Patient data must only be used for specific research projects with NHS ethics approvals or transfer to registries with ethics approval, to be used solely for research purposes. Access to patient identifiable records and source documentation is restricted to regulatory authorities with a legal right to access such data.	As above for 'Charities; Social and Community services; and other non-commercial research Funders'. In addition, access to the Trust's patient records must be managed according to the protocols agreed between the Trust and regulators and in accord with the regulator's legal responsibilities in handling such data.

16.3.3 Data Transfer and Storage

Methods for transferring data from Trust systems and locations to other internal or external are covered by the Trust's Information Security policy. All agreements and contracts covering research activities that involve the transfer of data must reference the standards set out in the Trust's data management policies and undergo review by the Trust's Data Protection Officer or the JRMO as applicable.

16.3.4 Approved use under this policy

Each data sharing agreement or research contract will determine, on a case-by-case basis, the use to which patient data can be put. The assumption shall be that, unless a Section 251 approval is in place, a patient is fully informed, explicit consent will be required to participate in the proposed research project and before data is accessed and transferred to partner organisations. This means that the patient should be made aware of the purpose, nature and scope of the research, including the partner organisations with whom the data will be shared. Given consent should be formally recorded. Patients should also be informed that they have the right to withdraw their consent for any further research participation should they wish to do so. Both the Trust and its research partners should have sufficient arrangements in place to facilitate the withdrawal of consent if required, and where appropriate, delete the data held. There are instances where right of erasure does not apply if processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority. This means that less reliance should be placed on consent as the lawful bases for processing.

For information on the NHS National opt our please refer to JRMO policy on consent.

Anything that falls within the scope of the UK policy framework for health and social care is a permitted use, which includes:

- Clinical trials
- Research registries, Trust managed and registries to which our data has been transferred.
- Non-commercial tissue banking activities.
- Genome and other "omic" databases.
- Basic science research studies that include the collection of data for analysis that supports the examination of tissue or other human materials.
- Prospective or retrospective research surveys.

16.3.5 Management of Data

In all cases, the Trust will ensure that suitable arrangements are in place for the transfer, storage and ongoing management of shared research data. Internal registries, databases and data collections in any form that contain patient information in identifiable, anonymised

or pseudo-anonymised formats must be notified to the Trust's Information Governance Team who will maintain a register of all data stores and their permitted uses.

In entering agreements with external organisations, the Trust will ensure that research contracts or data sharing agreements comply with the permitted uses set out in this policy and the Trust's rules on transferring and storing personal data.

The Trust will not enter into arrangements that grant third parties (commercial or non-commercial) exclusive access to the raw data that it holds (healthcare, research or operational) or include conditions limiting any benefits relating to that data that accrue to the Trust.

16.4. Definitions

Anonymised data: Data that is unrecognisable, even to the data owner. It cannot be re-identified by referring to the study ID or by processing it together with other information which is available or likely to be available. (See Recital 26, GDPR)

Direct Care Team: Those health and social care professionals who provide direct care to the patient, and others, such as administrative staff, who directly support that care. (See Policy 9)

Pseudonymised data: Identifiable data that has been replaced with alternative identifiers that bear no overt relationship to the true values. Re-identification of data can only be achieved with knowledge of the de-identification key. (See Article 4, GDPR)

Registry: A collection of information about individuals usually focused on a specific diagnosis or condition. Many registries collect information about people who have a specific disease or condition, while others seek participants of varying health status who may be willing to participate in research about a particular disease. Individuals provide information about themselves to these registries voluntarily. Registries can be sponsored by a government agency, HEIs or a non-commercial organisation, a healthcare facility, or a private company (United States National Institute for Health).

Research sponsor(s): An individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, management and financing (or arranging the financing) of the research (NHS Health Research Authority).

Section 251 approvals: Section 251 of the NHS Act 2006 (originally Section 60 of the Health and Social Care Act 2001) provides the statutory power to ensure that NHS patient identifiable information needed to support essential NHS activity can be used without the consent of patients. The power can be used only to support medical purposes that are in the interests of patients or the wider public, where consent is not a practicable alternative and where anonymised information will not suffice. Separate arrangements are in place in Scotland and Northern Ireland, see Central NHS and other data approvals for further information. In England and Wales, Section 251 approval provides a reliable basis in law to permit the disclosure and temporary use of identifiable NHS patient information for those

either wishing to obtain identifiable NHS patient information without consent, or data controllers who are asked to supply identifiable patient information without consent.

16.5. Duties and responsibilities

All staff working in the Trust	All staff working in the Trust are expected to comply with this policy.
Managers	Clinical Board Directors of Research, Joint Research Management Office Managers and Clinical Leads managing research groups must ensure that their staff comply with this policy.
Other posts	All staff involved in the delivery of research, including medical personnel, research nurses, data managers and processing staff will have specific duties under the protocols that govern the conduct of each research project, which will include sharing information with external sponsors of research.
Committees	The Trust Research Board will monitor the implementation of this policy and its regular review, in line with its remit to oversee all research in the Trust, following the UK policy framework for health and social care research 2018, GCP regulations and all other statutes and regulations that pertain to research.
Research staff working at Queen Mary University of London	All staff working in the University who have access to Barts Health patient data of some form must adhere to this policy and ensure they are compliant with it.

APPENDICES

Appendix 1: Guiding Principles

These are taken from the Department of Health & Social Care Guidance, 'Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation', published 15 July 2019.

Principle 1

Any use of NHS data, including operational data, not available in the public domain must have an explicit aim to improve the health, welfare and/or care of patients in the NHS, or the operation of the NHS. This may include the discovery of new treatments, diagnostics, and other scientific breakthroughs, as well as additional wider benefits. Where possible, the terms of any arrangements should include quantifiable and explicit benefits for patients which will be realised as part of the arrangement.

Principle 2

NHS data is an important resource and NHS organisations entering into arrangements involving their data, individually or as a consortium, should ensure they agree to fair terms for their organisation and the NHS as a whole. In particular, the boards of NHS organisations should consider themselves ultimately responsible for ensuring that any arrangements entered into by their organisation are fair, including recognising and safeguarding the value of the data that is shared and the resources which are generated as a result of the arrangement.

Principle 3

Any arrangements agreed by NHS organisations should not undermine, inhibit or impact the ability of the NHS, at a national level, to maximise the value or use of NHS data. NHS

organisations should not enter into exclusive arrangements for raw data held by the NHS, nor include conditions limiting any benefits from being applied at a national level, nor undermine the wider NHS digital architecture, including the free flow of data within health and care, open standards and interoperability.

Principle 4
Any arrangements agreed by NHS organisations should be transparent and communicated clearly to support public trust and confidence in the NHS and wider government data policies.

Principle 5
Any arrangements agreed by NHS organisations should fully adhere to all applicable national-level legal, regulatory, privacy and security obligations, including in respect of the National Data Guardian's Data Security Standards, the Data Protection Act, 2018, the General Data Protection Regulation (GDPR) and the Common Law Duty of Confidentiality.

Appendix 2: Examples of where research data is already collected

- The collection and storage of samples in national or local biobanks with associated anonymised data, for example the 100k Genome project.
- The collection of data for externally sponsored commercial or non-commercial clinical trials where data is collected and stored via sponsors electronic case report forms and stored in accordance with MHRA or other regulatory bodies' rules and regulations.
- A wide variety of organisations collect patient data via Barts Health participation in ethically approved national data collection projects, with data stored in managed registries. These include government organisations such as NHS Digital (via is ODS), The National Cancer Registration and Analysis Service, charities such as the National Irritable Bowel Registry, several Royal Colleges and a range of other not for profit organisations.
- The Picture Archiving and Communication Systems (PACS). This is a system based on the universal (Digital Imaging and Communications in Medicine) standard, which uses a server to store and allow facile access to high-quality radiologic images, including conventional films, …

Appendix 3: Potential commercial research partners

Companies that sponsor clinical trials of medicinal products and devices.

1. Companies involved in the collection of data for sale or distribution to pharmaceutical and device companies or other organisations for purposes that include the development of software applications that create clinician and patient benefits.
2. Application development companies that work with our clinicians to build patient-based apps for diagnostic or treatment purposes.
3. Companies that work on the development of new diagnostics.
4. Commercial entities involved in the use of artificial intelligence to develop new treatment modalities.
5. Companies involved in the development of research registries or other data stores that are accessible for a fee.
6. Providers of Internet-related services and products, which include online advertising technologies, search engines, cloud computing, software, and hardware.
7. Companies providing interactive computer-mediated technologies that facilitate the creation and sharing of information, ideas and other forms of expression, via virtual communities and networks.

This policy applies only to Barts Health.

FINANCIAL PROBITY IN RESEARCH

17: Identification and protection of Intellectual Property

17.1 Introduction

Both Queen Mary and Barts Health undertake activities that enable both parties to make progress in our understanding of the world and wish to ensure that any discoveries are developed to bring a benefit to society and the world. In order to ensure this can happen both organisations recognise the need to protect their intellectual property.

This IP policy has been created to inform staff members of the importance of IP protection and subsequent exploitation and advise how Barts Health undertakes to manage this. It protects both the interests of Barts Health and its staff.

It is incumbent upon Barts Health to exploit, whenever possible, anything that is produced by its employees or contractors where that product has potential commercial value or could lead to a new service development or create new efficiencies or savings.

17.2 Barts Health Intellectual Property Policy

17.2.1 Definition of IP

Intellectual Property (IP) can be defined as, but is not limited to inventions, designs, project results, prototypes, systems, processes, formulae, publications, internal reports, natural discoveries, ideas, knowledge or know-how. Types of IP include Copyright, Registered Designs and Design Rights, Patents, Trademarks, Database rights and Know-how.

IP is often described as being either Background IP or Foreground IP:

Background IP is all the IP that is relevant to a collaborative venture or project that is supplied by the parties at the start of the project. The usual ownership position with regards to Background IP is that the party that has created and supplied it will retain ownership of it and any improvements made to it during the course of a project.
Foreground IP is all the IP produced within the collaborative venture or project during its lifetime. Ownership of Foreground IP must also be formalised within a contract to avoid the default position of joint ownership between the parties arising, which can create unwanted restrictions on how Barts Health may commercialise any Foreground IP.

17.2.2 Application of Barts Health IP Policy

This policy applies to Barts Health staff and contractors working on behalf of Barts Health. The policy is to be regarded by Barts Health staff as the default position with regards to IP ownership. Although the policy refers to the most beneficial position for Barts Health in terms of IP ownership and subsequent income sharing, it is understood that it will not always be possible to achieve this.

Staff who are authorised to sign contracts with third parties, such as research or collaboration contracts, must consider and, if necessary, seek advice relating to IP matters before signing contracts.

17.2.3 Ownership

Barts Health employees have certain obligations relating to IP within their contracts of employment. The arrangements for the protection of Barts Health IP for contracted staff should include an undertaking to comply with the Barts Health IP Policy.

All IP made, written, designed or originated by staff during the course of employment with the Trust and in connection with their appointment shall be the property of the Trust to the fullest extent of the law. Staff should not make commercial use of services or products developed in the Trust's employment without the prior agreement of the Trust.

Staff should immediately disclose to the Trust, using the appropriate disclosure form, full particulars of any IP made, written, designed or originated by them during their employment with the Trust irrespective of whether it was so made or discovered during normal working hours or using the facilities of the Trust.

Staff must not register IP in their own name or make commercial use of services or products developed in the Trust's employment without the prior agreement of the Trust.

Staff waive all present and future moral rights in any copyright works in favour of the Trust and agree not to support or maintain nor permit any claim for infringement of moral rights in such copyright works.

Where an individual holds an honorary contract with another organisation but that individual's principal employer is Barts Health, then the ownership of any IP arising from their work is vested in Barts Health.

17.2. 4 Contracts

In circumstances where Barts Health is working in conjunction with another organisation the IP position will need to be determined within a collaborative agreement prior to the commencement of a project. In determining the position, the interests of Barts Health must be taken into account and ownership should be dictated by the level of input that the organisations have into the generation of IP.

All collaboration contracts will require review by the Trust before receiving final authorisation to ensure that Barts Health receives an adequate revenue share or if applicable, rights of ownership in IP arising from the collaboration.

Barts Health would advise that joint ownership of IP is avoided. Joint ownership of IP has the potential to present problems for the parties owning IP as they are not permitted to assign, licence or subcontract to third parties without the consent of the co-owner. As stated above it is advisable that ownership is agreed by specific contracts between the two parties prior to IP being created.

Should Barts Health decide not to prosecute a particular aspect of IP, ownership rights will be assigned to the individuals who have been instrumental in its generation. Where the Trust agrees to assign IP ownership rights to an employee an Assignment of Rights Agreement will be concluded. In these circumstances, the individuals will be free to take

whatever action they deem necessary at their own expense to protect and exploit the IP without further involvement of Barts Health.

Where third parties request the use of Trust trademarks or logos, they should obtain the prior written agreement from the Trust and agree to its control, typically by a Licence. Use of Trust trademarks and brands must be in line with the Trust's Brand Guidelines.
The JRMO is responsible for negotiating research contracts including all IP aspects. The JRMO is also responsible for advising on intellectual property matters, with the involvement of the Trust Commercial & Business Development Team, in all other commercial contracts that involve the Trust IP.

A contract is usually the major mechanism for protecting Barts Health's IP. All contracts and agreements for research projects taking place on Barts Health premises and/or utilising Barts Health resources must be reviewed by the JRMO.

The JRMO reviews all contracts and agreements to ensure adequate protection of its IP, including clarification of ownership. The JRMO will decide whether to accept or decline a contract proposal on behalf of the Trust. Ownership of both Background IP and Foreground IP must be formalised.

Where ownership of the IP does not vest in Barts Health, contracts should clearly set out:

- The distribution of income received from any commercialisation to the various parties;
- The level of each party's contribution to the development of the IP; and
- How any costs associated with protection of the IP should be borne.

Once a contract has been reviewed and agreed by the JRMO it must also receive authorisation by an authorised Barts Health Officer.

Failure to inform the JRMO of any contractual arrangement may make individuals liable under Barts Health's Policy on Misconduct in Research (see policy number 24).

17.2.5 Duty to keep records

Although it is difficult to establish when, from a concept or idea, a clearly definable piece of intellectual property emerges, it is vital that during the course of a research project the results are clearly recorded.

Employees, who are investigators and their fellow or subordinate researchers, as the research progresses, will keep laboratory notes to a standard format.

Once research into a concept or idea results in definable conclusions the outcome will be clearly recorded through an appropriately structured report.

Where an outcome has a potential commercial value, the report will be sent to the JRMO or a specifically designated individual for review and evaluation.

The potential commercial value of the IP will be assessed by Barts Health and, if necessary, action taken to protect the IP and initiate the commercialisation process.

17.2.6 IP Protection

Barts Health has a duty to adequately protect its IP. Ensuring that effective protection is maintained can only be guaranteed with the co-operation of its employees.

As all Barts Health employees (and appointed contractors) have a duty of confidentiality as stipulated within their employment contracts, they should not make public any confidential or unpublished information pertaining to the research they or their colleagues are undertaking.

The reason for this is that premature disclosure of research or ideas could have the effect of preventing the IP from being protected or ensuring that Barts Health has sole use and right to commercialise it. Employees should be aware that premature disclosure can be inadvertent and could arise through:

- Publishing in a thesis;
- Articles in journals;
- Presentations at lectures;
- Public use of the IP; or
- Social Media platforms.

Before discussions can begin with potential external partners a confidentiality undertaking will be concluded between Barts Health and the external organisation and signed on behalf of Barts Health by an authorised officer and the employee. This is typically via a Non-Disclosure Agreement (NDA) for which standardised versions are available.

All visitors to Barts Health's work sites whom are not employees of Barts Health will be required to sign a confidentiality agreement before they obtain access to sensitive research areas.

One of the ways that IP is automatically protected is via Copyright. Copyright is an unregistered right that arises automatically upon creation of books, computer programmes, publications, lecture notes, reports, laboratory notes, social media material etc. Although the right arises automatically, in order to make others aware of the Copyright it is advisable to add a note at the end of the text to the effect that Copyright belongs to Barts Health NHS Trust and this will protect all such texts.

Where, in the view of Barts Health, a piece of IP requires patent protection, Barts Health's patent attorneys will be approached to draft a specification and submit an application to the Patent Office. Such action will be taken only if a clear commercialisation route can be identified and forecast income streams exceed the costs of patenting.

Other areas of IP protection that Barts Health may consider protecting its IP include registering designs and applying for trademarks with the Intellectual Property Office.

17.2.7 Publication

Barts Health understands the importance of disseminating the results of its R&D activities, for the public health benefit and to further its research strategy. However, it is important that any IP contained in published material has been adequately protected to ensure that Barts Health's ability to successfully commercialise any potentially valuable IP is not compromised.

The JRMO and Commercial & Business Development Team will continue to raise awareness of the importance of protecting the Trust's IP and to seek to avoid the inadvertent

release of IP by individual staff members through both this policy and also through training materials.

Staff are encouraged to consult the JRMO before articles are submitted for publication or information is disclosed to a third party where they believe that potential Trust IP exists or where the staff member needs confirmation that no Trust IP will be released inadvertently.

Where there is a deliberate release of Trust IP without prior approval of the JRMO this could be considered a disciplinary matter.

Should protection be required the JRMO will take steps to ensure that such protection is put in place before publication of the research findings.

The JRMO will ensure that any delays in publication required in respect of this policy will be minimal and in no circumstances shall such delays exceed 6 months from the date of receipt of the article.

17.2.7 Commercialisation

There are a number of ways that Barts Health can exploit IP that it has developed. The principal methods of exploitation are as follows:

- Assignment of the IP rights to a commercial organisation: this would be a sale of the IP rights to another organisation
- Licensing Agreements: where companies are licensed to utilise Barts Health IP in exchange for a royalty based on the value of sales the company makes, enabling Barts Health to impose certain conditions on the use of the IP Rights
- The creation of spin-out companies that can then proceed to exploit the IP rights more freely than Barts Health may be able to, which will need to take into consideration current national regulations and guidelines

Other options might include:

- Sale of IP rights in exchange for specific initiatives for example funded posts, purchase of capital equipment.
- Through joint ventures with other non-commercial organisations, for example medical charities, local authorities.

The JRMO will take overall responsibility for ensuring that Barts Health's IP is made available to potential partners.

The decision to pursue a commercial development will rest with the Group Chief Medical Officer and the IP Management Oversight Group. The resources that NHS bodies devote should be commensurate with the likely benefits and with other calls on their funds.

17.2.8 Remuneration for inventors

Barts Health recognises that staff involvement with the development of its IP should be rewarded through a share in the proceeds of any successful commercialisation.

To enable this the proceeds are measured in terms of total Cumulative Net Income, and this is defined as the income received minus any patent or other protection costs, legal fees, relevant taxes and any relevant expenditure by Barts Health.

The inventors share will be as shown below:

Total Net Cumulative Income	Inventor's Share %	Barts Health Share %
0 - £10,000	90	10
£10,000 - £50,000	75	25
£50,000 - £200,000	50	50
£200,000 +	30	70

The Trust IP policy version that is valid on the date on the disclosure form, will determine how income will be shared between the inventor and the Trust.

Where multiple inventors (Barts Health employees) are involved in the creation of IP, the inventor's share shall be split between the inventors having regard to the level of their input. If, following discussion amongst the inventors, a split cannot be decided, it shall be determined solely by the Group Chief Medical Officer or other authorised Director.

In dealing with Barts Health exploitable intellectual property, the JRMO will bring to the notice of inventors and all those involved in the commercialisation process, Barts Health's policy on Standards of Business Conduct. The internal regulations in this policy will be strictly followed, particularly with regard to potential conflicts of interest.

17.3 Queen Mary policy *(Subject to a separate review by QM Innovation)*

17.3.1 Introduction

Queen Mary affirms the inherent value to its mission of research and its applications and their core role in our primary commitment to the public good.

Queen Mary will foster the free and open creation and dissemination of Intellectual Property or Know-how (IP) and its best use; this will include a clear framework providing for the allocation of time and resources to the authors or creators of IP, and generous terms for the allocation of the financial benefits of the commercialisation of that IP to those authors or creators.

This policy is based on the following principles:

- That IP produced at Queen Mary should be used in the public interest in general, whilst recognising that it may be appropriate for Queen Mary and/or inventors or authors to gain financial benefit from its commercialisation, with those benefits being defined so as to encourage those inventors or authors to commercialise that IP;

- That it is required to protect the traditional rights of scholars concerning their work and to encourage the free and open creation and dissemination of works produced by researchers and scholars;
- That any significant financial or other resource support by Queen Mary for the development of any IP should be identified, and that recognition should be made of Queen Mary's responsibility as a charity and recipient of government and charity funding to realise appropriately and proportionally any gains from that development, for the benefit of its future staff and students; in making use of significant Queen Mary resources for the development of any IP, a Queen Mary employee is accepting the terms of this policy;
- That the work done by academic staff in the creation and/or commercialisation of IP covered by this policy should be recognized in staff appraisals and assessments of workload and promotion.

The full Queen Mary Policy on Intellectual Property comprises this summary document as an overarching guide, together with any approved subsidiary documents covering particular areas in more detail.

17.3.2 Inventions

"Inventions" are any research outputs that can be reasonably identified as having commercial potential including patentable or potentially patentable discoveries or ideas and any associated technology required for their development or application.

All rights in Inventions created by a Queen Mary employee in the course of their employment, or otherwise but with significant use of Queen Mary resources, will generally belong to Queen Mary.

If an employee or employees of Queen Mary create an Invention outside the course of their normal employment duties, without significant use of Queen Mary resources, then that Invention will belong to the employee or employees, jointly if not otherwise agreed.

Ownership of Inventions created by an employee or employees of Queen Mary with an external body will be determined by a Queen Mary-approved agreement; where this has not been defined in advance, ownership will in the first instance belong to Queen Mary.

17.3.3 Academic works

"Academic Works" are those writings, research outputs other than Inventions, and other productions (for example video or audio recordings) that are aimed at communicating the progress or results of research or scholarship. The IP rights to the Academic Works created by individuals whilst Queen Mary employees, and the rights to any revenues derived from these, remain with their authors, however, Queen Mary has a licence to use those works and a right to sub-licence their use, in order to advance its higher educational mission ("Academic Purposes"). This is a condition of Queen Mary waiving its rights of ownership of the relevant IP.

Where Queen Mary involvement in the creation of an Academic Work consists of significant investment of additional funding or resources outside of the normal course of employment, then ownership and rights to any share of royalties or income shall be fairly apportioned between Queen Mary and the author/s.

Where Academic Works are created subject to an agreement between Queen Mary and a third party then any copyright issues will be handled according to the terms of such an agreement.

17.3.4 Teaching and administrative materials

“Teaching Materials” and “Administrative Materials” are any materials produced by Queen Mary employees in the course of teaching and administrative work, respectively, undertaken in the course of their employment.

Queen Mary agrees and acknowledges that all performers’ rights in any Teaching Materials, including any video or other recording of a Queen Mary employee’s lectures or presentations, or similar works which are performances in IP terms, are owned by the employee. Each employee grants Queen Mary rights to use such materials, and their recordings, for Academic Purposes.

Queen Mary owns the IP rights to Teaching Materials and Administrative Materials, whilst granting use of those materials by their creator for any purposes consonant with their Queen Mary employment.

With regard to Teaching Materials produced whilst they were in Queen Mary employment, Queen Mary grants any former employee the personal licence to unrestricted non-commercial use of that material elsewhere. This includes the use of that material as the basis for creating new teaching materials for another academic institution.

If Queen Mary decides to commercialise Teaching Materials outside its Academic Purposes, then those Queen Mary employees involved in their creation will have a fair and reasonable share of the proceeds of commercialisation.

A current or former Queen Mary employee may object to the use by Queen Mary of Teaching or Administrative Materials in cases where they are identifiable as a creator if the use of that material is felt to be to their detriment or misrepresents the creator. The Queen Mary IP Committee will rule on such objections.

If a current or future employee wishes to commercialise Teaching Materials, the agreement of Queen Mary is required, but will not unreasonably be refused. The terms of such agreement, which might include a share by Queen Mary in the proceeds of commercialisation, should be negotiated with Queen Mary Innovation (QMI).

17.3.5 Performances

IP ownership of recordings of creative performances, such as dramatic or musical performances, remains with the performer/s. For performances created by Queen Mary employees in the course of their employment, Queen Mary has automatic permission to use those works for Academic Purposes. For joint performances involving third parties, IP ownership will be according to prior agreements among those parties.

17.3.6 Software and Databases

Queen Mary recognises the value of open-source software and open data, and the related licensing arrangements, for promoting knowledge creation and dissemination.

Software or databases that are created as part of the process of communicating the progress or results of research or scholarship, and that do not have reasonably foreseeable commercial potential, are to be treated as Academic Works under this policy.
Any software or databases created by Queen Mary employees in the course of their employment that may reasonably be foreseen at any given time to have commercial potential shall be treated as Inventions from that point under this policy. Any cases of doubt should be referred to the Queen Mary IP Committee for a ruling.

17.3.7 Student creations

The IP rights to works created by Queen Mary students, including Inventions, are in general owned by the creator/s, with Queen Mary having permission to use them for Academic Purposes. If student works are created in connection with an agreement with an external body IP ownership will be determined by that agreement. If the works are created whilst the student is in employment using Queen Mary funds, or whilst using significant Queen Mary resources, then Queen Mary owns the IP rights. This includes cases where the student work is largely designed and led by a Queen Mary academic or academics, which could include research or other project work.

Notwithstanding the above, Queen Mary may from time to time provide financial and other resources through entrepreneurship schemes, competitions and initiatives with which its students can engage. Queen Mary may, at its discretion, choose to agree to joint ownership or to waive its claim to any IP generated through such activities in favour of the students. Any such agreements will be set out in the relevant terms of the internal scheme, competition or initiative.

17.3.8 Other staff and associates

The rights to all IP created by non-academic staff (staff without teaching or research as a major component of their contract), in the course of their employment or with significant use of Queen Mary resources, are owned by Queen Mary.

Unless agreed otherwise in any contract between Queen Mary and a third party, Academic Works and Inventions arising from the non-clinical work of clinical academics on Queen Mary contracts shall be treated in the same way as those arising from the work of academic staff. Those arising from the clinical work shall be treated under the terms of the contractual agreement with the appropriate health authorities; where these are not described the Queen Mary policies shall apply.

Academics or researchers who are affiliated with but not employed by Queen Mary (“Associates”) are generally required to transfer to Queen Mary any IP they create using Queen Mary resources in the course of their affiliation. Such Associates will be treated as if they were Queen Mary employees for the purposes of sharing revenue.

17.3.9 Disclosure

Queen Mary employees are required to disclose in a timely fashion all Inventions or other works of foreseeable commercial value that have been created in the course of their normal duties of employment with Queen Mary, or during joint work with an external body, or where significant use of Queen Mary resources has been made. Student Inventions where the IP is

owned by Queen Mary under Section 7 should also be disclosed. All such disclosures should be made to QMI.

Information relating to Inventions or other works that could reasonably be foreseen to have commercialisation opportunities should be treated by Queen Mary staff and students sensitively and disclosed only to relevant Queen Mary employees prior to protection by a suitable agreement.

Each School or Institute of Queen Mary should have a policy for encouraging innovation and achieving impact for its research and scholarship; this policy should cover the operation of a system that identifies any non-commercial use for the purposes of impact and discloses to QMI any works by members of their staff or (where relevant under Section 7) student body that have the potential for commercial use.

17.3.10 Commercialisation

Queen Mary's policies on the commercialisation of Inventions created by Inventors also apply in general to other works with commercial value created by authors, subject to any specific statements made within the IP Policy.

QMI, acting on behalf of Queen Mary, is responsible for the identification, evaluation, protection and commercialisation of Inventions owned by Queen Mary. Whilst this may not necessarily involve purely maximising financial return in general, QMI will work with the Inventors to identify appropriate third parties to commercialise the Inventions or works under the best terms.

QMI will agree with the Inventor(s) a strategy for the development, protection and commercialisation of an Invention. This will include an agreement with the Inventor's line managers covering the appropriate recognition of, and allowance for the time and other resources required for such activities.

Neither Queen Mary nor QMI will promote or commercialise any Invention that would clearly conflict with any ethical policies agreed by Queen Mary, nor with the ethical principles of the Inventor/s.

Queen Mary recognises that commercialisation of IP may not always be appropriate and that on occasion it is in the best interests of knowledge transfer or exchange to place IP in the public domain.

If QMI decides not, or is unable, to commercialise the Invention within a reasonable timeframe then the Inventor(s) may ask for it to be assigned to them. Such assignment will include a licence back for use by Queen Mary.

Queen Mary shall be solely entitled to use its name, trademark, service mark, corporate name, domain name or any other mark in respect of commercialization of any product or service.

17.3.11 Benefits

Queen Mary owns the revenues received from Commercialisation of its Inventions or other works, however, in the spirit of the principles in Section 1, the following sharing arrangements shall apply. Where more than one author or inventor has played a significant

role in the creation of an Invention and there is no prior agreement amongst them on the sharing of benefits then the Inventor benefits shall be shared equally between the Inventors. The sharing of Net Revenue from any works not covered by sections A and B below shall be consistent with the arrangements described and in line with the principle that the inventors or authors will have a fair and reasonable share of the proceeds of commercialisation.

A. Sharing of Revenue from Licence/Sale of Inventions

The income to be shared between Queen Mary and the Inventor(s) is defined as the cumulative Net Revenue from the licensing of Inventions, or from the total amount of the sale, to a third party. The following shall be deducted in calculating the Net Revenue: VAT, any patent protection or legal costs, any revenue sharing costs, employer tax liabilities, and any other expenses directly related to obtaining or commercialising the Invention (excluding QMI staff resource costs or any Queen Mary funds contributed to developing the Invention).

In the following, “Significant Internal Funds” means a total sum in the region of £50,000 from Queen Mary funding streams and/or patent and other legal expenditure, and “Significant QMI Resources” means an agreement reached with QMI on the strategy, means and likely timescales for commercialisation, and the reasonable efforts, normally within a one to two year period, by QMI to deliver on this including, but not limited to, seeking translational development funding, leading on new spinout investment, or marketing and negotiating licenses with third parties.

Where an Inventor or Inventors makes no use of Significant Internal Funds or Significant QMI Resources then they will have 90% of Net Revenue. Where use is made of either Significant Internal Funds or of Significant QMI Resources, then the Inventor/s will have 70% of Net Revenue. Where both such Funds and Resources are used then the Inventor/s will have 50%. The percentages or amounts under conditions where significantly greater or subsequent funds or resources are to be utilised will be determined by prior agreement between QMI and the Inventor/s.

The Queen Mary share of Net Revenue will be apportioned between Queen Mary and the Resource Centre. The latter will be held at the Faculty level and normally allocated to the School or Institute of the inventor(s), with a significant proportion of that allocation going to the research area of the inventor(s). Where the Queen Mary share of the Net Revenue upon sale, or cumulative license income, is less than £1,000,000, then the Resource Centre will be allocated the entire Queen Mary share. The distribution of any Queen Mary share that is in excess of these amounts will be decided by the Queen Mary Senior Executive.

B. Sharing of revenue arising from the formation of a new spinout company

Where any Invention is commercialised through the creation of a new spinout company, the academic founder benefits will be represented by shares in the spinout company.

For clarification, Queen Mary benefits are those realised from the sale of shares in the new

- deviation from agreed formal protocols or regulations, including accepted professional standards of behaviour and conduct, in carrying out research, and the failure in that context to avoid risk or harm to humans, animals used in research, and the environment where appropriate;
- The facilitation of misconduct in research or collusion in, or concealment of, such actions by others;

- The intentional and unauthorised use, disclosure of, removal of or damage to research-related property of another researcher, including:

  intellectual property, writings, data, apparatus, materials, hardware, software, any other substances or devices used in or produced whilst conducting research, infringement of data protection requirements or the confidentiality of research subjects, misuse or misappropriation of the work of others and, for example, the unethical use of material provided in a privileged way for review or assessment.

This policy applies to Barts Health and Queen Mary as indicated.

18. Costing research

18.1 Background

The guiding principles in the Higher Education Sector and NHS (through the UK policy framework for health and social care research, 2017[36]) is that through accountability and transparency all research undertaken in the public sector must be seen to offer the taxpayer value for money. Therefore, all research, whether funded through Barts Health or Queen Mary using internal resources or externally funded (for example, Research Council, DH, charity, industry), must be fully costed.

The costing of research projects is a multi-disciplinary task. It will be led by the Joint Research Management Office (JRMO)'s Costing and Contracting Team, working in conjunction with the principal investigator, relevant Barts Health and Queen Mary service departments (e.g. IT, Clinical Pathology, Pharmacy, Imaging, Animal House etc), Barts Health and Queen Mary Finance Departments. All costing with the exception of Barts Health commercially sponsored clinical trials that are required to use the National Costing Template Portal, will be costed using the Worktribe Research Management System.

18.2 Policy

Both Barts Health and Queen Mary will undertake to establish the Full Economic Cost (FEC) of all projects, including PhD Doctoral Training Partnerships and Queen Mary consultancy, regardless of its source of funding, including all direct costs and an apportionment of corporate overheads and other relevant support services, estates and indirect costs as appropriate in line with the relevant Queen Mary and Barts Health overhead policies. The JRMO will apply national costing values where these have been agreed with specific funding bodies.

The JRMO will assign a Worktribe unique record to each project, review the costing request, any protocol or specification and liaise with the principal investigator, service departments and collaborating institutions, as appropriate, to calculate the direct and indirect costs of the project.

The JRMO will define and document the full cost for the project, ensuring that in all cases the costs of all participating organisations are fully assessed and included in the final FEC costing.

The final costing will require approval from the JRMO, clinical department, Institute, Division or School as appropriate prior to submission to funding organisation.

The final application, study protocol or project specification and all supporting documentation must be provided to the JRMO by the Principal Investigator or a nominee and uploaded onto the Worktribe system. At this point, the Principle Investigator must declare any conflicts of interest that might affect the process of establishing a full and fair economic cost for the activity.

The full cost of the project and its method of calculation must be treated as confidential. The costing of such projects must, in all cases, including expressions of interest, outline

[36] UK policy framework for health and social care research at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

applications or first stage applications, be undertaken by the JRMO and the methods used to determine full cost can only be relayed to funders with the agreement of the office.

This policy applies to both Barts Health and Queen Mary.

19. Externally supported R&D pricing

19.1 Background

Pricing issues can be complex, and each project must be considered individually. Project costings should be drawn up by the lead investigator and JRMO to establish a base on which price negotiations can take place. A minimum of 5 days should be allowed prior to submission deadlines for the JRMO to complete a detailed costing in line with funder requirements.

19.2 Policy

Barts Health and Queen Mary will price externally funded projects in accordance with HEFCE and NHS pricing policies and the accepted guidelines of individual external funding body. Barts Health will use the National Agreed costing template for commercial studies. Queen Mary will price commercial studies at FEC plus in line with Queen Mary's Overhead Policy. Non-commercial projects will be costed according to the funder's conditions and nationally agreed pricing policies. In general, the principles relating to Full Economic Costing (FEC) will be adhered to by both organisations. All research activity, including PhD Doctoral Training Partnerships and Queen Mary consultancy, must be submitted to the JRMO for costing and the price to be charged will be determined by the office.

19.3 Non-Commercial

For the avoidance of doubt, non-commercial research includes all externally funded research projects and projects that are for educational purposes. These projects must not contain clauses that allow a commercial or for-profit entity to impose intellectual property rights restrictions or restrictions on publishing results, in particular by limiting further analysis or use of such results or by delaying the availability of data and results for more than six months.

19.4 Collaborative Research

Collaborative Research with a commercial entity is where a protocol or workplan predefining the research project, is developed by both parties in collaboration, or where a commercial entity is providing significant input, resource or an in-kind contribution to a project. Any reduction in price to be charged because of this contribution will be directly dependent on the resource requirements of the research, intellectual property rights, adherence to any overhead policy and the allowable cost rules of the funding body.

19.4 Commercial

Where a commercial entity commissions research and Barts Health or Queen Mary undertakes to carry out the work according to pre-determined processes set out in the company's protocol and where the primary principles associated with non-commercial funding of research programmes do not apply, the research is classified as being commercial. The principal commercial beneficiary of the results of this type of study will

normally be the funder of the research. Each project must be properly governed by the principles outlined in the externally supported R&D section of this document and based on FEC and a separate account should be kept for each research project through which funds should be channelled.

This policy applies to both Barts Health and Queen Mary.

20. Distribution of research project funds

20.1 Background

Although both Barts Health and Queen Mary operate identical systems for managing external research grant accounts, their policies governing the internal distribution of research project funds, particularly overheads, differ marginally.

This policy sets out the parameters on which the process of distributing funds from external funders of research will operate in both Queen Mary and Barts Health. It should be read in conjunction with, as appropriate the Trust's Standing Financial Instructions[37] and Queen Mary's Financial Regulation and Procedure Policies – see Appendix A to this Policy, Queen Mary Research Grants and Contracts Overhead: Policy and Governance.

20.2 Definitions

20.2.1 Direct Project Costs: Are project funds that will be paid directly from research project accounts and will include, for example:

- **Direct staff costs:** The costs of staff directly employed to undertake a research project, where the cost is charged directly to a specific research account. Examples will be research assistants, research fellows, and research nurses etc. who are employed on a grant code for the duration of the project.
- **Other direct costs:** Include all non-staff costs, including consumables, equipment, travel, sub-contracted services, disposables etc. These costs are also charged directly to project accounts.
- **Direct service support costs:** For NHS Include the costs of services provided by other internal departments that are directly attributable to the research. Items will include, but are not limited to, hospital service costs such as pharmacy, radiology, pathology tests and archiving. Costs may also include a co-investigator's departmental costs, where the principal investigator and co-investigator are from different departments.

20.2.2 Direct Allocated Staff Costs: Are where proportional staff costs are associated directly with a specific research project. Examples include a % of principal investigators time and co-investigators time is required to undertake and supervise the project.

20.2.3 Indirect project costs: Are institutional costs that are not directly related to a research project but are attributed in part to a project. Examples include estates and indirect costs, proportionally attributed service costs which may include IT Infrastructure and capital charges.

20.2.3 Distributions: Involve the movement of funds from project accounts to a range of institutional budgets, for example, transfers to Queen Mary/ Barts Health central or departmental staff or overhead accounts, service department accounts etc.

20.3 Distribution Policy

[37] Barts Health Policy, 'Standing orders, reservation and delegation of powers and Standing Financial Instructions, 29 July 2015: https://weshare.bartshealth.nhs.uk/trust-wide-policies

20.3.1 In the main, direct project costs will be charged to specific project accounts.

- **Direct staff costs**: Where a new member of staff is employed on a research project, the staff member's costs will be directly charged to the research account. Where a currently employed member of staff is to be paid in full, from project funds, the employee's staff costs will be charged directly to the project code for the duration of the project.
- **Proportionate staff costs:** Where a proportion of a salaried staff member's costs are attributed to a project, the sums involved will be transferred from the project account to the individual's departmental salary account code periodically. The period will be determined on a project by project basis but will not be longer than three months.
- **Variable service support costs:** Will be transferred from the research account to the relevant service department account periodically, according to the actual value of the services provided to the project in each period.

20.3.2 Indirect Project Costs:

- **Institutional overheads - Barts Health:** Overheads obtained from commercial clinical trials, where the full cost of the research is recovered from funders, will be distributed in the following proportions:
    - 50% JRMO account;
    - 40% to Clinical Board Research Development account; and
    - 10% to Investigator account.

  Overheads recovered from all other sources will be transferred to centrally managed accounts. The Trust will manage this resource and may provide funds to support bridging finance for staff appointments or other contingent requirements.

- **Queen Mary transfers:** All overhead transfers from Queen Mary research accounts will be as follows:

  Research overhead distribution Queen Mary:

Overheads	**Institute/ Faculty/Dept**	**Flexible Research Fund**
For all overhead bearing Projects	80%	20%

- **Proportionate service costs:** Where a proportionate charge for services is determined (as opposed to a variable cost), costs will be transferred from the project account to a specified service department account periodically. The period will be determined on a project-by-project basis but will not be longer than three months.

- **Capital charges and other indirect costs:** will be transferred to the relevant Barts Health Code periodically. Periods will not be more than three months.

20.4 End of Financial Year

It is important that all expenditure relating to services provided to a research project within a financial year are charged to that financial year and not brought forward or deferred to another. In this respect, all funds for services provided to research accounts, salary

contributions etc. must be transferred from individual research accounts to departmental accounts before annual accounts closure dates.

This policy applies to both Barts Health and Queen Mary.

20(a) Queen Mary Research grant and contract overheads, policy and governance

Introduction

1. Queen Mary University of London's mission is to create an excellent environment for research and researchers. Dedicated to the public good, we will generate and share new knowledge, challenge existing paradigms, and engage locally, nationally and internationally to create a better world.

2. The purpose of this policy is to ensure that we are recovering the appropriate overhead on our research grants and contracts, to enable us to continue to maintain and invest in high-quality facilities and equipment and maintain the excellence of our academic research.

3. A further purpose of this policy is to ensure equality of treatment of grants and contracts concerning overheads so that grants and contracts from similar sponsor groups with the same levels of obligations and conditions will carry the same level of overheads across the university. This ensures equality between investigators.

4. Moreover, we aim to reduce the time spent on the internal discussion of appropriate overhead rates by allowing grants which clear the hurdles to proceed rapidly through the system, thus freeing academic time for research.

5. This policy provides guidelines that cover financial and legal aspects which determine an appropriate overhead recovery.

6. Most research projects at Queen Mary are costed using Full Economic Costing (FEC). Exceptions to this are some EU funded programmes or industrial collaborations. Full Economic Costing (FEC) is a government-directed standard costing methodology used across the UK Higher Education sector for the production of consistent and transparent research project costs. The underlying principle of FEC is to establish the true cost of research, and for this to inform the amount requested from funders (the price).

7. In simple terms, FEC aims to capture all of the running costs of the research project, including consumables, travel costs, facility access, staff costs, estates, infrastructure costs and any other day-to-day project costs.

8. Understanding the true cost of a research project is critical to securing the correct level of funding in support to a project's research objectives. All research projects at Queen Mary are costed and approved using the Worktribe grant management system. Worktribe uses budget templates to make capturing the cost of conducting research easier, helping to ensure that we adhere to FEC principles.

Scope and Definitions

9. This policy applies to all Queen Mary initiated and managed research grant applications, collaborative bids with industrial or other partners, and to working with subsidiaries and to charity funders where overheads are recoverable. Any project costing must comply with the relevant funder's regulations and frameworks.

The list below sets out the definitions of terms used within this policy.

- **Overhead**: Overhead is calculated on Worktribe as the total grant income from sponsor less 100% FEC Directly Incurred Costs (fixed-term staff, consumables, equipment, travel and other directly incurred costs).

- **Overhead % Rate:** is calculated as [(Overhead)/(100% FEC Directly Incurred Costs)]x 100%

- **Full Economic Cost (FEC) Categories**

  (a) **Directly Incurred costs** are project-specific - they arise as a direct consequence of the project taking place and must be auditable at the project level (e.g. supported by supplier invoices)
  (b) **Directly Allocated costs** are not project-specific - they are incurred whether or not the project takes place and are estimated at project level e.g. Investigator time, Technician time (where not directly incurred) and Estates costs.
  (c) **Indirect costs** represent the costs of central and distributed services shared by other activities that are not project-specific e.g. Library services, Finance, Human Resources, and IT.

- **Transparent Approach to Costing (TRAC)** defines researcher, as "A Researcher in a project is anyone who will make a significant intellectual contribution to a research project. Typically, such a person would be qualified to carry out independent or supervised research, might provide an academic lead for research, or could provide expert advice to a research project. A researcher has a thorough understanding of what they are doing, can interpret results and devise appropriate ways forward (rather than, for example, carrying out a set of routine operations under carefully supervised conditions)". TRAC rates are updated each year and become effective from 1 February each year.

- The following broad categories of grants/contracts/projects are described to assist in determining the appropriate overhead:

  (a) **Charity Funded Research** – Where the Investigator conceives and develops a programme of work and approaches a charitable organisation for financial support. Queen Mary will own any foreground IP including results and data, which is unencumbered. There are no restrictions on publication. There are a small number of charities that do not comply with our policy and we encourage you not to apply to them, e.g. Rosetrees Trust. If you to you should be ready to explain why they are the only potential funders of your proposal.
  (b) **Studentships partially funded externally** – Where an external funder may provide financial support, materials, data and other in-kind benefits to a research student or students. There are no IP obligations and no restrictions on publications.
  (c) **UKRI/NIHR/Govt funded research** - Where the Investigator(s) conceives and develops a programme of work and secures funding from UK Government sponsors.

Queen Mary owns any foreground IP including results and data, which is unencumbered. There are no restrictions on publication.

(d) **Clinical Trials Non-Commercial Research** – Where Queen Mary is involved in a clinical trial that is funded by a non-commercial organisation such as MRC, NIHR or where the protocol is owned by another HEI or NHS Trust. Publication is permitted.

(e) **Industrial / Commercial funded Investigator-Initiated Research** – Where the Investigator conceives and develops a programme of work and approaches commercial organisations for financial and or other support. Queen Mary owns any foreground IP including results and data. There may be arrangements for joint IP, licensing and support of patent costs. The work produced can be published after a maximum of 6 months delay to allow the sponsor to assess IP.

(f) **Collaborative Industrial Research** – Where there is a degree of general collaborative interplay between parties that may lead to joint outcomes such as, publications, joint publications, and licences for data usage for academic purposes, possible data sharing and extend to licences and royalties and other IP considerations.

(g) **Studentships** fully funded externally where an external funder may provide financial support, materials, data and other in-kind benefits to a research student or students. There are no obligations on IP and no restrictions on publications.

(h) **Industrial Research with IP** – Where Queen Mary is approached by a private sector organisation to conduct research following the external organisation's programme or protocol. The Company own any foreground IP. The work produced can be published after a maximum of 6 months delay to allow the sponsor to assess IP.

(i) **Technical or Expert Service Provision** – Where Queen Mary is providing technical or expertise to another party for a research project and where Queen Mary is not a collaborative party. Examples include work delivered through the Genome Centre, AI Bayesian Unit, laboratories or Clinical trial units. Queen Mary does not own the IP and publication is not permitted.

(j) **Clinical Trials Contract Research** – Where Queen Mary is approached by a sponsor (a commercial organisation or subcontracted by an NHS Trust to conduct a clinical trial, in which the protocol belongs to the commercial company and where the commercial company are the legal sponsor).

Table 1: Appropriate Overhead Rates to be applied by sponsor category

Funder	Rate	Allowable variances
a) **Charity funded research**	No overheads obtainable	
b) **Studentships partially funded externally**	No overheads sought	If there are any restrictions on IP or publication, overheads are to be sought.
c) **UKRI/NIHR/Govt funded research**	80% FEC Minimum rate of 45% on DI staff FEC Where no DI staff exist, and only DA staff exist no rates apply	Minimum rate of 45% on DI staff can be discussed if there is equipment on a grant.
d) **Clinical Trials Non-Commercial Research**	80% FEC Minimum rate of 45% on DI staff FEC	Minimum rate of 45% on DI staff can be discussed if there is equipment on a grant.

	Where no DI staff exist, and only DA staff exist no rates apply	
e) **Industrial / Commercial funded Investigator-Initiated Research**	100% - 110%v FEC depending on IP (any license granted, exclusive/non-exclusive and publications terms (length of delay)	Discussion with VP R&I or Director Research Enterprise and Partnerships if you plan to bid lower than the stated rate
f) **Collaborative Industrial Research**	100% - 110%v FEC depending on IP (any license granted, exclusive/non-exclusive and publications terms (length of delay)	Discussion with VP R&I or Director Research Enterprise and Partnerships if you plan to bid lower than the stated rate
g) **Studentships fully funded externally**	100% - 110%v FEC depending on IP (any license granted, exclusive/non-exclusive and publications terms (length of delay)	Discussion with VP R&I or Director Research Services Enterprise and Partnerships if you plan to bid lower than the stated rate
h) **Industrial Research with IP**	120 % FEC	Discussion with VP R&I or Director Research Enterprise and Partnerships if you plan to bid lower than the stated rate
i) **Technical or Expert Service Provision**	130% FEC	Discussion with VP R&I or Director Research Services Enterprise and Partnerships if you plan to bid lower than the stated rate
j) **Clinical Trials Contract Research**	130% FEC	Discussion with VP R&I or Director Research Services Enterprise and Partnerships if you plan to bid lower than the stated rate

Governance

Oversight

10. The Vice Principal Research and Innovation Advisory Group (VPRAG) is responsible for oversight of research overhead recovery. Current membership includes the VP Research & Innovation, Faculty/School Deans for Research, Deputy Vice Principal's for Enterprise, REF, and Impact, the Director of the Doctoral College and Director of Research, Enterprise and Partnerships.

11. VPRAG will monitor, review, and when necessary challenge the level of overhead recovered through grants. In addition, they will where necessary form views on whether Schools and Institutes are bringing in sufficient grant overhead to offset their costs and support an excellent research environment. Rolling averages (3-year) will be created as it is acknowledged that available funding varies from year to year and that a portfolio

approach to funders is more resilient. Research Deans will feed-back any concerns raised at VPRAG to the wider School/Institute leadership and vice versa.

12. Queen Mary pre-award staff have been instructed to return certain applications from Investigators where overheads judged not at appropriate levels. They will also return applications where restrictive elements form part of the funder's standard grant terms and conditions (at the moment The Rosetrees Trust is the only funder where this applies). For any level of overhead below those given in Table 1, the reasons for the reduced level will be shared with the Vice Principal Research and Innovation and Director Research, Enterprise and Partnerships, who will not refuse reasonable requests. Justification for requests will be entered onto Work tribe (Queen Mary's grant management system) and authorised by the pre-award team, after consulting the Director and VP as necessary.

Regulations

13. All grants will abide by the funder's terms and conditions, and this policy to recover the appropriate overhead.

Financial Management

14. Grants that have been submitted without being registered on Work tribe for approval and are subsequently found to be costed at less than the minimum overhead at Annex A, could be cancelled or the School/ Institute will be required to make up the difference from their own funds.

15. Clinical Trial Units use senior management grade Professional Staff to carry out research delivery support. These staff need to be graded as research staff to attract allowable overheads. HR is in the process of attempting to change this for existing appointments and JRMO will cost future posts in line with this policy.

16. Overhead rates will be reviewed at least annually and will be updated within 1 week if funders change their rates

17. Worktribe costing questionnaires will be updated to deliver this policy and minimise work from academic or Professional Service staff working on grant applications.

Queen Mary University of London
18th November 2020

This Policy applies to Queen Mary only

21. Agreements with external organisations

21.1 Background

Agreements with external organisations can take several different forms including but not limited to:

- **Collaborative or Contract Research Agreements** in which the work plan is clearly described and agreed in advance in a project protocol with a predefined deliverable. Such agreements are made with the Dept. of Health, Research Councils, Charities and Industry.
- **Sponsored Post and Programme Agreements** in which research into an area of mutual interest to Barts Health or Queen Mary and an external organisation is to be financed by the external organisation. Such agreements are not bound by a protocol or specify a predefined deliverable and the external organisation could be a company.
- **Site Agreements** in which Queen Mary or Barts Health agrees for a local site to participate in a clinical trial for which the chief investigator is an employee of either organisation. This agreement outlines the delegation of sponsor responsibilities, as stated in the NHS UK policy framework for health and social care research, 2017, between two or more organisations.
- **Other agreements** such as Consultancy Agreements, Material Transfer Agreements, Confidentiality Agreements, Supplier Agreements, Studentships and Sub-Contracts.

21.2 Policy

All significant external collaborations must be covered by an appropriate agreement. The final responsibility for the wording of agreements will be with the JRMO and ultimately the Chief Medical Officer for Barts Health or Queen Mary's Chief Operating Officer.

The Director of Research Development is to be Barts Health's legal signatory for such agreements. Queen Mary's Chief Operating Officer is its Legal Signatory. The Director of Research, Enterprise and Partnership, Operations Manager Pre-Award and Queen Mary Associate Director for Business Development will act upon delegated powers from the two organisation's legal signatories and be an approved signatory within financial limits determined by the two organisations.

Agreements with external organisations must ensure at a minimum that:

- Appropriate costs to Barts Health and Queen Mary (including VAT, if appropriate) are properly recovered
- Queen Mary and Barts Health's intellectual property rights are properly protected
- All risks (e.g. liabilities) are properly considered and minimised
- Time scales and contract milestones are clearly defined
- There is a clear definition of quality
- Any external regulatory, ethical and financial approvals are obtained
- There are clear statements outlining the responsibilities of the different parties involved in the agreement

- There is an agreement to fulfil the obligations of confidentiality for personal information

Whenever possible, model agreements (usually NHS or Brunswick model templates) and standard wording will be used.

Where an External Organisation is unable to accept the standard contract wording, variations will be negotiated on their merits by the JRMO or Queen Mary Business Development. An external organisation's standard agreement cannot be accepted without a full review by the JRMO, to ensure compatibility with standard models. Careful consideration will be given to the use of external organisations' standard agreements and unacceptable clauses will be modified or removed. Should an acceptable compromise to contract wording not be possible in the best interests of Barts Health or Queen Mary, the agreement with the external organisation will not be signed.

Both Barts Health and Queen Mary reserve the right to refuse funding from external organisations on ethical or moral grounds. The JRMO will liaise with Barts Health and Queen Mary Officers to ensure that no contract negotiations are entered into with external funders that, in the opinion of either organisation, do not satisfy the criteria set out in their respective policies in this area or their published standards of business conduct.

Any internal dispute over the terms of an agreement, or its classification as commercial or non-commercial, will be referred to an appropriately qualified senior officer in Barts Health or Queen Mary. Where agreement cannot be reached with an external funder over the content of a contract (including price) the matter will be referred to an appropriately qualified senior officer, in Queen Mary or Barts Health, for a final decision, or made subject to the relevant dispute resolution process as appropriate.

This policy applies to both Barts Health and Queen Mary.

22. Queen Mary Export Controls and Sanctions Policy

1. Policy Context

1.1 Whilst this policy applies to everyone who carries out collaborative research, educates and supervises students and carries out research overseas, the risks are most prevalent for those working in:

a) aeronautical and space technology
b) applied chemistry, biochemistry and chemical engineering
c) applied physics
d) biotechnology
e) electrical and mechanical engineering
f) instrumentation and sensors
g) materials technology
h) nuclear technologies
i) production and process technology
j) telecommunications and information technology

1.2 Adherence to this policy is important to ensure staff and students of Queen Mary University of London (Queen Mary) are supported to stay within the law and to protect our reputation. To support compliance, new training and clear points of contact for further advice have been made available within the Joint Research Management Office. Online and in-person training are available to staff to help them understand the compliance requirements.

2. Policy Statement

2.1 Queen Mary increasingly engages in global partnerships and collaboration. While the great majority of these activities are not subject to policy and potential restrictions, Queen Mary is committed to observing all export control and sanctions regulations that apply to its work.

2.2 The regulations are not intended to restrict academic freedom but to support it. If sensitive technology falls into the wrong hands, it could undermine security or human rights, support terrorism or crime, or assist in the proliferation of Weapons of Mass Destruction (WMD). This could lead to more restrictive regulations. By ensuring that collaboration and exchange is conducted responsibly, we help to ensure that no undue legal restrictions are placed on our activities.

2.3 Failure to adhere to this policy can have significant consequences for Queen Mary and for individual researchers, potentially including loss of funding and inability to deliver on research grants and contracts, through to criminal convictions. On the other hand, compliance provides assurance to our staff, partners and collaborators, and strengthens Queen Mary's position in applying for research funding and participating in framework bids.

2.4 This policy outlines the procedures for identifying restricted activities and ensuring compliance in a proportionate manner. The Queen Mary Trusted Research and Compliance Board serves as the governing body responsible for ensuring regulatory compliance relating to research security. The Head of International Research and Innovation in the Research Services Directorate has operational responsibility.

2.5 All relevant staff must familiarise themselves with this policy, actively participate in training, and fully cooperate with the Queen Mary governing body and operation team to implement it. Our compliance is crucial not only for avoiding severe penalties and protecting our reputation but also for ensuring our ability to confidently expand our international presence in an increasingly competitive technological landscape.

OVERVIEW

3. Scope

3.1 This policy applies to everyone at Queen Mary. For the avoidance of doubt, this includes all academic staff, researchers, research students, visiting researchers and research students, research support staff, Queen Mary Innovation staff, research managers, support staff and administrators. Failure to knowingly adhere is a disciplinary and legal offence. Penalties range from unlimited fines for QMUL, compounded by reputational damage which could have a serious impact on the QMUL's overseas partnerships. Ultimately there is the ability for the government to impose up to 10 years' imprisonment for individual staff convicted of knowingly ignoring the policy.

4. Controlled Exports/Transfers

4.1 There are primarily two categories of controlled items:

a) 'Items' on UK Strategic Export Control List:

- **Dual-use items: '**Items' intended for civil use, but which could potentially be used for military, weapons of mass destruction (WMD) or security-related purposes. The main relevant disciplines are: nuclear engineering; viruses, pathogens, vaccines; chemicals with toxic properties; high strength materials; high specification electronics, computers, and telecommunications; automation; cryptography; optics and sonar; navigation; submersibles; aerospace; and space.
- **Military items:** any item specifically designed or modified for military use, regardless of the extent of the modification.

b) 'Items' with WMD end-use or end-user concerns:

- **WMD end-use concerns:** any 'item', even if not on UK Strategic Export Control List, is subject to control if you have been informed, you know or you have reason to suspect that it is or may be intended to be used in a WMD programme outside the UK. This includes exports/transfers outside the UK as well as teaching and research within the UK. These controls do not apply if there is only a theoretical possibility that items could be used in a WMD programme. Staff should remain vigilant for any indications that the item may be diverted for such use.
- **Destinations subject to sanction or other restrictions:** you have been informed or are aware that the export may be intended for military use in an embargoed destination (Appendix A) or where exports are prohibited by sanction legislation.

4.2 'Items', as used in this policy, includes the following:

a) **Goods**: equipment, components, materials, samples, chemicals and biological agents that meet the definitions of dual-use, military or WMD end-use as set out above;

b) **Technology**: the specific information required for the development, production or use of controlled goods. The controls only apply to the information which is peculiarly responsible for achieving or extending the performance levels, characteristics or functions of controlled

goods (except in the case of nuclear technology, to which the term 'required' does not apply). Controlled technology can take any form including data, research papers, designs, manuals, formulae and prototypes; and
c) **Software**: that is specially designed for the development, production or use of controlled goods.

4.3 The controls apply to the following activities:
a) **Physical exports** out of the UK of controlled items, on a permanent or temporary basis, including very small quantities. Such exports include hand carrying controlled software or technology on paper or on a laptop, mobile phone or memory device when travelling;
b) **Electronic transfers** out of the UK of controlled software and technology by any means including email, video conference, teaching overseas and online learning, downloading or accessing of documents by a person located overseas, and by telephone if information is communicated so as to achieve substantially the same result as if the recipient had read it. Electronic transfer includes computer-based services and activities that take place online, in the cloud or through distributed computing if it is subsequently downloaded or accessed by persons located outside of the UK. Controlled software and technology must be stored securely to prevent unauthorised access, using end-to-end encryption and identity and access management;
c) **Exports and transfers within or outside the UK** of any item subject to WMD end-use controls as described above;
d) **US-controlled items:** a US licence may be required to transfer US-controlled items to anyone in Queen Mary who is a foreign or dual national, or to anyone outside Queen Mary, in the UK or overseas; and
e) **Sanctions**: financial sanctions prohibit the transfer of funds or economic resources directly or indirectly to or for the benefit of a sanctioned individual or organisation. Trade sanctions restrict the supply of certain items, primarily military equipment, to sanctioned countries. US sanctions may also apply to supplying any US-origin or US-controlled item to sanctions targets in the UK and worldwide.
f) Export controls also apply throughout the duration of research projects. Material changes to project deliverables, end use, or overseas partners may bring such projects within the scope of export controls and will require a compliance check.

5. Exemptions

5.1 **In the Public Domain**: controls do not apply to software or technology that is "*available without restriction upon further dissemination (no account being taken of restrictions arising solely from copyright)*". The main considerations are:
a) the software or technology must be available to anyone, for example on a website, at an exhibition or at a conference open to the public;
b) the exemption applies if the software or technology is available to anyone in return for payment, for example in a subscription journal;
c) research intended to be published is not exempt until after it is published. Sending unpublished research work overseas, for example in the course of teaching, research collaboration or for peer review, is not exempt (unless the 'Basic Scientific Research' exemption applies); and
d) the act of publication is not itself subject to licensing unless the technology is otherwise restricted, for example if it is subject to the Official Secrets Act.

5.2 **Basic Scientific Research**: controls do not apply to technology that is "experimental or theoretical work undertaken principally to acquire knowledge of the fundamental principles

or phenomena or observable facts and not primarily directed towards a specific practical aim or objective". The main considerations are:
a) this exemption applies to research work that is not directed towards a specific short-term practical aim nor addresses a specific technical problem;
b) the technology developed in the course of a research project is likely to be exempt if the sole intended output is a published article in a peer reviewed scientific journal;
c) Technology Readiness Levels (TRL) 1-2 are generally considered to be exempt while TRL 3 is borderline and should be considered case-by-case; and
d) this exemption only applies to controlled dual-use technologies. It does not apply where there are weapons of mass destruction (WMD) end-use and/or end-user concerns. Basic Scientific Research exemption pertains to a limited range of research fields. Staff should consult with the International Research team during their assessment process.

5.3 **Patent Applications**: the controls do not apply to the minimum technical information required to support a patent application. This exemption does not apply to nuclear technology.

6. US Export Controls

6.1 US legal restrictions apply to certain items in the UK as follows:
a) US-origin military or dual-use items that have been imported into the UK directly or indirectly from the US;
b) items made or developed outside the US that incorporate any US-origin military content or over 25% (in most cases) by value US-origin dual-use content; and
c) items made or developed outside the US using US-controlled technology.

6.2 Although US law provides for a wide range of exemptions, a US export licence may be required to transfer such items not only out of the UK but also within the UK, including to a foreign or dual national within Queen Mary (staff, students or visitors). Failure to comply with US requirements can result in severe fines. But at the same time, due care must be taken to ensure compliance with UK anti-discrimination law if US restrictions prohibit access to an item by a foreign or dual national.

6.3 Some US sanctions prohibit the supply of all US-origin items (for example US-made laboratory equipment) to US sanctions targets. Such targets include some organisations and their staff operating in the UK and some foreign research institutions (notably in China) that may collaborate with UK universities, including sending staff or students to the UK. The use of US-origin items in working with such persons is not expressly prohibited but care needs to be taken to avoid giving them ownership or possession of such items.

7. Research Security compliance with National Security and Investment Act (NSI Act)

7.1 The NSI Act gives the government the right to scrutinise and intervene in certain acquisitions made by anyone, including universities, businesses, and investors, that could harm the UK's national security. The government can impose certain conditions on acquisitions and if necessary, may unwind or block an acquisition completely. Queen Mary staff should be aware of the Act when collaborating with other parties to acquire, sell or develop certain qualifying entities and assets. The government has powers to assess an acquisition whether it is completed, in progress or in contemplation stage if it reasonably suspects that such can or might give rise to a national security risk.

7.2 NSI Act applies to:

qualifying entity including but not limited to, a foreign or UK:

a) university, which is registered as a charitable organisation
b) private university
c) trust
d) university spin-out
e) university subsidiary (for example a company that a university has incorporated and carries out specific activities that the university operates)
f) research organisation
g) private company or corporation doing contractual work with a higher education institution or research organisation.

qualifying assets including land, tangible, moveable property, and ideas, information or techniques which have industrial, commercial or other economic value ('intellectual property').

7.3 **The 17 sensitive areas of the economy**: the external party acquiring a qualifying entity or asset in an area that is likely to give rise to national security risks, they or the University might be required by law to notify the government. The 17 sensitive areas of the economy that the government has identified are:

a) Advanced Materials;
b) Advanced Robotics;
c) Artificial Intelligence;
d) Civil Nuclear;
e) Communications;
f) Computing Hardware;
g) Critical Suppliers to Government;
h) Cryptographic Authentication;
i) Data Infrastructure;
j) Defence;
k) Energy;
l) Military and Dual-Use;
m) Quantum Technologies;
n) Satellite and Space Technologies;
o) Suppliers to the Emergency Services;
p) Synthetic Biology;
q) Transport.

7.4 **Examples of university research activities as qualifying assets**: Private companies, governments and other organisations are frequently involved in universities' research at early stages, often at a pre-commercial stage. Examples of these are contract or sponsored research, sponsoring a research position (e.g. a chair), and sponsoring a research theme. Universities can also be part of research centres in partnership with other public and private stakeholders. In addition, universities can develop spin-out companies for which they might retain some IP ownership. They can also host PhDs and other academic placements from various sources for which the IP might not reside entirely with the university.

If through these agreements a person gains control over a university or research organisation's qualifying assets, which can include both tangible moveable and intellectual property, for example where such assets are licensed out (exclusively or non-exclusively) by a university, then this is a qualifying acquisition under the NSI Act. It is also a qualifying acquisition if a party gains control over a qualifying asset generated by the research it has

funded. Any agreement that provides for this is also in scope of the NSI Act as a contemplated qualifying acquisition.

8. Awareness, Guidance and Training

8.1 The International Research team is responsible for maintaining up to date information on the regulations. The International Research team shall attend relevant external courses as appropriate, monitor mandatory training, and support staff to understand their responsibilities under this policy, what materials and wider support is available to them.

8.2 All staff, as defined in 3.1, within the Faculty of Science and Engineering are required to undertake the mandatory training course Protecting Your Research. Academic staff, researchers, and research managers will be required to complete more in-depth training in Trusted Research. The International Research team will periodically review which members of staff require awareness materials and/or training on the regulations and shall arrange this as needed, including during induction presentations for new staff. The International Research team shall maintain a record of all such training.

8.3 The International Research team shall provide an appropriate level of information on Queen Mary's website, including this Policy. All staff will also be directed to review other relevant Queen Mary policies, such as the Cyber Security Policy and the IT Services Policy on Traveling to High-Risk Countries.

8.4 The Trusted Research and Compliance Board and International Research team may consider further steps to raise awareness and to embed export controls and sanctions compliance in QMUL procedures. Examples of such steps may include: appointing Contact Points in Schools and Institutes to assist researchers with questions and liaison with the International Research team; putting export control issues on Schools' risk registers to ensure that they are included in routine reviews of activities; using the Annual Staff Review process to assess whether relevant staff require training and how effectively they are implementing this policy; sending staff concerned to attend external courses; or establishing a Steering Committee of certain relevant staff (such as Heads of Schools, Directors of Research and Directors of Graduate Studies) to help coordinate the implementation and eventual development of this policy.

PROCEDURES

9. Prospective Staff and Students: Academic Technology Approval Scheme (ATAS)

9.1 The risk of a transfer of sensitive technology that might be used in a weapons of mass destruction (WMD) programme occurring in the course of teaching or research in the UK is primarily managed by the UK government through the ATAS. Students, researchers and staff from certain countries applying to study or work in the UK at postgraduate level in relevant disciplines require an ATAS certificate before they will be granted a visa. Compliance with ATAS at QMUL is managed by the Academic Registry and Council Secretariat (ARCS).

9.2 A new ATAS certificate may be required if a student or researcher changes course or project while they are in the UK.

9.3 ATAS clearance applies only to activities in the UK. Obtaining ATAS clearance does not preclude the potential need for export control licence application. If ATAS cleared individuals (staff or students) engage in overseas activities, e.g. data transfers, collaborative research, attending conference overseas, separate export control compliance assessment will be required, including applying for export control licence application for conducting overseas activities above.

10 Prospective Partner and Technology Assessments

10.1 All prospective partners based in or with links to a sanctioned or embargoed country listed in Appendix A shall be screened against the UK and US sanctions lists. This applies to all individuals and organisations with respect to research grants and agreements, procurement, other sources of income, overseas partnerships and activities. The sanctioned or embargoed countries are divided into three categories:

a) **Highly Sensitive**: the non-government controlled territories of Ukraine, Iran, North Korea, Russia: any proposals for research activities involving, directly or indirectly, any individual or organisation based in or with links to these countries must be referred, with full details of the proposal, to the International Research team;
b) **Restricted**: partners in all other sanctioned and embargoed countries are more likely to raise research security concerns. Consider if there is evidence that they may be linked to the national military, any military industries, or does their research institution have links to the military or known to be involved in a weapons of mass destruction (WMD) programme. Activities in scope of the 17 sensitive areas of economy outlined in the National Security and Investment Act are more likely to raise national security and export control concerns.
c) **Other**: Activities with partners not listed in Appendix A need to assessed individually against UK Export Control list. Please also consider if there is evidence that the partners are linked to any military/defence industries or if their research institution have links to the national military or defence, or are known to be involved in a WMD programme, as restriction might still apply.

10.2 Proposed research activities, Material Transfer Agreements (MTAs), intellectual property licensing and education involving persons located outside of the UK must be evaluated to ensure compliance with research security and export controls. Such consideration shall apply to activities involving both of the following criteria:

a) activities in a relevant discipline as specified in section 1.1 and section 7.3;
b) potential export or transfer out of the UK or under US export controls.

10.3 When seeking advice from the International Research team, the Principal Investigator (PI) or proposer shall follow the process in the Research Security and Export Controls Compliance Flowchart (Appendix B) and complete an Export Controls Enquiry form (Appendix C). The International Research team in consultation with the PI/proposer, shall then determine whether export controls and NSI Act are in fact applicable. In cases of doubt, an enquiry shall be submitted to the relevant government agent or regulator.

10.4 In addition, Directors of Research in Schools and Institutes will routinely assess all other proposals that may involve an export/transfer out of the UK and, whenever they judge that there is a risk that export controls may be applicable, the PI/proposer shall be required to complete an Export Controls Enquiry form.

10.5 All ‘items’ identified as subject to export controls must be clearly flagged as such in all associated documents, records and labels.

10.6 Any transfers of controlled items should be covered by contractual provisions, e.g. research contract or MTA, through enhanced contractual provisions as detailed in Appendix D.

10.7 With respect to US controls, all concerned must be alert to the risk of the receipt of an item that is subject to US export controls and require that external partners inform them of whether any item they propose to send to Queen Mary is US-controlled. No activities involving US-controlled items may proceed without the prior written consent of the Head of International Research team. If US export controls are applicable, the International Research team will consult with those concerned, seek external expert advice if necessary, and prepare a compliance plan.

10.8 Some proposed partnerships/projects may be escalated to the Trusted Research and Compliance Board, who shall decide whether the proposed activities may proceed, if appropriate in consultation with Queen Mary’s banks, insurers and where appropriate with Partnerships Board, Research and Innovation Board or Senior Executive Team. If an activity with a sanctioned person or in an embargoed destination is approved, enhanced compliance measures shall be followed in all dealings with the sanctioned person.

10.9 Records of all research security and export control assessments and decisions shall be stored by the International Research team for at least four years.

11. Export licence applications, use and audits

11.1 If an export licence is required, the International Research team shall determine, on the basis of the export control classification of the specific item(s) and destination(s) concerned, which type of licence is required and shall register (in the case of Open General licences) or apply (in the case of Individual licences). The PI or proposer must provide all relevant details related to the proposed export or transfer.

11.2 When an export licence is obtained, the International Research team shall provide a copy to the PI or proposer and agree with them on how the conditions of the licence will be fulfilled, in particular:
a) **in all cases**: ensure that the items to be transferred, their destination country and recipients are covered by the licence;
b) **for physical exports**: ensure that the licence title and number are referenced on the shipping documents and on the export declaration completed by the freight forwarder;
c) **for electronic transfers**: ensure that the UK export control classification number and the export licence title and number are referenced on the documents and any covering emails; and
d) **for international travel**: any staff or student proposing to carry a controlled item overseas or to access controlled technology while they are overseas shall consult the International Research team who shall ensure that the appropriate export licences are in place. This may include also obtaining an export licence from the destination country if it is intended to carry a controlled item back from there to the UK.

11.3 All records of exports and transfers, as required by the licence, shall be stored by the PI and the International Research team for at least four years. The International Research team shall periodically verify these records are maintained correctly.

11.4 If Queen Mary obtains one or more export licences, Queen Mary will become subject to external audits by the Export Control Joint Unit to check compliance with the conditions of the licence(s) and that no controlled items are being exported without a licence.

11.5 If an external or internal audit finds any failures of compliance, or if these come to light in the course of routine business, the Trusted Research and Compliance Board and the International Research team shall be responsible for immediate investigation and corrective action, and submitting a voluntary disclosure to HM Revenue and Customs (for breaches of export controls or trade sanctions) and/or to the Office for Financial Sanctions Implementation (for breaches of financial sanctions), seeking appropriate external advice as appropriate.

12. Submitting NSI Act notifications

12.1 Submitting a mandatory or voluntary notification: there are two different ways to notify the government about an acquisition:

a) Mandatory notification: when Universities are legally required to tell the government about notifiable acquisitions in the 17 sensitive areas of the economy.
b) Voluntary notification: when Universities are a party to a completed or planned qualifying acquisition that is not covered by a mandatory notification e.g. when selling assets.

Queen Mary takes a risk-based approach to NSI Act notifications. The International Research team will support due diligence in ‘qualifying entity’ and ‘qualifying assets’, and will liaise with external parties and submit the notification to the government.

13. Associated guidance and procedures

The Appendices set out as part of this policy will be reviewed regularly in accordance with regulatory changes and best practices. All future revisions to these procedures will be dated for clear version control.

The Appendices include:

- Appendix A: Sanctioned and Embargoed Countries
- Appendix B: Research Security and Export Controls Compliance Flowchart
- Appendix C: Export Controls Enquiry Form
- Appendix D: Enhanced Contractual Provisions

Appendix A: Sanctioned and Embargoed Destinations

Version: November 2024

MOST SENSITIVE COUNTRIES	RESTRICTED COUNTRIES
Crimea, Donetsk, Luhansk (non-government controlled territory of Ukraine)	Afghanistan
Iran	Armenia
North Korea (DPRK)	Azerbaijan
Russia	Belarus
	Central African Republic
	China (including Hong Kong and Macao)
	Democratic Republic of the Congo

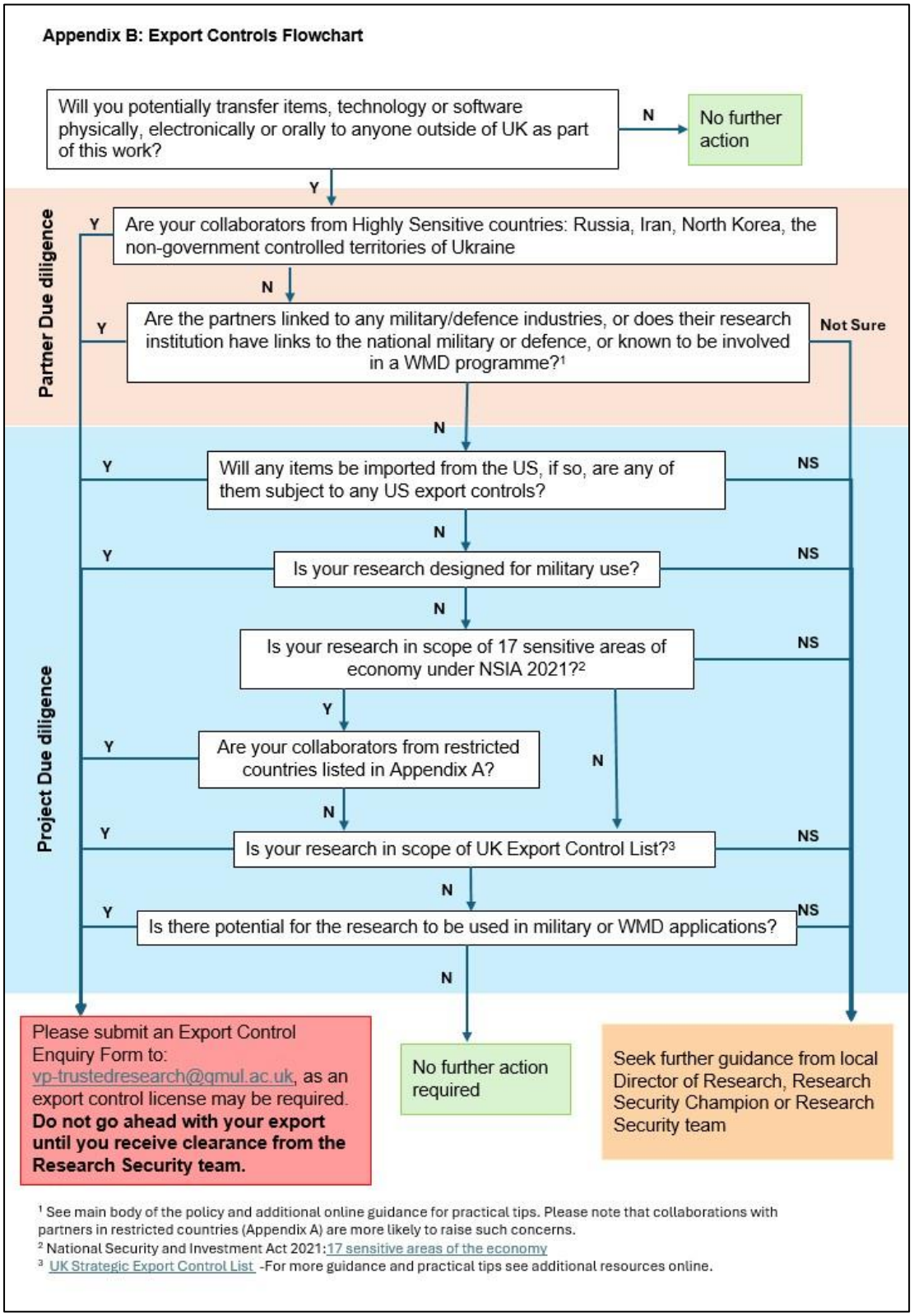
Iraq
Lebanon
Libya
Myanmar (Burma)
Somalia
South Sudan
Sudan
Syria
Venezuela
Zimbabwe

This list is intended to give an indication of countries of greatest potential risk. It was updated in September 2024 and will be updated in line with UK government guidance. Please also check potential collaborations against the UK Government list.

Sanctions assessments should be conducted by checking the name, address and country of the prospective partner individual or organisation against three sources:

Source	**Link**
UK financial sanctions list	https://search-uk-sanctions-list.service.gov.uk/
UK trade sanctions list	https://www.gov.uk/guidance/current-arms-embargoes-and-other-restrictions
US Consolidated Screening list	https://www.trade.gov/data-visualization/csl-search

Appendix B: Research Security and Export Controls Compliance Flowchart
Version: November 2024



Appendix C: Export Controls Enquiry Form
Version: November 2024

This form should be completed by the Principal Investigator or proposer of research projects as required by Section 10 of the Policy. This form is designed to help the International Research team to decide whether the goods, technology, software or knowledge (referred to as **"items"** in the form below) being exported requires a licence. Additional information may be required for a decision to be made. To submit the form and if you have any questions, please contact vp-trustedresearch@qmul.ac.uk.

Do not go ahead with your export until you receive clearance.

Section 1: Project Information				
Project Title				
Project number on Worktribe				
PI or Proposer				
Department				
Email				
Funder (if any)				
Date				
Section 2: Item Information				
Description of the item(s). This must include specific technical details. This can be attached as a separate technical specification document.				
Intended overseas recipient(s) and their address				
Section 3: End-Use				
1.	What is the intended use of the item(s)?			
		Yes	**No**	**Unsure**
2.	Have you been informed, do you know or do you have reason to suspect that the items are or may be intended to be used in a programme related to Weapons of Mass Destruction i.e. nuclear, chemical or biological weapons or missiles capable of delivering them?			
3.	Have you been informed, do you know or do you suspect that the items are intended to be used for any military purpose?			
Section 4: US-controlled items				
		Yes	**No**	**Unsure**
1.	Will any item or component originate from the United States?			

2.	If yes, is any item known to be subject to US export controls? (The supplier should be asked to advise.) If the US Export Control Classification Number is known, please provide it here.			
Section 5: Exemptions				
		Yes	**No**	**Unsure**
1.	Does all software and technology related to this proposal meet the definition of 'already in the public domain': "*available without restriction upon further dissemination (no account being taken of restrictions arising solely from copyright)*".			
2.	Does all technology related to this proposal meet the definition of 'basic scientific research': "*experimental or theoretical work undertaken principally to acquire knowledge of the fundamental principles or phenomena or observable facts and not primarily directed towards a specific practical aim or objective*".			
Section 6: Military and Dual-Use Controls				
		Yes	**No**	**Unsure**
1.	Is any item specially designed or modified for military use? If yes, please provide more information here.			
2.	Is any item listed in the UK Strategic Export Control List? • if any item may meet the criteria, provide your best estimation of its classification. • if an classification is close but your export does not meet the control threshold, please also provide the reference and explain why item is not controlled under this classification. Please refer to the 'Goods Checker' tool and check all relevant key terms, Please provide more information here.			

Appendix D: Ensuring adequate contractual clauses
Version: November 2024

If you are involved in research that is, or might be, subject to the export control regime, you must ensure that all agreements (including any Material Transfer Agreements) adequately address export control and research security, before and throughout the duration of the research project.

All agreements must require:

- The parties to comply with any applicable export control requirements, including obtaining any necessary licences or approvals prior to exporting anything subject to an export control regime. Any breach of this requirement must allow a party to immediately terminate the agreement.
- That when a party is sending material or information that is subject to export control strictions, it will first notify the recipient.
- The parties to provide each other reasonable assistance in complying with export control requirements, or any funder conditions relating to export control.

Many widely used template agreements do not include all of these obligations, so it is likely that changes will need to be made. Queen Mary's JRMO Contracts Managers have template wording that they can provide

This Policy applies to Queen Mary Only
Agreed January 2025

HUMAN RESOURCE ISSUES IN RESEARCH

23 Access to work at Barts Health Honorary Research Contracts and Letters of Access

23.1 Introduction

This policy covers individuals, who wish to work with Barts Health employees on research projects or research collaborations, at any of its hospital sites.

Individuals who are not directly employed by Barts Health but who work on Barts Health premises or with Barts Health patients or employees, or who wish to access our patient records or facilities must ensure that before they undertake any research activities appropriate access arrangements are in place.

Access approvals can take several forms and depend on the type of activity that individuals wish to engage in. Examples include:

- Honorary Contracts (Clinical or Research).
- Letters of Access.
- Escorted Site Visitor permissions.

The appropriateness of the access arrangement will depend in each case on what the person is intending to do whilst on-site or what data they need to access to undertake their research. This is in accordance with the NHS Research Passport Good Practice Guidance[38] to which Barts Health signed up in May 2010 and reaffirmed at the time of the Trust merger in 2012.

Generally speaking, the following outcomes are likely:

a) The research activity is closely linked to clinical work being undertaken by the person: An Honorary Clinical Contract (HRC) issued by Barts Health HR is appropriate.

b) The research activity involves contact with patients and will have an impact on the clinical care of the patients involved in that research: An HRC issued by the JRMO is appropriate.

c) The research activity involves contact with patients and/ or identifiable patient data, but it will have no impact on the clinical care of the patients involved in that research: A Letter of Access (LoA) issued by the JRMO is appropriate.

d) The research activity involves no access to patient or identifiable patient data (e.g. research being undertaken only involves access to anonymised healthcare records, interviews with staff or attendance at staff meetings): A Letter of Access (LoA) issued by the JRMO is appropriate.

Researchers must have in place appropriate access arrangements when visiting or working at Barts Health. There is a mutual advantage in these arrangements as the access authority is a legal arrangement where the NHS body authorises researchers to undertake a range of

[38] https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

activities within its organisation enabling university and other non- NHS employees to benefit from NHS indemnities to the same extent as its own employees. The NHS organisation must discharge its duty of care, for which the Chief Executive is personally accountable. By issuing university and other non-NHS staff with HRCs and/or LoAs, Barts Health ensures that all researchers working on its premises or otherwise with its staff, patients, their organs, tissue or data are contractually bound to take proper account of the NHS duty of care. Thus, appropriate access arrangements afford protection to both parties.

23.2 Policy

Barts Health requires all individuals who do not have a contract of employment to obtain appropriate access authority (e.g. HRC or LoA) before any direct or indirect contact with patients for the purposes of research.

Barts Health appreciates that the process established by this policy places an administrative burden on those who need to work across several NHS organisations. It has, therefore, implemented the Research Passport scheme recommended by the Department of Health. This has established an agreed and secure procedure by which individuals need only be granted one honorary contract by an NHS organisation to carry out duties in any other NHS organisation where the original and the standard honorary contract will be accepted.

Honorary contracts are not intended to grant any form of employment status with Barts Health.

The responsibility for ensuring that honorary contracts or LoAs are in place rests with the Barts Health consultant or another member of staff sponsoring the individual. They shall work in consultation with the JRMO, Clinical Director, Head of Nursing or General Manager of the appropriate clinical directorate or Medical Director or Director of Nursing and Quality.

Barts Health's HR Department has an application form for the issue of Honorary Clinical Contracts and the JRMO will generally use the Research Passport Form as the appropriate document to initiate an application for an HRC or LoA. Each application must be sponsored by a consultant if the applicant is a medical or dental practitioner or by another senior member of staff for other applicants.

Applicants seeking access to the Trust for research purposes will be required to have undergone an evidenced occupational health assessment before an HRC or LoA is issued.

Applicants will also be required to supply an Enhanced Criminal Records check to the JRMO before an HRC or LoA is issued, in line with Barts Health's arrangements for the protection of children and vulnerable adults.

It shall be the responsibility of the relevant substantive employer to arrange the required checks on behalf of its employees. Where applications are made to Barts Health's HR Department concerning Honorary Clinical Contracts, Barts Health will normally undertake these checks.

Although the JRMO may process and provide access clearance access to specific systems and sites, including obtaining ID badges, needs to be arranged by the relevant local Barts Health manager (as specified in your Letter of Access/ Honorary Research Contract). That person will have access to the necessary forms through the Trust's intranet (WeShare). They are also responsible for ensuring the person undertakes any relevant training, including

Barts Health's Statutory and Mandatory training. These things are not arranged centrally through the JRMO.

23.3 Application

This policy applies to all individuals who are not employees of Barts Health who wish to have contact with patients or patient data for the purposes of conducting research. All principal investigators and support staff working on a research project who have direct contact with patients must be covered by an appropriate level of access (that is, an honorary contract or a LoA).

The principal investigator is the designated lead who has overall responsibility for a research project. He or she will normally be the grant holder. Other staff associated with the research programme, for example laboratory staff of other organisations should be considered on a case-by-case basis. However, in all instances, staff with access to tissue and/ or patient data will be bound by current regulations on confidentiality and data protection.

Following the policy in this area recommended by the Department of Health, Barts Health in agreement with other NHS Trusts will accept suitably qualified NHS staff who have undergone standard pre-employment checks to work on research projects authorised by the JRMO. Each such person will be issued with an LoA under the NIHR Research Passport Scheme.

As the JRMO operates across Queen Mary and Barts Health under a memorandum of understanding, Queen Mary staff working within the JRMO do not need to follow the process set out in this policy and are automatically eligible for honorary contract status at the point of employment.

23.4 Concerns about non- Barts Health researchers

Members of staff with concerns about researchers or other honorary contract holders working in their clinical area should raise these concerns with their line managers. If a delay in issuing approvals could result in potential harm to patients, staff or a breach of the law, individuals should raise the concerns with an appropriate professional lead or by using Barts Health's whistle-blowing procedures.

Managers with issues of concern should check the name and details of the honorary contract holder or access holder and raise the concerns with the local sponsor or professional lead as soon as possible. The sponsor or professional lead will take action as appropriate, which may include ending the honorary appointment or access arrangement.

Individuals wishing to check whether proper reporting arrangements are in place for an honorary contract holder or access holder can check details with the JRMO.

This policy applies only to Barts Health and JRMO Queen Mary staff

24: Research Misconduct

This policy is subject to ongoing review.

24.1 Barts Health Policy

24.1.1 Background

The validity of research and other academic endeavour is based on the implicit assumption of honesty and integrity by the research investigator and on the explicit premise that research data are properly obtained, reliable and verifiable. Queen Mary University of London (Queen Mary) and Barts Health NHS Trust (Barts Health), working in partnership, must uphold this principle and endeavour to maintain public trust in the research process. This is summarised in the following Joint Policy Statement on Research Misconduct.

This policy recognises the need for Barts Health and Queen Mary to augment their standard policies and guidelines to address issues relating to misconduct in research. The guidelines should be read in conjunction with other relevant related policies of each organisation, including research integrity, whistle-blowing and disciplinary policies.

24.1.2 Policy statement

Barts Health is committed to:

- maintain the highest standards of rigour and integrity in all aspects of research; ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards;
- support a research environment that is underpinned by a culture of integrity and based on good governance, best practice and support for the development of researchers;
- use transparent, robust and fair processes to deal with allegations of research misconduct should they arise; and
- work together to strengthen the integrity of research and reviewing progress regularly and openly.

Barts Health is responsible for ensuring that the research carried out under their aegis is carried out legally, in the public interest and in accordance with best practice. This policy applies to anyone involved in research at Barts Health, whether as an employee, student, research manager or in some other capacity, and includes researchers holding substantive or honorary employment contracts at either organisation who are responsible for visitors or engaged in external research collaborations.

All individuals undertaking research at Barts Health are obliged to comply with this policy and to conduct, record and report their research in line with all relevant laws and regulations, and research policies endorsed by Barts Health.

All employees of Queen Mary or of other Trusts who carry out research involving Barts Health patients, patient samples, patient records, premises, facilities, staff and services must be bound by Barts Health policies and hold a current Barts Health honorary contract or Letter of Access for Research with clear lines of reporting and accountability at Barts Health. All employees of Barts Health, or other Trusts and Universities, who carry out research

involving Queen Mary premises, facilities, engagement with staff, research samples, records, information or Queen Mary's intellectual property, must be bound by the policies of the other relevant Trust or University; if relevant hold an honorary contract, and have clear lines of reporting and accountability whilst undertaking research.

All employees of Barts Health, and individuals permitted to work under their oversight, have the responsibility to report any cases of suspected research misconduct and must fulfil their responsibilities where appropriate as outlined in the UK policy framework for health and social care research, 2017.

Any designated Chief or Principal Investigator must accept a key role in detecting and preventing research misconduct and must adopt the role of a guarantor on published outputs from the work they have oversight for as Chief Investigator/ Principle Investigator. Researchers must comply with and aid in any necessary monitoring and auditing of research projects required by Barts Health, Queen Mary or other body. Any complaints, incidents or risks relating to research must be reported through the approved Barts Health mechanisms. Any such complaints, incidents or risks should be logged using an appropriate Trust reporting system by the JRMO for Barts Health.

Allegations of misconduct will be handled and investigated in line with the research misconduct procedures of the employing organisation. Barts Health and Queen Mary will inform each other's HR Departments (or those of other organisations) immediately upon notification of any allegations of research misconduct that have been reported that involve both organisations and/or employees that have contracts with both organisations. Suitable arrangements between the organisations will then be made to address the allegations with reference to the Joint Procedure.

24.1.3 Principles

Barts Health will investigate all allegations of research misconduct relating to the work of any employee, student, or anyone else involved in research within their organisations.

No detrimental action of any kind will be taken against any person making an allegation through this policy in good faith, in line with Barts Health and Queen Mary Whistleblowing Policies and Public Interest Disclosure Legislation.

Any allegations made will be investigated thoroughly and in accordance with the highest standards of integrity, accuracy and fairness.

Investigations will be carried out in such a way as to appropriately safeguard the confidentiality of the interested parties, as necessary.

Bearing in mind appropriate levels of confidentiality as needed, the outcome of the investigation will be made known as quickly as possible to all parties with a legitimate interest in the case.

24.1.4 Definition of Research Misconduct

For the purposes of this policy, research misconduct includes carrying out, attempting or planning any of the following (as well as any other examples that might reasonably fall within the remit of the policy and its documentation):

- The fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research;
- The deliberate, dangerous or negligent deviation from agreed formal protocols or regulations, including accepted professional standards of behaviour and conduct, in carrying out research, and the failure in that context to avoid risk or harm to humans, animals used in research, and the environment where appropriate;
- The facilitation of misconduct in research or collusion in, or concealment of, such actions by others;
- The intentional and unauthorised use, disclosure of, removal of or damage to research-related property of another researcher, including:

    intellectual property, writings, data, apparatus, materials, hardware, software, any other substances or devices used in or produced whilst conducting research, infringement of data protection requirements or the confidentiality of research subjects, misuse or misappropriation of the work of others and, for example, the unethical use of material provided in a privileged way for review or assessment.

Misconduct in research can include acts of calculated omission as well as acts of commission. It excludes genuine errors or differences in interpretation or judgement in evaluating research methods or results, or misconduct unrelated to research processes.

24.2 Queen Mary Policy

24.2.1 Introduction

Queen Mary is committed to the highest standards of integrity and probity in the conduct of research and our procedures are aligned to those established by the United Kingdom Research Integrity Office (UKRIO). The policy covers allegations of research misconduct brought against any present member of staff of Queen Mary in respect of research undertaken while employed by the University.

24.2.2 Scope

This policy is designed to cover staff (academic and professional services supporting research) and honorary staff. It is intended to support other members of Queen Mary and those external to the organisation, to raise concerns or make complaints where the individual has a genuine and reasonable belief of research misconduct, which is in the interest of Queen Mary or of the public to be investigated.

The University uses the definition of research misconduct specified in the Universities UK *Concordat to Support Research Integrity*. This conceives of research misconduct as '*behaviours or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld'*. The forms these might take might be summarised as follows:

(vii) Fabrication: the making up of results, data, or any other information presented on documentation.

(viii) Falsification: the inappropriate manipulation of research data, processes, and other materials.

(ix) Plagiarism: the appropriation of the intellectual property or work of others without their knowledge or permission.

(x) Failure to meet legal, ethical, and professional obligations: This might be deviation from the formal protocols and regulations governing research, leading to risks of harm to people or the environment. Examples include ethics approvals and disciplinary codes of conduct. Other examples include misuse of personal data and improper conduct in peer review.

(xi) Misrepresentation: This is applicable to research data, authorship, and declarations of conflicts of interests by researchers and funders.

(xii) Improper dealing with allegations of misconduct: This includes failure to investigate alleged research misconduct and reprisals against whistle-blowers.

Honest errors, which are clearly unintended and acknowledged, and differences in interpretation do not amount to research misconduct.

Allegations of research misconduct involving visiting staff will be referred to the institution that employs them.

Matters, unrelated to research conduct, pertaining to individual staff circumstances or concerns should be addressed through Queen Mary's Grievance Resolution Policy and Procedure. (https://hr.qmul.ac.uk/procedures/policies/grieve/)

It is the responsibility of the Research Integrity Committee to determine whether research misconduct has taken place. To this end, it will delegate competence to a Research Integrity Panel. The Research Integrity Panel, following investigation, may recommend a case for consideration under University disciplinary procedures once it has made its final determination on behalf of the Committee: https://hr.qmul.ac.uk/media/hr/policies/Discipline-Policy-Updated-2021.pdf. This will be directed to the head of school and the line manager of the respondent, or another appropriate management contact. The Director of Human Resources will be informed.

Decisions about subsequent disciplinary action are a matter for the relevant disciplinary panel. However, these do not have any bearing on the final determination of the Committee or the Panel as to whether research misconduct has occurred.

24.2.3 Making a Complaint of Research Misconduct

Any person becoming aware of an allegation of potential research misconduct should immediately inform the Research Integrity Office in writing, either directly using the dedicated email address, at research-integrity@qmul.ac.uk, or through their Faculty Research Integrity lead, who are contactable through faculty research managers. The Research Integrity and Assurance Officer will ensure that the Named Person (http://www.jrmo.org.uk/performing-research/research-integrity/) is made aware and initiates the actions outlined in this procedure.

Where an allegation has been made orally or briefly, the Named Person will request that the complainant provides a substantive written outline of the allegation along with any supporting evidence. The complainant will be issued with a dedicated proforma. They will be asked to ensure that their complaint, in its entirety, is presented on this document.

Upon submission of the complaint, the Named Person, with support from the Research Integrity and Assurance Officer, will make an initial assessment of its substance. This will be based entirely on the information presented to them on the dedicated proforma.

If there are major concerns about immediate risk to safety, suffering to animals, negative environmental consequences (where this might contravene the law or fall below good practice), or that experimental results will be destroyed, the Named Person will take urgent action to ensure that any such potential or actual detriment, danger, illegal activity, or risk is prevented as much as possible. To ensure legal and governance compliance, appropriate advice will be obtained. On instruction, the Research Integrity Office will take steps to secure all relevant information and evidence so that it can be available to those undertaking any consequential investigation. This may include, but is not limited to:

(vii) Liaising with ITS securing all relevant electronic and physical information and records, materials and locations associated with the work.
(viii) Liaising with Human Resources and relevant line manager(s) to:
(ix) Request the temporary suspension of the respondent in accordance with the relevant provisions of the Queen Mary disciplinary policy.
(x) Request the temporary barring of the respondent from part, or all, of the premises of QMUL and any of the sites of any partner organisation(s), such as Barts Health; and/ or
(xi) Request a temporary restriction be placed on the respondent requiring him/her not to have contact with some or all the staff of QMUL and/or and those of any partner organisation(s), such as Barts Health.
(xii) Liaising with Faculty, or clinical board, managers, review the risk that evidence could be destroyed, risk to individuals and any respondents' responsibilities for supervision, teaching and management.

On receipt of a substantive written allegation, accompanied by any supporting evidence, the Research Integrity Office, on behalf of the Named Person, will formally acknowledge receipt of the allegations by letter to the Complainant, with a copy of any relevant information about how their complaint will be considered. The complainant will be reminded that the information they have provided in writing, on the dedicated proforma, will define the scope of any subsequent investigation.

A meeting of the Research Integrity Committee will be arranged to consider the complaint and appropriate route in accordance with the UKRIO procedure. This is essentially a triaging stage before an investigation and should consider whether the complaint(s) are:

(iv) mistaken, frivolous, vexatious and/or malicious.
(v) should be referred directly to the organisation's disciplinary process or other internal process.
(vi) are sufficiently serious and have sufficient substance to justify a formal Investigation.

The Research Integrity Committee will decide whether to convene a panel to investigate the complaint. An important consideration will be the intentionality of the alleged misconduct.

The Named person will, on behalf of the Committee, inform the Director of Human Resources and the Chief Governance Officer and University Secretary of all disclosures they determine an investigation is required. They will request any evidence of further, distinct instances of proven misconduct in research by the respondent, unconnected to the allegations under investigation.

24.2.4 Investigating a Complaint

Where the matter is to be investigated, the Research Integrity Committee will then determine:

(i) who should undertake the investigation – the Named Investigator.
(ii) the composition of the Panel convened to investigate.
(iii) the policy to be followed.
(iv) the scope of the concluding report.

In deciding who should undertake the investigation, the Research Integrity Committee will check with the proposed investigator that they:

(i) do not have a potential conflict of interest, as defined by this policy.
(ii) are able and willing to conduct the investigation in a timely way.
(iii) are adequately experienced or knowledgeable about conducting investigations of this nature and are confident they have received adequate training.
(iv) do not believe themselves conflicted in any other respect.

The Named Investigator may need to contact the respondent's substantive (primary) employer, where an honorary contract is held and the Research Integrity Office may need to contact external sponsors, funding organisations and/or collaborators, as dictated by their policies. The Named Investigator shall liaise with the Employee Relations Advisory Service relevant to the School/Institute of the respondent, to ensure that the rights of the respondent and the integrity of the investigation are not compromised by any such actions.

24.2.4 Remit and composition of a panel convened by the Research Integrity Committee to investigate a complaint of research misconduct.

The Panel will investigate complaints of research misconduct, in accordance with University standard operating procedures, including interviews with complainants and respondents where applicable, and recommend a course of action to the Named Person. The investigative process will be led by the Named Investigator.

The Panel will be appointed for the purpose of investigating a specific complaint and will make its final determination on behalf of the Research Integrity Committee from whom its authority is delegated.

The Panel will be comprised as follows:

(i) At least one member of the Research Integrity Committee, who shall chair the Panel. Other members may be appointed to ensure the Panel is comprised of an odd number.
(ii) A research integrity champion within the University with disciplinary knowledge relevant to the specific case.
(iii) An external expert with disciplinary knowledge relevant to the specific case, if applicable.
(iv) A representative from the partner organisation, if applicable.

The Panel should always be comprised of an odd number of members. The exact number may vary according to the expertise required for a specific case.

Administrative support will be provided to the Named Investigator and to the Panel by the Research Integrity and Assurance Officer.

The Named Investigator will be responsible for the collection of evidence, which usually should involve the conducting of interviews with relevant parties such as the respondent.

Using the evidence collected, the Named Investigator will write a draft report, with recommendations. They will present this to the Panel and take questions. The respondent will have been given the NI's report before the panel meeting and be allowed to submit comments in response for their consideration.

The Panel will formally consider the draft report presented to them by the Named Investigator. They may request revisions to it or for the collection of additional evidence.

Once the Panel has agreed a final version of the report, it will be presented to the Named Person. The report will:

(i) Summarise the conduct of the investigation.
(ii) State whether the allegations of misconduct in research have been upheld in whole or in part, giving the reasons for its decision and recording any differing views.
(iii) Make recommendations in relation to any matters relating to any other misconduct identified during the investigation; and
(iv) Address any procedural matters that the investigation has brought to light within QMUL and/ or BHT and relevant partner organisations and/ or funding bodies.
(v) Ensure compliance with the scope agreed at the outset of the investigation.

In addition to reaching a conclusion over the nature of the allegations, the Panel should also, in the report, make recommendations with respect to:

(i) Whether the allegation(s) should be referred to the relevant organisation's disciplinary process.
(ii) Whether any action will be required to correct the record of research (e.g., informing publishers, correcting, or retracting publications etc.).
(iii) Whether action will be required to inform external organisations such as funders, collaborators, business partners, regulators (such as MHRA, HRA, GMC, NMC as applicable), professional bodies etc.
(iv) Whether organisational matters should be addressed by QMUL and/or BHT through a review of the management of research; or
(v) Other matters that should be investigated e.g., clinical trials the respondent may have been involved in, in case of any subsequent regulatory inspection.

The Named Person will make the Panel report available to the respondent and to the complainant(s) for comment solely on the factual accuracy of the report. This is unless there are proven reasons not to arising from legal or safety concerns. Comments are to be returned within 10 working days. Modifications will only be made to the draft report where it is found to contain errors of fact. No other information will be shared with the complainant or respondent.

Once initiated the investigation will progress to the natural endpoint irrespective of:

(i) The complainant withdrawing the allegations at any stage.
(ii) The respondent admitting, or having admitted, the alleged misconduct, in full or in part; and
(iii) The respondent or the complainant resigning or having already resigned their post(s).

It might form the basis of a separate investigation, as in some instances it may be necessary to refer the matter to an external authority for further investigation.

24.2.5 Appeals by respondents

The respondent has the option of appealing against the report of the Panel. This is distinct from the outcome of its deliberations and subsequent recommendations. The grounds for appeal and the process will be explained in the outcome letter resulting from the investigation.

The grounds for appeal are as follows:

(iii) Procedural irregularity in the investigation.

(iv) The emergence of new evidence that was not available during the investigation.

Appeals should be made in writing to the Named Person. The respondent should specify which of the grounds for appeal they wish to cite. They should then explain the reasons for this, providing evidence if applicable.

The appeal will be considered by an independent panel that will decide whether further action or investigation is required. If so, they will reinitiate the investigation process as described in this policy. Their decision will be based on the written information provided to them. The Panel will be appointed by the Named Person. They will not have had any previous involvement in the investigation.

24.2.6 Right of response by complainants

Complainants will have the right to provide a written response to the Named Person at the following stages of the investigation:

(iv) After the initial assessment by the Named Person if a decision is taken to dismiss the complaint.

(v) After triage by the Committee if a decision is taken to dismiss the complaint.

(vi) At the conclusion of an investigation after being notified of the outcome.

24.2.7 Reporting of Outcomes

If all or part of the allegations are upheld, the Named Person, in consultation with the Director of Human Resources, shall determine whether the matter should be referred to the QMUL disciplinary process. At this point, research misconduct will have been proven. If the allegations proceed to disciplinary processes, the report of the Panel shall form the basis of the evidence that the Disciplinary Panel receives. All the information collected and brought to light through this policy will be transferred to the disciplinary process.

The Named Person will inform the following of the outcome of their report if the allegations are upheld in full or in part:

(i) The respondent

(ii) As relevant to their employment status, the Principal (QMUL), Chief Executive (BHT)

(iii) The Director of the School, Institute or Clinical Body

(iv) As relevant to their employer, the Research/Clinical Director

(v) The Academic Secretary

(vi) If the respondent has left the University and moved on to alternative employment by another university or in a research role, the Director of Research or nearest equivalent

(vii) The complainant(s)

When the allegations were found to have some substance, but due to a lack of clear intent to deceive or due to their relatively minor nature, the Research Integrity Committee can decide

that the matter should be addressed through QMUL competency, education and training mechanisms, or other non-disciplinary processes. The Research Integrity Committee can agree remedial actions who will ensure that relevant remedial actions are taken through management structures with support from relevant School/Institute Human Resources. Any such recommendations are actioned via the Head of School, Institute, or Clinical Board if applicable. This may include:

(i) Retraction/correction of articles in journals.
(ii) Notifying other organisations involved in the research, such as funding bodies, research collaborators, industry collaborators, Queen Mary Innovations etc.
(iii) Discussion with funders about withdrawal/repayment of funding.
(iv) Notifying participants/participants' doctors of any potential medical issues that may arise, ensuring due diligence in line with reporting duties of all clinical professionals' duty of candour and duty of care.
(v) Notification of misconduct to regulatory bodies (such as the MHRA, the Healthcare Commission, the Home Office (for research involving animals), other professional bodies, etc.).
(vi) A review internal management, training, supervisory procedures for research as appropriate; and/ or
(vii) Undertaking further investigations of other projects, the Respondent was involved in (especially Clinical Trials of Investigational Medicinal Products) to assure the organisation that the data are robust and there is no evidence of research misconduct with respect to these other projects.

If the allegation is not upheld following an investigation, both the respondent and complainant will be informed of the reason for this normally within 10 working days. The final report will be shared.

Where allegations have not been upheld, the Named Person will take steps as are appropriate based on the seriousness of the allegations, to protect the reputation of the respondent and any relevant research project(s). Where the case has received any publicity, the respondent shall be offered the possibility of having an official statement released for internal and/ or external purposes.

The Research Director will submit a report of all disclosures and any subsequent actions taken to the Audit and Compliance Committee. Where the issue falls within the purview of the Committee, a detailed report will be submitted, in other cases a summary report, to allow the Committee to monitor the effectiveness of the policy. Copies of the report will be retained for a minimum of three years by the Integrity office.

24.2.8 Timescales:

The investigation will be conducted to the following timescales:

(i) Upon submission of their proforma, the complainant will be notified of the outcome of the initial assessment of their complaint, by the Named Person, within 10 working days.
(ii) The Research Integrity Committee will meet to triage the complaint and, if required, appoint a Named Investigator and Panel within 21 working days.
(iii) The Named Investigator and Panel will seek to complete their work within 60 working days.
(iv) Following the submission of the Panel report, the Named Person and the Research Integrity Committee will deliberate and notify the relevant parties of the outcome within 15 working days.

Should the Research Integrity Committee or the investigating Panel require more time for their deliberations, they will seek agreement for an extension from the Named Person. This may be necessary in cases that are particularly complex or involve external parties. The complainant and respondent will be notified accordingly.

24.2.9 Guidance on implementation of the policy

Confidentiality

Queen Mary will treat all disclosures in a confidential and sensitive manner. The identity of the individual making the allegation will be kept confidential so long as it does not hinder or frustrate any investigation. However, the investigation process may reveal the source of the information and the individual making the complaint may need to provide a statement as part of the evidence required. The individual making the complaint will be informed if it is felt that their identity needs to be disclosed or is likely to become apparent in the progress of an investigation.

Queen Mary expects the individual making the complaint and all others involved in any subsequent investigation to observe strict confidentiality in relation to the nature of the complaint, the identity of those involved and any other information relating to the investigation.

During an investigation, identifiable complainants will be provided with the following information:

(i) Acknowledgement of the complaint.
(ii) Notification of the different stages of the investigation, such as the referral of the complaint to the Research Ethics Committee and the appointment of a Named Investigator and panel.
(iii) Notification of the outcome of the investigation.

At the discretion of the Named Person, the complainant may be provided with a full or redacted version of the final report arising from the investigation. This will be determined by considerations of confidentiality and legality.

During an investigation, the respondent will be provided with the following information:

(i) Notification of the complaint being submitted.
(ii) Notification of the different stages of the investigation, such as the referral of the complaint to the Research Ethics Committee and the appointment of a Named Investigator and panel.
(iii) Notification of the outcome of the investigation.

The respondent will be entitled to a copy of the final report arising from the investigation. However, redactions may be made at the discretion of the Named Person. These will be determined by considerations of confidentiality and legality.

Support for respondents and internal complainants

Respondents and internal complainants will be made aware of the support provided by their School/Faculty management and other organisational support, such as the Employee Assistance Programme, during the investigative process. However, they will also be allocated a local Research Integrity champion unconnected to the investigation.

Suspension

The Named Person or the Research Integrity Committee may consider, in the early stages of the investigation, whether the respondent could jeopardise the progress of an investigation, for example by destroying records. If so, they can recommend that the individual should be suspended from duty. Any such suspension will be governed by policies outlined at paragraph 12 of this policy.

If necessary, the funders and other stakeholders should be notified that the respondent has been suspended.

Anonymous allegations

This policy strongly encourages individuals to sign any disclosures they make. In exceptional circumstances, concerns expressed anonymously may be considered at the discretion of Queen Mary. In exercising this discretion, the factors to be considered will include:

(i) the seriousness of the issues raised.
(ii) the credibility of the concern; and
(iii) the likelihood of confirming the allegation from attributable sources.

The information that anonymous complainants are provided about the investigation will be decided at the discretion of the Named Person on a case-by-case basis.

Good faith

Those making allegations of research misconduct in good faith will be afforded appropriate protections in accordance with the University policy on whistleblowing: https://hr.qmul.ac.uk/procedures/policies/pid/#. This is irrespective of the outcome of any investigation. However, the policy stipulates that those found to be making vexatious or malicious allegations may be subject to disciplinary action.

Conflicts of interest

All involved in the investigative process, at any stage, should declare potential conflicts of interest to the Named Person. On the basis of the information provided, the Named Person will decide whether further participation in the process is appropriate.

Conflicts of interest, in the context of a research misconduct investigation, are defined as the following:

(i) A close personal relationship with either the respondent or the complainant.
(ii) A professional relationship with either the respondent or the complainant. This might include supervision or co-authorship
(iii) A financial interest that might be affected by the outcome of the investigation.
(iv) A professional interest that might be affected by the outcome of the investigation. This might relate to publication or funding.

Conflicts of interest do not necessary include being acquainted with a respondent or complainant, or being employed in the same department or faculty

Role of other professional services teams in the investigation

The role of other professional services teams is advisory only. Determining whether research misconduct has taken place is the entirely the responsibility of the Research Integrity Committee.

The investigative process will be undertaken by the Named Investigator with support from the Research Integrity and Assurance Officer. However, advice may be sought from other professional services teams, such as the Academic Registry and Human Resources, on relevant matters. This is to ensure compliance with regulatory and governance requirements.

The Human Resources team will be regularly updated on the progress of any investigation in case of referral for consideration under disciplinary procedures.

The Named Person will ensure that other professional services teams are appraised of new information, that becomes apparent during the investigation, relevant to their remits.

Learning lessons from an investigation

Following the conclusion of an investigation, the final report will be considered by a meeting of the Research Integrity Committee. The Committee will reflect on whether the specific case has implications for research integrity best practice within the University, or for the investigative process. Subsequently, the Committee may undertake or initiate the following:

(i) The formulation and promulgation of new policies and procedures within the University.
(ii) The provision of confidential high-level briefings.
(iii) The development of appropriate training programmes.
(iv) The sharing of anonymised information within, and beyond, the University to promote best practice and compliance.

The Research Ethics Committee will endeavour to ensure that those involved in the investigative process are provided with an appropriate programme of training.

24.2.10 Review

The Secretary to Council and Director of Research may review this policy following the conclusion of an investigation if any procedural or other problems were experienced during an investigation, or if there is a change to best practice or national guidance in respect of public interest disclosures.

The policy should be reviewed every 3 years as a matter of course.

This policy applies to Barts Health and Queen Mary as indicated.