How to guide: Getting your practice ready to do research

This guide describes the things you need to do to get your practice ready to start doing research i.e. the steps you should take before your first study.

Key information you should be aware of:

Practices should be aware of their responsibilities with regard to research. Practices continue to be responsible for their own patients' care, and retain responsibility as data controller for the patient records held by the practice (see the data protection guide for more detail).

- 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 retains responsibility as data controller for data in the practice system.
- The practice is responsible for ensuring that all staff who may be involved in a study, have an understanding of what is involved.
- Practice staff are responsible for ensuring oversight of all data use (see the data protection guide), ensuring that persons accessing the practice are suitably trained and only undertaking activities appropriate and approved as part of the study (see the staff guide).
- 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.
- NHS R&D departments (West Yorkshire R&D for all GP practices in West Yorkshire) and CRN are responsible for advising practices with regard to their participation in 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.
- Principal Investigators are responsible for the conduct of a specific study at a research site. Tasks may be delegated but responsibility remains with the Principal Investigator.
- Practices are responsible for ensuring an appropriate privacy notice is displayed within the practice and is on the practice website.

Highlights

- Consider what types of research you want to do, and what you can do
- Get your staff ready and aware of what they need to do
- Consider appointing a research lead
- Prepare a research file and documents
- Get contracts in place
- Advice and support are available from the Clinical Research Network (CRN) and West Yorkshire Research and Development (WYRD)
- Infrastructure funding is available from the CRN

See also

- Data protection guide
- Research training guide
- Roles and terminology guide
- Finance guide
- Staff guide

Full guide

Considering what you want to do

- Practices should consider what types of research projects are of interest, and how much time and resource they are able to make available for research. As a guideline, practices may consider:
    - Does the practice only want to get involved with studies adopted by the National Institute of Health Research portfolio (see definitions)? These studies may include service support costs (see definitions). Non-portfolio studies may also include payments.

- Are there particular topic areas of interest?
- Are there particular areas where the patient population is likely to be of interest to researchers? For example a high prevalence of a particular condition?
- Is the practice only able to consider participating in research where their time will be funded?
- Is the practice only interested in participating as a Participant Identification Centre (PIC) (a PIC is where the practice participates only to identify and invite participants, but does not receive consent or conduct any research activity)?
- What staff time is the practice able to offer? Admin staff time? GP time? Nurse time? Or simply practice space for external researchers to do research?
- What facilities do the practice have which could be of interest to a research study (e.g. medicine storage, equipment such as specialist scanners, freezers)?
- Is a member of practice staff willing to act as a Principal Investigator (PI) - responsible for research at the site? Many studies require sites to appoint a PI.

Getting your staff ready and aware of what they need to do

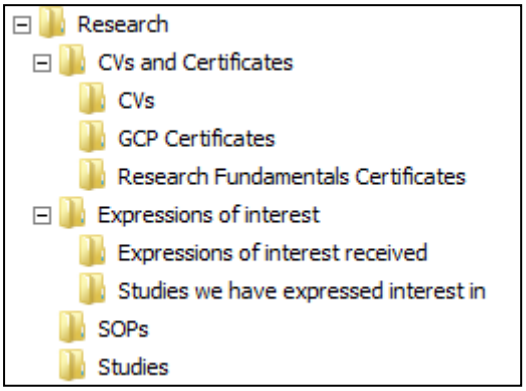
- Practices should consider appropriate training for research, which may include CRN Fundamentals of research training, Good Clinical Practice, Informed Consent training, and study-specific training.
- Practices are advised to communicate with all practice staff who may be involved, to ensure everyone is aware of the reasons for doing research, what may be required of them, and things they should look out for. Alternatively the CRN or West Yorkshire Research and Development may be able to present to staff.

Staffing

- Practices should identify a lead for research, who takes responsibility for overseeing the study and liaising with the study team.
- Practices should consider appointing a research nurse or other specialist.
- Practices should ask all involved staff (at any level of involvement) to complete a research CV. The template research CV can be found here.
- Practices should consider identifying deputies for key research roles to ensure cover in case of illness or annual leave.

Preparing a research file and documents

- **Research file/folders:** We would recommend that your practice begin a research file (electronic and/or paper). This could include GCP certificates and any other research related information, for example any interest you have expressed in specific studies, which will be useful if you apply for start-up or cluster funding at some point. Here is a suggested electronic file arrangement you may wish to create.



- You will need a secure place where confidential study documents (e.g. signed consent forms) can be stored.
- Both the electronic and paper file storage should be accessible to staff working on the study but able to be kept confidential to anyone else.

Getting contracts in place

- Practices will need to hold a contract with the Local Clinical Research Network in order to receive any service support cost payments for research studies. This should be requested by the CRN study lead.
- Practices may consider applying for Research Ready status from the Royal College of GPs: https://www.rcgp.org.uk/clinical-and-research/our-programmes/research-at-rcgp/support.aspx

Advice and support are available from the Clinical Research Network (CRN) and West Yorkshire Research and Development (WYRD)

- Practices are advised to liaise with the Clinical Research Network and West Yorkshire Research and Development, or equivalents in other areas, for advice about starting to do research. Advice can also be found on the West Yorkshire Research and Development website (www.westyorksrd.nhs.uk), the HRA website (www.hra.nhs.uk), the NIHR CRN website (https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm) and the RCGP website (https://www.rcgp.org.uk/clinical-and-research/our-programmes/research-at-rcgp.aspx).
- Practices may consider applying for infrastructure funding from the CRN (when available).

Processes

- Practices should agree a process for researchers and CRN nurses who may access the site – ensuring that they know appropriate fire and health and safety procedures and receive badges/access fobs/smartcards as required (see the staff guide).

Informing patients

- You must make sure patients are aware that patient records may be accessed for use in research, and shared with other organisations for that purpose. This means displaying a privacy notice on the practice website, physically in the practice, and within any practice materials given to patients when they join the practice. The statement should mention that patients can opt out. You should share this information as widely as possible, to ensure patients have the opportunity to see the information and object if they wish. There is advice available from the BMA on privacy notices: https://www.bma.org.uk/advice-and-support/ethics/confidentiality-and-health-records/gdpr-privacy-notices-for-gp-practices. See also the data protection guide.
- Your Patient Participation Group (PPG) should be aware and supportive of your drive to get ready to do research. They can also help to suggest what research might be welcomed by your patients.
- Where practical, we would recommend making available a notice board or an area for research within your waiting room(s). If you have access to add material to the information displayed on the screens in your waiting rooms, you could consider including some slides about research. If you would like us to supply slides, please contact West Yorkshire R&D.

Other initiatives to consider

- You can promote Join Dementia Research (https://www.joindementiaresearch.nihr.ac.uk/) to your patients – all the practice needs to do is promote the initiative and patients engage directly with researchers.

- Clinical Practice Research Database is a system which extracts anonymised data from your patient record system for use in approved research. Practices can learn more and sign up here: https://cprd.com/generalpractitioner
- The RCGP surveillance centre is a similar system which extracts pseudonymised data from the patient record system and also provides a dashboard back to the practice to help with Quality Improvement. Practices can sign up here: https://docs.google.com/forms/d/e/1FAIpQLSf7e2KpVHY-lLZnJAvB-_GaJIHBGGuvj7fiOpFpEBirzlQVrQ/viewform

Glossary of Acronyms and Terms

BMA	British Medical Association
CRN	Clinical Research Network
GCP	Good Clinical Practice training
PI	Principal Investigator
PIC	Participant Identification Centre
PPG	Patient Participation Group
RCGP	Royal College of General Practitioners
SIV	Site Initiation Visit
SOPs	Standard Operating Procedures