

## How to guide: Managing research staff arrangements

This guide outlines the responsibilities of practices in managing external research staff and internal staff working on a research project.

### Key information you should be aware of:

- Please note that external research staff could be from another NHS organisation, from a Higher Education Institute (HEI), from a Health and Social Care organisation (HSC) or be a staff member of the National Institute for Health Research (NIHR) Research Delivery Network (RDN).
- The practice Principal Investigator (PI) is responsible for ensuring that any external research staff have been appropriately screened and have appropriate training and experience.
- Practices should ask to see an external research staff member's letter of access (LoA) before granting them access to the practice to support a study. Letters of Access are provided by WY R&D to verify the above.
- WY R&D provide this service to all West Yorkshire general practices using the NIHR Human Resources (HR) Good Practice Resource Pack.
- Internal staff must be suitably qualified and trained to undertake research activities; this does not require additional LoA, but the Principal Investigator must be confident of their abilities and must delegate duties to staff using the delegation log.
- The practice PI is responsible for delegating research activities via the study delegation log to all research staff working on a study, whether internal or external.

### Highlights

- Processes
- Practice and principal investigator (PI) responsibilities

### Also see

- Roles and terminology guide
- Principal Investigator guide
- Delegation log guide

### Full guide

The [HR Good Practice Resource Pack](#) has been reviewed and updated in light of the Data Protection Act 2018 (DPA 2018) and the UK General Data Protection Regulation (GDPR) which came into force in the UK on 25th May 2018.

### Processes

- As recommended by the Department of Health and Social Care (DHSC) the West Yorkshire R&D team uses the HR Good Practice Resource Pack to support the West Yorkshire general practices by issuing letters of access (LOA) where appropriate.
- The HR Good Practice Resource Pack contains information and documentation to support the process for handling HR arrangements for researchers and provides a streamlined approach for confirming details of the pre-engagement checks they have undergone with the NHS/HSC.
- It applies to NHS/HSC organisations and HEIs in England, Scotland, Wales and Northern Ireland, and has been developed in parallel with other arrangements across the UK to streamline the process for setting up research in NHS/HSC organisations.
- The Resource Pack includes details of:
  - A Research Passport system for issuing honorary research contracts (HRCs) or letters of access to HEI researchers who need to undertake their research within the NHS/HSC. The research passport provides evidence of the pre-engagement checks undertaken on the researcher in line with NHS Employment Check Standards; and
  - Arrangements for sharing and accepting pre-engagement checks between NHS/HSC organisations when NHS/HSC staff wish to undertake research within the NHS/HSC outside of their employing organisation.
- The WY R&D team cannot issue honorary contracts.

## Practice and principal investigator (PI) responsibilities

- The practice PI is responsible for ensuring that any external research staff have been appropriately screened and have appropriate training and experience. Reviewing the external research staff member's letter of access is sufficient to ensure this for studies that are not Clinical Trials of Investigational Medicinal Products (CTIMPs).
  - PIs should check the letter is in date and references the correct study. For RDN staff this may be a blanket letter for all NIHR studies.
  - It is considered best practice to keep a copy of the letter of access in the site file.
- The practice PI is responsible for delegating research activities via the study delegation log to all research staff:
  - Delegated research activities to external research staff must only be **POST** participant consent unless an appropriate agreement (**NOT JUST THE LoA**) is in place to make the external research staff member a member of the direct care team.
  - For CTIMPs it is considered best practice to keep a copy of the research staff member's CV and appropriate training for research activities on the site file. The PI should request these for external staff before delegating these research activities.
  - Should the practice PI wish to hold a copy of the external research staff member's CV and training certificates for a non-CTIMP study, they may request these from the external research staff member before delegating any research activities.

## Glossary of Acronyms and Terms

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| CTIMPs | Clinical Trials of Investigational Medicinal Products                  |
| DHSC   | Department of Health and Social Care                                   |
| GCP    | Good Clinical Practice training  |
| HEI    | Higher Education Institute   |
| HR     | Human Resources  |
| HRC    | Honorary Research Contract   |
| HSC    | Health and Social Care (the equivalent of the NHS in Northern Ireland) |
| LoA    | Letter of Access   |
| PI     | Principal Investigator   |
| RDN    | Research Delivery Network  |