



*National Institute for
Health Research*

Research in the NHS – HR Good Practice Resource Pack

**HR Good Practice:
Information for
researchers, R&D and
HR staff in Higher
Education Institutions
and the NHS**

Information for Researchers, R&D and Human Resources (HR) staff in Higher Education Institutions (HEIs) and the NHS

1 Introduction

Research is an integral part of NHS activity, and is often undertaken in partnership with HEIs and others.

As a result of the partnership arrangements that characterise research, this activity raises a number of HR management issues for NHS organisations. Research within the NHS is often undertaken by NHS staff not directly employed by the host NHS organisation, or by non-NHS staff, particularly researchers employed by universities. This raises issues about responsibility, accountability, patient safety and duty of care. Research is also frequently undertaken across a number of NHS organisations and requires arrangements for both NHS and non-NHS staff to work across those organisations. The Research Governance Frameworks published by the UK Health Departments require all parties undertaking research within the NHS to be clear about responsibilities and liabilities. One of the ways this is achieved is through using HR procedures appropriately.

The UK Health Departments are working to promote a streamlined regulatory and governance environment that facilitates high-quality clinical research while protecting the rights, dignity and safety of patients. As part of these activities, the UK Health Departments have coordinated the development of a good practice resource pack to help the NHS and other research employers take a consistent approach to handling HR arrangements for those undertaking research in the NHS.

The *Research in the NHS – HR Good Practice Resource Pack* consists of:

- a Research Passport system for HEI researchers who need to undertake their research within NHS organisations; and
- standardised procedures for issuing Honorary Research Contracts (HRCs) or Letters of Access (LoAs), in line with the nature of the researchers' activity, and the NHS and / or employer's responsibility for that activity
- standardised procedures for handling HR arrangements for NHS and HEIs researchers who need to work across one or more NHS organisations

The Research Passport system and associated procedures have been developed in parallel with national arrangements for obtaining permission from NHS organisations to undertake research.

2 Benefits of the HR Good Practice Resource Pack

- Clarifies accountability and responsibility for researchers in the NHS, resulting in increased patient safety and improved risk management.
- Improves employers' management oversight and quality assurance of their research staff
- Provides clear HR processes, in line with NHS Employers' Check Standards, resulting in more efficient work processes.
- Minimises duplication of activity, resulting in better use of resources.

- Facilitates research within the NHS, resulting in faster study set-up.

3 The Research Governance Frameworks

The Research Governance Frameworks published by the UK Health Departments make clear that appropriate allocation of responsibility, and hence a clear understanding of liability, is fundamental to good overall governance of research. It helps everyone work together to manage risks, so that the research can go ahead safely, even in difficult settings.

The NHS and HEIs have responsibilities as employers of researchers. Only the employer can be accountable for the suitability of the individual in terms of training, experience and conduct. The substantive employer retains the primary accountability and liability for the actions of their researchers. Once NHS organisations have given permission for research that affects their legal duty of quality and common law duty of care, they then accept vicarious liability for harm due to clinical negligence (see Research in the NHS: indemnity arrangements¹ and Responsibilities, liabilities and risk management in clinical trials of medicines²).

The HR Good Practice Resource Pack clarifies the areas of responsibility, and hence liability, of NHS organisations and HEIs in relation to researchers. Neither NHS organisations nor HEIs should take responsibility for issues that are outside their ability to fully discharge.

The guide describes the communication between an NHS organisation and the substantive employer of a researcher (either another NHS organisation or the HEI) that is necessary to fulfil the overall governance arrangements. The system also relies on good internal communication within organisations, particularly between HR and research support functions. Organisations will need to agree internal mechanisms for allocating responsibility between HR and R&D departments for discharging the activities described in this guidance.

NHS organisations should make arrangements for appropriate management and supervision of all research activity for which they are responsible. This includes ongoing oversight of the security and health and safety of individuals.

4 Summary of Research in the NHS – HR Good Practice Resource Pack

- Researchers with a substantive employment contract with one NHS organisation do not need an honorary research contract to conduct research in another NHS organisation. NHS organisations can accept an existing NHS contract of employment, but additional pre-engagement checks may occasionally be required. NHS organisations should accept the [NHS to NHS proforma confirmation of pre-engagement checks](#) from the researcher's substantive employer as evidence that the appropriate clearances are in place and inform the researcher's substantive employer of her/his activities in their organisations by issuing the [NHS to NHS Letter of Access](#).
- Researchers with an honorary clinical contract with one NHS organisation do not need

¹ Research in the NHS: indemnity arrangements, Department of Health, 2005
<http://www.dh.gov.uk/assetRoot/04/12/52/84/04125284.pdf>

² Responsibilities, liabilities and risk management in clinical trials of medicines, Department of Health and Universities UK, 2004
http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/AZ/Researchgovernance/DH_4082518

additional honorary research contracts to conduct research in other NHS organisations. Additional pre-engagement checks may occasionally be required. NHS organisations should accept the [NHS to NHS proforma confirmation of pre-engagement checks](#) from the researcher's substantive employer as evidence that the appropriate clearances are in place and inform the researcher's substantive employer of her/his activities in their organisations by issuing the [NHS to NHS Letter of Access](#).

- Researchers with no contractual relationship with the NHS require an honorary research contract only if the planned activities of the researcher involve interacting with individuals in a way that has a direct bearing on the quality of their care, i.e. the researcher could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to patients or service users to whom the NHS organisation has a duty of care.
- The substantive employer retains responsibility for other research activities that do not affect the NHS organisation's duty of care.
- An honorary research contract does not confer the right of access to confidential information for research without explicit consent.
- Researchers who do not require an honorary research contract may require additional pre-engagement checks to undertake permitted research activities in NHS organisations.
- Decisions on requirements for pre-engagement checks, induction and training rest with the NHS organisations but should be commensurate with the role of the researcher, type of research and the duty of care.
- There should be a system at local level for identification and local managerial control/supervision of all individuals carrying out research in or through the NHS.

5 Researchers in the NHS

Those involved in conducting and supporting research in the NHS fall into a number of categories:

- i) staff with substantive NHS employment contracts;
- ii) researchers with a substantive university employment and an honorary NHS clinical contract, e.g. clinical academics;
- iii) researchers with substantive university employment contracts and no honorary NHS clinical contract;
- iv) researchers who are contracted to provide NHS services, e.g. GPs, who may or may not have a substantive university employment contract;
- v) researchers with substantive employment contracts with other employers, e.g. social workers;
- vi) university undergraduate or postgraduate students (some of whom may also have substantive NHS employment contracts);
- vii) researchers in any of the above categories conducting research where the participants are NHS staff.

Different arrangements are needed for each of these categories, and these are outlined below. In addition, researchers in any of the above categories may need to conduct research activities across more than one NHS organisation.

5.1 Staff with substantive NHS employment contracts

Staff with a substantive employment contract with one NHS organisation may wish to conduct research in or through another NHS organisation, when the research forms part of their NHS duties. **An honorary research contract issued by the other NHS organisation is not required.**

Where NHS staff wish to conduct research activities within GP practices or through other independent contractors an [NHS to NHS LoA](#) between the employing NHS organisation and the PCT is sufficient. **An honorary research contract issued by the PCT is not required.**

Where NHS staff wish to conduct research in another NHS organisation that will not have a direct bearing on the quality of care, the vicarious liability for the actions of the individual rests with the substantive NHS employer, and **an honorary research contract is not required.**

Researchers who are NHS staff should submit their CV and the [NHS to NHS proforma confirmation of pre-engagement checks](#) (completed by their substantive employer) to the NHS organisation hosting their research. The NHS organisation hosting the research can then issue the researcher with the [NHS to NHS LoA](#). The researcher's substantive employer is informed of her/his activities by being sent a copy of the NHS to NHS LoA.

The NHS organisation hosting the research and the substantive employer should refer to the [Process Flowchart for NHS to NHS arrangements](#), the [Research Passport: Vetting and Barring Scheme Guidance](#) and the [Frequently Asked Questions Supplement](#) for operational details.

5.2 Researchers with a substantive university contract and an honorary NHS contract, e.g. clinical academics

Individuals with a substantive university contract and honorary NHS contract are commonly referred to as clinical academics. Such individuals include medical staff as well as other clinical staff.

Clinical academics do not need an honorary research contract in order to undertake research in the partner NHS organisation where they undertake their clinical duties. This will be covered by their honorary clinical contract. In accordance with the recommendations of the Follett Report, universities and NHS organisations responsible for medical education and research are expected to have joint strategic planning arrangements, with joint subsidiary mechanisms responsible for human resource policies and procedures for staff with academic and clinical duties.

Therefore when **clinical academics wish to conduct research in other NHS organisations they should be treated as staff with substantive NHS contracts.**

Researchers who are clinical academics should submit their CV and the [NHS to NHS proforma confirmation of pre-engagement checks](#) (completed by their substantive employer) to the NHS organisation hosting their research. The NHS organisation hosting the research can then issue the researcher with the [NHS to NHS LoA](#). The researcher's substantive employer is informed of her/his activities by being sent a copy of the NHS to NHS LoA.

The NHS organisation hosting the research and the substantive employer should refer to the [Process Flowchart for NHS to NHS arrangements](#), the [Research Passport: Vetting and Barring](#)

[Scheme Guidance](#) and the [Frequently Asked Questions Supplement](#) for operational details.

5.3 Researchers with substantive university employment contracts and no honorary NHS clinical contract

Arrangements for researchers with substantive university employment contracts and no honorary NHS clinical contract differ depending on whether or not the research activities could have a direct bearing on care. Activities that could have a direct bearing on the quality of care are those that could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to an individual to whom the organisation has a duty of care (see [Algorithm of Research Activity and Pre-Engagement Checks](#)).

Where a researcher is conducting activities that will have a direct bearing on the quality of care, the individual will be accountable to the NHS organisation that gave permission for this activity. **An honorary research contract should be issued to clarify and confirm this accountability.**

When researchers conduct activities with no direct bearing on the quality of care, the vicarious liability for the actions of the individual rests with the university substantive employer, and **an honorary research contract is not required.**

In both case this type of researcher will be processed through the Research Passport System.

The Research Passport is a form which enables HEI employers to share pre-engagement information about their researcher with NHS organisations hosting the researcher's activity. The Research Passport scheme provides:

- clear guidance on the relevant checks required;
- a robust process for HE employers to document and evidence the checks which have been undertaken; and
- clear principles that enable NHS organisations to record and rely on those checks for the duration of the Research Passport.

What are the benefits of the Research Passport?

- Clear HR processes, in line with NHS Employment Check Standards, operated jointly by HEI and NHS employers, thereby minimising duplication.
- Clarifies accountability and responsibility for researchers, resulting increasing patient safety, improving risk management, and for employers improving quality assurance of research staff.
- One set of checks is undertaken on a researcher conducting research in the NHS.
- One standard form is completed for each researcher.
- The form is completed by the researcher and her/his employer, and validated by an NHS organisation, enabling an Honorary Research Contract or Letter of Access to be issued, according to the nature of the research activity.
- The completed and validated Research Passport is presented to all the relevant NHS organisations.
- No duplication of checks.
- Faster study start-up.

The NHS organisation hosting the research and the substantive employer should refer to the [Guide to Completing the Research Passport Form](#), and the [Process Flowcharts on the Research Passport System](#) for operational details.

Once the Research Passport Form is validated, the host NHS organisation can issue an [HRC or LoA](#) depending on the nature of the research activity.

5.4 Researchers who are contracted to provide NHS services

Where Independent Contractors such as GPs, or practice staff, undertake research as part of their routine clinical services, their personal professional indemnity arrangements are expected to provide them with adequate cover for that activity. It is the contractor's responsibility to check that the professional indemnity will cover the proposed research or whether additional premiums are required.

Where Independent Contractors undertake research on patients outside their routine clinical practice, their personal professional defence arrangements may not extend to cover such research activities. NHS Indemnity arrangements specifically do not extend to Independent Contractors (or their staff) while they are working under contract for services to the NHS. **Therefore, issuing an NHS honorary research contract to this group of researchers does not bring them under the ambit of NHS Indemnity arrangements.**

Independent Contractors may be employed by an NHS organisation under certain circumstances, in which case NHS Indemnity arrangements would apply in the same way as for other NHS staff (see Indemnity Arrangements within Primary Care³). Where an Independent Contractor is undertaking research as an NHS employee, the [NHS to NHS LoA](#) can be used.

Researchers with substantive university employment contracts who are also Independent Contractors (e.g. GPs) may wish to undertake research involving patients outside their routine clinical practice. Where an Independent Contractor is undertaking research as a HEI employee, the Research Passport System may be used.

The NHS organisation hosting the research and the substantive employer should refer to the [Guide to Completing the Research Passport Form](#), and the [Process Flowcharts on the Research Passport System](#) for operational details.

Once the Research Passport Form is validated, the host NHS organisation can issue an [HRC or LoA](#) depending on the nature of the research activity.

5.5 Researchers with other substantive employment contracts, e.g. social workers

The arrangements for researchers conducting research within the NHS who are employed by local government, charities or other organisations are similar to those described above for university-employed staff. However, except where local arrangements have been made to extend the Research Passport System between NHS organisations and other partners, there will be no established method to share information from employers about pre-engagement

³ Indemnity arrangements within Primary Care – who is responsible for what?, NHS R&D Forum, 2005

http://www.rdforum.nhs.uk/workgroups/primary/indemnity_arrangements.doc

HR Good Practice: Information for researchers, R&D and HR staff in Higher Education Institutions and the NHS Research in the NHS: HR Good Practice Resource Pack

checks. Where there are no local arrangements to enable sharing of information about pre-engagement checks to take place, NHS organisations hosting research may themselves need to undertake appropriate checks on researchers and claim the costs of such checks from the employer or research funder.

5.6 Undergraduate or postgraduate students

Undergraduate and postgraduate students may conduct research as part of their healthcare placements. A memorandum of understanding between the HEI and the NHS organisation will be in place for healthcare placements. This should confirm the accountability arrangements between the organisations. Students on healthcare placements should have appropriate pre-engagement checks conducted when they start their healthcare placement in the NHS⁴Any research conducted as part of healthcare placements should come within the existing arrangements for such students. Students should be supervised within clinical settings by NHS employees or HE staff with honorary clinical or research contracts who themselves are covered by NHS Indemnity. Therefore, **students conducting research as part of their healthcare placements do not need to complete a Research Passport Form and do not require an honorary research contract or Letter of Access.**

Postgraduate students may conduct research within the NHS other than through healthcare placements. If the student is not appropriately clinically qualified to undertake research activities that may have a direct bearing on the quality of care, the student should be supervised by a clinical supervisor who is an NHS employee or an HEI employee with an honorary clinical or research contract. Therefore, **students supervised under close clinical supervision may not require honorary research contracts.**

Where a postgraduate student is appropriately clinically qualified and experienced direct supervision is not appropriate and the student must complete a [Research Passport Form](#), and be issued with an [HRC](#) (if the research will have a direct and foreseeable impact on the duty of care) or a [LoA](#).

Where a postgraduate student is undertaking research that is not covered by a healthcare placement agreement, and clinical supervision is not available or not appropriate, the student must liaise with their host HEI to complete a [Research Passport Form](#).

Pre-engagement checks on students should be arranged by the HEI through an appropriate department, e.g. Registry. The NHS organisation hosting the research and the substantive employer should refer to the [Guide to Completing the Research Passport Form](#) and the [Process Flowcharts on the Research Passport System](#) for operational details.

Once the Research Passport Form is validated, the host NHS organisation can issue an Honorary Research Contract, or Letter of Access, depending on the nature of the research activity.

In any of the above situations, where NHS staff are undertaking a course of study that includes a research component, e.g. a nurse undertaking a PhD, the arrangements for NHS staff undertaking research should be used. The NHS organisation hosting the research and the substantive employer should refer to the [Process Flowchart for NHS to NHS arrangements](#), the [Research Passport: Vetting and Barring Scheme Guidance](#) and the [Frequently Asked Questions Supplement](#) for operational details.

⁴ <http://www.nhsemployers.org/PlanningYourWorkforce/MedicalWorkforce/MMC/Pages/MedicalstudentsCRS.aspx>
HR Good Practice: Information for researchers, R&D and HR staff in Higher Education Institutions and the NHS Research in the NHS: HR Good Practice Resource Pack

5.7 Researchers conducting research where the participants are NHS staff

All employers have a common-law duty of care for the health, safety and welfare at work of all their employees. Where research involves NHS employees as participants, the duty of care of the NHS organisation to its employees is non-delegable and the NHS organisation will always be liable, regardless of who employs the researcher. **Where the individual conducting the research is not substantively employed by the NHS organisation, an honorary research contract will not affect accountability or liability and should not be issued.**

When NHS employees take part in research as participants outside work, e.g. through professional bodies, their participation is outside the NHS employer's duty of care, even if their participation makes use of knowledge or experience gained as a result of their employment. **If a researcher with no contractual relationship with the NHS conducts such research, the research has no impact on the NHS organisation and an honorary research contract should not be issued.**

5.8 Research hosted by organisations outside the NHS

Participants in research may sometimes be identified by virtue of their past or present status as patients or service users of an NHS organisation, e.g. where potential participants are identified from medical records by a clinical care team, but the research is then conducted by a separate organisation.

When individuals identified by virtue of their past or present status as patients or service users of an NHS organisation take part in research that is hosted by a university, the NHS organisation does not retain a duty of care for any healthcare provision during the course of the research by the university hosting the research. **It is therefore not appropriate for the NHS organisation to issue honorary research contracts to researchers conducting research in external organisations.**

5.9 Management of HR arrangements for researchers

In addition, to the specific HR arrangements for the groups of researchers described above, NHS organisations hosting the research must:

- ensure that arrangements are put in place for handling access to identifiable patient data
- make arrangements for appropriate management and supervision of the researcher activity
- give permission for the research.

Employer/places of study of researchers must:

- facilitate sharing of information about their staff member through the channels outlined in the Resource Pack
- ensure through contracts, codes of conduct, training and disciplinary arrangements that staff using confidential information in research understand and exercise a duty of confidentiality and uphold their responsibilities under any HRC or LoA they have been issued
- maintain records and oversight of the research activity of their staff
- maintain supervision of academic aspects of research activity as appropriate.

The staff involved in research in NHS organisations may frequently change during the course of a research project. Internal systems must be set up to ensure that changes to research teams are notified by Principal Investigators and the necessary arrangements (as described above) are put in place. The letter of permission for research from the NHS organisation to the Principal Investigator should include reference to the requirement to notify any changes to research teams, or any changes in the circumstances of researchers that may have an impact on their suitability to conduct research.

This resource pack has been developed with help from:

- The UK Health Departments
- NHS R&D Forum
- NHS Employers
- UK Clinical Research Collaboration (UKCRC)
- UK Clinical Research Network (UKCRN)
- Universities UK
- Universities and Colleges Employers Association (UCEA)
- Association of Research Managers and Administrators (ARMA)
- Medical Schools Council (formerly CHMS)

Table 1: Summary of forms of contractual arrangement available for individuals undertaking research in the NHS

Forms of contractual arrangement that can be issued to cover research activity	Substantive Employer							
	(1) HE Substantive Employee	(2) Substantive HE with Honorary Clinical NHS Contract (Clinical Academic)	(3) HE Student on a formal healthcare placement	(4) HE Student NOT on a formal healthcare placement	(5) NHS Substantive Employee	(6) Independent Contractor e.g. GP (providing NHS services under contract)	(7) Commercial Researcher	(8) Commercial Researcher under contract to HE (non- commercial research) ⁵
HRC	YES ⁶	NO	NO	YES ⁶	NO	NO	NO	YES ⁶
LoA accepting an HRC	YES ⁷	NO	NO	YES ⁷	NO	NO	NO	YES ⁷
LoA (no HRC required)	YES ⁸	NO	NO	YES ⁸	NO	NO	NO	YES ⁸
NHS to NHS LoA	NO	YES ⁹	NO	NO	YES ⁹	NO	NO	NO
Service Level Agreement	NO	NO	NO	NO	NO	YES ¹⁰	NO	NO
Healthcare Placement Agreement	NO	NO	YES	NO	NO	NO	NO	NO
Is a Research Passport needed?	YES ¹¹	NO ¹²	NO	YES ¹¹	NO ¹²	NO	NO	MAYBE ¹³

⁵ Applies only to HEs contracting researchers to undertake research funded and sponsored by non-commercial bodies

⁶ Appropriate where the Trust owes a duty of care to research participants and the researcher's activity will have a direct impact on patient care.

⁷ Appropriate where the Trust owes a duty of care to research participants and the researcher's activity will have a direct impact on patient care and the researcher already holds an HRC with another NHS organisation.

⁸ Appropriate where the Trust owes a duty of care in respect of the research activity and the researcher's activity has no direct impact on care but involves access to NHS patients, data or facilities.

⁹ Covers all types of research activity i.e. direct and indirect impact on patient care, where the researcher has a contractual relationship with the NHS.

¹⁰ HR issues should be addressed in a service level agreement unless covered by Trial Agreement e.g. Data Monitors

¹¹ Yes, where evidence of pre-engagement checks are required

¹² NHS to NHS proforma confirmation of pre-engagement checks should be used for those with an existing substantive or honorary clinical NHS contract.

¹³ Yes, to facilitate sharing of pre-engagement checks