Leeds and York Partnership NHS
NHS Foundation Trust

R & D

Responsibilities of Staff Involved in Research

Information leaflet 5

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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This leaflet aims to explain the requirements and implications of the Research Governance Framework for Health and Social Care (RGF) in relation to the role and responsibilities of each researcher. A separate leaflet details the duties of the Chief / Principal Investigator.

The RGF was established by the Department of Health in 2001 (with revisions in 2005 and 2008) and aims to 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

Researchers are those who conduct the study under the guidance of the Chief Investigator and Principal Investigator / Local Lead (in smaller studies a person maybe a CI / PI and a researcher). Researchers are the people who will interact with participants – they will collect data (or tissue) from, test equipment with or issue medication to those taking part.

As a Researcher you have responsibility to:
- Develop proposals that are ethical and have appropriate Research Ethics Committee (REC) approval
- Ensure any research conducted follows agreed protocol and legal guidance
- Ensure participant welfare whilst involved with the study
- Provide research results to participants as appropriate

Before Research Begins

Researchers and their teams must be aware of and account for the following:

- Informed Consent – All studies must have appropriate arrangements for obtaining and recording fully informed consent from all research participants.
- Data Protection Act – Confidentiality and security of personal information must be ensured.
- Health and Safety Act – The safety of participants and other staff must be given priority at all times.
- Research Ethics Committee Approval – All research involving patients and users of the NHS, NHS premises or facilities must be reviewed independently to ensure it meets ethical standards. This must be done before the research commences.
- NHS R&D Approval – This considers issues such as sponsorship and the scientific rigour of the project and must be given by the host Trust before research commences.

The RGF states that those acting as **Researchers must have:**

- The necessary research training, expertise and experience
- Access to the resources needed to conduct the proposed research successfully
- Adequate supervision, support and training

Researchers hold the **day to day responsibility of conducting the research.** The RGF outlines their responsibilities, which include:

- Ongoing communication with the PI
- Timely reporting of recruitment to the R&D Department and any other appropriate regulatory bodies
- Accepting their agreed role within the wider research team
- Ensuring participants understand what is asked of them (this may include taking Informed Consent)
- Assisting care professionals to deliver appropriate care to the patient while involved in research
- Protecting the integrity and confidentiality of clinical and other data / records generated by the research (e.g. ensuring it is accurate and secure)
- Coding data to ensure that identifying information is separate to data
- Appropriate reporting of adverse events or reactions
- Appropriate reporting of any failures e.g. suspected misconduct
- Disseminating results via the peer-review process
- Adhering to any requirements outlined in an honorary contract

Further Resources

Research Governance Framework in Health and Social Care (2005 and 2008) https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition

For Research Ethics Committee details see http://www.nres.nhs.uk/

www.leedsandyorkpft.nhs.uk/professionals/RD