Queen Mary University of London

And

Barts Health NHS Trust

RESEARCH MANAGEMENT POLICIES

Approved by Queen Mary University of London 7th June 2012

Approved by Barts Health NHS Trust 23rd August 2012

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Introduction and Rationale

These core policies have been constructed to enable The Barts Health NHS Trust (BH) and Queen Mary University of London (QMUL), to develop coherent and collaborative approaches to managing their joint office and research activities. They are designed to ensure there is clear guidance for research managers and research active staff in relation to requirements issued in the following main documents:

- Research & Development for a First Class Service
- Best Research for Best Health
- The DH Research Governance Framework for Health & Social Care
- The Follett Report
- Medicines for Human Use (Clinical Trials) Regulations 2004; and
- The NHS Plan, individual disease & profession based strategies e.g. the NHS Cancer Plan, Making a Difference.

The Policies have been drafted by a working group drawn from managers in the Joint Research Management Office (JRMO) and Professional Services Managers in QMUL and the Trust. A collaborative approach was adopted in order to address the following issues:

i. The Research Governance Framework requires all research active organisations to have systems in place to meet its requirements from 1st April 2004. Policy-making is a time consuming exercise and because of this it was felt to be more efficient for the two organisations to draw up a common set of policies that could be adapted and ratified by their respective Management Boards.

ii. Collaboration has enabled the two organisations to draw on each others' respective strengths, agreeing a common set of policies and principles that ensures that there are clear and consistent standards for researchers to work to.

iii. 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 largely consistent set of rules and regulations.

Section A: Ethical Standards for Research

1. Ethics Policy

1.1 Background

Robust scrutiny of the ethical aspects of any research that involves human subjects or the use of animals is at the heart of the Research Governance Framework. It is the responsibility of all researchers to ensure that research is conducted to the highest ethical standards, in line with current guidance[1].

1.2 The Policy

All national and local permissions and approvals must be in place prior to any study activity taking place. Researchers should follow national, local and sponsor guidelines and SOPs to ensure appropriate submissions are made.

Where a researcher is unclear whether their research requires NHS REC or QM REC and/or local R&D approval, they MUST seek clarification from the JRMO. Contact details can be obtained through the JRMO website.

Specific definitions exist to define research sites, which have specific implications for ethical approval. [2]

All regulatory applications must be submitted using the Integrated Research Application System (IRAS)[3]. Researchers are advised to carry out the IRAS training module prior to completing the form. Advice and guidance should be sought from the JRMO, before completion of the form.

The Investigator has overall responsibility for ensuring that the research meets the standards laid down by the REC. This includes:

- Compliance with requirements to protect the rights, health & safety, privacy and dignity of trial subjects
- Notification of annual reports to required bodies (e.g. REC, MHRA and sponsor)
- Notification of changes to the protocol to the REC and the JRMO
- Maintaining high standards of record keeping
- Ensuring participants have given fully informed consent (please see Consent Policy)
- Ensuring that research is assessed in accordance with the JRMO Peer Review Policy

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[1] The Royal College of Physicians (1997) Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects.
The Declaration of Helsinki (2000) Ethical Principles for Medical Research involving Human Subjects.
Local Research Ethics Committees HSG (91)5.
Ethics Committee Review of Multicentre Research. Establishment of Multicentre Research Ethics Committees HSG (97)23.
Governance Arrangements for NHS Research Ethics Committees, 2001.
General Medical Council (1999) Good Medical Practice.
Home Office (1986) The Animals (Scientific Procedures) Act
The Data Protection Act 1998.
The Research Governance Framework for Health and Social Care 2001 and revised 2005.
The Medicines for Human Use (Clinical Trials) Regulations 2004.

[2] Governance Arrangements for Research Ethics Committees (GAfREC) Harmonised edition, September 2011

[3] Please refer to IRAS user manual located at
https://www.myresearchproject.org.uk/help/Contents/IRASHelp_UserManual.pdf

- Ensuring full accountability for all trial supplies (including trial medication, clinical equipment and devices)
- Ensuring investigator and trial team are appropriately trained (e.g. GCP and RGF)

For trials falling under the EU directive, investigators and trial team members must attend GCP training prior to study commencement and attend refresher training once very two years. For trials not under the EU directive the investigator and the trial team must attend Research Governance Training prior to commencing research activity.

The JRMO must be kept informed of all proposed and ongoing research. For Trust or QMUL sponsored studies a copy of the completed ethics application form must be submitted to the JRMO before it is submitted to the REC. The investigator of the study must also keep a copy of the full ethics application form and any correspondence from the REC; this should be filed within the trial master file.

Principal investigators have a duty to ensure that applications for ethical approval are accurate and complete. This includes ensuring that the appropriate documentation has been obtained from regulatory bodies and any commercial or non-commercial sponsor.

Any data that by itself, or in conjunction with other easily obtainable information, can identify a specific person will remain protected by The Data Protection Act 1998. Contracts should draw attention to the obligations of confidentiality and make it clear that the agreement is dependent on the conditions of confidentiality being met.

Ethical approval should not be viewed as an automatic license to begin research. Investigators must also ensure they have the appropriate contractual agreements in place and Trust or College approval, particularly a Final JRMO Approval letter.

Failure to obtain appropriate ethical approval constitutes research misconduct and may result in formal disciplinary action being taken.

The JRMO will monitor and audit studies to ensure that all research within the Trust and College has appropriate ethical approval (through an ethics application screening system pre-REC application) and that consent for the research is being taken as specified in the ethics application.

Note: This Policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

2. Queen Mary Policy on Research Ethics

2.1 Scope

This policy relates to all research involving human participants and materials derived from human participants carried out within or by Queen Mary, University of London, and its staff and students, wherever located. (N.B. this is research that does not fall within the remit of an NHS Research Ethics Committee.)

The College is committed to the promotion of high quality research by both staff and students. Quality research requires that those carrying it out act ethically at all times.

In relation to research this means that all studies must be carried out with honesty, integrity, and due care for the rights of participants and researchers. It must always be mindful of the need to minimise any risk that cannot be eliminated.

2.2 Policy

Research involving human participants (and materials derived from human participants) must be carried out ethically; that is to say it should:

- treat its participants with care, dignity, and compassion at all times
- not intrude nor otherwise compromise the integrity of the participants or those related to them or their physical or emotional environment
- the researcher should obtain specific permission to make his/her enquiries, and that permission should extend to the methodology, the content, and the eventual handling of the research material
- the research project, including its purpose, must be fully explained in the initial approach, and the participant must give written consent to participate – except in exceptional circumstances
- research should be independent and not subject to conflicts of interest.

Research involving those under 17, and those without the capacity to give informed consent, must only be carried out with the consent of a parent or guardian. Research with any vulnerable groups must be conducted with the guidance and supervision of expert intermediaries.

The participant's anonymity and the confidentiality of their responses must be safeguarded at all times, and not breached in any circumstances unless the participant has given express permission. Eventual, or potential, use of the research material must be clearly explained before permission is sought. All researchers should be aware of the College's Research Data Management Policy. All data must be stored, handled and disposed of as per the College's Information Security, Data Protection and Records Retention Policies.

The Senate of Queen Mary has granted authority to Queen Mary Research Ethics Committee to establish criteria, processes and procedures to enact this policy. Queen Mary Research Ethics Committee also has authority, delegated to it by Senate, to make decisions about whether individual research proposals meet the ethical criteria of this policy.

2.3 Procedure for obtaining ethical approval

Information about the process for obtaining ethical approval for research is available at: http://connect.qmul.ac.uk/research/ethicscommittee/index.html

Contact

For further advice please contact:
Hazel Covill

Secretary to the Research Ethics Committee
JRMO
Email: h.covill@qmul.ac.uk

Note: This policy applies only to Queen Mary University of London

3. Consent to Participate in Research

3.1 Background

The primary purpose of the policy is:

- To ensure any participant taking part in research is willing;
- That, in taking part, any research participant is exercising informed consent; and
- To give guidance to staff on obtaining consent from vulnerable groups.

3.2 The Policy

Standards for obtaining consent are important for researchers.

3.2.1 Standards for 'All' types of research

Before submitting an application to the Research Ethics Committee, all researchers should:

- Ensure that template information (such as a participant information sheet) is in an intelligible form (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. The College and Trust would particularly encourage researchers to seek advice from local community groups and the Trust Health Advocacy Service. Failure to engage local ethnic minority groups may have implications for the validity of the research sample;
- Read and adhere to current National Research Ethics Service (NRES) guidelines and templates on writing a participant (patient) information sheet and consent form.

3.2.2 Procedures for obtaining consent to participate in research

Published on the website of the National Research Ethics Service (www.nres.npsa.nhs.uk) are guidelines which Trust and College researchers should adhere to. They include, but are not limited to, ensuring that:

- Protocol(s) involving participants (patients), 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
- Ensure research is conducted in an open and transparent manner i.e. researchers should:
  i. clearly identify any conflict of interest, personal benefit to be gained from the research (including financial) and any involvement with a commercial entity that might constitute a conflict of interest
  ii. ensure that consent covers consent to participate, consent to process personal data and consent to use images gathered during research where this is relevant
- Seek approval for the study from the sponsor and gain local NHS and/or institution permission(s).

Chief/ Principal investigators are required to ensure that all research staff working on a research project abide by the standards set by the National Research Ethics Service.

Consent for research should always be obtained in writing, be signed and dated by the person taking consent, the participant/their representative and a witness. The participant should receive one copy of the signed consent form and a second and third should be kept in the medical notes and trial site file respectively. The researcher should ensure that the original is stored in a secure manner.

In order to be able to demonstrate compliance with Good Clinical Practice & Research Governance requirements the researcher must be able to show that:

- The participant was consented 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
- Appropriate advocacy or translation arrangements were made available, and clearly documented. Ideally all participants requiring advocacy or translation should have this provided in person and not simply by telephone
- The participant is 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
- Where there are changes to the arrangements for obtaining consent after ethical approval has been granted, these must be notified to the Research Ethics Committee that approved the study and the Research Governance and GCP Managers in the JRMO
- Participants should not be offered financial inducements that may encourage them to take undue risks. However reimbursement of expenses and moderate inconvenience allowances are permitted

3.2.3 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.
Scheduled purposes include:

- obtaining scientific or medical information about a person which may be relevant to any other person
- research in connection with disorders or the functioning of the human body

Researchers should be guided by existing published HTA codes of practice. Human tissue is most commonly obtained from:

a) the participant/donor directly, as part of an ethically approved project
b) a licensed tissue bank
c) a diagnostic archive

In the case of (a), the participant/relative must have given informed consent or a DH compliant post mortem form, whichever is appropriate. If, in taking consent, the participant/relative states that there are certain types of research they do not wish the tissue to be used for, researchers must respect this and be able to demonstrate that the end use is not in conflict with the participant/relatives' wishes.
In case of (b) and (c), tissue banks and diagnostic archives will usually only provide tissue to projects with ongoing ethical approval and will ensure that participant/donor information is not available to the researcher.

All research must have ethical approval and specific consent. Both the consent forms and participant information sheet must conform to NRES guidelines.

If it is not feasible to contact participants to obtain consent for use of samples collected at an earlier stage, the REC must confirm that it is acceptable for the research to proceed without it.

Particular care is needed where research involves tissue or organs of the deceased. Consent of relatives must be obtained (see above exceptions). Arrangements must be described for the respectful disposal of material once the research has been completed.

Researchers should ensure that the participant information sheet makes clear which organisation(s) have access to the sample(s). This is particularly important where a commercial organisation is directly involved in the research, or where the samples may be passed on for further research and/or commercial exploitation.

Researchers may not sell samples for profit (in cash or in kind).

Any personal data (including de-identified data) passing outside the European Economic Area (EEA) is subject to Section 8 of The Data Protection Act.

This requires explicit participant consent to the transfer. The participant consent form must contain a section that gives permission for a named investigator to transfer information to a named organisation that is based outside the EEA.

3.2.4 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 capacity to consent
- Participants in emergency situations

The involvement of frail elderly people, those living in institutions and pregnant women should also be given special consideration.

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

For all groups consent must still be freely given and based on information which is provided in a form that is understandable to each individual (and/or their legal representative).

Individuals lacking 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) 6, for further information.

3.3 Monitoring

The JRMO will monitor whether all research within the Trust and College has appropriate ethical approval and that consent for research is being taken as specified in the ethics application through its routine auditing process.

Further Information may be obtained from:

1) Research Governance and GCP Managers, Joint Research Management Office

2) National Research Ethics Service (NRES) Head Office:

4-8 Maple Street
London
W1T 5HD
020 7725 3431

www.nres.npsa.nhs.uk
Email queries@nres.npsa.org.uk

3) Medicines & Healthcare Products Regulatory Agency: www.mhra.gov.uk

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

Section B: Assuring the Scientific Quality of Research

4. Peer Review of Research

4.1 Purpose of the Policy

A key component of good research practice is the need for **all** research to have been subject to independent peer review[4]. In this situation independent is taken to be independent of the research team not necessarily the department or institution. Similarly, UK law on the conduct of clinical trials requires host and sponsor organisations to ensure that research practice adheres to recognised international standards.

If carried out appropriately, peer review addresses the scientific quality and relevance of the research, its financial implications and aspects of health and safety. It is, therefore, an important means of ensuring that the organisation knows about research being conducted which uses its staff, patients and facilities and is satisfied that it is safe, affordable and of good quality.

This is particularly important for research which is not externally funded and subject to review at that stage. Evidence of peer review is required as part of the process of obtaining ethical approval for research.

Failure to obtain a peer review committee's approval for research or falsely claiming that this is in place may constitute research misconduct. Procedures for dealing with this are outlined in policy 22: Misconduct and Complaints.

4.2 Scope

The policy applies to all staff conducting clinical research or external staff using the Trust or College as a base or site for their research.

This includes student research, although the primary responsibility for the quality of the research lies with the relevant university.

4.3 Summary of the Policy

To ensure that the Trust and College has a review process in place which is robust, but both appropriate and proportional, the Policy sets out:

- The two levels of review needed for all research
- Guiding principles for establishing committees
- Advice on protecting novel ideas if applications are sent to external experts for review; and
- Reporting mechanisms.

4.4 The Policy

General Approach

All research should undergo both scientific peer review and local departmental review to establish the financial implications of it for the institution and department, and also how the particular research fits in with departmental research strategies and portfolios.

Scientific peer review should be carried out by those people in a position to make a judgment about the scientific quality, relevance and probity of the research. Those undertaking local departmental review should be able to address the practicalities of

[4] The Declaration of Helsinki (1996), The Research Governance Framework for Health and Social Care 2001 and revised 2005.

undertaking a specific piece of work in the organisation. Both should be independent of the research team.

The purpose of this policy is not to be prescriptive about whether this would best be carried out at a Faculty, Clinical Academic Group, (CAG) specialty or sub- specialty level or even across teams / organisations. It is for staff in each CAG and Faculty to set out the most appropriate model for them.

Which Research Needs Review
All research which uses Trust patients, healthy volunteers, samples, Trust or College staff, facilities, or resources must be subject to some form of review.
Please note: review should be proportionate and take into account other review processes the research may have been subject to and the likely impact on the organisation.

Proportionality of review

Externally funded research - Research which requires external funding normally has scientific peer review built into the application process. However, this still requires local institutional review (as described above). This includes commercial and non-commercially funded research.

Own account/internally funded research - It is important that own account and unfunded research is subject to a thorough peer review process in order to make sure the Trust and College can demonstrate that all its research meets the required standards of quality and probity.

Student research - Student research and other projects which are short term and have minimal resource implications should be treated proportionately, with the emphasis on general appropriateness and the impact the research could have on the institution, service delivery and on patients. CAG and Faculty may wish to consider a fast track form of review for these studies to ensure there is no unnecessary delay in commencement.

Research in small sub-specialties or small departments - Researchers working in small sub-specialties or small departments where there are limited numbers of people able to provide independent expertise, may wish to send their research for external review. However, if a researcher chooses this route they must

- Make sure that their ideas are adequately protected
- Make the findings of the external reviewer available to the local peer review committee

Establishing Committees
Each CAG and Faculty must establish a committee to review its research proposals. Each committee should formally adopt specific terms of reference; advice on the content of these can be given by the JRMO. In addition to this general statement on the purpose of the committees, it is essential that the responsibilities of researchers and the local committee are explicit for each local system. Each review committee should formally adopt the standard operating procedures of the JRMO and publicise them to all staff that fall within their remit. Adequate administrative support will be essential if committees are to function effectively. Additional guidance should be sought from the JRMO.

Criteria Used for local review
Local review committees can undertake both scientific and local review. However, it is recognised that if the research has not been scientifically reviewed as part of a funding application, external independent review should be sought. The committee should ensure that the research has been comprehensively assessed in the following areas:

Study design; risks and benefits of the study; and potential impact. Additionally they should always assess the suitability of monitoring and quality control arrangements, the adequacy of the research site, adequacy resources, current research burden on participant population and suitability of research for the departmental portfolio.

A standard form for peer review is available from the JRMO. If the research has been peer reviewed externally then this should be noted in the appropriate sections of the form All research should be costed by the JRMO prior to the local review to ensure that costs and resources can be assessed by the committee.

Committee Composition

It is crucial that the committee has a sufficient range of expertise to address all the relevant criteria. Committees are often well placed to judge scientific quality but do not always involve people able to assess the impact on routine clinical work and related services such as Pathology, Pharmacy or Imaging. Failure to address these issues at the outset may lead to problems when the research is underway. An important part of the decision making process will be the affordability of unfunded or part funded research.

Reporting Processes

Internal Reporting

The Chair of each local committee, or their designated deputy, should ensure that staff who fall within their remit are aware of the following:

- How to send research for peer review, including a named contact person, telephone number and email address
- The frequency of meetings
- The expected turnaround time for applications
- How researchers will be notified of the results
- Any special arrangements

The outcome of the committee's deliberations should be submitted along with the JRMO or QM REC submission.

A report of all the projects the committee has reviewed and their decisions should be sent to the relevant general manager at least every quarter.

The JRMO will advertise the procedures for each committee on the JRMO website and, when there are changes, in the R&D News Bulletin.

Further advice on peer review can be obtained from the JRMO's Research Governance and GCP Managers.

Confidentiality Guidance for Research Peer Review

All project outlines or protocols sent for review should be clearly marked as confidential. Protocols and project outlines that are sent outside the Trust or College should only be sent once agreement has been received that the reviewer is willing to carry out the review. If there are any concerns surrounding intellectual property or pending patents, advice regarding confidentiality agreements should be sought from the JRMO or QMUL Innovation ltd **prior** to sending out any documentation.

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

5. User Involvement Policy

5.1 Background

The involvement of service users and local communities in the research process aims to enable researchers to work 'with people' rather than 'for people'. Users can help identify real needs for research and help keep research focused on these needs and concerns. The involvement of users can empower them, 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[5].

Experiences of the organisations that have already involved users in research have indicated the importance of training both users and researchers to provide understanding, knowledge and skills. There is often a conflict between the agendas of users and researchers, and when involving users in the actual research process clear ground rules establishing the overall purpose of the research, ownership, and dissemination of results needs to be agreed from the beginning. It is recognised that users cannot be expected to represent all the views within their community and may often represent the views of only a small minority.

5.2 Policy

Researchers should respect the diversity of human culture and conditions, and take full account of ethnicity, gender, disability, age and sexual orientation in its design, undertaking, and reporting. Researchers should take account of the multi-cultural nature of society. It is particularly important that the research evidence available to policy makers reflects the diversity of the population.[6]

Where possible, clinical research should be pursued with the active involvement of service users and carers, including, where appropriate those from hard to reach groups such as the homeless.[7]

Service users, carers and participants should be involved, when possible, in the design, conduct, analysis and dissemination of research and also in the strategic direction and setting of priorities.

Once established, findings from research should be disseminated promptly and fed back as appropriate to participants and other interested parties. Special arrangements should be made to ensure access to information for those with a low level of literacy, English as second language, or a disability.[8]

The College and Trust should seek current advice from the appropriate national, local and Trust or College based patient or interest groups. Current guidance should be sought and followed on recruitment, training and involvement of users in the activities of individual research groups as well as in College and Trust corporate activities, such as Clinical Governance or Modernisation groups. Within the Trust, advice can be sort from the Patient Liaison and Advice Service, the Communications Department and the JRMO.

Users involved in research should be recompensed in line with established good practice.[9]

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[5] Research Governance Framework for Health and Social Care, DH, 2001 revised March 2004.
[6] NHS Executive (1999) Involvement Works. Second Report of the Standing Group on Consumers in NHS Research.
[7] NHS Executive (2000) Working Partnerships. Consumers in NHS Research 3rd Annual Report.
[8] Department of Health (2000) Research & Development for a First Class Service.
[9] INVOLVE (2006) A Guide to Paying Consumers Actively Involved in Research.

Further advice can be obtained from:

NIHR website
http://www.rdinfo.org.uk/flowchart/UserInvolvement.htm

INVOLVE
Wessex House Upper Market Street Eastleigh
Hampshire
SO50 9FD
Tel: 02380 651088
Email enquiries: admin@invo.org.uk
Website: www.invo.org.uk

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

Section C: Information to support Research Governance

6. Project Registration Policy

6.1 Background

All NHS organisations in receipt of NHS R&D Support Funding are required to maintain an accurate database of all research that uses Trust staff, patients, premises, equipment or facilities. The College as the Trust's principal collaborating organisation uses a significant level of infrastructure support. The Trust is also a host site for research led by other collaborating centres and more informal use of Trust patients to supplement samples drawn from other organisations. The purpose of this policy is to ensure that research carried out by the Trust or the College, together with other collaborating organisations, is recorded comprehensively and in a way that promotes:

- Sharing of information across organisations involved in joint research or where a researcher holds more than one contract
- Maintenance of confidentiality and appropriate handling of sensitive information; and
- Monitoring compliance of research with the Research Governance Framework Policy 1.

6.1.1 Overall responsibility for maintaining an accurate database of research lies with the JRMO. This includes entering data, verifying & cleaning the database.

6.1.2 The JRMO will also share activity data with the College and other collaborating organisations to promote accurate recording of research activity across all of its research projects.

6.1.3 The Trust and College may use projects recorded on the database as a mechanism for undertaking monitoring and/or audits of GCP and / or research governance compliance.

6.1.4 It is the responsibility of all investigators to ensure that the following steps are taken to ensure that their projects are properly registered:

- Peer review undertaken;
- Costing by the JRMO;
- Ethical approval, as appropriate;
- Trust indemnity;
- No disclosure of valuable IP has been made; and
- MHRA approval is obtained, as appropriate.

6.2 At the point of registration

6.2.1 The principal investigator or funder must ensure that the JRMO is aware of any project that should be regarded as 'confidential'.

6.2.2 The JRMO is notified of research that may be sensitive if publicly disclosed (e.g. where the research uses animals or where the research is likely to lead to the development of potentially valuable Intellectual Property) and advised of how the research should be recorded.

6.2.3 Where research takes place across more than one site and where the Trust or College is sponsor (or a legal representative), it is the responsibility of the Chief Investigator to notify the JRMO of all organisations involved and to obtain the appropriate approval (s) from the JRMO prior to activity taking place at any site.

6.3 Following registration

6.3.1 Changes to a project and project termination should be notified to the JRMO as soon as possible and in accordance with sponsor and/or JRMO SOPs.

- No project activity may commence until the JRMO has provided the PI with final approval documentation.
- Investigators must update the JRMO during the active stage of the project (e.g. annual reporting requirements, safety reporting, project delays/halts, changes in project details –amendments).
- Investigators must update the JRMO at the close of the project (e.g. end of trial notifications, publications and archiving).

Note: this policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

7. Dissemination Policy

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 ensuring that significant outputs from this activity are made available as widely as possible both within and beyond the research community. [10]

The Research Governance Framework requires public sector organisations to actively disseminate the findings of their work to appropriate public sector, academic and public audiences. In addition, effective dissemination is an important means of raising the profile of an organisation, enhancing the recruiting and retention of staff and improving academic and clinical practice.

The purpose of this policy is to ensure that staff undertaking research, at The College and the Trust, are:

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

7.2 The Policy

This policy applies to all research which is led by or involves significant input from College or Trust staff, honorary employees, short term appointees and visiting staff using Trust 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[11] by professional and funding bodies. [12]

Before research is initiated:

- Bids for research funds from income streams held by the College, Trust or associated charitable, government or commercial organisations, should include a broad dissemination strategy, encouraging quality research to be widely disseminated and freely accessed.

- During the course of 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 it should be decided at an early stage who will be credited as authors, as contributors and others who will be acknowledged in the publication. This should, were possible, be clearly documented in the project protocol or outline. Special attention should be given to external collaborators and any funder acknowledgments.

Upon completion of the project:

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

[11] Medicines for Human Use (Clinical Trials) Regulations, 2004 (and all its amendments) and EU Directive 2001/20/EC & GCP Directive 2005/28/EC and the Data Protection Act, 1998.

[12] GMC Good practice in research and Consent to research (2010)
Committee on Publication Ethics (COPE) Guidelines on Good Publication Practice

- Investigators should report results in a way that is transparent and open to audit. Researchers will normally produce publications in academic journals. However, the College and Trust 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 the College or Trust 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, The College and The Trust would normally expect that external contracts do not unnecessarily restrict the organisations publication rights. In addition, Contracts and Costings officers and investigators should 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 The College.

- 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 i.e. authorship should be in line with the degree of input to the paper and the project upon which it is based. Conflicts of interest (i.e. those which, when revealed later, would make a reasonable reader feel misled or deceived) must be declared to editors by researchers, authors and reviewers.[13]

- In relation to citations, researchers should ensure that they appropriately reference their employer in any publication. QMUL staff must adhere to the Colleges Citation policy (see 8 below).

[13] GMC Conflicts of interest - guidance for doctors September 2008, QMUL - Standards of Business Conduct , BH Trust - Standards of Business Conduct (Including declaration of interest)

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

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

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

8. Queen Mary's Citation Policy

This policy has been developed in response to the need to develop a standard Queen Mary citation policy for research publications and grant applications as well as the dissemination of research findings. It builds on the policy first adopted for RAE 2008 and is now reinforced for the forthcoming REF 2014 census.

8.1 Acknowledging Queen Mary

In all public events, presentations and debates involving QM staff discussing work undertaken as an employee of QM, participants must make clear that they work for:

Queen Mary, University of London

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. It is crucial that all research and academic debate in whatever form undertaken by QM staff is associated with the name Queen Mary, University of London. 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 Queen Mary, University of London. This includes ensuring that Queen Mary, University of London is clearly visible on websites, email addresses and signatures and business cards.

While other affiliations (schools, faculties, research institutes, centres, etc.) may be included, QM must appear in a prominent position.

Examples of Acceptable Affiliation:

1. Joe Bloggs, Queen Mary, University of London

2. Joe Bloggs, Communications Manager, Queen Mary, University of London

3. Joe Bloggs, School of History, Humanities and Social Sciences, Queen Mary, University of London

4. Joe Bloggs, Barts & The London School of Medicine and Dentistry, Queen Mary, University of London

8.2 Citing Queen Mary for Research Purposes

Similarly, all research activity undertaken by QM employees must make it clear that they work for QM.

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 QM, and via the use of QM resources and facilities. It is not acceptable to drop the QM name because the affiliation is considered too long.

8.2.1 How to cite Queen Mary for research purposes

Research outputs by QM authors are indexed in Web of Science under more than thirty different institutional names. ThomsonReuters, the publisher of Web of Science, reported that the comma in the current name of the university adds 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 QM is able to maximise its academic reputation as well as the financial rewards of REF and other forms of success.

For these reasons, it has been agreed by QMSE that for the purposes of research publications, there should be no punctuation in the name: the comma after Queen Mary must be excluded. 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 records. It will be the responsibility of each researcher to ensure that the affiliation details are correctly recorded.

Examples of Acceptable Citations:

5. Researcher name, Queen Mary University of London

6. Researcher name, Barts Cancer Institute, Queen Mary University of London

7. Researcher name, School of Physics and Astronomy, Queen Mary University of London, Mile End Road, London E1 4NS

8. 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 which could have serious consequences. We will, therefore, be monitoring this closely. If there is no significant improvement over the next six months, we will move to a system of financial penalties described below.

8.3 Monitoring and Enforcement

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 Emma Bull, Director of Library Services to monitor publists 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 QM academics are identifying their affiliation.

Staff who do not identify themselves as working for Queen Mary University of London in public presentations or use the citation policy described above, will be sent a warning letter which will be copied to their Head of Institute or School and the faculty Vice-Principal and Executive Dean. If there has been no significant improvement, the faculty VP and Executive Deans will impose a financial penalty on any school or institute whose staff member does not include the affiliation: Queen Mary University of London in their

research publications or who fails to refer to Queen Mary University of London in their media or other public profile activities.

Given the exceptional importance of this policy for the forthcoming REF, we expect all schools, institutes and professional services to take the necessary steps to support staff in promoting their affiliation with their employer.

Authorisation

This policy has been approved by the Queen Mary Senior Executive (QMSE).

Contact for questions about this policy:

Mrs Emma Bull
Director of Library Services
Email: e.j.bull@qmul.ac.uk

Date of policy

October 2011

9. Use of Participant Information for Research

9.1 Background

9.1.1 The Data Protection Act[14], Caldicott Report[15], Research Governance Framework[16], ICH-GCP[17], funding and professional bodies[18] and National Information Governance Board [19] have all issued guidance on how patient information for the purposes of research should be gathered, handled, stored and disclosed.

9.1.2 The purpose of this policy is to ensure that Trust and College staff undertaking research, which uses research participant information, are aware of their responsibilities with regard to use of existing medical records, as well as creation of new hard copy/electronic patient records for research.

9.2 The Policy

9.2.1 This policy applies to 3 main areas:

- Use of existing records for the purpose of identifying or enrolling participants in a study, obtaining and storing participant data for research, or retrospective note-based studies

- Compilation, handling, audit and storage of research documentation utilised for research

- New or existing electronic files of research participant information for the purposes of research

General Guidelines

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

- Organisations outside the Trust, including the College, wishing to access personally identifiable data for the purposes of research must comply with the Trust Data Protection Policy Annex on 3rd Party Access[20].

- Participant information used for research whether it be existing records or records created purely for the purposes of research must conform to accepted standards laid out by the National Information Governance Board (NIGB), EU and UK law, professional bodies and funding organizations regulations. All staff must make sure they are aware of these standards before commencing a research project.

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

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[14] Data Protection Act, 1998
[15] Caldicott Committee (1997) Report on the Review of Patient - Identifiable Information
[16] Department of Health (2004) Research Governance Framework for Health & Social Care and The Department of Health (2003) Code of Confidentiality.
[17] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996.
[18] MRC Guidelines for Good Clinical Practice in Clinical Trials, 1998. Safeguarding Good Scientific Practice (1998) Joint Statement by the Director General of the Research.
[19] National Information Governance Board http://www.nigb.nhs.uk/
[20] Public Interest Disclosure Act, 1998.

- The confidentiality of records that could identify individual participants should be protected. Where data is needed for the purposes of research investigators should:
    - seek consent for disclosure wherever practicable
    - de-identify data where possible
    - keep disclosures to a minimum

- 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 express consent wherever this is practicable.

- Where it is not practical for the person who 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 significant public interest to be served

- Where a clinician or an academic controls access to personal information on research participants they must not allow access to any staff member unless:

    - The person has been properly trained
    - Appropriate ethical and Trust/College approval has been obtained
    - The person is subject to a duty of confidentiality

- Records used for research are NOT the property of the Investigator 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 care of the patient; or
    - 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 college or Trust researchers in future research projects[21]

- All records used for research must conform to NHSLA Risk Management Standards[22] , Trust and College Data Security and Management Policies.

- All projects Submitted to JRMO will be reviewed to ensure it is consistent with the Data Protection Act and local policy requirements[23].

- Researchers must conform to the Trust and College Data protection policies and should seek guidance from the JRMO and Trust and College Information

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[21] Research Councils UK (RCUK) policy on Research data-sharing – information can be found at http://www.rcuk.ac.uk/research/Pages/DataPolicy.aspx. An example of a specific policy is the MRC policy on Data Sharing September 2011

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

[23] Barts Health NHS Trust Data Protection Policy May 2009
QMUL Data Protection Policy November 2009

governance teams.

Use of Trust Medical Records Service

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

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

- All requests for records for research should supply the name & 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.

Note: This policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

Section D: Minimising Risk in Research and Development Activities

10. Minimising Risk in Research and Development Activities

10.1 Background

A significant volume of research activity is undertaken by The College and the Trust, funded through a variety of external and internal sources. 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:

- Clinical Risk
- Employment Risk
- Contractual Risk
- Asset Risk
- Reputational Risk

Detailed policies on each of the areas set out below are contained in various sections of this core research management policies document. Reference will be made to each relevant policy. By adhering to College and Trust policies, staff will minimise the risks associated with carrying out their research remits

10.2 Policy

Staff undertaking research in the College and Trust will adhere to national and local regulatory frameworks and the relevant College and Trust research management policies, to ensure that the risks associated with undertaking research are minimised.

10.3 Regulatory Compliance

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

- Obtaining External or Internal Ethical Approval – See policy numbers 1 and 2
- Obtaining regulatory approval from an appropriate regulatory body i.e. The Medial and Healthcare products Regulatory Agency
- Adherence to Good Clinical Practice or Good Laboratory practice and the declaration of Helsinki when undertaking research
- Adherence to the published Research Governance Framework for Health and Social Care; and
- Adherence to College and Trust policy with regard to 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 Trust and College policies. Access to these policies is via the Trust or College's web sites. Particular attention should be paid to the following core policies:

- Health and Safety policies of the Trust and College
- Complaints policies of the Trust and College
- Policies relating to Clinical Studies
- Risk Management Strategy & Policy (COR/POL/004?2012-001)
- Adverse Incidents Policy (COR/POL/041/2012-001)

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 – Policy Number 14
- Ensuring that the value to any patients or volunteer subjects participating in research projects outweighs the personal risks surrounding such participation. The 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 staff, who will carry out a research remit in the organisations 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, staff involved in research shall pass the responsibility for all contractual matters to the Joint Research Management Office, who will negotiate contract terms, prices 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

The College and Trust 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 have a duty to ensure that the assets of the College and the Trust 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 7 - Dissemination Policy
- Policy 15 - Identification and Protection of Intellectual Property
- Policy 16 - Exploitation of Intellectual Property
- Policy 17 - Costing Research Policy
- Policy 18 – Externally supported R&D Pricing Policy

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

10.9 Responsibility for Minimising Risk in relation to 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, Good laboratory Practice, national regulations and The College and Trust's standing orders and corporate policies. Clinical academic Group, faculty Managers and the Joint Research Management Office are charged with a duty to ensure that staff adhere to this regulatory framework.

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

11. Research Data Management at QMUL

11.1 Policy Background

A 2008 HEFCE-funded report defines research data as "the evidence base on which academic researchers build their analytic or other work." Data management, including planning for long-term storage and sharing, is an increasingly important aspect of the UK Research funding environment. Most grant applications for research which will generate digital data sets require a data management plan that meets the 2011 Research Councils UK (RCUK) 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:'[24]

RCUK now require all funded universities to have a data management policy and road map that will meet their expectations for data sharing in place with full implementation by 2015. This is to ensure we make it clear how publicly funded data can be accessed for at least ten years after publication. Our policy should deliver the following criteria:

- Publicly funded research data should be made openly available in a timely manner
- Data with acknowledged long term value should be made accessible
- RCUK recognises that there are legal, ethical and commercial constraints on release of research data. To ensure that the research process is not damaged by inappropriate release of data, research organisation policies and practices should ensure that these are considered at all stages in the research process
- 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 at http://www.dcc.ac.uk/resources/data-management-plans/funders-requirements.

11.2 Policy

(i) Research data will be managed to the highest standards throughout the research data lifecycle as part of the University's commitment to research excellence.

(ii) Queen Mary research data will be registered and managed in accordance with the University's policies, guidelines and standards, and funder, legislative and ethical requirements.

(iii) Data deemed to be of interest to future research, particularly data that substantiate research findings, will be offered for deposit either in a Queen Mary or an appropriate external repository.

(iv) Where possible publicly funded research data should be made available for access and re-use.

(v) Data must be retained intact in an appropriate format and storage facility according to funder requirements and relevant data legislation. Where retention is not specified as a condition of funding, data should normally be stored for a period of at least 10 years from the date of any publication which is based upon it.

(vi) Where research data is not retained it should be disposed of according to University guidelines.

(vii) When planning research activity where research data may be created or reused, researchers must prepare and maintain data management plans that explicitly

[24] http://www.rcuk.ac.uk/research/Pages/DataPolicy.aspx

address data capture, management, integrity, confidentiality, retention, sharing and publication.

(viii) Principal Investigators or those in equivalent roles have lead responsibility for ensuring that research data management requirements are observed during a research project or programme.

(ix) Those responsible for research staff and students should ensure that researchers in their areas are aware of the University's policy regarding research data and its associated guidelines and procedures.

(x) All researchers are expected to familiarise themselves with and act in accordance with this and other QM policies relating to research practice.

(xi) The University will provide advice, training and support regarding research data management

(xii) The University will provide means and services enabling registration, deposit, storage, retention of and access to research data.

Note: This policy applies only to Queen Mary University of London

12. Clinical Trial Compensation

12.1 Background

Clinical trials and other research studies undertaken by employees of the College or the Trust 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 in accordance with 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 now generally thought that where a subject is harmed by a trial, the prospect of compensation should not depend on whether the trial happens to be company-sponsored.

This document sets out the College's and Trust's policy in relation to compensation payments. It sets out applicable criteria and procedure for making compensation of those subjects injured in non-company sponsored trials for which there is no alternative equivalent compensation available or in company-sponsored trials where 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, i.e. an individual, whose participation in piece of research derives from either:
   - Having sought or accepted medical care within the Trust primarily for treatment of a condition the investigation of which is the subject of the clinical trial; or
   - 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; or

c) A child in utero - a child subsequently born alive whose mother was a trial subject while the child was in utero. While this policy at a minimum also would apply to non-patient volunteers (i.e. "healthy volunteers"), arrangements for this category of Trial Subjects are receiving further considerations.

All research studies must first be submitted to and approved by an appropriate NRES Ethics Committee and Joint Research Management Office. Failure to obtain such approval, or disregard of any conditions for an approval, would be a breach of the investigator's terms of employment within the College or Trust. Further, the investigator could bear personal responsibility for any harm resulting to a patient.

12.3 Coverage

The College or Trust will pay compensation to trial subjects suffering bodily injury in accordance with this policy.

Compensation will be paid when, on 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 to her child in utero. However, since strict criteria are laid down by the NRES Research Ethics Committee 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 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 the College or Trust is not responsible (e.g. the 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 the College's insurance policy or, in the case of the Trust, The Department of Health national insurance provisions.

The undertaking given by the College and Trust extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the course of 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 NRES Ethics Committee and the College or Trust, 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 limit imposed on the College or Trust, 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; or
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 the College or Trust 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 Trust or College policy.

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

Claims pursuant to this policy should be made by the trial subject to the Trust 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 the Trust or College to review any medial records relevant to the claim. The College or Trust 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 the College or Trust 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 the Trust's Policy for handling of Clinical Negligence and Personal Injury Claims will apply to this clinical trials compensation policy except where the procedures are in conflict, in which case the wording of this clinical trials compensation policy will take precedence.

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

Note: This policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

13. Policy for the Safe and Secure Handling of Medicines in Clinical Trials

13.1 Background

The purpose of this policy is to ensure that the Trust and College comply with the relevant guidelines for the safe and secure handling of clinical trial medication.[25]

This policy applies to all drug trials that involve Trust patients and healthy volunteer studies managed by or treated on Trust or College property.

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

Where a 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.

13.2 Scope

This Policy applies to all trials falling within the scope of the EU directive regardless of licensing status, indication, funder, sponsor or source. For guidance on establishing if a trial falls under this directive there is the MHRA's algorithm entitled "is this a trial of a medicinal product?."[26] Researchers should always seek JRMO advice if there is any doubt, the JRMO will, if required, contact the MHRA helpline for a final decision on whether or not a trail falls under the scope of the EU directive.

13.2 Policy

Regulatory and local approvals

In addition to ethical and local NHS approval, trials involving an investigational medicinal product (IMP) should follow current submission guidelines and the processes required to submit an application the Medicines Health care products regulatory Agency (MHRA).

A relevant Ethical Review Committee must first approve any clinical trials involving patients of the Trust or healthy volunteers. A Principal Investigator wishing to prescribe drugs for an in-house trial should ensure that where appropriate the licensing authority (MHRA) has been informed. This may involve application for a Clinical Trial Authorisation (CTA). This must cover clinical trials of unlicensed products, sponsored by pharmaceutical companies. Prior to prescribing clinical trial material the Principal Investigator, or pharmaceutical company trial co-ordinator should discuss with the Trust'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.

Local appropriate pharmacy approval must be sought and received. Only upon receipt of all appropriate approvals will the Trust or College permit a trial to start.

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[25] The Declaration of Helsinki (1996); ICH Good Clinical Practice (1996); EU Directive 2001/20/EC & GCP Directive 2005/28/EC; The Medicines for Human Use (Clinical Trials) Regulations 2004 (and all its amendments); The Data Protection Act 1998; The Research Governance Framework for Health and Social Care 2001,Revised 2004

[26] Algorithm is at http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con009394.pdf

Prescribing and Administration
All prescribers and persons administering IMP must be suitably trained and delegated to do so by the principal investigator.

All IMP should be prescribed using a pharmacy approved prescription. The prescription must be clearly labelled "For clinical trial use."

Patient Safeguards
Informed consent must be obtained as per local and national policies. The Principal Investigator is responsible for informing patients with regard to trial medication and the potential for any harmful effects Arrangements must be in place to indemnify the Trust or College for any claims against them relating to medicine-induced injury.

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

Supply and storage
All medication intended for clinical trial use should be delivered to the Pharmacy Department and stored under its direction. It is normally inappropriate for stock to be stored on wards, clinics or private offices. Where normal arrangements would seriously affect the running of the trial, the pharmacist may consider authorising alternative arrangements. This must be documented and an audit of the procedures and conditions must be carried out. The trial will be subject to on-going audit by the pharmacist in these circumstances. Any significant breaches of GCP, or the safe and secure handling of medicines policy, may result in suspension of the trial whilst satisfactory arrangements are put in place.

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

Information
Pharmacy should hold within a 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.

Note: This policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

14. Use of Medical Devices in Research

14.1 Background

Medical Devices are utilised in research in a number of ways:

- Development of a new device in-house may be the primary purpose of the project
- Devices may be purchased or introduced on loan in order to enable research to be carried out
- Existing devices may be altered for use in research; and
- 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 the purposes of research have undergone basic safety checks
- Appropriate departments within the Trust and College are aware of and have approved the use of the device
- The risk associated with experimental devices is minimised
- Experimental devices do not pass into mainstream usage without consideration of safety, fitness for purpose, capacity for sterilisation, training needs of potential users, maintenance and cost effectiveness
- Any incidents or near misses relating to experimental devices are reported using the Trust incident reporting procedure

14.2 Policy

This policy is designed to ensure that the Trust and College meet their legal obligations concerning the use of medical devices in Clinical Research.

This policy follows the Trusts existing guidance in the context of devices used in research. This policy is applicable to Trust and College personnel using medical devices with in research, regardless of type of participant or setting.

It should also be noted that any devices that are developed ‘in house’ and not on the market are not covered by any MDA regulations and therefore, it is the responsibility of the Trust or College to ensure that their use is safe and appropriate.

14.3 General Points

All research that intends to use human subjects must have appropriate ethical approval (See Ethics policy with in this document). All devices whether used to carry out the research developed as the subject of research must be registered with the Trust Clinical Physics / Equipment Department and JRMO. Researchers not involving Trust patients or staff should seek advice and guidance from the JRMO and Trust Clinical Physics / Equipment Department, who will on a case-by-case basis provide risk management and safety reviews. It is the responsibility of individual CAGs or Faculties to ensure that all equipment in use is included in an equipment inventory. CAGs and Faculties must also ensure that Clinical Physics are notified if equipment is re-located. All experimental equipment intended for clinical interventions must be clearly labelled and registered as 'Research Only.' Medical equipment intended for research must not be used in routine clinical practice without written approval of Clinical Physics.

14.4 Purchasing Equipment for Research

All equipment purchased for use in research, either by the Trust or College must go through the approved Trust or College 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 Equipment, Clinical Physics and Clinical Risk Departments before introducing a new piece of equipment.

Where a tendering process is required, Clinical Physics and Clinical Equipment should be informed and a tender specification approved. These departments 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 / Equipment.

14.5 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 the Trust or College 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 / Equipment 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 the College or Trust undertakes no commitment to purchase, even if the equipment proves itself in use
ii. Be clear about whether or not the Trust or College must pay for wear and tear. If expected, the amount should be specified in advance
iii. Be clear about whether the College or Trust 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 i.e. 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 overall value for Money
vii. Follow the Trust or College 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, the Trust or College
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 Trust assets. It must not be included on the Trust’s or College asset register

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 the Trust or Colleges business case rules apply.

14.6 Safety Testing

All new portable devices for use in the Trust or on Trust 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 / Equipment informed. All new equipment will be given a full functional and electrical safety test before use. This will either be carried out in house or Clinical Physics / Equipment will arrange for the Supplier/Manufacturer to carry out the appropriate tests. All tests will be documented and held by Clinical Physics / Equipment.

For research not using trust patients or staff, individual arrangements should be made with Clinical Physics / Equipment for safety testing prior to use.

14.7 User Training

Before the 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 CAG or Faculty rather than the manufacturer, their adequacy must be checked by Clinical Physics / Equipment.

14.8 Maintenance

Researchers must be clear who provides maintenance for any equipment used in research. Maintenance will normally be carried out to 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 20 years after the end of the research, depending on which period is longer.

14.9 Risk Management

All equipment to be used in clinical interventions must be capable of disinfection unless it is designated '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, i.e. new products or amended existing products, must be subject to a risk assessment by Clinical Physics / Equipment.

In the event of an incident or near miss involving equipment for research, 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. Trust and College incident reporting policies should be followed.

14.10 Storage of Devices

Custodians of equipment and investigators should ensure that medical devices are stored in accordance with manufacturer's instructions. Where a device is experimental, advice on storage should be sought from the Clinical Physics Department. All experimental devices may not be stored in a way that may lead staff to believe they are for routine clinical use.

14.11 Disposal of Devices

Medical Equipment which 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 in accordance with the Radioactive Substances Act, 1993 and the Radiation Protection Officer advised.

14.12 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). [27]

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

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
- investigation, replacement or modification of the anatomy or of a physiological process, or
- control of conception; and

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 with the intention of marketing them to another legal entity, as opposed to treating their own patients, MHRA would regard such manufacture as being covered by the Regulations.[28] This would include transfer between the College and Trust. 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, 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 [29] clearly sets out procedures. Advice and guidance should always be sought from the JRMO.

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[27] 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**
[28] The Medical Devices Regulations: Implications on Healthcare and other Related Establishments, Bulletin No. 18 Competent Authority (UK), February 2011
[29] MHRA-EC Medical Devices Directives Guidance Note 1 (Guidance for Manufacturers in Clinical Investigations to be Carried out in the UK, February 2012)

The Trust and College (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; and
- 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.

Note: This policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

15. Indemnity Policy

15.1 Background

Clinical Trials and other research studies undertaken by employees of the Trust, College and external Researchers, carry an element of risk for research subjects, (who may be Trust Patients or volunteers entering College projects), researchers, research sponsors and employing organisations. 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 in order for the Compensation Policy to come into force.

15.2 Policy

(a) Commercially Funded Trials

All organisations in the UK are required to ensure that before any trial funded by a commercial concern, pharmaceutical company or Devices Company commences, a properly authorised and signed Form of Indemnity for Clinical Studies is completed by the JRMO, and submitted with the Research Ethics Application. This Form will be in the prescribed Association of the British Pharmaceutical Industry (ABPI) format. This legally binding agreement provides indemnity for both trial subjects, the Trust or the College, 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 the Trust or College indemnified from liability to pay the claim.

(b) Non Commercially Sponsored Trials

In general where a trial is sponsored by a non-industrial organisation the funder that might be Research Council, Government Organisation, Charity, Trust etc, shall remain responsible for the design of the study and any materials, drugs or equipment supplied, if they have written the protocol and are providing the drugs or devices. Where a collaborative study is entered into, individual employing organisations are responsible for the acts of their employees whilst on related business. Responsibility for protocol and product liability will vary according to the nature of the trial and the acceptance of responsibility by the funder. Thus indemnity may be provided by:

- A commercial company that is lending support to a non-commercial study by contributing free drugs, with or without additional financial support, that might be unlicensed for a condition or indication that is the subject of the research study being undertaken and for which the company is not providing indemnity. The company will be expected to provide a guarantee that the products supplied are the subject of a manufacturers warranty
- A funding organisation, such as the MRC, on strictly limited Terms and Conditions that are not in the ABPI prescribed format
- The College or Trust that in the absence of an agreement with a funder takes responsibility for meeting product liability claims; or
- Where an unlicensed product is used beyond the trial period, on a named patient basis, or for humanitarian purposes, 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.

15.3 Negligence

Organisations are required to indemnify research subjects and 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 College 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 Indemnity, which sets out the terms under which the indemnity is issued. Once Ethics Approval has been given for a study, the Office will issue a Final Letter of Indemnity. The Indemnity covers College or Trust staff only, and Investigators from other organisations, must submit a similar Letter of Indemnity to the JRMO and Ethics Committee, before conducting a study on College or Trust premises. Investigators must continue to appraise the Office and Ethics Committee(s) of changes to the Protocol/Project Specification in order 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 Investigators 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 the College or Trust Policies on Health and Safety at work.

15.5 Insurance

The College 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. The JRMO must bring to the attention of the College's Purchasing Officer any instances where additional cover needs to be purchased from an external insurer.

The Trust insures its liabilities through the NHS Litigation Authority's liabilities to third parties scheme.

Note: This policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

Section E: Financial Probity in Research

16. Identification and Protection of Intellectual Property

16.1 Background

Intellectual Property can be defined as inventions, designs, project results, prototypes, systems, processes, formulae, publications, internal reports, natural discoveries, ideas, knowledge or know-how derived or developed as part of an employee's work for the Trust.

The Trust is obliged to protect and where possible exploit to the advantage of the NHS generally, and in particular for the financial benefit of the Trust, the product of its research activities. The following Intellectual Property Policy is geared towards protecting the interests of the Trust and its staff with regard to their Intellectual Property Rights.

16.2 Trust Policy

Ownership

The rights to any Intellectual Property (IP) developed by individual employees of the Trust during the normal course of their employment are vested in the Trust.

Where the principal employer of an individual who holds an honorary contract with another organisation is the Trust, then the ownership of any IP arising from their work is vested in the Trust.

Should an employee have a joint appointment with another organisation then the ownership of any IP developed by the individual will be joint between the employing organisations. The determination of ownership in these circumstances will be on a "case by case" basis and will be subject to a written agreement between the parties with due regard to the financial investment of each organisation in the development of each item of IP.

Should the Trust decide not to prosecute a particular piece of IP, then ownership rights will be assigned to the employee, who will be free to take whatever action he deems necessary at his own expense to protect and exploit the IP without further involvement of the Trust.

Contracts

A contract is usually the major mechanism for protecting the Trust's IP. All contracts and 'agreements' for research projects taking place on Trust premises and utilising Trust resources must be reviewed by the JRMO and signed by an authorised Trust Officer. Failure to inform the JRMO may make individuals liable under the Trust's Policy on Misconduct in Research (see policy number 23).

The JRMO must review all contracts and agreements to ensure appropriate protection and exploitation of IP and clarification of ownership.

Ownership of both background IP (IP that Trust employees bring to a project) and foreground IP (IP generated during the course of a project) must be formalised.

Where ownership of the IP does not vest in the Trust, contracts should clearly set out the distribution of income, received from the exploitation, to the various parties, according to the level of their individual contributions to the development of the IP.

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.

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

IP Protection

The Trust has a duty to adequately protect its IP. Ensuring that effective protection is maintained can only be guaranteed with the co-operation of the Trust's researchers.

All Trust employees will keep confidential unpublished information pertaining to the research they or their colleagues are undertaking.

Before discussions can begin with potential external research sponsors, a confidentiality undertaking will be concluded between the Trust and the external organisation and signed on behalf of the Trust by an authorised officer and the employee.

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

Copyright is automatic and applies to books, computer programmes, publications, lecture notes, reports, laboratory notes, etc. Adding a note at the end of the text to the effect that copyrights belongs to Barts Health NHS Trust will protect all such texts.

A copy of all copyright texts will be sent to the JRMO, which will maintain a central register of all of the Trust's copyright material.

Where, in the view of the Trust, a piece of IP requires patent protection, the Trust's patent agents 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.

Publication

The Trust 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 the Trust's ability to successfully exploit any potentially valuable IP is not compromised.

Staff will, therefore, be encouraged to consult the JRMO before articles are submitted for publication or information disclosed to a third party.

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.

Note: this policy applies only to Barts Health NHS Trust (QMUL Policy is in draft).

17. Exploitation of Intellectual Property

17.1 Background

It is incumbent to exploit, whenever possible, the product of its research activity, if that product has potential commercial value or could lead to a new service development. Should a commercialisation route be defined then the income streams that could arise from the successful exploitation of the Trust's Intellectual Property (IP) will provide a valuable contribution to the Trust's infrastructure costs and an attractive source of unencumbered research funding.

The principal methods of exploitation are as follows:

- Outright sale of IP to commercial organisations.
- Licensing Agreements: where companies are licensed to utilise the Trust's IP in exchange for a royalty based on the value of sales the company makes.
- Sale of IP rights in exchange for specific initiatives e.g. funded posts, purchases of capital equipment, etc.
- Through joint ventures with other non-commercial organisations, e.g. medical colleges, local authorities, etc.
- The creation of spin-out companies.

The College has developed a policy for the Exploitation of Intellectual Property which differs from that of the Trust and is contained in the second section of this policy.

17.2 Barts Health NHS Trust IP Policy

The Trust will establish the mechanisms required to identify its IP and its commercial potential. 'NHS bodies should minimise the risk that they take on by assigning or licensing any IP to commercial or other organisations able and willing to meet all or most of the costs of exploitation' (Research Governance Framework, 2001). The JRMO will take overall responsibility for ensuring that the Trust's IP is made available to potential industrial partners, providing services through a contracted IP portfolio management company or through an in-house provision.

Staff involved in Research & Development activity in the Trust are required to bring to the attention of the Director of Academic Health Sciences any item of IP developed in the course of their employment.

The decision to pursue a commercial development will rest with the Director of Academic Health Sciences. The resources that NHS bodies devote should be commensurate with the likely benefits and with other calls on their funds.

The Trust recognises that staff involvement with the development of its IP should be rewarded through a share in the proceeds of any successful exploitation. Income received by the Trust will be distributed in the following manner:

Net Total Cumulative Income[30]	**Inventor's Share**[31]	**Trust Share**
	%	%
0-£5,000	100	0

[30] Net income is the residual value after the deduction of all Trust expenses and charges.
[31] Inventor's share to be split between inventors; if there is more than one inventor a ratio will be agreed between them.

£5,000-£45,000	75	25
£45,000-£100,000	50	50
£100,000 +	33.3	66.7

In dealing with Trust exploitable intellectual property, the JRMO will bring to the notice of inventors and all those involved in the commercialisation process, the Trust'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 University of London IP Policy

Objectives:

a) The objective of this policy on intellectual property is to provide an incentive to inventors to monitor research findings with a view to commercial exploitation rather than lose possible revenue through premature disclosure. Staff or students of the College should not publish nor disclose potentially patentable results until advice has been obtained on protection. Premature publication will lead to loss of rights and ownership. Advice on patenting and the use of confidentiality agreements for discussions with third parties can be obtained from Queen Mary Innovation. This advice will be provided in a timely manner to avoid inhibiting the dissemination of knowledge.

b) Any member of staff or any student of the College may in the normal course of his/her duties or studies, or whilst using College resources, make an invention, discovery, design or other original work, including computer software, which might be the subject of intellectual property rights, such as for example, copyright or patent rights (collectively defined herein as an "Invention"). A definition of forms of intellectual property is contained in Appendix 3.

   Subject to the exceptions listed in Section 16.4, any such invention shall belong to the College, and it is the responsibility of the member of staff or student to notify the College of any such invention, which might have commercial value.

   Accordingly, any member of staff who makes such an Invention must promptly inform the Head of Department and Queen Mary Innovation of the Invention in writing. Likewise any student of the College who makes such an Invention must promptly inform his/her supervisor or tutor of the Invention in writing, who in turn should inform Queen Mary Innovation.

c) The College shall:
   - in respect of inventions which it owns, decide whether the submission, prosecution and maintenance in force of patent or other intellectual property protection in relation to the Inventions is reasonably necessary and justified in the circumstances, and
   - Working with the inventors use reasonable endeavours to identify appropriate third parties to commercially exploit the Invention and negotiate the best possible terms under which such third parties would be permitted to exploit the invention commercially.

   Whilst the College will endeavour to act in good faith to maximise the commercial value in the best interest of both the College and its employees and students, the College cannot accept any liability whatsoever for any act or omission in relation to the matters referred to in this clause.

If the College decides not to exploit an invention it will offer to assign the invention to the inventor(s), subject to any conditions of the funders of research leading to the invention, on terms to be agreed in good faith.

d) The exploitation of inventions may be by outright sale or license granted to a third party for a revenue stream or by assignment to a company set up to carry out the exploitation for an equity shareholding in the company. The basis of the incentives to inventors, whether employees or students of the College, in each of these options is set out in sections 17.3.1 and 17.3.2 respectively.

17.3.1 Sharing of Income from Sale or License of an Invention

a. The Net Income from the sale or license of an Invention to a third party will be apportioned between the inventors collectively and the College according to the following scale which provides a strong incentive at all levels of Net Income:

	Inventor(s) %	***College**** **%**
First £5,000	100	0
Next £45,000	75	25
Next £50,000	50	50
In excess of £100,000	$33^{1/3}$	$66^{2/3}$

The College will provide an annual statement to inventors of the income received from Inventions that have been licensed or sold together with details of the apportionment according to this Section.

b. Net Income for the purposes of paragraph 16.2(a) above means sums received by the College as a result of exploitation of the invention but does not include any funding of future research and development by a third party (whether related to the invention or otherwise).

c. The following shall be deducted in calculating the Net Income:
   - Value Added Tax.
   - Direct costs associated with seeking patent protection and legal expenses directly related to the exploitation of the invention
   - Any other expenses directly related to the obtaining or exploitation of the invention
   - Any payment due under a revenue sharing agreement to a third party involved in the research leading to the invention

d. If an employee is entitled to a share of Net Income derived from more than one Invention and those Inventions are not closely related then the Net Income received will not be aggregated but will be treated quite separately when the division of Net Income is calculated. Where inventions are directly related Net Income will be aggregated. Where Net Income is not separately apportioned but relates to two or more inventions the College will apportion the Net Income to the inventors on a fair and equitable basis for the operation of this policy.

e. Where an invention is the result of work by two or more inventors the Net Income will be shared in proportions to be agreed between the co-inventors concerned. In the absence of agreement as to their respective shares this will be determined by an independent arbitrator appointed by the Principal of the College on a fair and equitable basis. Should the arbitrator nominated be unacceptable to a party, the matter will be referred to an arbitrator appointed by the President for the time being

of the Law Society. The costs of the arbitrator will be borne out of the Net Income which the inventors are sharing.

f. The College shall account to the inventor for his/her share of Net Income within 90 days of receipt or the date upon which the extent of the inventor's share is determined or agreed (whichever is the later) together with a written statement evidencing the account due.

g. Net Income paid to an inventor shall be subject to income tax as appropriate. An inventor may waive all or part of his/her personal payment and request that it be used for research purposes within his/her department. Any resulting payment to research budget within the department will not be taxable provided notification is made before payment has been made to the inventor.

h. To facilitate payments under this policy, inventors must keep the College informed of their contact details once they leave the College.

17.3.2 Sharing of Equity in Companies Established to Exploit an Invention

a. Through a long-term commercial arrangement, the College works with IP Group PLC to identify, develop and secure investment in new College spinout opportunities arising from research at the College. The College-IP Group partnership provides IP Group with a first right to invest in each new College spinout company whilst providing the College with dedicated seed capital for its spinouts and access to IP Group's business expertise and resources. Experience both at the College and at other universities has shown that each new company arises from different circumstances and that it is not feasible to devise a formula for distributing the initial equity set aside for the College/founders which will be fair in all cases. It is, however, possible to set out the main factors, representing historic and future contributions to the protection and exploitation of the Invention, which need to be taken into account.

b. For the founder inventors the following contributions may be relevant:
    - the extent of their personal contribution to the invention made available to the company (number of inventions, value of know-how etc), the time commitment which (with College approval) they propose to devote to the company, often a crucial factor for success
    - the extent to which they are acting as entrepreneur in setting up the company and perhaps attracting investment
    - the extent of any personal cash investment in the company

c. For the College the following contributions may be relevant:
    - use of the College's name
    - the amount and nature of the IP to be licensed or assigned to the company bearing in mind that the College owns the Inventions of its employees and students
    - the investment in salaries, running costs, equipment and infrastructure which allowed the work giving rise to the inventions to be undertaken
    - the investment in protecting the Inventions in terms of patent costs and the time of College staff
    - the investment in establishing the company in terms of the time of College staff and legal costs
    - the investment in future nurturing of the company by College staff and provision of board expertise
    - the access to space and facilities (if any) which the College intends to grant to the company

- the need to retain some equity to reward new inventors (not founders) who may generate further Inventions through a "pipe-line" agreement
- access to the expertise of other research groups in the College
- The extent of any cash investment in the company.

d. As a general rule, the contribution of the College's inventions, its investment in protecting the inventions and the investment in staff alone should merit typically 60% of the initial equity available for the College/founders together. The aim should be to reflect the College's true contribution to the company so as to achieve a fair return on its investment if successful, while incentivising the academic staff and students through providing them with an equity stake of typically 40% of that available to the College/founders together. See also Appendix 4.

e. The Chief Administrative Officer (or his/her delegated authority in Queen Mary Innovation) will be responsible for the negotiation of the initial equity distribution in companies with the academic founders and any other stakeholders such as external funders of the research (if appropriate) and any company management. Once the negotiation is complete, a chain of approval will be sought from the academic founder's Head of School, the Faculty Vice-Principal, the Chairman and Board of Queen Mary Innovation and ultimately the Principal on behalf of the Council. The decision to formally approve or reject investment is made by the joint College–IP Group Investment Committee. *(Note: there may be circumstances whereby IP Group does not take up its rights to invest in a College spinout company and in such circumstances the College will work with founders to explore alternative routes to secure investment*.)

f. Where there are two or more inventors as founders of the company, the equity share allocated to the founder inventors will be shared in proportions to be agreed between the founder inventors concerned. In the absence of agreement as to their respective shares this will be determined by an independent arbitrator appointed by the Principal of the College on a fair and equitable basis. Should the arbitrator nominated be unacceptable to a party the matter will be referred to an arbitrator appointed by the President for the time being of the Law Society. The costs of the arbitration will be borne by the founder inventors.

g. The founder inventors will be responsible at their own cost for obtaining appropriate legal and financial advice in relation to becoming a shareholder (and director where appropriate) in the company.

17.3.3 Exceptions to the Policy

The College recognises that the ownership of copyright in original work requires special consideration. In many cases, the academic works of members of staff produced at his/her own initiative are central to the development of his/her academic reputation and career, however, in other situations, such as the development of distance learning materials at the instigation of the College they contribute to a key business activity. Hence the following exceptions are made to the generality of the policy:

a. Nothing in this policy shall detract from the right of an author to be acknowledged as such and to ensure that his/her work is treated in a suitable fashion. This moral right, being personal, is separable from any copyright in the original work.

b. The ownership of copyright in research papers, review articles, and books written by academic staff will normally be waived by the College in favour of the author(s), subject to any conditions placed on the works by the funder. However the copyright in original works created by academic staff in the normal course of their employment at the direct instigation of the College for the purpose of tuition of students such as lecture notes, e-learning or distance learning programmes shall belong to the College

and members of staff shall not be entitled to a proportion of the income from tuition of students. In this latter case a member of staff will be granted a royalty-free, non-exclusive license to use the materials he/she created for their own bona fide teaching or research purposes, provided this use is not in competition with the College's programmes.

c. The ownership of copyright in theses, dissertations and other written work of students will vest in the author.

17.3.4 Distribution of College Share

The College share of Net Income from sale or license of an invention or from the sale of equity in companies established to exploit an invention will be divided equally between the College and the resource centre (whether School, Faculty, Institute or Department) of the inventor(s). Where there are several inventors in more than one resource centre, the distribution will be pro-rata to the number of inventors in each resource centre.

17.3.5 Further Information

For further information or advice please contact: innovation@qmul.ac.uk

Note: This policy applies to Barts Health NHS Trust and Queen Mary University of London as indicated.

18. Costing Research

18.1 Background

The guiding principles in the Higher Education Sector and NHS (through the Research Governance Framework[32]) 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 the Trust or College using internal resources, or externally funded (e.g. Research Council, DH, charity, industry), must be fully costed. The costing of research projects is a multi-disciplinary task and typically will involve the principal investigator, relevant Trust and College service departments (e.g. Clinical Pathology, Pharmacy, Imaging, Animal House etc), the Trust and College Finance Departments and the Joint Research Management Office (JRMO). Both organisations will undertake to establish the Full Economic Cost (FEC) of all projects, regardless of its source of funding, including all direct costs and an apportionment of corporate and other relevant support services, estates and indirect costs. The JRMO will apply national costing values where these have been agreed with specific funding bodies.

18.2 Policy

The final study protocol or project specification and supporting documentation must be provided to the JRMO by the principal investigator (PI) or a nominee. At this point the PI must declare any conflicts of interest that might affect the process of establishing a full and fair economic cost for the activity.

The JRMO will review the protocol 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 their respective organisations are fully assessed and included in the final FEC costing.

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 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.

Note: This policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

[32] Research Governance Framework for Health and Social Care, DH, March 2004.

19. Externally Supported R&D Pricing Policy

19.1 Background

Pricing issues can be complex and each project must be considered individually. Project costing 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

The Trust and College will price externally funded projects in accordance with HEFCE and NHS pricing policies and the accepted guidelines of each external funding body. The Trust will use the National Agreed costing template for commercial studies. In general the principles relating to Full Economic Costing (FEC) will be adhered to by both organisations.

19.3 Non Commercial

- NIHR Funding (i.e. DH funding) to NHS Organisations are subject to 100% Direct Research Costs and a nominal overhead rate.

- University research projects will be subject Full Economic Costs and priced according to the standard overhead policies for non-NHS organisations.

- Research Council (RC) awards will be costed at Full Economic cost and priced according to the support the RCs are, from time to time, prepared to provide.

- Charities: all applications are costed at the Full Economic Cost although these organisations will pay direct research costs only.

- Company: Include non-commercial research collaborations for the benefit of the public and supporting College and the Trust's R&D Strategies. These collaborations will be costed according to FEC principals and the price will be determined and negotiated through the JMRO. Protocol responsibility, data ownership and intellectual property rights in such collaborations in the first instance will be with the Trust and College.

- Material Transfer Agreements (MTA's) and Confidentiality Agreements (CAs) must be approved by the Trust or College. In the absence of funding (or when incomplete funding is available) agreements can be concluded providing the material or information to be made available is considered of sufficient value to the organisations research goals to warrant internal funding of the research work.

- Sponsored Posts and Programmes: The price to be charged will be the direct costs plus a negotiated proportion of the indirect costs. Sponsored Posts and Programmes will not usually predefine a research outcome and will be for a minimum of one year. Such agreements must be worded in accordance with the Trust and College's Externally Supported R&D Policy - Agreements with External Organisations (Policy 20).

- Collaborative Research: For funded posts and programmes, the price to be charged will be the direct costs plus a negotiated proportion of the indirect costs. A protocol will predefine the research project and will be developed by both parties in collaboration. The subsidised price to be charged will be directly dependent on the resource requirements of the protocol.

19.4 Commercial

- When a major objective of entering a research project is the generation of income rather than the primary principles associated with non-commercial funding of research programmes, the research is classified as being commercial. The principal beneficiary of the results of this type of study will 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.

- The JRMO will use the nationally agreed Industry Costing template for NHS organisations to cost Trust commercial studies and will ensure that the price charged will be equal to or greater than the full cost of the research.

- The College will ensure industry-funded contract research will be equal to or greater than the full cost determined by the JRMO. Companies will design the protocol/specification and own the results and intellectual property rights arising from the research.

- For the avoidance of doubt, a project will be classified as being "commercial" if the contract allocates ownership of the resultant intellectual property to the commercial entity or where any restrictions are placed on the College or Trust's right to publish the results of a study.

Note: This policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

20. Policy on the Distribution of Research Project Funds

20.1 Background

Although both the Trust and QMUL 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 QMUL and The Trust.

20.2 Definitions

- **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. Proportional staff costs are also included in this category, for example, where a proportion of the cost of a principal investigator's salary or those of other colleagues in the Trust or College are included in a project budget.
    - **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:** Include the costs of services provided by other internal departments that are directly attributable to the research. Items include hospital service costs including pharmacy, radiology, pathology tests etc. Costs may also include co-investigator's departmental costs, where the principal investigator and co-investigator are from different departments.

- **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 institutional overheads, proportionally attributed service costs and capital charges.

- **Distributions:** Involve the movement of funds from project accounts to a range of institutional budgets, for example transfers to College/Trust central or departmental staff or overhead accounts, service department accounts etc.

20.3 Distribution Policy

20.3.1 Direct project costs

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 on a periodic basis. 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 on a periodic basis, according to the actual value of the services provided to the project in each period.

20.3.2 Indirect Project Costs

- **Institutional overheads - Trust:** Overheads obtained from commercial and non-commercial externally funded research projects will be transferred to centrally managed accounts. The Trust will manage the resource and may provide funds to support bridging finance for staff appointments or other contingent requirements.

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

Research Overhead Distributions College

Overheads	**Institute/ Faculty/Dept**	**Central Overheads**
For FEC Projects SMD	**60%**	**40%***
For FEC Projects Non-Med	**100%**	**0%**
Non - FEC projects	**100%**	**0%**
Note: Institutes or departments may agree individual distribution arrangements with their respective Faculty/School management.		

- **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 on a periodic basis. 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 Trust Code on a periodic basis. 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.

Note: This policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London

21. Agreements with External Organisations Policy

21.1 Background

Agreements with external organisations can take several different forms:

- **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 DH, Research Councils, Charities and Industry.

- **Sponsored Post and Programme Agreements** in which research into an area of mutual interest to the Trust or College and the 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.

- **Consultancy Agreements** in which the College or Trust is contracted by an external organisation (usually a company) to provide advice relating to a predefined area of expertise. Such arrangements usually arise because of the expertise of a particular Trust or College employee and will name that employee as the appointed consultant. Conditions in the relevant person's substantive contract of employment covering 'Work for Outside Bodies' should also be referred to in conjunction with this policy.

- **Material Transfer Agreements** in which the Trust or College receives material (e.g. a pharmacological agent) from, or provides material to, an external organisation for the purpose of achieving a predefined research objective.

- **Confidentiality Agreements** in which the Trust or College's confidential information and that of the external organisation is protected through a commitment of the receiving party not to disclose confidential information to a third party. Such agreements are made between organisations with similar interests to allow strategic discussion between them while at the same time protecting their academic and commercial interests.

- **Studentships** arranged with The College or the Trust must be supported by an appropriately worded Studentship Agreement.

- **Site Agreements** in which The College or the Trust 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 research Governance Framework 2001, between two or more organisations.

- **Sub-Contracts** in which the College or Trust agree for other organisations to participate in a study where the work plan is clearly described and agreed in the project protocol/ description of work, with predefined deliverables. Such agreements are made with other HEI's, NHS organisations, Research Organisations, Facility Providers.

- **Supplier Agreements** in which the College or Trust has a relationship with a company to supply a service, device or drug as described and agreed in a project protocol with predefined deliverables.

21.2 Policy

All significant external collaborations must be covered by an appropriate agreement. The final responsibility for the wording of agreements will be the responsibility of the JRMO and ultimately the Director of Academic Health Sciences for the Trust and College's Chief Operating Officer.

The Director of Academic Health Sciences is to be the Trust's legal signatory for such agreements. The College's Chief Operating Officer is its Legal Signatory. The Head of Research Resources 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 organizations must ensure at a minimum:

- Appropriate costs to the Trust and College (including VAT, if appropriate) are properly recovered
- The College and Trust'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 agreement to fulfil the obligations of confidentiality for personal information

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

Where the External Organisation is unable to accept the standard contract wording, each variation will be negotiated on its merits by the JRMO. An external organisation's standard agreement cannot be accepted without a full review, to ensure compatibility with standard models.

Careful consideration will be given to the use of an External Organisation's standard agreement and unacceptable clauses will be modified or removed.

Should an acceptable compromise to contract wording not be possible in the best interests of the Trust or The College the Agreement with the External Organisation will not be signed.

Both the Trust and College reserve the right to refuse funding from external organisations on ethical or moral grounds. The JRMO will liaise with the Trust and College Offices 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 the Trust or College. 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 the College or Trust for a final decision.

Note: This policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

Section F: Human Resources Issues in Research

22. Access to Work at NHS sites: Honorary Research Contracts Letters of Access

22.1 Introduction

It is necessary for all those not directly employed by Barts Health NHS Trust (BH) but who work on Trust premises or with Trust patients, records or employees, to have in place appropriate access arrangements.

Appropriate access arrangements will vary from an Honorary Contract (Clinical or Research) through Letters of Access down to being an escorted Site Visitor. 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 in order to undertake their research. This is in accordance with the NHS Research Passport Good Practice Guidance[33]

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 issued by BH HR is probably 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 Honorary Research Contract (HRC) issued by the JRMO is probably appropriate

c) The research activity involves contact with patients 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 probably 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): The appropriate access level for the researcher is probably as a site visitor. Visitor access should be arranged with the person being visited and will follow whatever is normal for the relevant site.

Researchers must have in place appropriate access arrangements. There is mutual advantage in this arrangement. The NHS body accepts researchers with honorary contracts and so university and other non- NHS employees are covered, like NHS staff, by NHS indemnity. 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 honorary contracts and, to a lesser extent, LoAs, Barts Health NHS Trust 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.

22.2 Application

This policy applies to all individuals who are not employees of Barts Health NHS Trust 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 should be covered by an appropriate level of access (i.e. honorary contract or LoA). The principal investigator is the designated lead who has overall responsibility for a research project. He or she will normally be the

[33] http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

grant holder. Other staff associated with the research programme e.g. 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 should be bound by current regulations on confidentiality and data protection. The arrangements for applying for an honorary contract do not apply retrospectively to existing honorary contracts for consultant medical and dental staff. However, existing honorary consultant medical and dental staff are subject to the ongoing requirements of honorary contract holders, including the wearing of badges, regular appraisal and supervision arrangements by a current Trust employee, and maintaining professional registration.

In accordance with policy recommended by the Department of Health and the NHS R&D Forum, Barts Health NHS Trust under agreement with other NHS Trusts will accept suitably qualified NHS staff who have undergone standard pre-employment checks to work within research projects authorised by the R&D. Each such person will be issued with a LOA in accordance with the NIHR Research Passport Scheme.

22.3 Policy

Barts Health NHS Trust requires all individuals who do not have a contract of employment to apply for and be appropriate access (e.g. HRC or LoA) before having direct contact with patients for the purposes of research.

In some cases, research relies on data or samples being accessed by external bodies e.g. for biochemical analysis. Where these external bodies are other NHS organisations, a duty of confidentiality already applies. However, where a non NHS body is involved:

a) This should be made clear in the patient information sheet for the study; and
b) Arrangements to protect the confidentiality of the patient must be in place. The nature of these arrangements should also be included in the patient information sheet. This is particularly important for collaborators outside the EU where the Data Protection Act does not apply.

Barts Health Trust appreciates that the process established by this policy places an administrative burden on those who need to work across a number of NHS organisations. The Trust has, therefore, implemented the Research Passport scheme recommended by the Department of Health and the NHS R&D Forum. This has established an agreed and secure procedure by which individuals need only be granted one honorary contract by an NHS organisation in order to carry out duties in any other NHS organisations where the original and standard honorary contract will be accepted.

Honorary contracts are not intended to grant any form of employment status with Barts Health NHS Trust.

The responsibility for ensuring that honorary contracts or LoAs are in place rests with the Trust consultant or other member of staff sponsoring the individual, in consultation with the R&D Manager, Clinical Director, Head of Nursing or General Manager of the appropriate clinical directorate or Medical Director or Director of Nursing and Quality if not clear.

The Trust'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 for to JRMO for access for research as set out above will be required to have undergone an evidenced occupational health assessment before an HRC or LoA is issued.

Applicants to the JRMO for access for research will also be required to supply an Enhanced Criminal Records Bureau check to the R&D office before an HRC or LoA is issued, in line with the Trust's arrangements for the protection of children and vulnerable adults.

It shall be the responsibility of the relevant substantive employer to arrange those checks on behalf of its employee. Where application is made to the Trust's HR Department in relation to an Honorary Clinical Contract the Trust will normally undertake these checks itself.

22.4 Concerns about non-Trust researchers

Any member of staff with concerns about researchers or other honorary contract holders working in their clinical area should raise the concerns with his or her manager. If a delay will 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 the Trust's whistle-blowing procedures.

Managers with issues of concern should check the name and details of the honorary contract holder and raise the concerns with the 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.

Individuals wishing to check whether proper reporting arrangements are in place for an honorary contract holder may check with the JRMO.

Note: This policy applies to <u>both</u> Barts Health NHS Trust and Queen Mary University of London.

23. Misconduct and Complaints

Procedure for Investigating Allegations of Research Misconduct

23.1 Queen Mary University of London Policy

23.1.1 Introduction and Scope

Queen Mary is a research-led Institution, recently ranked 11th in the UK in the Research Assessment Exercise, committed to maintaining the highest standards of integrity and probity in the conduct of research.

This Procedure is based on the Procedure for the Investigation of Misconduct in Research by the UK Research Integrity Office (UKRIO) and outlines the action to be taken when an allegation of misconduct in academic research is brought against any present or past member of staff of the University in respect of research undertaken while employed by the College. A separate procedure is in place for allegations of research misconduct against students.

The Procedure will provide a report that might require action using the College's disciplinary process or through other non-disciplinary processes. It is not intended to be used as part of any disciplinary or regulatory process, and should be viewed as a separate procedure.

23.1.2 Summary of Procedure

The Named Person is responsible for receiving allegations of misconduct in research, and for appointing a Named Investigator who carries out the detailed investigation of the complaint as outlined below. The Named Person is a nominee of the Principal (the role of the Named Person as outlined in the Procedure will be filled by the Senior Vice-Principal). The Named Investigator is appointed from the academic sectoral representatives on the College Research Board.

There shall be four stages of enquiries into an allegation:

1. **Registering the Complaint**: the Named Person receives and acknowledges the allegation;
2. **Preliminary Investigation**: the Named Person passes the allegation to a Named Investigator, who conducts a preliminary investigation to determine that the allegations fall within the definition of misconduct and the contractual status of the Respondent;
3. **Screening Stage**: by the Named Investigator, to gather information and evidence, and to determine whether there is *prima facie* evidence of misconduct in research; and
4. **Formal Investigation**: a panel is convened to examine all relevant facts to determine whether, on the balance of probabilities, misconduct appears to have occurred.

23.1.3 Stage One: Registering the Complaint

Allegations must be made in writing (where possible) to the Named Person accompanied by any supporting evidence.

Upon receipt of allegations of misconduct in research, the Named Person shall formally acknowledge receipt of the allegations by letter to the Complainant (and his/her representative by agreement), in which he/she shall also advise him/her of the Procedure that will be followed.

The Named Person shall pass responsibility for the investigation of a particular allegation to the appropriate Named Investigator.

23.1.4 Stage Two: Preliminary Investigation

(i) The Named Investigator shall review the nature of the allegations and, where they concern situations that require immediate action to prevent further risk or harm to staff, participants or other persons, suffering to animals or negative environmental consequences (where this might contravene the law or fall below good practice), then the Named Person shall take immediate appropriate action to ensure that any such potential or actual danger/illegal activity/risk is prevented/eliminated.

(ii) It may also be necessary to notify legal or regulatory authorities. As a consequence, the College may be required to comply with an investigation led by a legal or regulatory body, which will ordinarily take precedence over this Procedure.

(iii) Where allegations include behaviour subject to defined sanctions in the College's disciplinary process, then the Named Investigator shall take steps to implement that disciplinary process.

(iv) In both cases, this Procedure may continue in parallel but may have to be suspended, to be concluded later, or may have to be declared void by the Named Person.

(v) The Named Person or Named Investigator may consider that the situation presenting as misconduct may in fact be a result of a dispute or misunderstanding between individuals. Those situations not considered to be serious in nature might be resolved by informal discussion and/or arbitration and/or dispute resolution, without the requirement for a formal investigation. Where appropriate, opportunities to resolve matters through mediation should be considered. It may still be appropriate to conduct an initial investigation to establish whether the allegation may have sufficient substance to warrant a Formal Investigation of misconduct in research.

(vi) Where the allegations are within the definition of misconduct in research, the Named Investigator shall inform the Named Person, Principal, Head of Human Resources, Head of Research Grants Administration/Joint Research and Development Office and Academic Secretary or their nominees. They will be provided in confidence with the following information:

- The identity of the Respondent
- The identity of the Complainant
- Details of all sources of internal and external funding
- Details of all internal and external collaborators for the research in question
- Other details that the Named Investigator considers appropriate

(vii) The Named Investigator shall then, in conjunction with the Head of Human Resources and Head of Research Grants Administration/Joint Research and Development Office or their nominees, investigate the contractual status of the Respondent and the contractual details specific to the research project(s) related to the allegations.

(viii) The Named Investigator may need to contact the Respondent's primary employer, where an honorary contract is held and any external Sponsors, funding organisations and/or collaborators. The Named Investigator shall liaise with the Human Resources Department to ensure that the rights of the Respondent and Complainant, and the integrity of the investigation are not compromised by any such actions.

(ix) The Respondent shall be informed of the preliminary investigation in a confidential meeting, with a representative of the Human Resources Department in attendance and may be accompanied to this meeting by a colleague or trade union Representative. If the allegations are made against more than one Respondent, the Named Investigator shall inform each individual separately and not divulge the identity of any other Respondent. A summary of

the allegations in writing shall be given to the Respondent (and his/her representative by agreement) at the meeting, together with a copy of the Procedure to be used and the timeframe of the investigation.

(x) This Procedure aligns with the College's Whistleblowing policy. In accordance with that policy, the allegation and identity of the Complainant will be kept confidential so far as is reasonably possible by the Named Person/Named Investigator until any Formal Investigation is launched, save for the provisions in paragraphs 22.4.6 – 22.4.9 above.

23.1.5 Stage Three: Screening

(i) The Named Investigator shall ensure that all relevant information and evidence are secured, so that any investigation conducted under this Procedure can have access to them. This may include, but is not limited to:

a. Securing all relevant records, materials and locations associated with the work, copies of which shall be provided to the Respondent

b. Liaising with Human Resources and the relevant line manager(s) to:
- Request the temporary suspension of the Respondent from duties on full pay
- Request the temporary barring of the Respondent from part, or all, of the premises of the College and any of the sites of any partner organisation(s); and/or
- Request a temporary restriction be placed on the Respondent requiring him/her not to have contact with some or all of the staff of the College and those of any partner organisation(s)

(ii) Such actions shall only be taken where there is a clear risk to individuals or that evidence might be destroyed, and will take into account the Respondent's responsibilities for supervision, teaching and management. A review of any such action will be taken throughout the Procedure to ensure that it is not unnecessarily protracted. The implementation of this stage of the Procedure does not imply guilt.

(iii) Once initiated the Procedure will progress to the natural end-point irrespective of:

a. The Complainant withdrawing the allegations at any stage

b. The Respondent admitting, or having admitted, the alleged misconduct, in full or in part

c. The Respondent or the Complainant resigning, or having already resigned, his/her post

(iv) All contributions to the process of screening will be recorded and maintained for subsequent use. As part of the Screening Stage the Named Investigator will:

a. Review the submission and supporting evidence provided by the Complainant

b. Review the evidence and supporting documentation from the Respondent

c. Review any background information relevant to the allegations

d. Interview the Respondent, the Complainant and other individuals who might provide relevant information

e. Produce a report of the findings of the Screening Stage

(v) The Screening Stage will normally aim to be completed within 30 working days from the receipt of the allegations.

(vi) When there is clear evidence of an infringement that might contravene the College's disciplinary code, the Named Investigator will consult the Head of Human Resources on the full and accurate transfer of all case information to the disciplinary process. A full written record shall be kept of this decision. When the Named Investigator considers that the allegations are sufficiently serious and have sufficient substance to warrant recommending a Formal Investigation, the Named Investigator shall take immediate steps to set up a Formal Investigation.

(vii) When the allegations have some substance, but due to a lack of clear intent to deceive or due to their relatively minor nature, the matter shall be addressed through the College's competency, education and training mechanisms, or other non-disciplinary processes, rather than through the Procedure's Formal Investigation stage. The investigation using the Procedure would then conclude at this point.

(viii) If the Named Person decides that the allegations are mistaken, frivolous, vexatious and/or malicious, the allegations will then be dismissed. This decision shall be reported in writing to the Respondent and all the parties who had been informed initially.

23.1.6 Stage Four: Formal Investigation

(i) The Investigation Panel shall examine the evidence collected during the Screening Stage following the original allegations and investigate further as required.

(ii) The Named Investigator shall inform the following (or their nominees) that a Formal Investigation of the allegations is to take place:

a. Respondent (and his/her representative by agreement)
b. Complainant (and his/her representative by agreement)
c. Named Person
d. Principal
e. Head of Human Resources
f. Head of Research Grants Administration
g. Academic Secretary
h. Named Person of any Partner Organisation with which either the Respondent and/or Complainant has an honorary contract, and through him/her the Heads of Organisation, Personnel and Research

(ix) The Investigation Panel must be appointed within 30 working days of the Named Investigator recommending a Formal Investigation. The Investigation Panel will not work to a prescribed timetable but will work as quickly as possible without compromising the Principles of the Procedure.

(x) The Investigation Panel shall consist of at least three, and always an uneven number of, senior members of staff. In selecting the panel the Named Investigator shall take into consideration the subject matter of the allegations and any potential conflicts of interest.

(xi) It is a requirement that one or more members of the Investigation Panel be selected from outside the College, particularly where allegations are especially serious or involve senior staff. Such external members replace internal members of the Investigation Panel rather than being in addition to them.

(xii) At least two members of the Panel shall have experience in the area of research in which the alleged misconduct has taken place, although they shall not be members of the Department concerned. Where allegations concern highly specialised areas of research the Investigation Panel shall have at least one member with specialised knowledge of the field. It is desirable, but not essential, for the Panel to include a member who either holds or has held judicial office or to be a barrister or solicitor of at least ten year's standing.

(xiii) The Principal, or his nominee, shall approve the panel members and may veto nominations for the Investigation Panel, recording the reason for the veto in writing and communicating it to all parties.

(xiv) Once convened, the membership of the Investigation Panel shall not be changed or added to. Members who are not able to continue will not be replaced. In the event that the Chair stands down or the membership falls below three, the Named Investigator will take steps to recruit additional members or re-start the Formal Investigation process.

(xv) To perform its task the Investigation Panel shall:

a. Review the submission(s) and supporting evidence provided by the Complainant

b. Review the response(s) and supporting evidence from the Respondent

c. Review background information relevant to the allegations

d. Review any interviews conducted with the Respondent, the

e. Complainant, and other staff who may provide relevant information to assist the Investigation Panel

f. Call expert witnesses to give advice if necessary

g. Seek guidance from UKRIO and its advisers, where necessary

(xvi) The Investigation Panel shall be serviced by the Academic Secretariat, through whom all documentation and all other communication should be passed.

(xvii) Communication, either written or oral, by any party (to include Respondent, Complainant or any other member(s) of staff) directly with members of the Panel will not be admitted as part of the documentation relating to the case except when it takes place at the request of the Panel, or at formal meetings called by the Chair of the Investigation Panel.

(xviii) A Formal Hearing will be held during which the Respondent will be given the opportunity to set out his/her case and respond to the allegations made against him/her. He/she will be allowed to ask questions, to present evidence, call witnesses and raise points about any information given by any witness (including the Complainant). The Complainant and other staff may also be invited to provide evidence when members of the Panel consider that it may have relevance to the investigation.

(xix) The Chair shall report the progress of the Investigation Panel to the Named Investigator by the Chair on a bi-weekly basis. If it is believed that the investigation will take more than one calendar month, progress reports shall be made on a monthly basis.

(xx) The Investigation Panel shall provide a draft report of its findings to the Named Person, who will make it available to the Respondent and the Complainant for comment on the factual accuracy of the report. Modifications will only be made when the report contains errors of fact and matters that have bearing on the facts.

(xxi) The Investigation Panel shall then provide to the Named Investigator a final report that:

a. Summarises the conduct of the investigation

b. States 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

c. Makes recommendations in relation to any matters relating to any other misconduct identified during the investigation

d. Addresses any procedural matters that the investigation has brought to light within the College and relevant partner organisations and/or funding bodies

(xxii) In addition to reaching a conclusion over the nature of the allegations, the Investigation Panel may make recommendations with respect to:

a. Whether the allegations should be referred to the relevant organisation's disciplinary process

b. Whether any action will be required to correct the record of research

c. Whether organisational matters should be addressed by the College through a review of the management of research

d. Other matters that should be investigated

(xxiii) The Named Investigator shall inform the following of the conclusion of the Formal Investigation:

a. The Respondent and the Complainant

b. The Named Person, Principal, the Head of Human Resources, the Academic Secretary, the Head(s) of the relevant Department(s) and any other relevant members of staff

c. If the Respondent and/or the Complainant are employed on joint clinical/honorary contracts, the Named Person, the Head of Personnel and the Head of Research of the other organisation(s)

d. Where appropriate, the responsible person within any relevant partner organisations, funding bodies and/or regulatory or professional bodies

(xxiv) Evidence of further, distinct instances of misconduct in research by the Respondent, unconnected to the allegations under investigation; or misconduct in research by another person or persons, shall be submitted to the Named Person in writing, along with all supporting evidence, for consideration under the initial steps of the Procedure.

23.1.7 Outcomes

If all or any part of the allegations are upheld, the Named Person, the Head of Human Resources and at least one other member of senior staff shall then decide whether the matter should be referred to the College's disciplinary process or for other formal actions.

If the allegations are deemed to be frivolous, vexatious and/or malicious the Named Person shall consider recommending to the appropriate authorities that action be taken under the College's disciplinary process against anyone who is found to have made frivolous, vexatious and/or malicious allegations of misconduct in research.

The Respondent shall not have the option of appealing against the report of the Investigation Panel. The Respondent has the statutory right of appeal if the matter is referred to the College's disciplinary process.

23.1.8 Following the Investigation of Research Misconduct

23.1.8.1 Disciplinary Process

If the allegations proceed to the College's disciplinary process, the report of the Investigation Panel shall form the basis of the evidence that the Disciplinary Panel receives. All the information collected and brought to light through the Procedure will be transferred to the disciplinary process.

23.1.8.2 Records

The Named Investigator shall be responsible for keeping a written record of all decisions taken throughout all the steps of the Procedure, in conjunction with the Academic Secretariat. The Chair of the Investigation Panel shall assume responsibility with the Academic Secretariat for keeping accurate records of the activities, deliberation and reporting of the Panel. The Academic Secretariat will maintain the file for the case and archive this appropriately at the completion of the Procedure.

23.1.8.3 Specialised research

It is recognised that the subject area of certain cases may be so specialised as to require equally specialised advice as to how to resolve or correct matters arising from the misconduct in research; the recommendations and experience of the Investigation Panel may prove particularly useful if this is the case.

23.1.8.4 Support provided to the Complainant

Where allegations have been upheld (in full or in part), or found to be mistaken but not frivolous, vexatious and/or malicious, then appropriate support, guidance and acknowledgment shall be given to the Complainant, given that his/her role in the process will most likely have been stressful and may well have caused friction with colleagues. The Named Person shall take whatever steps he/she considers necessary to support the reputation of the Complainant. For example, if the case has received any publicity, the Complainant shall be offered the possibility of having an official statement released for internal and/or external purposes.

23.1.8.5 Support provided to the Respondent

Where allegations have not been upheld (in full or in part), the Named Person shall take such steps as are appropriate, given the seriousness of the allegations, to support the reputation of the Respondent and any relevant research project(s). Appropriate support and guidance shall be given to the Respondent, given that his/her role in the process will most likely have been stressful and may well have caused friction with colleagues. As above, 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.

23.1.8.6 Handling wrongful allegations

If the Investigation Panel has found that the Complainant's allegations were frivolous, vexatious and/or malicious, the Named Person will consider recommending that action be taken against the Complainant, under the College's disciplinary process.

23.1.8.7 Other actions that may be required or be considered appropriate

Following the conclusion of the Procedure, the Investigation Panel may need to recommend additional measures in addition to those that may be taken by way of the College's disciplinary process. Any such recommendations will be actioned through the College's management structure. This may include:

a. Retraction/correction of articles in journals
b. Withdrawal/repayment of funding
c. Notifying patients/patients' doctors of any potential medical issues that may arise
d. Notification of misconduct to regulatory bodies (such as the MHRA, the Healthcare
e. Commission, the Home Office [for research involving animals], professional bodies, etc.)
f. Notifying other employing organisations
g. Notifying other organisations involved in the research, such as funding bodies
h. Adding a note of the outcome of the investigation to a researcher's file for any future requests for references; and/or
i. Review internal management and/or training and/or supervisory procedures for research

23.2 Barts Health NHS Trust Policy

The validity of research and other academic endeavour is based on the implicit assumption of honesty and objectivity by the research investigator and on the explicit premise that research data can be verified. Both the Trust and Universities working in partnership must uphold this principle and endeavour to maintain public trust in the research process. As stated by the DoH[34], *'Employers of staff undertaking health and social care research have responsibility for developing and promoting a quality research culture in their organisation and for ensuring that their staff are supported in, and held to account for, the professional conduct of research… dealing with non-compliance or misconduct, and learning from complaints.'*

This policy recognises the need for the Trust and College to augment its standard policies and guidelines to address issues relating to misconduct in research. The guidelines should be read in conjunction with the Trust Disciplinary Policy, Whistle-blowing Policy and where appropriate the Standards of Business Conduct, Grievance policy, Harassment Policy and Investigations Policy. These policies apply to researchers who are employees of the Trust or other University or NHS employees holding honorary contracts and engaged in clinical research activities within the Trust. The College's Procedure for Investigating Allegations of Misconduct in Academic Research should also be considered with these policies.

'Research misconduct' includes research fraud, non-disclosure of research fraud, violations of Trust research policies including this policy, violations of ethical approval, financial probity, and local procedures for approval of research and indemnity arrangements.

'Research fraud' includes: the intentional fabrication or falsification of research data; the omission in publications of conflicting and/or non-conforming observations or data; the theft of research methods or data from others; the plagiarising of research ideas, results or publication(s); or other failure to follow established protocols, deviations from accepted practices in carrying out or reporting results from research.

In the case of misconduct, some professional groups will be subject to disciplinary action by their professional bodies as follows:

- Doctors are responsible to the General Medical Council;
- Nurses, health visitors and midwives are responsible to the United Kingdom Central Council;
- State registered practitioners are responsible to the individual board of the Council for Professions Supplementary to Medicine; and
- Social care professionals will be one of the responsibilities of the General Social Care Council.

23.2.1 Policy

All NHS employees of other Trusts who carry out research using Trust patients, patient samples, patient records, premises, facilities, staff and services must be bound by Trust policies and hold a current Trust honorary contract or Letter of Access for Research with clear lines of accountability, see section 21 (Access to Work at NHS sites: Honorary Research Contracts and Letters of Access). The Trust and College will inform their opposite HR Departments (or those of other organisations) immediately upon notification that an

[34] Research Governance Framework for Health and Social Care. DoH, March 2004.

allegation of misconduct has been reported. Suitable arrangements between the organisations will then be made to address the allegations.

Researchers must fulfil their responsibilities as outlined in the Research Governance Framework for Health and Social Care1. Main responsibilities include;

- Ensuring that any research undertaken follows the agreed protocol;
- Helping care professionals to ensure that participants receive appropriate care while involved in research; and
- Protecting the integrity and confidentiality of clinical and other records and data generated by the research and for reporting any failures in these respects, adverse drug reactions and other events or suspected misconduct through appropriate systems the principal investigator must accept a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs.

Researchers must comply with and aid in any necessary monitoring and auditing of research projects required by the JRMO. Any complaints, incidents or risks relating to research must be reported through the normal Trust/ QMUL mechanisms and brought to the attention of the Director for Research Development, the relevant Officer within the University or other organisation and the JRMO. Any such complaints, incidents or risks should be logged by the JRMO. All investigations will be carried out with due regard to the following:

- The overall responsibility for the investigation will lie with a suitably qualified and experienced member of staff;
- An appropriate investigation will be conducted that is commensurate with the scale of the allegations;
- In the case of research fraud the appropriate clinical lead must be informed of all the allegations made and of the final outcome of the investigation;
- Where appropriate any external funding organisations and / or collaborating organisation must be notified and kept informed. Individuals who are suitably qualified and able to comment on any relevant clinical information, research data and publications will judge the evidence collected during the course of the investigation;
- Where appropriate, the investigation will include previous work by the researcher and the researcher will be requested to withdraw all pending related abstracts and manuscripts if found fraudulent, and whilst the research is under investigation;
- The Medical Director will take the necessary action recommended by the findings from the investigation including referral to the relevant professional body, where appropriate; and
- Individuals suitably qualified and experienced to comment on any relevant clinical information, research data and publications will hear any appeal.

23.3 Definitions

Accepted Procedures (for research) include but are not limited to the following:

a. Gaining informed consent where required
b. Gaining formal approval from relevant organisations where required
c. Any protocols for research contained in any formal approval that has been given for the research
d. Any protocols for research as defined in contracts or agreements with funding bodies and sponsors
e. Any protocols approved by the Medicines and Healthcare products Regulatory Authority (MHRA) for a trial of medicinal products
f. Any protocols for research set out in the guidelines of the College and other relevant partner organisations
g. Any protocols for research set out in the guidelines of appropriate recognised professional, academic, scientific, governmental, national and international bodies

h. Any procedures that are aimed at avoiding unreasonable risk or harm to humans, animals or the environment
i. Good practice for the proper preservation and management of primary data, artefacts and materials
j. Any existing guidance on good practice on research

The **Complainant** is a person making allegations of misconduct of research against one or more Respondents.

An **honorary contract** can be issued to:
a. A clinical academic working in both a university and an NHS organisation, in which case the NHS organisation would issue the honorary contract
b. An NHS consultant with an arrangement to undertake teaching and/or research in a university, in which case the university would issue the honorary contract
c. A researcher employed by a university and undertaking a research project in an NHS organisation, in which case the NHS organisation would issue the honorary contract

Misconduct in research is taken to include:
a. Fabrication
b. Falsification
c. Misrepresentation of data and/or interests and or involvement
d. Plagiarism
e. Failures to follow accepted Procedures or to exercise due care in carrying out responsibilities for:
    - Avoiding unreasonable risk or harm to:
        i. humans
        ii. Animals used in research; and
        iii. The environment
    - The proper handling of privileged or private information on individuals collected during the research.

The **Named Person** is the individual nominated by the College to have responsibility for receiving any allegations of misconduct in research; initiating and supervising the Procedure for investigating allegations of misconduct in research; maintaining the record of information during the investigation and subsequently reporting on the investigation to internal contacts and external organisations; and taking decisions at key stages of the Procedure. The Named Person shall be a senior member of staff with significant knowledge and experience of research but should not be the Principal; the Head of Research; or the Head of Human Resources.

The **Respondent** is the person against whom allegations of misconduct in research have been made.

The **standard of proof** used by the Investigation Panel is that of "on the balance of probabilities."

23.4 Principles

a) Those responsible for carrying out this Procedure must be aware that there may be occasions when a balance has to be struck in the application of the Principles: for example, it may, in certain circumstances prove to be impracticable to undertake a detailed screening of the allegations without releasing the Complainant's identity to the Respondent.

b) The Named Person should be responsible for resolving any such conflicts between the Principles, keeping in mind at all times that the primary goal of this Procedure is

to determine the truth of the allegations. The Named Person can seek guidance from UKRIO and other bodies, as well as seeking legal advice.

c) The confidential nature of the proceedings is essential in order to protect the Complainant, the Respondent and others involved in the Procedure. It is important that in the conduct of an investigation using this Procedure that the principles of confidentiality and fairness are applied with appropriate balance for both the Respondent and the Complainant.

d) The identity of the Complainant or the Respondent should not be made known to any third party unless:
   i. It has been deemed necessary (by those conducting the investigation) in order to carry out the investigation;
   ii. It is necessary as part of action taken against the Respondent when (at the end of the Procedure and the College's disciplinary/appeals processes) the allegations have been upheld;
   iii. It is necessary as part of action taken against a person who has been found to have made malicious, vexatious or frivolous allegations;
   iv. It is the stated policy of the employer/funder/other national body that the identity of individuals proved through appropriate disciplinary and appeals processes to have committed misconduct in research should be made public.

e) Any disclosure to a third party of the identity of the Complainant or Respondent, or of any other details of the investigation, should be made on a confidential basis. The third party should understand this, and that he/she must respect the confidentiality of any information received. Breaching confidentiality may lead to disciplinary action, unless covered by the Public Interest Disclosure Act and/or the College's own grievance or whistle-blowing procedures.

f) The investigation of any allegations of misconduct in research must be carried out fairly and in accordance with the statutory human rights of all parties involved. Those responsible for carrying out this Procedure should do so with knowledge of:
   i. The statutory obligations of the College and the rights of employees according to current law
   ii. Any additional rights and obligations particular to the institution and/or its employees – for example those bestowed by university statutes and ordinances.

g) Those responsible for carrying out the Procedure should recognise that failure to transfer information could lead to the process being unfair to the Respondent and/or the Complainant.

h) In using this Procedure, and in any action taken as a result of using the Procedure, care must be taken to protect:
   i. Individuals against frivolous, vexatious and/or malicious allegations of misconduct in research
   ii. The position and reputation of those suspected of, or alleged to have engaged in, misconduct, when the allegations or suspicions are not confirmed
   iii. The position and reputation of those who make allegations of misconduct in research in good faith, i.e. in the reasonable belief and/or on the basis of supporting evidence that misconduct in research may have occurred

Note: This policy applies to Barts Health NHS Trust and Queen Mary University of London as indicated.