How to guide: Understanding roles and terminology

This guide outlines the roles and terminology commonly used in research.

Key information you should be aware of:

Practice staff should be aware of their responsibilities with regard to research, and should understand both research roles and commonly used research terminology.

- The practice is responsible for ensuring that all staff who may be involved in a study have an understanding of what is involved.
- All staff involved in the consenting of patients will need to complete Good Clinical Practice (GCP) training.
- All staff involved in research at the practice must have completed study specific training where this is required for the study.

Highlights

- Roles
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- Terminology
  - Research sites
  - Research study documents
  - Other

See also

- Getting your practice ready to do research guide
- Research training guide

Full guide

Roles

- Chief Investigator (CI)
  - The chief investigator is the overall lead researcher for a research project. In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project:
    - The Chief Investigator's responsibilities are set out in more detail in the UK Policy Framework for Health and Social Care Research.
- Principal Investigator (PI)
  - An individual responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person.
- Research Sponsor
  - The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project:
    - All health and social care research should have a sponsor. This includes all research that involves NHS patients, their tissue or information.
    - Two or more organisations may agree to act as co-sponsors or joint sponsors. Co-sponsors allocate specific sponsor responsibilities between them whilst joint sponsors each accept liability for all of the sponsor's responsibilities.
    - A sponsor can delegate specific tasks to any other individual or organisation that is willing and able to accept them.
    - Any co-sponsorship, joint sponsorship or delegation of tasks to another party should be formally agreed and documented by the sponsor(s).

        - The sponsor's responsibilities are set out in more detail in the UK Policy Framework for Health and Social Care Research.
- Collaborator
    - An organisation other than the sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting.
- Local collaborator
    - A person undertaking certain types of straightforward research procedure, not requiring the appointment of a Principal Investigator and/or a site agreement. Local collaborators at NHS sites should still seek approval from their R&D office
- Trial Steering Committees or Study Steering Committees
    - All primary research projects are required to establish a Trial Steering Committee (TSC) or Study Steering Committee (SSC). The role of the TSC/SSC is to provide overall supervision for a project on behalf of the Research Sponsor and Research Funder and to ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. It should be noted that the day-to-day management of the project is the responsibility of the Chief Investigator, and as such the Chief Investigator may wish to set up a separate Project Management Group (PMG) to assist with this function.
- Data Monitoring Committee (DMC)
    - A group of independent scientists who monitor the safety and scientific integrity of a clinical trial. The DMC can recommend to the sponsor that the trial be stopped if it is not effective, is harming participants, or is unlikely to serve its scientific purpose. Members are chosen based on the scientific skills and knowledge needed to monitor the particular trial. Also called a data safety and monitoring board, or DSMB.

Terminology – Research sites

It is important to note that you may be asked to put up a poster to promote a research study. You can do this without being any of the site descriptions below:

- Research Site
    - A research site is responsible for research activities, such as:
        - Any protocol-specified assessment to determine whether the potential participant is eligible for the research study (e.g. a screening blood test or x-ray).
        - The recruitment (informed consent) of participants into the research study.
        - The delivery of research activities and procedures as specified in the research protocol.
        - Providing data from the clinical records.
- Participant Identification Centre (PIC) site
    - PICS are National Health Service (NHS) or Health and Social Care (HSC) organisations that identify potential research participants. They are not research sites. An NHS/HSC organisation is operating as a PIC when it meets the following three criteria:
        - Identifies potential research participants by processing personal data (e.g. through carrying out a search of a patient records database to identify individuals that meet a study's eligibility criteria).
        - Is following the sponsor(s)/protocol instructions in identifying potential research participants.
        - Directs these potential participants elsewhere without undertaking any further research activity for that study (i.e. the research occurs at another organisation).
- Multicentre trial/study
    - A trial or study conducted at several geographical sites; trials are sometimes conducted among several collaborating institutions, rather than at a single institution - particularly when large numbers of participants are needed.

- Lead site
    - In the case of a multi-site trial/study, the site for which the Chief Investigator is also the Principal Investigator.

Terminology – Research documentation

It is important to note that the study documents listed below will have been scrutinised and approved by an Ethics committee during the Health Research Authority (HRA) approval process. It is important you only approved versions of documents are used:

- Protocol
    - A document that describes the objectives, design, methodology, statistical considerations (or other methods of data analysis) and organisation of a research study.
- Patient information sheet (PIS)
    - Researchers must provide a patient information leaflet to everyone they invite to take part in a research study, to ensure people can make an informed decision about this. The PIS explains what taking part will involve and should include details about: why the research is being done, how long it will last, and what methods will be used; the possible consequences; contact details; how the results will be shared with others.
- Consent form
    - A consent form (sometimes called ICF or informed consent form) must be used to record the consent process and a participant's agreement to take part in a research study. When producing the consent form consideration should be given to what is appropriate for the type of study and the participants who will be involved.
- Delegation log
    - The delegation log provides clarity regarding who is responsible for undertaking what activity during delivery of the study. The delegation log is a tool to be maintained throughout the life time of the study at that participating research site. Research activities are delegated by the Principal Investigator (PI).
- Case report form (CRF)
    - A case report form (CRF) is designed to collect the patient data in a clinical trial. It can be a printed paper or an electronic document. It is designed to record all of the protocol required information to be reported to the sponsor on each trial participant. The size of a CRF can range from a one-time 'snapshot' of a patient's physical condition to hundreds of pages of electronically captured data obtained over a period of weeks or months. It can also include required follow-up visits months after any intervention or treatment has stopped.
- Organisational information document (OID) and schedule of events costing attribution template (SoECAT)
    - If a study is non-commercial, the sponsor of the study is responsible for preparing an organisational information document (OID) and a schedule of events costing attribution template (SoECAT). These documents capture all the information around study activities to be undertaken at a local level. A template OID and SoECAT will be reviewed and approved by the HRA for each type of participating site to ensure that there is clarity on the resource implications for participating NHS organisations delivering the research.
- Model agreement/contract
    - If a study is commercial, the sponsor of the study is responsible for preparing an appropriate agreement. The January 2021 model Clinical Trial Agreement (mCTA) and Clinical Research Organisation model Clinical Trial Agreement (CRO-mCTA) templates should be used without modification for industry-sponsored clinical trials throughout the UK Health Services.

Terminology – Other

If you would like to understand more terminology used in research the National Institute for Health Research (NIHR) provide a useful glossary: https://www.nihr.ac.uk/glossary