For more information including copies of this leaflet please contact the Research & Development Department or visit the website

http://www.leedsandyorkpft.nhs.uk/professionals/RD

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Further general information on the Data Protection Act 1998, Freedom of Information Act 2001 and Caldicott Principles can be obtained from the LYPFT Information Governance Department.

In relation to research there is an e-learning module on the Medical Research Council website http://www.byglearning.co.uk/mrcsc-lms/login/index.php.

Data Storage for Research Studies

Information leaflet 6

Leeds and York Partnership NHS Foundation Trust

www.leedsandyorkpft.nhs.uk/professionals/RD
This leaflet explains the requirements and implications of the Research Governance Framework for Health and Social Care (RGF) in relation to the use and storage of data obtained as part of the research process. ‘Research Data’ is defined here as the recorded factual material, collected in order to investigate research ideas, which is then kept and accepted in the scientific community as necessary to validate research findings.

The RGF was established by the Department of Health in 2001 (with revisions in 2005 and 2008) and improve research quality and safeguard the public. It does this by aiming to:

- Enhance ethical and scientific quality
- Promote good practice
- Reduce adverse incidents and ensure lessons are learned
- Prevent misconduct

**Researcher responsibilities**

High quality and safe research is at the heart of the NHS and relies on the personal and scientific integrity of all involved. When obtaining, using or storing data, Researchers need to be aware of and comply with the following regulations:

- Data Protection Act 1998
- Freedom of Information Act 2001
- Caldicott Principles

**Project documentation**

Two sets of documentation are usually required during a research project:

- The Investigator Site File / Project Master File (ISF / PMF)
- Case Report Form (CRF)

These may be ‘hard copy’ paper records or electronic data, or a combination of both (where both are used there must be clear links from one to the other).

**The Investigator Site File (ISF)**

This should contain all the administration documentation relating to a research project, including the following:

- Research protocol – all versions should be included, with the current version clearly marked
- All agreements made in relation to the study e.g. publication, Clinical Trials Agreement, Intellectual Property rights.
- Investigator Brochure (if applicable)
- Approvals letters – from Research Ethics Committee, NHS R&D Department, approvals for any amendments applied for
- Master codes for pseudo-anonymised case records
- Annual reports made to statutory bodies e.g. REC, R&D Departments, project funders, MHRA.
- Safety reports / other reports from project sponsors, MHRA etc.
- Copies of incident reports made to sponsors and Trust Risk Management e.g. serious / Adverse Event / Reaction reports
- Minutes of Project Management Group meetings as appropriate

The ISF should also include examples of the following:

- Participant Information Sheets (PIS) - all versions should be included, with the current version clearly marked
- Participant Consent Forms – all versions should be included, referencing which PIS they relate to. Examples of consent forms should be blank.
- All data collection tools – questionnaires, interview schedule, psychometrics etc.

**Case Report Form (CRF)**

These should contain the individual research record for each participant. Each participant’s CRF should contain:

- A consent form – appropriately signed and dated, clearly showing which version of the PIS was viewed and retained by the participant
- An assent form signed by the legal representative of the participant, if appropriate
- All data collected from the participant e.g. physiological / psychometric test results, questionnaire responses, interview transcripts.
- Any incident reporting relating to that participant only

**Storage of information**

Information may be on paper or electronic copy. **Paper records** must be stored:

- In a lockable filing cabinet, ideally in a restricted access room
- On NHS / University property – home storage is not recommended and no identifiable data should be home stored
- So that ISF and CRF data is kept separate, to preserve anonymity
- So it is available for audit and monitoring purposes

**Electronic records must be stored:**

- On password protected NHS / University networks
- As encrypted data on portable storage devices (CDs, memory sticks etc.) or laptops
- With ISF and CRF data in separate files in different locations on the computer, to preserve anonymity
- On a medium that is unlikely to become obsolete within the designated time of storage

**Duration of storage**

This is defined by the type of research and the policy of the organisation sponsoring the research. Specific advice