How to guide: Responding to Expressions of Interest (EoIs)

This guide outlines the process for expressing interest in specific studies and outlines some important points to consider before expressing interest. The term Expression of Interest (EoI) can refer to the information a practice receives about a study, as well as interest in a study as expressed by the practice. EoIs (usually in the form of an email) may be sent to a practice by West Yorkshire Research and Development, the local Clinical Research Network (CRN), or direct from a study team.

Key information you should be aware of:

Please note that expressing interest in a study does not commit the practice to participate; nor does it guarantee involvement. If you receive information about a study direct from a study team, and the study is recruiting via the NHS, you will need to ensure all appropriate approvals are in place. This would include Health Research Authority (HRA) approval and approval by a Research Ethics Committee (REC). Both of these approvals are in the form of a letter which should be available from the study team. Where the information about a study comes from West Yorkshire Research and Development or the CRN, these approvals should already be in place.

- 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 Principal Investigators (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. (See Appointing a Principal Investigator guide for more information).
- 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 Clinical Research Network (CRN) 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 is involved.
- 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

- Assessment of Feasibility
- Submitting EoIs

See also

- Getting your practice ready to do research guide
- Roles and terminology guide
- Site Initiation Visit etc. guide
- Data Protection guide

Full guide

Assessment of feasibility

Before expressing interest in a study, the practice(s) must first consider whether the study is feasible for the practice(s).

Note that some studies require minimal involvement from practices (such as surveys, questionnaires and interviews). If this is the case, a detailed consideration of feasibility may not be required.

- There is usually a deadline for expressing interest, and at times, this is a very tight deadline. Therefore, it may be helpful to have a checklist to which you may refer to help you assess feasibility.

If the information about the study has come via West Yorkshire Research and Development or the CRN, an overview of the information you need should be in the EoI email. You may need to check the Protocol or Participant Information Sheets for more information.

- Below are some suggested points you may wish to consider when determining feasibility. This is not necessarily an in-depth feasibility analysis, but more of a surface review. Please also note that this is not a comprehensive list, and there may be other points to consider based on local circumstances. Therefore, it may be good to create your own checklist, as suggested above:
    - **STAFF**: Does the practice have staff available to deliver the study if required?
        - Are they appropriately trained or experienced to do this (see the Research Training guide for more information)? Note that the study team may provide study specific training.
        - Does the study require that a Principal Investigator be appointed at the practice and if so, is someone available and appropriately trained and/or experienced to do this (see also PI Guide)?
        - Is there sufficient interest and enthusiasm for research among practice staff who will be involved?
    - **FACILITIES**: Does the practice have the appropriate facilities to deliver the research? For example, this may include one or more of the following:
        - Clinic room(s).
        - Safe data storage (electronic or paper). See also the Data Guide.
        - Equipment (sometimes, some or all of this may be supplied by the study team)
        - Are there any IT requirements, such as the installation of some software? If so, will this be done by the practice, the local IT provider or the study team? Is such an installation possible in view of firewalls and security? (Please feel free to check with West Yorkshire Research and Development (WY R&D) and/or your IT provider since some prior work may have already been done to allow this within the IT network). It is often the case that practices cannot install software themselves, so engaging with the IT provider and/or WY R&D will often be required.
    - **COSTS:** Service Support Cost (SSC) payments may be provided to the practice via the CRN, Research Costs may be provided by the study team. Some studies also include Excess Treatment Costs. These are paid quarterly in arrears via the national payment system to the site where they are incurred.
    - **TIME:** Does the practice have the time to carry out the local requirements of the study? (Note some time may be bought back by means of Service Support Costs).
    - **PATIENTS:**
        - Is there a specific recruitment target (number of patients recruited to the trial) for the practice? If so, does the practice have the sufficient number of patients on their clinic list which meet the inclusion criteria for the study? It is generally expected that 10% of patients approached about a study may wish to participate.
        - Is there another study being delivered at the practice which is already recruiting patients with the same characteristics, or has one been delivered recently? If so, will it be appropriate for these patients to be approached again?
        - Is the study relevant to the patient population of the practice? While there is a need to avoid making assumptions, it may be easier to recruit patients to a study if this is relevant to them.

Submitting EoIs

- Once a practice has determined that a study is feasible to be delivered at the practice(s), an expression of interest (EoI) should be made promptly. There is often a short deadline for this.
- Please be sure to send your EoI to the contact supplied in the EoI email.
- Save a copy of your EoI. Not all practices may be selected for involvement in a study, since the study team may only require a specific number of practices, or practices with specific criteria and/or previous research experience. Therefore, it may be useful to have a list of EoIs sent by the practice as evidence for any applications for research funding which may be made by the practice.

- Wait for a response from the study team, the CRN or West Yorkshire Research and Development before implementing anything related to the study.
- Please note that for some studies, a response may not be received. This should be understood to mean that the practice has not been selected to deliver the study.

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