How to guide: Training your practice staff to support research delivery

This guide outlines the training available to prepare your practice staff to support the delivery of research at your practice.

Key information you should be aware of:

Practice staff should be aware of their responsibilities with regard to research, and be adequately trained to carry out the task(s) delegated to them. Practices continue to be responsible for their own patients' care. Please note that some very simple studies (such as ones which require the practice to send a text message to patients inviting them to participate in a survey) may not require staff to complete all the training mentioned below.

- The practice is responsible for ongoing treatment of its patients, and for ensuring that patients and patient data are treated with due care.
- The practice is responsible for ensuring that all staff who may be involved in a study have an understanding of what is involved.
- Most studies will require that a Principal Investigator (PI) be appointed at the practice. PIs are responsible for the conduct of a specific study at each research site (the GP practice). Tasks may be delegated but responsibility remains with the PI.
- Many studies require that staff who will be involved in recruiting participants and receiving consent must have completed NIHR Good Clinical Practice (GCP) training. Check the protocol and/or with the study team for clarification.
- All staff involved in research at the practice must be familiar with latest protocol requirements and Standard Operating Procedures (SOPs).
- All staff involved in research at the practice must have completed study specific training where this is required for the study.
- All staff involved in research at the practice must first have their specific task(s) approved by the PI, indicated by an entry on the Delegation Log.
- NHS R&D departments and the Clinical Research Network (CRN) are responsible for advising practices about their participation in research.
- The Clinical Negligence Scheme for General Practice is responsible for providing insurance for negligence in the delivery of research. The Sponsor insurance is responsible for insuring any problems with the design of the research.
- Sponsors are responsible for the initiation, management and financing of a specific study.
- Chief Investigators are responsible for the conduct of a specific study within the UK.

Highlights

- General training for practices
- Training for staff involved in consenting participants
- Study specific training
- Protocol and SOPs
- Delegation of duties
- Keeping up-to-date

See also

- Getting your practice ready to do research guide
- Roles and terminology guide
- Data protection guide

Full guide

General training for practices

- An Introduction to Research Delivery in Primary Care (offered by West Yorkshire Research and Development):
    - This free 20-minute training session provides a basic overview of research delivery, addresses some common concerns and includes a Q&A section.
    - It is intended for all practice staff supporting research in some way, if they will not be receiving consent from patients. This would generally include practice managers, admin staff, receptionists, practice nurses and others not involved in the consent process.
    - To arrange this for your practice, please email research@bradford.nhs.uk.

Training for staff involved in consenting participants

- Staff who will be involved in the consenting of patients will need to complete GCP training:
    - Enrol for GCP training via the National Institute for Health Research (NIHR) Learn website https://learn.nihr.ac.uk.
    - A certificate should be downloaded and saved by the member of staff completing this training.
    - Staff members who will be carrying out any tasks requiring a GCP certificate for a study should ensure a copy of their GCP certificate is in the Site File for the relevant research project (see the site file guide for more information).
    - While there is no specific expiry for GCP training, some studies do have a requirement that it be up-to-date. Therefore, it is recommended that GCP refresher training is completed every 2 years via the National Institute for Health Research (NIHR) Learn website: https://learn.nihr.ac.uk.

Study specific training

- For many studies (with the exception of very simple studies) the study team will provide study specific training. This is sometimes called a Site Initiation Visit (SIV). SIVs could be completed via video-conferencing or conference calls:
    - It is important to ensure all staff who will be involved in the study attend a SIV. If this is not possible, pertinent information should be shared with involved staff as soon as possible.
    - Staff should feel free to ask questions of the study team if anything requires clarification.
    - If there is a Training Log in the Site File (see Site File guide for more information), an entry should be made for each staff member who attends any study specific training such as SIVs.

Protocol and Standard Operating Procedures (SOPs)

- A latest version of the Protocol and any SOPs should be kept in the Site File (see Site File guide for more information):
    - It is the responsibility of the PI to ensure the latest version of these documents is in the Site File.
    - All staff with any assigned tasks associated with the research project must be familiar with the requirements of their task(s) as outlined in the latest version of the Protocol and SOPs.

Delegation of duties

- For many studies (with the exception of very simple studies) the Site File should contain a Delegation of Duties Log (Delegation Log). A delegation log delegates specific duties to specific members of the team.
- The delegation log template should be provided by the study team, although it's the responsibility of the PI to complete and maintain the Delegation Log.
- Where a Delegation Log exists:

- All staff involved in the research project at the site (GP practice) should only carry out tasks that they have been delegated to carry out by the PI. The staff member should be named on the Delegation Log with their particular task(s) noted.
- Before agreeing to any task, all staff members should ensure that they are appropriately trained to carry out that task.
- Staff listed on the Delegation Log should not carry out any task(s) until this has been approved and signed off by the PI.
- Activities should have a start date and, when the person stops undertaking the duty, it should have an end date.

Keeping up-to-date

- During the course of a research project, there may be changes to the following:
  - Changes to documents such as the Protocol and SOPs, and participant facing documents:
    - See Site File guide.
    - All staff should be made aware of the changes and ensure that they complete any assigned tasks in line with adjustments made in these documents.
  - Staff changes:
    - Where a new member of staff will be carrying out tasks related to a research project, they should be appropriately trained in line with this guide.
    - All staff should be made aware of the changes and ensure that they complete any assigned tasks in line with adjustments made in these documents.

Glossary of Acronyms and Terms

CRN	Clinical Research Network
GCP	Good Clinical Practice training
PI	Principal Investigator
SIV	Site Initiation Visit
SOPs	Standard Operating Procedures