

computer software), design rights, trademarks and confidential information (trade secrets).

What do I need to do before I start a research project involving the NHS (BLT)?

Apply for funding

If you are planning on applying for funding whether from a commercial source or a non-commercial source (such as a research council or a charity) you should contact the Research Grants Dept in the Joint BLT/QMUL R&D Office for information and advice.

All research incurs some cost and Research Grants are able to provide detailed costing figures and also provide a contract negotiation service for commercially funded research. If you require further information about grant funding or costing, please contact Colleen Colechin on 020 7882 7252.

Seek peer review

All research being carried out within BLT should receive a peer review from a individual completely independent of the study. You must include signed evidence from whoever carries out the review. All 'own account' research projects must be reviewed by the relevant Directorate peer review committee.

You should obtain the review prior to submitting your ethics application. The R&D Office have compiled a template peer review form and guidance. For more information, please contact Johanna Piper on 020 7882 7274 or Siobhan Lim on 020 7882 7250.

Apply for Trust approval

Under the RGF, NHS Trusts are required to record and formally approve all research involving Trust patients, staff or their tissue, samples or data before the research may commence.

If your project involves BLT patients, you should first send a copy of Parts A,B & C of the ethics form, the patient information sheet / consent form, a copy of the protocol and a completed Data Protection Act form (available from the R&D Office website) to the R&D Office for project registration. On receipt, the R&D Office can organise sponsorship and indemnity for your project (BLT or QMUL employees only). For assistance in registering your project, please contact Helene Provstgaard on 020 7882 7261.

Apply for ethical approval

You will need to complete the national ethics form from the COREC website, www.corec.org.uk. The local committee for the BLT area is East London & the City Research Ethics Committee. For more information about your ethics submission and details of ethics training courses, please contact Dr Helen Cadiou on helen.cadiou@bartsandthelondon.nhs.uk

Research Governance Training

The R&D Office provides training in Research Governance. If you would like to attend a course please contact the R&D Office on the number below.

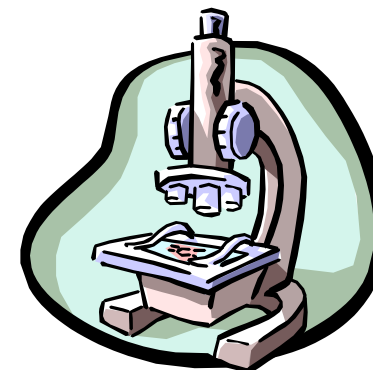
For more information about Research

Governance please contact:-

Johanna Piper (Research Governance & GCP Manager for BLT) or Siobham Lim (Research Governance & GCP Manager for QMUL), Joint R&D Office, 42-46 New Road, Whitechapel, London, E1 2AX, Tel: 020 7882 7274 / 7279.

Barts and The London 
NHS Trust

Research Governance



 Queen Mary
University of London

What is Research Governance?

Research Governance is the means by which organisations ensure that research carried out in health and social care is of good quality and that it protects participants.

What is the Research Governance Framework (RGF)?

The RGF defines the obligatory and auditable systems that health and social care organisations and their research partners should have in place to demonstrate that good research practice is occurring. The Framework aims to set standards to ensure high quality research is conducted in the NHS through the establishment of a registration, approval and monitoring process. (To view the full RGF, go to www.dh.gov.uk).

Why has Research Governance been introduced?

The RGF pulls together a number of acts, bills, standards and legislative initiatives to ensure that all areas of research in human subjects are covered by a single framework in order that research best practice can become standard practice at a national level. Although most research is conducted to high standards, there are incidences when things go wrong. The RGF aims to make sure that organisations and individuals are aware of the potential risks, take steps to prevent them and also manage the risks effectively.

The purpose of the RGF is also to protect patients by enhancing ethical and scientific quality within research, promoting good practice, reducing adverse events and preventing research fraud and misconduct. Research Governance also aims to protect researchers by ensuring that they demonstrate that their research is ethically and financially sound and is being managed appropriately.

When does Research Governance apply?

Research Governance applies to all research that is carried out using NHS patients, tissue, data, staff or equipment. The Framework applies to everyone involved in research including all research staff, students, sponsors, managers, employing organisations, ethics committees and research participants. You don't have to be the Principal Investigator of a study to be responsible for ensuring that Research Governance is being implemented.

What are the main Research Governance requirements?

The main sections of the RGF relate to standards, responsibilities, systems and mechanisms. The five main Research Governance standards are outlined below: -

Research Ethics Approval

All research involving patients, service users, care professionals, volunteers, their tissue or data must be reviewed by an ethical committee before it can commence to ensure that ethical standards have been met. The dignity, rights, safety and well-being of research participants should be a primary consideration in the planning and execution of a study. Fully informed consent is at the heart of ethical research, particularly in children and vulnerable adults.

Science

All research carried out in the NHS should be of high quality and executed to high scientific standards. All research projects involving the NHS must receive an independent expert review (or a Peer Review) from an individual outside the immediate research team, before it commences to assess the quality and feasibility of the research proposal.

Information

Data used for research purposes should be dealt with in accordance with the Data Protection Act (1998) relating to patient confidentiality and the protection of personal data. Sensitive and personal data should be protected and stored securely. The public should have free access to information on the research being carried out and details of the findings, in a format they can understand.

Health, Safety and Employment

The health and safety of research staff and patients should be given priority at all times. Researchers should put measures in place to prevent and handle any potential health and safety issues arising from the research project. Non-NHS researchers requiring access to NHS patients for research purposes will require an honorary contract. Honorary contracts protect staff working within health and social care organisations as well as NHS patients.

Financial Probity

Financial probity and compliance with the law, and H.M. Treasury rules for use of public funds are as important in research as in any other area. If a project is receiving external funding, arrangements should be place for the financial management of the project. All research should be fully costed to ensure that any additional costs that NHS Trusts incur due to hosting research are accounted for.

Intellectual Property

The RGF states that arrangements should be in place for the management of intellectual property (IP). IP can be protected in a number of ways such as patents (e.g. a novel compound for therapeutic use or a new type of medical instrument), copyright works (includes

