

- Check that there is a copy of the signed consent form in each patients notes.
- Ensure that any confidential information is stored in a secure location with limited access.
- Look at your work environment, does it conform to the Trust Health and Safety in the workplace policy?
- Check that any hazardous substances used within the study, or clinical area where patients and staff are working, are stored in a safe and legal way.
- Check to make sure that any study medications are stored in line with Trust policy and are known to the Trust's Clinical Trials Pharmacist.
- Have you made provision for archiving of documents once the study is ended?
- If a subject is withdrawn, ensure that clear reasons for this are recorded in the source documents (patient notes).
- Make sure you have updated Standard Operational Procedures (SOP's) for your research practice.

Need more information?

If you require further information on research Audit, Good Clinical Practice or the Research Governance Framework, you can look on the Trust's Research and Development intranet site or alternatively contact Johanna Piper or Siobhan Lim on the contact details overleaf.

Useful Information

For Archiving Issues contact

- Catherine Redfern 020 7377 2409

For Data Protection advice contact

- Nicola Gould 020 7377 7000 ext 2008

For Ethics advice contact

- Dr Helen Cadiou 020 7882 7272

Clinical Trials Pharmacist

- Alex Farrell 020 7377 2924

For examples of Standard Operational Procedures visit the R&D intranet site.

If you would like a list of essential documents please contact Johanna Piper or Siobhan Lim

Training

The joint R&D Office provides training in Good Clinical Practice, Research Governance and understanding Research Ethics. If you would like to attend a course please contact Ann Smith, on 020 7882 7250.

Contact details:

Johanna Piper, Research Governance & GCP Manager (BLT),
Tel: 020 7882 7274.

E-mail: johanna.piper@bartsandthelondon.nhs.uk

Siobhan Lim, Research Governance & GCP Manager (QMUL),
Tel: 020 7882 7279.

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A guide to preparing for internal research audit to ensure compliance with Research Governance and Good Clinical Practice (GCP).



Introduction

Barts and The London NHS Trust and Queen Mary University of London are initiating a programme of research audit to assess compliance with the Research Governance Framework for Health and Social Care, and the Medicines for Human Use (Clinical Trials) Regulations 2004 covering clinical trials involving investigational medicinal products .

The Research Governance Framework requires that all NHS organisations, where research is being conducted, should carry out formal audit of a selection of research projects and activities.

The Framework states that the minimum standard of 10% of current projects should be routinely audited. Projects will be identified through risk assessments carried out in R&D, through reports of poor practice or on a voluntary basis.

The Medicines and Healthcare products Regulatory Agency (MHRA) have been directed by the Department of Health to audit research processes within the NHS to assure compliance to the regulations.

The MHRA are able to carry out obligatory audits within Trusts to assess compliance with Good Clinical Practice (GCP) so it is essential that BLT and QMUL are prepared for an audit from the MHRA.

Johanna Piper and Siobhan Lim will be carrying out audits of research activity within the Trust and QMUL and will also be providing advice on how to ensure that your research project is compliant with the regulatory requirements, even if your project does not receive an internal audit from the R&D Office.

Why is audit required?

- To protect the researcher and the Trust's reputation.
- To protect funding.
- To measure compliance with regulatory requirements.
- To measure compliance with Trust Policy.
- To maintain patient safety.
- To improve data quality.
- To improve performance.
- To prepare for external audit processes from the MHRA in the case of clinical trials.

What will be audited?

- Knowledge of Requirements.
- Trial Documents.
- Trial Processes.
- Patient Information and Consent.
- Clinical Environment.
- Storage and Archiving Processes.
- Record Keeping.
- Operational Procedures.
- Training and Development
- Details of Serious Adverse Events

How to prepare for an audit

There are some simple actions that can be taken to ensure that you and your team are prepared for an internal research audit.

Make sure that everyone involved with the research has a knowledge of the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Research Governance Framework .

Check that you have all the appropriate legal documentation for conducting the study and that it is compiled in a site file.

Make sure that patient notes are easily accessible to validate data and in-case of an emergency.

Ensure that any resources used for the research have been included in the R&D costing.

Make sure that there is evidence of research and study related training and education for all staff involved in research.

Check that all information entered in the patient notes matches the information recorded on case report forms or research documents.

Make sure that all researchers have signed a signature log to validate their data entries.

If the person taking consent is not the Chief Investigator, make sure that the person has been identified in writing by the Chief Investigator as being qualified and capable of taking informed consent for that particular study.

- Make sure that any changes to the protocol and official research documents has been reported to the Ethics Committee and R&D in the form of an amendment.

