



*National Institute for
Health Research*

Research in the NHS – HR Good Practice Resource Pack

**Background Information:
Honorary research contracts:
principles and legal
requirements**

Honorary research contracts: principles and legal requirements

This document should be read in conjunction with the relevant Research Governance Framework and the algorithm on the National Institute of Health Research (NIHR) website¹ which provides guidance on the pre-engagement checks that should be carried out in particular research situations and whether or not an honorary research contract is required. For information relating to independent contractors, see also the NHS R&D Forum's document *Indemnity Arrangements within Primary Care*².

Summary:

- 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 inform the researcher's substantive employer of her/his activities in their organisations, by providing them with a copy of the NHS to NHS Letter of Access.
- Researchers with an honorary clinical contract with one NHS organisation do not need additional honorary research contracts to conduct research in other NHS organisations. Additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations, by providing them with a copy of 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.
- Substantive employers retain responsibility for other research activities that do not affect the NHS organisation's duty of care.
- Honorary research contracts do not provide a mechanism for access to confidential patient information without consent. Access to confidential patient information, either with patient consent or statutory support, does not require an honorary research contract.
- 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 NHS organisations but should be commensurate with the role of the researcher, the 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

¹ Research in the NHS - Human Resources (HR) Good Practice Resource Pack
http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

² Indemnity arrangements within Primary Care – who is responsible for what?
NHS R&D Forum, Primary Care Working Party, 2005
http://www.rdforum.nhs.uk/workgroups/primary/indemnity_arrangements.doc

NHS.

1. Duty of care and duty of quality

- 1.1. Duty of care is the common law obligation to exercise a level of care towards an individual, as is reasonable in all the circumstances, to avoid injury to that individual or his property.
- 1.2. Once NHS organisations have given permission for research that affects their legal duty of quality and common law duty of care, they are then vicariously liable for clinical negligence and other negligent harm to individuals to whom they owe a duty of care. In general, NHS organisations have a duty of care to patients, service users and visitors. The liability for a breach of that duty is based upon the relationship of the parties, the negligent act or omission and the reasonable foreseeability of loss to that individual.
- 1.3. There is a legal duty on each NHS organisation to put and keep in place arrangements for the purpose of monitoring and improving the quality of healthcare provided by and for that organisation. Healthcare means services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness; and the promotion and protection of public health.
- 1.4. NHS Indemnity covers negligent harm to patients and volunteers taking part in research that has been authorised by an NHS organisation. NHS Indemnity covers the actions of staff in the course of their employment and other researchers including clinical academic staff with honorary clinical contracts and those conducting clinical research, when the NHS organisation owes a duty of care to the person harmed.
- 1.5. NHS organisations are not liable for the actions of researchers that will not 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.
- 1.6. The Research Governance Frameworks require researchers not employed by any NHS organisation who interact with individuals in a way that has direct bearing on the quality of their care to hold an NHS honorary contract.
- 1.7. When individuals who are patients or service users of an NHS organisation take part in research that is not hosted by or through that NHS organisation, e.g. by a university or in a private facility, the NHS organisation does not retain a duty of care for any healthcare provision by the external body³. Where the participants were referred by the NHS organisation, the NHS organisation should have systems in place for ensuring the suitability of referrals.

2. Substantive employment

- 2.1. Employment can be described as performing work for the benefit of an employer (i.e. to fulfil its role and purpose) for remuneration. This arrangement is formalised through a legal contract in which the employer and employee agree on roles and responsibilities. This employer is described as the substantive employer.

³ External body here does not refer to Independent Sector Treatment Centres, as such providers treating NHS patients benefit from the referring PCT's CNST membership see Independent Sector Treatment Centres (ISTCs) and CNST NHSLA, 2006
<http://www.nhs.uk/NR/rdonlyres/79E694BA-A4AB-45A4-95B8-E0A7499DCB99/0/ISTCsfactsheet.doc>

- 2.2. Substantive employers are vicariously liable for any negligent acts committed by their employees during the course of their employment. Malpractice claims against staff employed by the NHS (i.e. other than independent contractors) are managed by the NHS employer and the costs borne by the NHS organisation (usually through a scheme, e.g. the Clinical Negligence Scheme for Trusts⁴).
- 2.3. Staff with a substantive contract with one NHS organisation may wish to conduct research in another NHS organisation. This research will form part of their NHS duties and should be covered by a NHS to NHS Letter of Access. The substantive NHS employer confirms the appropriate pre-engagement checks are in place for their employee to undertake their role within the host NHS organisation. The NHS organisation where the research is being conducted should notify the substantive NHS employer of each project that the researcher is involved in.

3. Clinical academics

- 3.1. Individuals with both clinical duties and academic duties hold a single job. In these cases, clear and unequivocal statements must be made, and communicated to staff, about their accountability and lines of reporting in accordance with the principles in the Follett report. Clinical service is the responsibility of NHS organisations, and clinical academics are accountable to them through their honorary clinical contracts for their clinical work. Research is the responsibility of universities, and clinical academics are accountable to them through their substantive contract for their research and other academic work
- 3.2. University and NHS partnerships responsible for clinical education and research should establish joint strategic planning arrangements, with joint subsidiary mechanisms responsible for human resource policies and procedures for staff with academic and clinical duties. Clinical academics do not need an honorary contract for research activity in the NHS organisation where they undertake their clinical duties as this should be covered by their existing contractual arrangements. When clinical academics wish to conduct research in other NHS organisations this should be covered by a NHS to NHS Letter of Access, in the same way as for all other staff with substantive NHS contracts and an additional honorary research contract is not required (see 2.3 above).

4. Honorary research contracts

- 4.1. Honorary engagement can be described as performing work for the benefit of an organisation (i.e. to meet its role and purpose) without remuneration.
- 4.2. Where an individual is conducting activities under an honorary engagement that will have an impact on the care of patients, the individual will be accountable to the NHS organisation for this work. Accountability means clear statements about the person to whom the individual staff member reports, and about the procedures, codes of practice and other rules and regulations that apply to the work in question. An honorary research contract clarifies and confirms this accountability. As part of these accountability arrangements, NHS organisations should inform the researcher's substantive employer of the researcher's activities in the host organisation.

⁴ For an explanation of NHS indemnity in relation to independent contractors see Indemnity arrangements within Primary Care – who is responsible for what? NHS R&D Forum, Primary Care Working Party, 2005
http://www.rdforum.nhs.uk/workgroups/primary/indemnity_arrangements.doc

5. Accountability arrangements for researchers with no contractual relationship with the NHS

- 5.1. An honorary research contract is only required when the research could have a foreseeable and direct impact on patient care. A foreseeable and direct impact on patient care means situations where the actions of a researcher 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. In other situations, e.g. if the need for an intervention is revealed during the course of a research interview with a patient, an honorary research contract is not required. However, researchers should still ensure that appropriate arrangements are in place for situations where care interventions may become necessary, and these arrangements should be explained in the participant information sheet.
- 5.2. Where an individual conducting research is not performing any activities that might have a direct and foreseeable impact on patient care, the vicarious liability for the actions of the individual should be retained by the substantive employer, and an honorary research contract is not appropriate. This is similar to the situation applying to other individuals who work for the benefit of their substantive employer but who conduct work within or involving an NHS organisation, e.g. regulatory inspectors. Inappropriate use of honorary contracts could potentially transfer to the NHS organisation liability that should be retained by the substantive employer, with damaging consequences for the NHS organisation.
- 5.3. Where an honorary research contract is not appropriate, an individual may still be conducting activities which should meet specific legal, ethical or regulatory standards. The requirement of an individual to conduct activities to an appropriate standard will be met through:
- ethical review of the project, and
 - patient consent where required⁵, and
 - permission from the relevant NHS organisation, and
 - registration with a statutory regulatory professional body, where relevant,
- and*
- a letter from the NHS organisation outlining the researcher's responsibilities, copied to the researcher's employer.
- 5.4. 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.
- 5.5. NHS Indemnity for clinical negligence can also provide cover in the event of negligence by staff conducting research with NHS permission but who do not require

⁵ The requirement for explicit consent applies to research unless disclosure is justified exceptionally in the public interest or has support in law in England and Wales under section 251 of the NHS Act 2006, as amended. Guidance relating to confidentiality and consent in research should be consulted for further details. For activities involving the use of human tissue please refer to the Human Tissue Authority for details of consent exemptions from the Human Tissue Act (2004)

honorary research contracts, if the NHS organisation has a duty of care to the person harmed. Consideration should be given, in any contract or agreement between the NHS organisation and the substantive employer, to the NHS having the right to recover losses should they arise. It should be noted that this eventuality would be unlikely if the systems for issuing honorary research contracts outlined in this document are in place.

6. NHS staff as research participants

- 6.1. 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. Under the harmonised edition of GAfREC⁶, research involving NHS staff recruited as research participants by virtue of their professional role or equivalent research involving the staff of social care providers, is excluded from the normal remit of RECs, Permission must be obtained from the staff member's NHS organisation. 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 is therefore not appropriate. When NHS employees participate in research outside work, 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.

7. Pre-engagement checks

- 7.1. NHS organisations should consider the type and/or degree of pre-engagement checks (e.g. criminal record, occupational health) and the extent of subsequent induction or training that is required, ensuring that these are commensurate with the role of the researcher, the type of research and the duty of care. Pre-engagement checks may still be required for researchers who do not need an honorary research contract. NHS Employers (<http://www.nhsemployers.org>) and the UK health departments offer further guidance and advice on issues relating to those working within the NHS as employees, honorary staff, contractors, students or volunteers.
- 7.2. All individuals working within the NHS are required to disclose anything that might compromise their position, such as a recent conviction.
- 7.3. Occupational health clearance is required for those who will interact directly with patients as part of their normal duties. Where health clearance has been obtained from an NHS organisation, and the individual retains a substantive employment contract with that organisation, the individual is responsible for ensuring that occupational health details are up to date. An occupational health check from an HEI might be suitable for the NHS environment in which a researcher will be working, and therefore may not need to be repeated. NHS Employers provide further guidance in their Occupational Health Check Standard (<http://www.nhsemployers.org/recruitmentandretention/employment-checks/employment-check-standards/pages/occupationalhealthchecks.aspx>).
- 7.4. Individuals whose research activity is concerned with the provision of health services and is of such a kind as to enable the researcher to have access to persons in receipt of such services in the course of her/his normal duties are required to provide a

⁶ <http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/>

standard criminal record disclosure. Individuals whose research involves regulated activity as defined by the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012), are required to provide an enhanced criminal record disclosure with checks against the relevant Independent Safeguarding Authority (ISA) barred list(s) .

- 7.5. Individuals throughout the UK may also apply for a basic disclosure, which is the lowest level of disclosure and is available to anyone for any purpose, on payment of the appropriate fee. This service is operated by Disclosure Scotland. A basic disclosure contains details of convictions considered unspent under the Rehabilitation of Offenders Act 1974 or states that there are no such convictions. This type of disclosure is only issued to the applicant. It is not job-specific or job-related and may be used more than once.
- 7.6. All GPs have to provide an enhanced disclosure, and details of checks against the relevant ISA barred lists, in order to provide services to the NHS.
- 7.7. Students on healthcare placements should provide an appropriate level of criminal record disclosure before starting their healthcare placement in the NHS, which takes account of the level of supervision to be given.
- 7.8. A criminal record disclosure carries no period of validity. Risk and use of resources need to be balanced when deciding the frequency of checks required. Individuals holding honorary research contracts should have a criminal record check at the start of their honorary engagement. This need not be repeated for the duration of the honorary research contract unless the details of the individual's research activity change and a higher level of disclosure is required or the individual's circumstances change in a way that might affect a criminal record check.