In some cases they may also need to:

- Inform care professionals that a patient is involved in the study and ensure that they agree to retain overall responsibility for the patients care
- Ensure that data on recruitment to the study is reported in a timely way

In LYPFT the PI is supported in the fulfilment of their duties by local Research Assistants and Clinical Studies Officers. The PI can delegate appropriate duties to these staff using the study delegation log.

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

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

R&D contacts

Alison Thompson, Head of Research and Development athompson11@nhs.net
Zara Brining, Governance Administrator zara.brining@nhs.net
Sinead Audsley, Research Governance Manager sinead.audsley@nhs.net
General R&D mailbox research.lypft@nhs.net

Address

R&D, St.Mary's House, St.Mary's Road, Leeds, LS7 3JX

Telephone

0113 8552387

Leeds and York Partnership NHS
NHS Foundation Trust

R & D

Chief and Principal Investigators (project leaders)

Information leaflet 3

This leaflet aims to explain the requirements and implications of the Research Governance Framework for Health and Social Care (RGF) in relation to those leading research projects; Chief Investigators (CI) and Principal Investigators (PI) / local leads.

The RGF was established by the Department of Health in 2001 (with revisions in 2005 and 2008) with the aim of improving research quality and safeguarding 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

The Chief Investigator

This is the person with overall responsibility for the research. All the applications for Research Ethics Committee and R&D approvals must be submitted by the Chief Investigator.

The Principal Investigator / Local Lead

This is a senior person designated as being responsible for the research at their site where the research will be conducted.

The Principal Investigator takes responsibility for the conduct of the research at their site and is accountable for this to their employer, to the sponsor of the research (via the employer) and to any care organisation within which the research takes place (or through which any organs or tissues are accessed).

Principal Investigators must have sufficient experience and expertise in the design and conduct of research to be able to work to the levels set down by the RGF (some of which are given below) or to be able to delegate these responsibilities to others and to lead accordingly.

For some single site projects the CI and PI roles may be combined.

Roles and responsibilities

The Research Governance Framework says it is the responsibility of the Principal Investigator / local lead to ensure that:

- The dignity, rights, safety and well being of participants are given priority at all times by the research team
- The research is carried out in line with the RGF
- The host NHS Trust R&D Director is informed that the study is planned and that R&D approval has been given before research commences
- Information that arises from the research, that is relevant to the participants care, is passed on to their care professionals (unless otherwise requested by the REC or the participant)
- The study complies with all legal and ethical requirements
- Each member of the research team is qualified by education, training and experience appropriate to their role in the study
- Students and new researchers have adequate supervision, support and training
- The research has the active involvement of service users and carers at all stages
- The research follows the protocol approved by the R&D Department, Research Ethics Committee (REC) and the sponsor
- Any proposed changes / amendments to the protocol (or any deviations) are submitted for approval to the R&D Department, REC, the sponsor and any other appropriate body
- Any adverse events or critical incidents relating to the research are reported via incident reporting procedures to the R&D Department, REC and, if appropriate, the Medicines and Healthcare Products Regulatory Agency (MHRA)
- Procedures are in place to ensure the collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage
- Arrangements are made at the end of the research for appropriate archiving of data
- Reports required by the R&D Department (and others with legitimate interest) are produced on time and to an acceptable standard
- The findings of the research are open to critical review, using accepted professional and scientific channels
- Once established, findings from the research are disseminated promptly and fed back to participants via a lay summary
- They adopt the key role of guarantor on published outputs in order to prevent scientific misconduct
- Arrangements are in place for the management of financial and other resources for the study, including any intellectual property arising
- All data and documents associated with the research are available for audit at the request of the appropriate authority

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