How to guide: Site selection / initiation visit (SIV)

Key information you should be aware of:

Please note that expressing interest in a study does not commit the practice (site) to participate; nor does it guarantee involvement.

- Some studies may not require the study team to confirm that the practice can be involved (such as a study which simply asks a practice to send patients and/or staff a link to a survey).
- Other studies may require that individual practices be selected to participate by the study team.
- Where a study team selects a practice to participate in a study, a Site Initiation Visit (SIV) is usually arranged.
- The practice is responsible for the ongoing treatment of its patients, and for ensuring that patients and patient data are treated with due care.
- Most studies will require that a Principal Investigators (PI) be appointed at the practice. PIs are responsible for the conduct of a specific study at each research site. 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.
- The practice is responsible for ensuring that all staff who may be involved in a study have an understanding of what this involves.
- Sponsors are responsible for the initiation, management and financing of a specific study.
- Chief Investigators (CIs) are responsible for the conduct of a specific study within the UK.

See also

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

Full guide

Site selection

- Some studies may not require the study team to confirm that the practice can be involved (such as a study which simply asks a practice to send patients and/or staff a link to a survey). This will usually be made clear in the Expression of Interest (EoI) email you receive from the Research Delivery Network (RDN), from West Yorkshire Research & Development (WY R&D) or from the study team. If in doubt, please feel free to ask the question of the sender of the EoI.
- Other studies may require that individual practices be selected to participate by the study team. Depending on the complexity of a study, this may be based on one or more of the following:
    - Demographics of the practice's patient population (i.e. sufficient numbers of potential participants meeting the inclusion criteria for the study)
    - Previous research experience of the practice
    - Previous recruitment figures demonstrated by the practice
    - Staff skills, experience and training
    - Availability of a PI
    - Other factors specific to the study
- If site selection is required for a study, do not start any study procedures until this has been confirmed by the study team.
- Due to the number of EoIs received by study teams, they may only reply to practices that are selected to participate. Therefore, no reply can usually be assumed to mean that your practice has not been selected for a particular study on that occasion.
- Even if your practice is not selected to participate, it would be good to save a copy of the interest expressed. This could be helpful to establish intent and interest, for example when applying for future research infrastructure funding.

Site Initiation Visit (SIV)

- Where a study team selects a practice to participate in a study, a SIV is usually arranged. This could be in the form of a telephone call, video conference, or face-to-face meeting.
- The study team should tell you who will need to be present for the SIV, but you should also make sure all relevant staff are included from the practice point of view.
- The SIV is not only an opportunity for the study team to explain details of the study, provide necessary training and give direction as to completing the delegation log etc., but it is also an opportunity for staff members to ask questions and raise concerns.
- Attendance at a SIV should be documented and could be used in staff appraisals.

How to guide: Delegation of duties log (or delegation log)

Key information you should be aware of:

The delegation log (stored in the Site File, usually alongside research CVs and GCP certificates) is a list of study-related duties assigned to staff members. It is a live document which must be kept up to date if staff working on the study change roles or leave etc. The Principal Investigator is responsible for duties carried out in connection with the study, but the delegation log enables them to delegate some specified duties to other staff. Staff members must only carry out duties to which they are assigned on the delegation log. Please note that some very simple studies (e.g. surveys) may not have a delegation log. If in doubt, staff should always check with the study team before handling any study-related task.

- The practice is responsible for ongoing treatment for its patients, and for ensuring that patients and patient data are treated with due care.
- Most studies will require that a PI be appointed at the practice. PIs are responsible for the conduct of a specific study at each research site (e.g. 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.
- NHS R&D departments and the RDN are responsible for advising practices with regard to their participation in research.
- The practice is responsible for ensuring that all staff who may be involved in a study have an understanding of what this involves. The study team will ensure any study specific training is provided (this should be detailed in the OID).
- 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.

Full guide

Delegation of duties log (or delegation log)

- A delegation log should exist for studies, apart from very simple studies (e.g. surveys).
- Blank delegation logs are usually supplied by the study team as part of the Investigator Site File (ISF). As an example, a template to a delegation log is available here: https://myresearchproject.org.uk/help/help%20documents/Signature_And_Delegation_Log_Template_v1-2.docx
- The name of each staff member who will carry out a study-related task must appear on the delegation log. Alongside their name, the reference for the specific task(s) should be clearly marked. This should be initialled by the staff member and signed and dated by the PI.

- The PI is responsible for ensuring that any staff member listed on the delegation log is sufficiently trained, qualified and/or experienced to carry out the task to which they are assigned.
- The delegation log should be kept up to date, with start and end dates for staff that have been assigned and/or relieved of specific tasks. An end date should be entered if a staff member leaves the practice.
- Some study teams may ask for up to date copies of the delegation log. This should be sent promptly when requested.
- Additional pages of a delegation log should be clearly marked as such so that it is clear how many pages there are (e.g. 1 of 3).
- As with all research documentation, any corrections on the delegation log should be marked with one straight line through the error. The person making the correction should initial and date the correction. Nothing should be deleted by being marked illegible or with correction fluid.

How to guide: Site file maintenance

Most studies will require that a site file be held and maintained by each recruiting site. Site files are often provided by the study team and may be in paper or electronic format.

Key information you should be aware of:

- A site file must contain current versions of all documents being used in the study. Previous versions must be kept in the file but crossed through and marked 'superseded'.
- The site file must also contain delegation logs and research CVs for all persons listed in the delegation log.
- Site files may be checked by sponsors or study monitors at any time.
- Site files may be held electronically if agreed by the study sponsor.
- Site files must be kept securely, but accessible by persons delivering the study for reference.

Highlights

- The National Institute for Health Research (NIHR) provides a comprehensive list of suggested site file contents: https://www.nihr.ac.uk/documents/suggested-investigator-site-file-contents/11537

Full guide

Contents

- Site files are often provided by the study team and may be in paper or electronic format.
- The NIHR has provided a comprehensive list of suggested investigator site file contents, recommending the inclusion of a contents page, and advising that each section should be signed and dated upon completion: https://www.nihr.ac.uk/documents/suggested-investigator-site-file-contents/11537
- Please note, this is a *suggested* contents list. Please discuss a study's site file with the study team; they will often provide the site file and request that the site keep this maintained.
- As per the NIHR website, the suggested list is as follows:
    - Section 1 - Protocol / amendments - to include:
        - Current protocol
        - Protocol amendments
        - Historical protocols
    - Section 2 - Sample CRF/ QLQ Diary Cards. *Note: If too bulky to put in file place file note in this section stating where it can be found.*
    - Section 3 - Regulatory approval documentation
    - Section 4 - Site signature /responsibility log
    - Section 5 - Curriculum Vitae. *Note: CVs for all research personnel listed in the signature/responsibility log should be included.*
    - Section 6 - Patient Identification form and Patient recruitment /screening form
    - Section 7 - Sample of current and all historical Patient Information / Informed Consent form and GP Letter. Completed patient Information and Informed Consent Forms.

- Section 8 – Correspondence. *Note: File in chronological order all correspondence to/from the coordinating research body. File email communication. Include a separate section here for newsletters.*
- Section 9 - Minutes from the initiation meeting, monitoring logs and notes of telephone calls. *Note: If the study is not monitored then state this in a file note in this section. Document telephone call in relation to agreements or significant discussions regarding trial administration, trial conduct, adverse events or protocol violations.*
- Section 10 - Blank serious adverse event forms and guidelines for their completion.
- Section 11 - Notification of serious adverse events and/or safety reports:
    - by Investigator to co-ordinating research body
    - by co-ordinating research body to Investigator
    - by co-ordinating research body to regulatory authorities (if this will not be supplied place a file note stating this).
- Section 12 - Randomisation details. *Note: to include instructions (if applicable).*
- Section 13 - Instructions for handling trial medication and trial related materials and shipping records. Note: This responsibility is normally that of the clinical trial pharmacist if this is the case place a file note in this section stating this.
- Section 14 - Clinical Laboratory:
    - Laboratory normal reference ranges (including revisions)
    - Laboratory certificate(s)
- Section 15 - Contracts:
    - Investigator Commitment Statement/Study Acknowledgement
    - Indemnity
    - Confidentiality
    - Clinical Trial Agreement including financial details.
    - Completed and signed FDA 1572 form (if applicable)
    - Financial disclosure letter (if applicable)
- Section 16 - Investigator's brochure and safety alert letters/Updates
- Section 17 - Completed data queries
- Section 18 - Study training materials
- Section 19 - Miscellaneous (specify).

After the completion of the trial, the following must also be filed in the site file:

- Section 20 - Investigational product(s) accountability at site. Note: This will be with the clinical trials pharmacist.
- Section 21 - Documentation of Investigational product destruction. Note: if destroyed at site this will be with the clinical trials pharmacist.
- Section 22 - Final report from Investigator to REC.
- Section 23 - Clinical study report to document results and interpretation of trial.

- Practices should liaise with study teams about the site trial requirements for specific studies.
- Where a document is amended with a new version, outdated versions should be marked 'superseded' and placed behind the current version in the site file.
- It is the responsibility of the PI to ensure the site file is maintained. The physical maintenance of the site file may be done by a staff member delegated by the PI.
- Please continue to refer to the NIHR website for current guidance related to site files, and liaise with study teams if you have study specific queries.

How to guide: Appointing a Principal Investigator (PI)

Key information you should be aware of:

Most studies (except some very simple studies such as questionnaires) will require that a PI be appointed at the practice. PIs are responsible for the conduct of a specific study at each research site (e.g. the GP practice). Tasks may be delegated but responsibility remains with the PI.

Full guide

Appointing a Principal Investigator (PI)

- The study team will be able to advise whether a PI needs to be appointed for the study being delivered at a practice (a PI will generally need to be appointed for all but the simplest of studies). IRAS guidance notes: 'Principal Investigators are expected to be in place at participating NHS / HSC organisations where locally employed staff take responsibility for research procedures'.
- If a PI is required for the study, there will be a need to ensure the potential PI has the appropriate skills/training to carry out the role, as well as the time and subject interest.
    - Most studies (except for very simple ones not involving consenting of participants) require the PI to hold an up to date GCP certificate. While there is no official expiry for GCP certificates, most studies require these to be within the past 2 years.
    - The study team may also provide some study specific training which they require the PI to attend.
    - The study team may require a copy of a simple research CV for the PI. This should be signed and dated. A template for this CV can be downloaded here.
    - While not a requirement, there may be some additional PI training available. Please check with WY R&D to see what might be available locally.
- A PI is responsible for oversight of the study at the local site (in this case, the GP practice). Therefore, it is important that they have an understanding of what will be required and have the capacity to handle these responsibilities. This may include the following (this is not an exhaustive list, and depending on the type of study, the responsibilities may be much less):
    - Setting up and maintaining the site file
    - Carrying out the study in line with the protocol and any SOPs supplied by the study team
    - Delegating responsibilities at the practice relating to the study (completion of the delegation log)
        - Ensuring all practice staff involved in the study are aware of the site file and that those with delegated responsibilities are properly trained to do so
    - Providing data to the study team where applicable
    - Reporting Adverse Events
- In some cases, a local collaborator rather than a PI is required. The guidance states that "the role of the Local Collaborator is to facilitate the presence of Sponsor / CRO [contract research organisation] research staff." [IRAS guidance]

Glossary of Acronyms and Terms

NIHR	National Institute for Health Research
RDN	Research Delivery Network
GCP	Good Clinical Practice training
ISF	Investigator Site File (or Site File)
OID	Organisational Information Document
SIV	Site Initiation Visit
SOPs	Standard Operating Procedures
AEs	Adverse Events
PI	Principal Investigator
CI	Chief Investigator