

## Research Passport Scheme Policy

### Executive Summary

This policy covers the NHS research community in Northumberland Tyne and Wear and sets out the processes by which researchers are allowed access to NHS organisations.

#### The need for this policy

The national health research strategy, *Best Research for Best Health*, published by the Department of Health in 2006, sets out the benefits of research within the NHS as:

- identifying innovative ways of preventing, diagnosing and treating disease.
- providing information on the costs, effectiveness and broader impact of health technologies.
- providing the evidence base to increase the quality of patient care, ensure better patient outcomes and contribute to improved population health

Research is an integral part of NHS activity and its conduct requires support from a variety of services. Streamlining processes for allowing researchers to work across NHS organisations is seen by the Department of Health as a key element of improving the conduct and delivery of studies. A commitment to streamline these processes is, therefore, a central element of the membership agreement between NHS organisations and the Comprehensive Local Research Networks (CLRN) which provide NHS support funding.

The policy sets out the responsibilities of Human Resource, Occupational Health and Research and Development departments, and the NIHR Clinical Research Networks. The roles and interactions of service departments within NHS Trusts and Higher Education Institutions (HEIs) are set out.

#### The issues to be addressed

Inconsistency and the lack of clear guidance about the requirement for HRCs have meant that HRCs have, in the past, been issued inappropriately in parts of the NHS. This has led to significant delays and frustration and also placed inappropriate liability on NHS organisations. Similarly, duplication of pre-engagement checks wastes considerable time and resource for both HEIs and NHS organisations and causes delays in study set-up.

This policy implements the *Research in the NHS – HR Good Practice Resource Pack*. The Pack was developed to streamline NHS approval for access by non-NHS researchers and researchers from other NHS organisations to NHS facilities, staff and service users. Procedures are included in this policy for its implementation in NHS organisations and Higher Education Institutions (HEIs). The national initiative to implement these improvements is widely known as the Research Passport Scheme.

There are two ways that a researcher from outside an NHS organisation can be allowed access to patients, staff or facilities. He or she can be granted either an Honorary Research Contract or a Letter of Access. The policy sets out which of these is appropriate for different categories of staff and for research roles undertaken.

#### Expectations

Timely and effective contribution to research is dependant upon the rapid and flexible deployment of human resource. Current systems and their variation between organisations is a barrier to this.

This document sets out a policy consistent with all the national Human Resources requirements and approved by DH and NHS Employers. The Policy is to be implemented within NHS organisations which are Member Organisations of the Northumberland Tyne and Wear CLRN and adhered to by HEIs wishing to undertake research in the NHS.

## 1. Introduction

1.1. Definitions of terms used are in Section 8.

- 1.2. The UK Clinical Research Collaboration (UKCRC) is a partnership of organisations working to establish the UK as a world leader in clinical research, by harnessing the power of the NHS. The UKCRC is 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 its activities, it has coordinated the development of the *Research in the NHS – Human Resources Good Practice Resource Pack* to help the NHS, HEIs and other research employers take a consistent approach to handling Human Resources arrangements for those undertaking research in the NHS. The Pack forms the basis for this policy and should be read alongside it. The Pack also includes template documents including example *Honorary Research Contracts (HRCs)*, letters of access (*LoA*) and letters of agreement with other NHS organisations. All relevant documents are included in this policy as appendices. The Pack will be updated from time-to-time and the current copy will be available on the website listed below.
- 1.3. Research within the NHS relies on working in partnership with the Higher Education sector and is often undertaken by non-NHS staff, including staff employed by HEIs. This relationship calls for clear understanding about responsibility, accountability, patient safety and duty of care. The *Research Governance Framework for Health and Social Care* published by the Department of Health requires all parties undertaking research within the NHS to be clear about responsibilities and liabilities. One of the ways this is achieved is through appropriate use of *HRCs*.
- 1.4. The NHS Organisations within the Northumberland, Tyne and Wear area are partners in the National Institute for Clinical Research Clinical Research Network (NIHR CRN) via its contract with the Northumberland Tyne and Wear Comprehensive Local Research Network (NTW CLRN). The NHS Organisations have agreed in this contract to implement the Research Passport Scheme. The CLRN's Lead Research Management and Governance Manager is supporting Research & Development Managers and Human Resources staff across NHS organisations and HEIs within NTW CLRN to implement a uniform policy to reduce inconsistencies and ensure a smooth process for NHS access for researchers.
- 1.5. **The Research Passport Scheme** covers access to the NHS for researchers from HEIs and other NHS organisations, covering the issuing of *HRCs*, *LoAs* as well as the *Research Passport*.

1.6. **The Research Passport** is:

- one standard form and associated documents (Right to work, verification of identity checks, CV, CRB Disclosure, and Occupational Health clearance), providing evidence of one set of completed checks on a researcher
- required by a researcher whose substantive contract is with an HEI who:
  - has no honorary clinical contract with the NHS
  - during the course of the research will have a direct bearing on care **OR**
  - has direct contact with patients or service users

1.7. The *Research Passport Application Form* is completed by the researcher and her/his employer, all relevant documents attached, and validated by an NHS organisation. The completed Research Passport (Form and documents) is presented to all the relevant NHS organisations in order for an *HRC* or *LoA* to be issued rapidly, with no duplication of checks.

1.8. An Honorary Research Contract is:

- required by a researcher whose substantive contract is with an HEI who:
  - has no honorary clinical contract with the NHS
  - during the course of the research will have a direct bearing on care

1.9. A Letter of Access is:

- required by a researcher whose substantive contract is with an HEI (Letter 1) who:
  - has no honorary clinical contract with the NHS organisation where access required
  - does not require an HRC (has no direct bearing on care)
- required by a researcher whose substantive employer is another NHS organisation (Letter 2)

**Research Passport Scheme Policy**

Effective: February 2011

Review: January 2012

**1. Scope of Policy and Objectives**

This policy and procedure applies to all research conducted by individuals whose substantive employment is external to the NHS organisation in which the research is being conducted (HEI and NHS staff).

The primary objective is the implementation of the Research Passport Scheme via the adoption of the *Research in the NHS – HR Good Practice Resource Pack*.

**2. NHS Organisation Responsibilities**

2.1 The Newcastle upon Tyne Hospitals NHS Trust is responsible for:

- Ensuring the implementation and the requirements outlined within this Policy are observed and will receive regular performance reports from the Research & Development Department.
- Ensuring their individual Directorates are made aware of the policy and their responsibilities within it and that staff are appropriately trained.

2.2 The Trust's Research & Development Department is responsible for:

- Providing a single point of contact for externally employed individuals seeking to conduct research in the NHS organisation.
- Assessing the need for an HRC or LoA from the individual's employment status and the nature of the proposed research project or programme.
- Assessing the need for pre-engagement checks with advice from Human Resources.
- Ensuring that Research Passport evidence of appropriate pre-engagement checks in accordance with NHS Employment Check Standards are forwarded to the Human Resources Department so that an HRC or LoA can be issued if needed.
- Training staff within the organisation to ensure compliance with the Research Passport Policy
- Auditing the organisation's performance and providing performance reports on the use of the Research Passport Scheme to the Board.

2.3 The Trust's Human Resources Department is responsible for:

- Ensuring appropriate pre-engagement checks in accordance with NHS Employment Check Standards have been completed for:
  - External researchers (HEI), in order to complete a research passport, when the organisation is the first NHS organisation approached by the researcher.
  - NHS staff from another NHS organisation on applying for access to patients, staff or premises.
- Undertaking checks where appropriate for:
  - Staff with substantive contracts within the organisation that are undertaking research in another NHS organisation

- Staff from another organisation (NHS or HEI) that will be working with children and/or vulnerable adults
- Reviewing Occupational Health clearance documents for external researchers to ensure appropriate clearance/ status for research role and liaising with Occupational Health department where additional local checks are required (i.e. additional to national requirements, but required by Trust).
- Liaising with Human Resources and Occupational Health departments of the substantive employers (NHS organisation, HEI or contacted Occupational Health service) of researchers applying for access where additional information is required or additional checks are needed to meet national requirements. [If these additional checks (i.e. to meet national not local requirements) are undertaken by an organisation other than the substantive employer, then these will be charged back]
- Providing information about staff employed by organisation to other NHS organisations where staff member applying for access to undertake research (where agreed by member of staff).
- Issuing an HRC or LoA in response to a request from the Research & Development Department for an external researcher.
- Ensuring that internal procedures for processing pre-engagement checks and the issuing of contracts are efficient and turnaround timelines are adhered to, so enabling the research process.
- Training Research & Development staff within the organisation to ensure compliance with the Research Passport Policy and current employment law.
- Working with the Research & Development Department to audit compliance with this policy.
- Notifying other NHS Human Resources departments where access has been granted, of any new disclosures or changes to health status where relevant to research role.
- Human Resources responsibility may be delegated to the Research & Development department where appropriate. Training should be given and delegated responsibilities should be officially documented.

#### 2.4 The Trust Occupational Health Department is responsible for:

- As requested by Human Resources, review Occupational Health, health status or clearance documents (e.g. fit slips) submitted by researchers from other organisations (another NHS organisation or HEI) wishing to have access to staff, patients or premises, providing feedback on additional requirements or requests for clarification to Human Resources. [Human Resources will liaise with researcher or substantive employer where additional information is required or additional checks needed to comply with national requirements].
- Issuing fit slips/other documentation required for staff within the organisation (i.e. those with substantive contracts) wishing to undertake research in another NHS organisation, showing clearance level and current health status.
- Carrying out additional health checks on external researchers as required locally (i.e. additional to national requirements but required by NHS organisation) for access to staff, patients or premises.
- Training Research & Development and Human Resources staff within the organisation to ensure compliance with the Research Passport Policy and current Occupational Health guidance/regulations.

- Ensuring compliance with this policy by undertaking audit of records using locally approved systems. Provide reports of audit to Research & Development and the CLRN

### **3. HEI Organisation's Responsibilities**

#### **3.1 The HEI Executive Board is responsible for:**

- Ensuring the implementation and the requirements outlined within this Policy are observed and will receive regular performance reports from the research departments.
- Ensuring their individual schools/departments are made aware of the policy and their responsibilities within it and that staff are appropriately trained.

#### **3.2 The HEI Research Services departments are responsible for:**

- Assessing the need for an HRC or LoA from the nature of the proposed research project or programme.
- Assessing the need for pre-engagement checks with advice from Human Resources and the NHS organisation where access is required.
- Ensuring that researchers have evidence of appropriate pre-engagement checks in accordance with NHS Employment Check Standards.
- Training staff within the organisation to ensure compliance with the Research Passport Policy
- Auditing the organisation's performance and providing performance reports on the use of the Research Passport Scheme to the Board.

#### **3.3 The HEI Human Resources Department is responsible for:**

- Undertaking pre-employment checks in accordance with NHS Employment Check Standards for such checks (where appropriate) for staff within the organisation that are undertaking research in an NHS organisation.
- Requesting Occupational Health clearance documents and additional checks from HEI Occupational Health Department or contracted Occupational Health service to ensure appropriate clearance/status for research role.
- Liaising with Human Resources and Occupational Health departments of the NHS organisations where researchers are applying for access, where additional checks or information is required. Checks undertaken by the NHS organisation to meet national requirements will be charged to the substantive employer. Checks required locally by the NHS organisation where over and above national requirements are not charged to the substantive employer.
- Providing information about staff employed by organisation to NHS organisations where staff member applying for access to undertake research (where agreed by member of staff).
- Ensuring that internal procedures for processing pre-engagement checks are efficient and turnaround timelines are adhered to, so enabling the research process.
- Training research department staff within the organisation to ensure compliance with the Research Passport Policy and current employment law.
- Working with the research departments to audit compliance with this policy.

- Notifying NHS Human Resources departments where access granted, of any new disclosures, changes to health status or performance issues where relevant to research role.
- 3.4 The HEI Occupational Health Department is responsible for:
  - Carrying out health and immunisation status checks for researchers employed by the HEI who require access to NHS staff, patients or premises.
  - Issuing fit slips/other documentation required for staff within the organisation wishing to undertake research in an NHS organisation, showing clearance level and current health status. Fit slips will be submitted to NHS organisations confirming clearance level to NHS standards as amended from time to time: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_073132](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073132).
  - Training research department and Human Resources staff within the organisation to ensure compliance with the Research Passport Policy and current Occupational Health guidance/regulations.
  - Ensuring compliance with this policy by undertaking audit of records using locally approved systems. Provide reports of audit to Research Services and the CLRN.

#### **4. Researcher Responsibilities**

- Complete forms required for research role (as guided by research department of substantive employer):
  - Research Role Assessment Form
  - Research Passport Form and Appendix
  - CRB Disclosure/Model Declaration
  - Occupational Health Assessment Questionnaire
- Provide copies of documents requested by research departments, Human Resources or Occupational Health, for verification purposes. For example:
  - Personal identification (e.g. passport, birth certificate)
  - Curriculum Vitae
  - Professional Registration
  - Right to live and work in the UK
  - Employment contract
  - Study protocol/description
  - Documentary record of vaccinations or test results
- Liaise with research departments in HEI (if applicable) and/or NHS organisations
- Attend Human Resources and Occupational Health departments of HEI and NHS organisations as requested
- Submit updated documents to employer and NHS organisations as soon as become available:
  - Details of project extensions
  - Additional projects (on appendix form)
  - Renewed CRB disclosure
  - Renewed Occupational Health clearance
- Disclose to employer details of any arrest (on any charge) or summons on a criminal charge

- Notify employer of any change to health status
- Notify employer of any change to right work status e.g. Certificate of Sponsorship and/or Leave to Remain in the UK

## 5. Process/Procedure

The procedure for an external researcher gaining access to an NHS organisation to undertake research will vary depending on the researcher's employment status and the nature of the project. Details are found in the *Research in the NHS – Human Resources Good Practice Resource Pack* and in the following appendices:

- Appendix 1 Document Requirements - Staff  
Flowchart showing contract requirements for each type of staff and project
- Appendix 2 Document Requirements – Students  
Flowchart showing contract requirements for type of student and project
- Appendix 3 HEI Flowchart  
Flowchart from Pack showing process for application and issue of documents for researchers, Human Resources and Occupational Health staff in HEIs
- Appendix 4 NHS Flowchart  
Two flowcharts from Pack showing process for application and issue of documents for research at a single site and at more than one site researchers, detailing procedure within NHS organisations
- Appendix 5 Process for Applying for Access to Undertake Research in the NHS  
Two tables, one for HEI staff without a contract with the NHS and one for NHS staff, showing process for application, checking and issue of documents for research and responsibilities

Template documents can be found in the following appendices:

- Appendix 6 NTW CLRN Research Role Assessment Form
- Appendix 7 Research Passport Application Form and Passport Appendix (forming the Research Passport alongside attachments)
- Appendix 8 Occupational Health Assessment Form
- Appendix 9 HRC Cover Letter and HRC
- Appendix 10 Letter of Access 1 – For researchers who do not require an *HRC* (HEI staff with not NHS contract or direct bearing on care)
- Appendix 11 Letter of Access 2 – For NHS researchers

The procedure for processing requests for access is indicated in the flowcharts and table in Appendices 3-5, depending on whether a single or multiple sites are involved in the research.

## 5.1 Research Passport Scheme contacts for HEIs and the NHS Trusts within NTW CLRN .

Details of primary contact for researchers for each organisation will be listed on the NTW CLRN website [www.ntw-clrn.crncc.nihr.ac.uk](http://www.ntw-clrn.crncc.nihr.ac.uk) For all requests for access, the Research & Development Department at the NHS organisation will be the first point of contact and will liaise with Human Resources and Occupational Health staff to facilitate the process.

## 5.2 HEI Staff

A researcher from an HEI will provide details of their research project by completing the Research Role Assessment Form. The HEI Research Services Department will then assess the need for a Research Passport, an *HRC* or *LoA*. The *Research Passport* template document is accepted as the standard form for application for a new Research Passport, or when complete, as the basis for issuing an *HRC*. The tables and flowcharts in Appendices 1 and 2 should be used in making the judgement as to whether an *HRC* is needed and the HR department will advise what checks are required.

Researchers with no contractual relationship with the NHS require an *HRC* 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 intention is that in the course of their research, the researcher could 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.

***HRCs do not provide a mechanism for access to confidential patient information without consent.*** Access to confidential patient information only, either with patient consent or statutory support, does not require an *HRC*, unless the use of this data has a likely bearing on the quality of patient care.

**Researchers with an *honorary clinical contract*** with one NHS organisation do not need an *HRC* to conduct research in other NHS organisations. A *LoA* will be issued. Additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations.

Substantive employers (usually HEI's) retain responsibility for other research activities that do not affect the NHS organisation's duty of care.

## 5.3 Staff with NHS Contracts

A researcher with a substantive contract with the NHS wishing to undertake research in another NHS organisation will provide details of their research project by completing the Research Role Assessment Form (Appendix 6). The Research & Development Department at the new NHS organisation will then assess the need for a *LoA*. The tables and flowcharts in Appendices 1 and 2 should be used in making the judgement as to what checks are required as well as advice from the HR Department

Researchers with a substantive employment contract with one NHS organisation do not need an *HRC* to conduct research in another NHS organisation. The NHS organisation will normally accept an existing NHS contract of employment, but

additional pre-engagement checks may be required depending on the research role undertaken and any local requirements at subsequent NHS organisations (e.g. MRSA screening). A LoA should be issued detailing the researcher's responsibilities. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations via a copy of the LoA.

#### 5.4 Pre-engagement Checks

**Researchers who do not require an HRC may require additional pre-engagement checks** to undertake permitted research activities in NHS organisations.

**Criminal Records Bureau (CRB) checks** undertaken by another NHS organisation or HEI will be accepted as part of the Research Passport Scheme as a valid pre-engagement check up to a maximum of 3 years since the last check was completed (other than for research involving children and/or vulnerable adults). Guidance on when a CRB check is required should be obtained from the HR Department.

**Researchers should complete an Occupational Health Health Assessment Form as part of the application process.** The template form shows the checks and immunisations required to be carried out by the researcher's substantive employer where applying for access to undertake research on NHS patients, staff or premises. Guidance on specific requirements for working with particular populations can be given to HEI Occupational Health staff by NHS Occupational Health departments. Occupational Health departments must be notified of new researchers employed by the organisation (or in the case of the need for additional local checks, researchers from other organisations), by Human Resources, early in the process so that appointments can be given for any checks and immunisation schedules required in good time for undertaking the research role within the NHS.

**Occupational Health screening performed by another NHS organisation or HEI** (in accordance with the *Research in the NHS – Human Resources Good Practice Resource Pack* and NHS requirements) will be accepted as part of the pre-engagement checks for *Research Passports*, *HRCs* and *LoAs* without the need to routinely repeat this, unless the specific research project requires this.

Staff should be contacted by their Occupational Health department (i.e. where they hold a substantive contract) every 3 years to check that their health status has not changed and issue an updated fit-slip. This does not need to be face-to-face contact and can be done via telephone or email. If there is a change in role, and a higher level of clearance is required the substantive employer should undertake additional checks and issue a new fit slip.

## 6. Monitoring

HEIs and NHS organisations (research or Human Resources departments, as agreed locally) will log details of checks undertaken on staff and run regular reports to ensure that such checks remain valid for the duration of the researcher's engagement. Systems should flag checks that are nearing their end date (within 3 months), or reports run monthly to show those that will expire within 3 months. Researchers should be contacted to notify them that the validity period is about to expire and give details of the reapplication process, providing required forms.

**The researcher must present updated checks to all NHS organisations** for which they have gained access. Systems should flag contracts that are nearing their end date (within 3 months) or reports run monthly to show those that will expire within 3 months.

Researchers should be contacted to notify them that the contract is about to expire and give details of the reapplication process, providing required forms.

**NHS organisations will log the details of *HRCs* and *LoAs* issued and end dates.** *HRCs* and *LoAs* should be issued for the duration of the project(s), with extensions granted should the project(s) timescale be extended. Researchers must provide evidence of updated CRB and Occupational Health clearance/checks to the NHS organisation where required to be renewed during the course of the project.

NHS Research and Development departments will log the date when applications for access are received and the issue date for *HRCs* and *LoAs* into a system(s) which can be queried for reporting turnaround timelines for applications to Human Resources, the Board and the CLRN as requested.

**HEIs and NHS organisations will log details of project start and finish dates** alongside staff working on projects. The researcher must notify their employer if the project is extended and notify all other organisations where access is required of new timelines. Reports should be generated to ensure all staff are covered by valid disclosures and clearance for the duration of the project.

The CLRN will monitor turnaround times for all organisations and any issued raised by researchers.

## **7. Definitions**

7.1 Criminal Records Bureau Checks – see Trust policy.

7.2 Clinical Negligence

Clinical negligence is defined as “a breach of duty of care by members of the health care professions employed by NHS bodies or by others consequent on decisions or judgments made by members of those professions acting in their professional capacity in the course of their employment, and which are admitted as negligent by the employer or are determined as such through the legal process”.

The term health care professional includes hospital doctors, dentists, nurses, midwives, health visitors, pharmacy practitioners, registered ophthalmic or dispensing opticians (working in a hospital setting), members of professions allied to medicine and dentistry, ambulance personnel, laboratory staff and relevant technicians.

7.3 NHS Indemnity

NHS Indemnity applies where:

- (a) The negligent health care professional was:
  - i. Working under a contract of employment and the negligence occurred in the course of that employment;
  - ii. Not working under a contract of employment but was contracted to an NHS body to provide services to persons to whom that NHS body owed a duty of care;
  - iii. Persons, not employed under a contract of employment and who may or may not be a health care professional, who owe a duty of care to the persons injured. These include locums, medical academic staff with honorary contracts; students; those conducting clinical trials’ charitable volunteers; persons undergoing further professional education, training and examinations; students and staff working on income generation projects.

NHS Indemnity does not apply to family health service practitioners working under contracts for services, e.g. GPs (including fundholders), general dental practitioners, family dentists, pharmacists or optometrists; other self employed

health care professionals e.g. independent midwives; employees of FHS practices; employees of private hospitals; local education authorities; voluntary agencies.

NHS Indemnity covers negligent harm caused to patients or healthy volunteers in the following circumstances: whenever they are receiving an established treatment, whether or not in accordance with an agreed guideline or protocol; whenever they are receiving a novel or unusual treatment which, in the judgment of the health care professional, is appropriate for that particular patient; whenever they are subjects as patients or healthy volunteers of clinical research aimed at benefiting patients now or in the future

## **8. Common Law Duty of Care**

In *tort* a duty of care exists where there is a relationship between two parties, particularly where this is a relationship of trust (e.g. between service provider and service user, doctor and patient, patient and carer, employer and employee). The leading case in the UK on this issue is *Caparo Industries Plc. V Dickman (1990) 1 All ER 568*, in which the House of Lords set out the following three-part test:

- Harm must be a “reasonably foreseeable” result of the defendant’s conduct. Foreseeable damage means that in the particular circumstances and not with the benefit of hindsight, that a hypothetical “reasonable person” would have foreseen damage (per *Roe v Minister of Health (1954) 2 AER 131*)
- A relationship of “proximity” between the defendant and the claimant
- It must be “fair, just and reasonable” to impose liability.

In order to satisfy or ‘discharge’ that duty of care an organisation must ensure that the standard of care provided meets reasonable expectations, bearing in mind generally accepted good practice standards.

## **9. Legal Duty of Quality of Care**

The Health and Social Care (Community Health and Standards) Act 2004 (Ch. 43) states that “it is the duty of each NHS body to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care provided and for that body.”

## **10. Equality Statement**

Implementation of the Research Passports Policy must comply with anti-discrimination legislation and particular care should be taken not to include unlawful discriminatory conditions or requirements in relation to age, disability, race, nationality, ethnic or national origin, gender, religion, beliefs, sexual orientation, domestic circumstances, social and employment status, HIV status, gender reassignment, political affiliation, staff organisation/trade union membership, marriage and civil partnership or pregnancy and maternity.

## **11. Audit and Monitoring**

11.1 Compliance with this policy will be monitored by the Director of Human Resources. Information will be presented to the Corporate Governance Committee on an annual basis who will identify appropriate action plans to address any areas of the process which can be improved upon and will continue to monitor any plans until completion.

11.2 Monitoring will include reporting of information from ESR and personal file audits to identify:

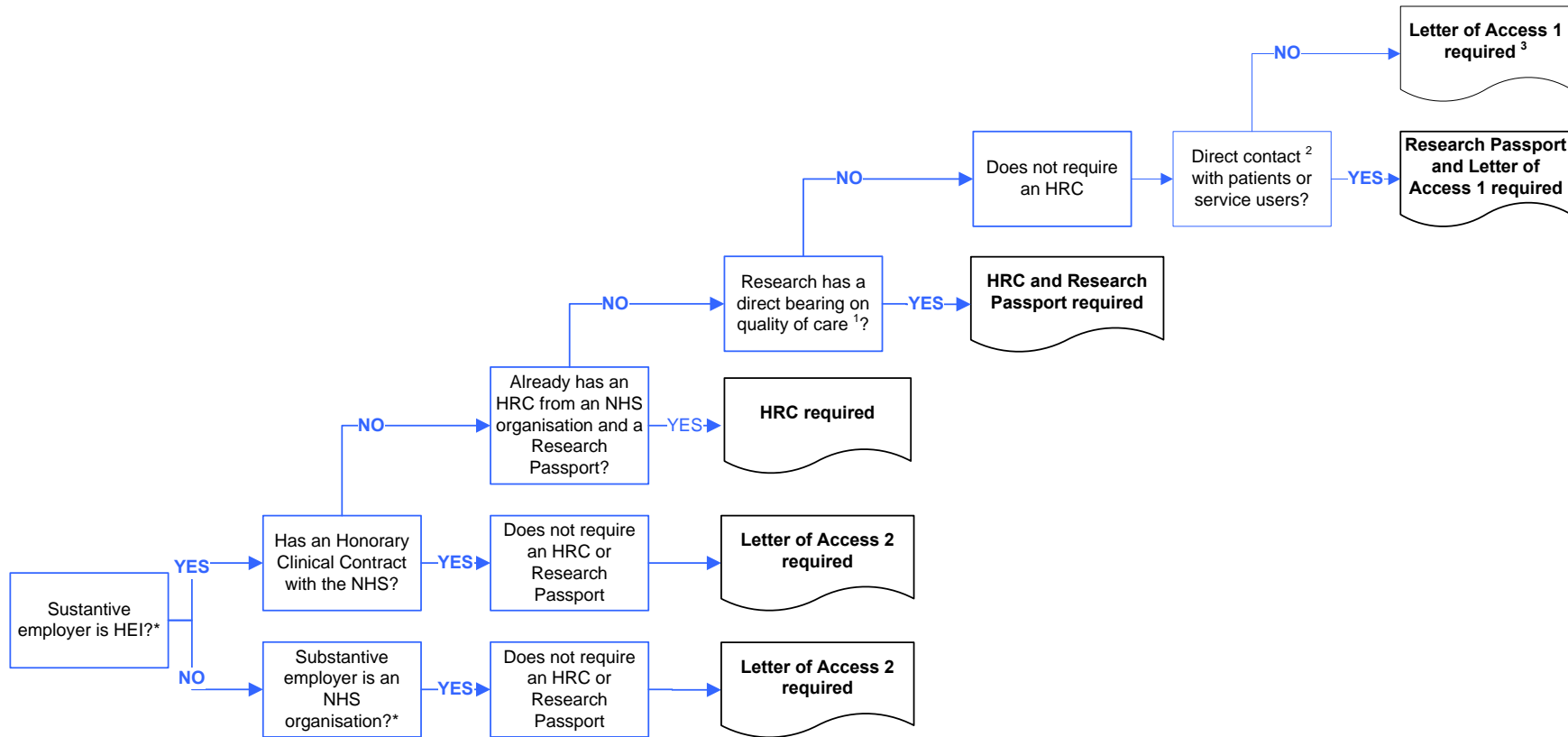
- All pre-employment checks are completed where appropriate in accordance with NHS Employment Check Standards.

## **10. Further Guidance**

For further information and guidance please contact the Research & Development Department and/or the Human Resources Department (HR Manager (Recruitment), Staff Engagement or HR Medical & Dental as appropriate).

Author: Director of Human Resources

## Appendix 1: Document Requirements - Staff



### KEY

\* For staff working for organisations other than the NHS, agreements need to be in place between organisations to allow sharing of information on staff or reimbursement of costs for checks undertaken by an NHS organisation where required. Staff can then be processed as per the HEI staff route.

<sup>1</sup> A “direct bearing on the quality of care” is where in the course of their research activity the researcher intends to 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.

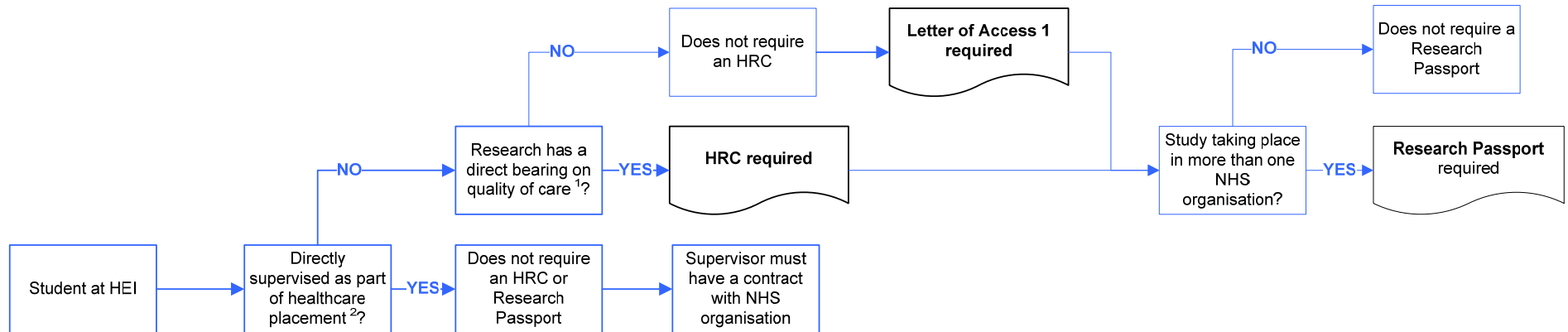
<sup>2</sup> Will have face-to-face contact

<sup>3</sup> In some situations an OH clearance is needed when working on NHS premises e.g. lab.

Letter of Access 1 – for researchers who do not require an HRC

Letter of Access 2 – for NHS Researchers

## Appendix 2: Document Requirements - Students



### KEY

<sup>1</sup> A “direct bearing on the quality of care” is where the researcher intends to 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.

<sup>2</sup> Undergraduate and postgraduate students working within the NHS (healthcare placements or research) are expected to be supervised within the clinical setting. The supervisor should be an appropriately qualified person with an NHS substantive employment contract, honorary clinical contract or honorary research contract.

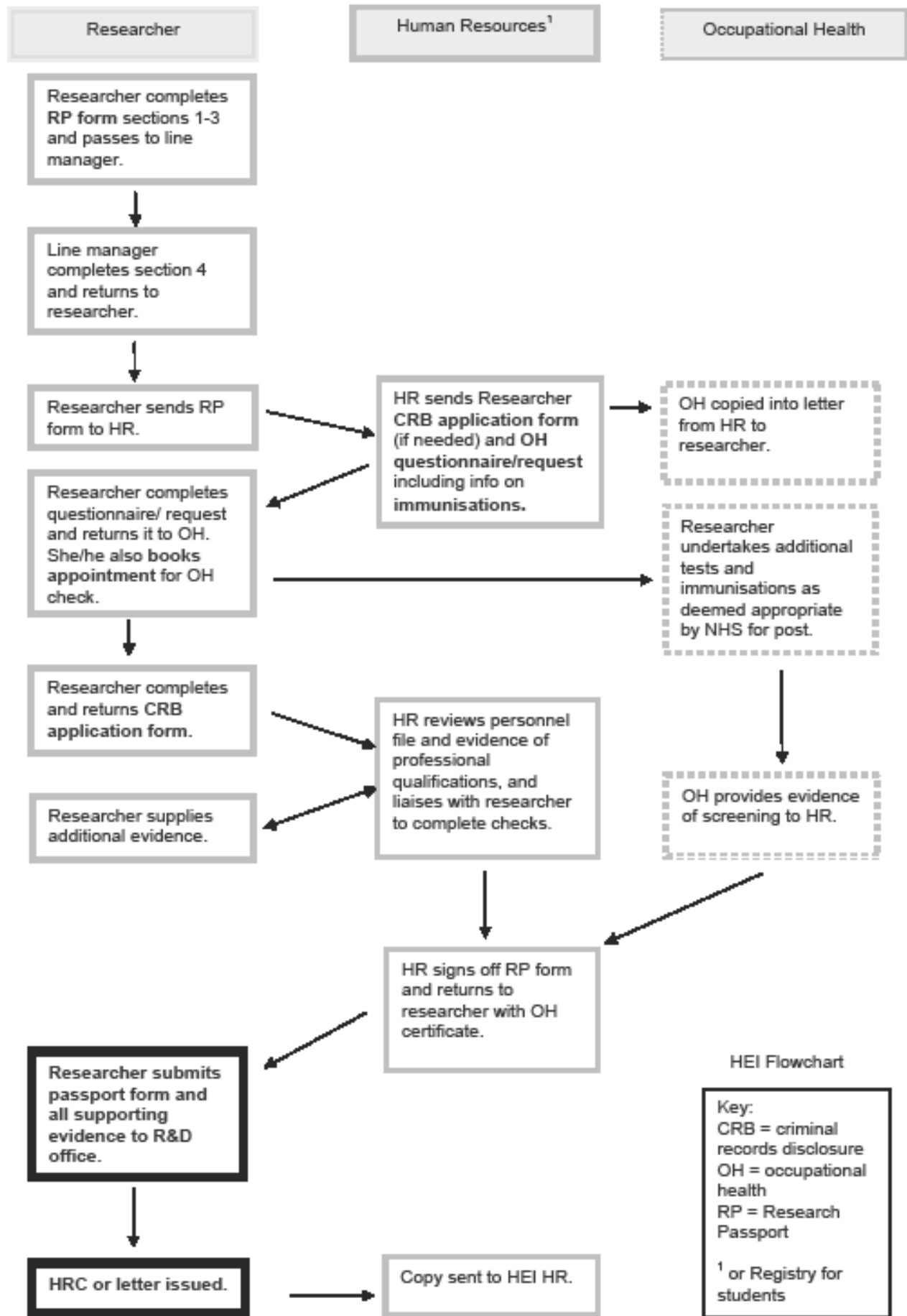
Postgraduate students that are appropriately clinical qualified and experienced should be treated as researchers. If they do not have a contractual relationship with the NHS, they should obtain an honorary research contract or letter of access depending on whether they have direct contact with patients and/or direct bearing on patient care.

HRC – Honorary Research Contract

Letter of Access 1 – for researchers who do not require an HRC

### Appendix 3: HEI Flowchart

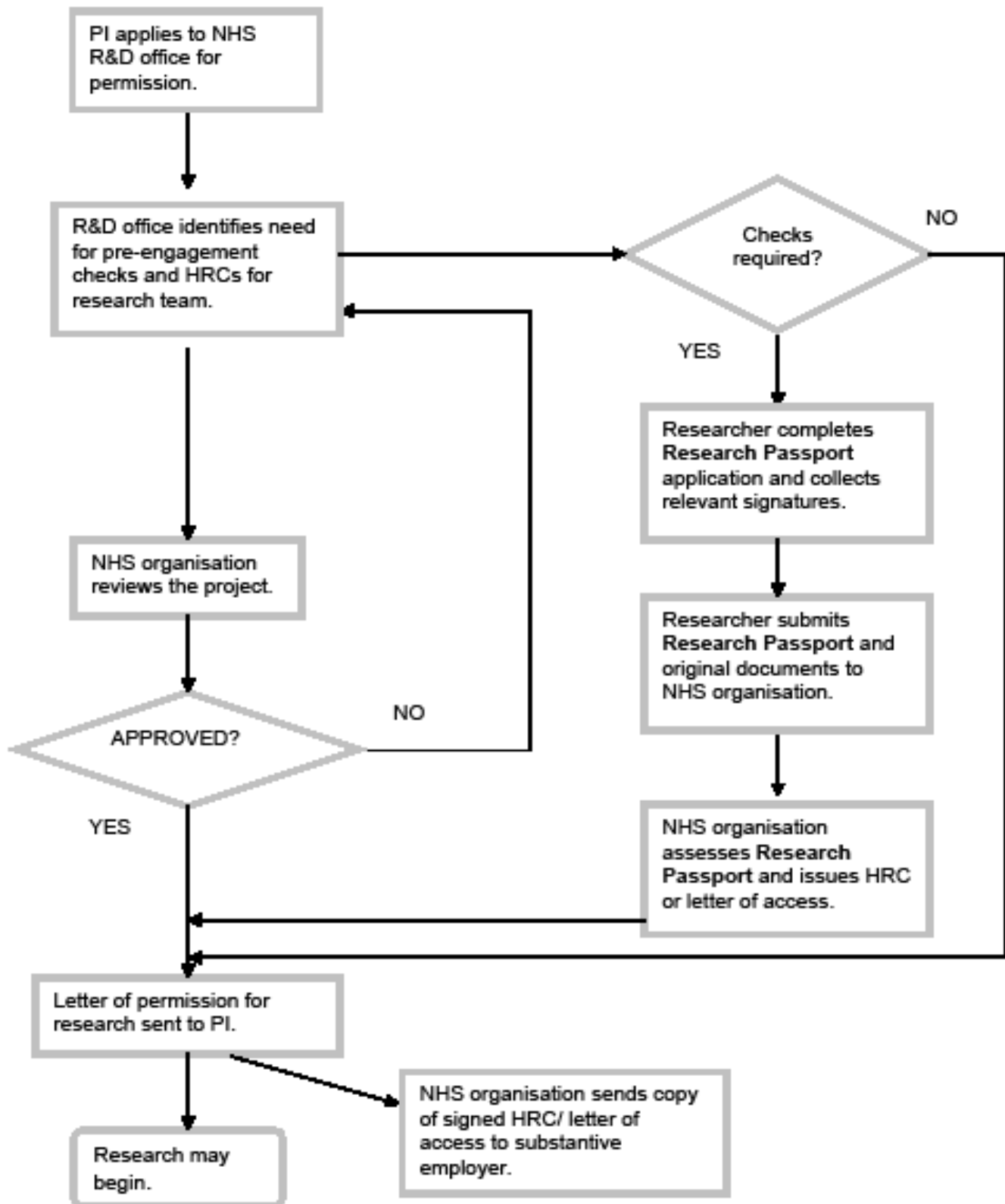
[from *Research in the NHS – HR Good Practice Resource Pack*.



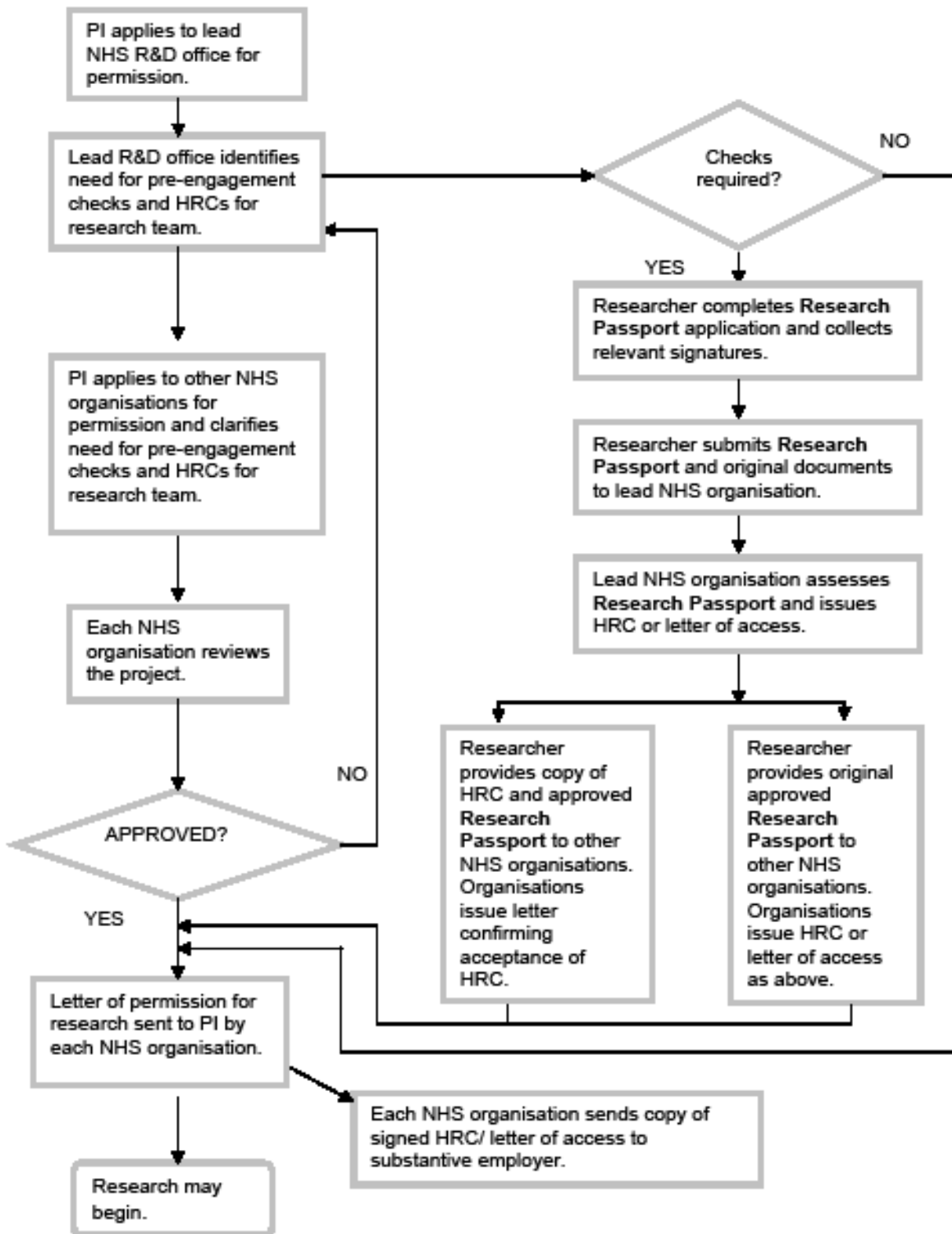
## Appendix 4: NHS Flowchart

[from *Research in the NHS – HR Good Practice Resource Pack*.

### Research at a single site



**Research at more than one site**



**Key:**  
HRC = honorary research contract

## Appendix 5: Process for Applying for Access to Undertake Research in the NHS

### HEI Staff Research Passport Scheme Application Process CLRN

Step	Who	Task
1	Researcher	Complete section 1 of the <i>Research Role Assessment Form</i> (appendix 6) and make contact with Research Passport Lead for employer.
2	HEI Research Passport Lead	<p>Assess Research Role Assessment Form and project details for requirement for <i>Research Passport/HRC/LoA</i>, CRB check (including level and additional checks) and Occupational Health clearance using Appendices 1-2. Gain advice from NHS Human Resources if not clear.</p> <p>If applicable, get researcher to complete a CRB disclosure application form and request CRB.</p> <p>If applicable, get researcher to complete <i>Occupational Health Assessment Questionnaire</i> (minimum standard - appendix 8), send to Occupational Health department and send researcher for Occupational Health checks as required.</p>
3	Researcher	<p>If requested by Research Passport Lead, complete sections 1-3 of <i>Research Passport Application Form</i> and the <i>Appendix</i> (appendix 7) and take form to academic supervisor or line manager.</p> <p>If requested, complete <i>Occupational Health Assessment Questionnaire</i> (minimum standard - appendix 8) and attend Occupational Health department for checks and immunisations as required for research role.</p>
4	Academic Supervisor/ Line Manager	If requested by Researcher, complete section 4 of <i>Research Passport Application Form</i> and send to Human Resources.
5	HEI HR	Complete section 5 of <i>Research Passport Application Form</i> .
6	HEI OH or contracted OH service	Review <i>Occupational Health Assessment Questionnaire</i> sent by Human Resources and undertake checks and immunisations as needed for required level of clearance. Issue a fit slip containing details of clearance level to HEI Human Resources.
7	HEI HR	Forward returned documents (application form and fit slip) to researcher, keeping copies.
8	Researcher	Complete section 6 of <i>Research Passport Application Form</i> and attach documents as applicable (e.g. CRB disclosure certificate, ISA registration number, professional registration, fit slip).

9	Researcher	<p>Take all required documents to Research Passport Lead in NHS organisation to apply for access.</p> <p>If a Research Passport is required, the first NHS organisation will validate the <i>Research Passport</i>.</p>
10	NHS Research Passport Lead	<p>Review documents submitted by researcher for completeness and appropriate level of checks/clearance for role. Send copies of documents to Human Resources with a request for contract required (<i>HRC</i> or <i>LoA</i>).*</p>

\* Documents can be issued by Research & Development Department if delegated by Human Resources

Step	Who	Task
11	NHS Human Resources*	<p>Review documentation submitted for appropriate level of CRB check (if required), professional registration and Occupational Health clearance (gain advice from Occupational Health where needed). Request further information through Research Passport Lead. Issue <i>HRC</i> or <i>LoA</i> as appropriate, copying in substantive employer Human Resources and Research &amp; Development Department.*</p> <p>Request additional local checks required by organisation (i.e. those over and above national requirements) from Occupational Health and notify researcher of need.</p>
12	NHS Human Resources/Research & Development	<p>Complete section 7 of <i>Research Passport Application Form</i> if additional checks undertaken.</p> <p>Complete section 8 of <i>Research Passport Application Form</i> to validate <i>Research Passport</i>.</p> <p>Issue <i>HRC</i> or <i>LoA</i>.</p>
13	Researcher	Take validated <i>Research Passport Application Form</i> along with other required documents to subsequent NHS organisations where applying for access.
14	Researcher	<p>If there are changes to the projects listed on the <i>Research Passport Application Form</i>, amend <i>Appendix</i> form.</p> <p>If there is a change to tasks undertaken/role, seek advice from HEI Research Passport Lead on any additional requirements (CRB, Occupational Health and contracts). Present any changes and new documents to all NHS organisations in which role has changed.</p> <p>If you are arrested (on any charge), are served a summons on a criminal charge, or there is a change in your health status you must notify your employer.</p>
15	HEI Human Resources	If changes to researcher status (disclosures or health), notify Human Resources at all NHS organisations where researcher is working.
16	HEI Research Passport Lead	Monitor end/renewal dates for checks, clearance and contracts. Request renewals in collaboration with researcher and Human Resources

\* Documents can be issued by Research & Development Department if delegated by Human Resources

## NHS Staff Research Passport Scheme Application Process

Step	Who	Task
1	Researcher	Complete section 1 of the <i>Research Role Assessment Form</i> (appendix 6) and make contact with Research Passport Lead for employer.
2	NHS organisation Research Passport Lead	<p>Assess <i>Research Role Assessment Form</i> and project details for requirement for CRB check (including level and additional checks) and OH clearance.</p> <p>Check with Human Resources department if CRB is in place at appropriate level (if required) and OH clearance of sufficient level for research role. If applicable, get researcher to complete a CRB disclosure application form and request CRB.</p>
3	NHS organisation Human Resources	<p>Request CRB where none in place or not of sufficient level where appropriate.</p> <p>Ask Researcher to complete the <i>Occupational Health Assessment Questionnaire</i> (minimum standard - Appendix 8) where full details not available in records and send researcher for Occupational Health checks and immunisations as required for research role.</p>
4	Researcher	If requested, complete <i>Occupational Health Assessment Questionnaire</i> and attend Occupational Health department for additional checks and immunisations as required for research role.
5	NHS organisation Occupational Health or contracted Occupational Health service	Review <i>Occupational Health Assessment Questionnaire</i> if presented and undertake checks and immunisations as needed for required level of clearance. Issue a fit slip containing details of checks and clearance level to NHS organisation Human Resources.
6	NHS HR/R&D	Complete section 2 of <i>Research Role Assessment Form</i> and attach fit slip if relevant.
7	Researcher	Collate form and relevant documents (CRB disclosure certificate, professional registration and fit slip) and present to NHS Research Passport Lead in other NHS organisations where applying for access.
<b>Following tasks to be completed by other NHS organisation i.e. where not substantial employer of researcher requesting access</b>		
8	NHS Research	Review documents submitted by researcher for completeness and appropriate level of checks/clearance for role. Send copies of

	Passport Lead	documents to Human Resources with a request for <i>LoA</i> .*
9	NHS Human Resources	<p>Review documentation submitted for appropriate level of CRB, professional registration and Occupational Health clearance (gain advice from Occupational Health where needed). Request further information through Research Passport Lead. Issue <i>LoA</i>, copying in substantive employer Human Resources and Research &amp; Development Department.*</p> <p>Request additional local checks required by organisation (i.e. those over and above national requirements) from Occupational Health and notify researcher of need.</p>
10	Researcher	Attend Occupational Health Department if requested, to undertake additional local checks.

\* Documents can be issued by Research & Development Department if delegated by Human Resources

Step	Who	Task
11	Researcher	<p>If there are changes to the projects listed on the <i>Research Role Assessment Form</i>, notify all NHS organisations where have a <i>LoA</i> in writing.</p> <p>If there is a change to tasks undertaken/role, seek advice from local Research Passport Lead on any additional requirements (CRB, ISA and Occupational Health). Present any changes and new documents to all NHS organisations in which role has changed.</p> <p>If you are arrested (on any charge), are served a summons on a criminal charge, or there is a change in your health status you must notify your employer.</p>
12	NHS Human Resources	If changes to researcher status (disclosures or health), notify Human Resources at all NHS organisations where researcher is working.
13	NHS Research Passport Lead	Monitor end/renewal dates for checks, clearance and <i>LoA</i> . Request renewals in collaboration with researcher and Human Resources

## Appendix 6: CLRN Research Role Assessment Form

### Research Role Assessment Form

#### Section 1 - To be completed by researcher

<b>Name:</b>		<b>Date of birth:</b>	
<b>Post title:</b>			
<b>School/Institute/ Directorate</b>			
<b>Contact address:</b>			
<b>Email address:</b>		<b>Tel no.:</b>	
<b>Professional reg. no.:</b> *		<b>ISA reg. no.:</b>	

**Research Categories** Please tick all that apply to your work, or will do during course of current project(s)

√	<b>Description of research</b>
	Direct contact with patients/service users and direct bearing on the quality of their care (not children or vulnerable adults)
	Direct contact with children and direct bearing on the quality of their care
	Direct contact with children but <b>no</b> direct bearing on the quality of their care
	Direct contact with vulnerable adults and direct bearing on the quality of their care
	Direct contact with vulnerable adults but <b>no</b> direct bearing on the quality of their care
	Direct contact with patients/service users, but no direct bearing on the quality of their care (e.g. observer)
	Indirect contact with patients/service users and direct bearing on the quality of their care (e.g. some types of telephone interviews)
	Indirect contact with patients/service users, but no direct bearing on the quality of their care (e.g. telephone interviews, postal questionnaires)
	Access with consent to identifiable patient data, tissues or organs with likely direct bearing on the quality of their care
	Access with consent to identifiable patient data, tissues or organs, but no direct bearing on the quality of their care
	Access without consent to identifiable patient data, tissues or organs, but no direct bearing on the quality of their care
	Access to anonymised patient data, tissues or organs only (including by research staff analysing data)
	Working on NHS premises (e.g. laboratory work) only
	Direct contact with staff (e.g. interviews)

	Access to identifiable staff data
	Access to anonymised staff data only
Give brief description of role:	

Where relevant I consent to details relating my current CRB and Occupational Health checks being provided by my employer to the appropriate NHS organisation to confirm details as necessary to assist with an assessment of my suitability to undertake the research category given above.

**Signed:**

**Date:**

Project Title	Start Date	End Date	NHS Manager

**HEI staff with no contract with the NHS should now complete the Research Passport Application Form and meet with the HEI research services department**

**NHS staff should now complete section 2 below.**

**Section 2 – To be completed by NHS employer for NHS staff only**

<b>For completion by Line Manager:</b>	
I confirm that the above information is correct	
Signed:	Date:
Print name:	Job Title:
<b>Date employed:</b>	<b>Date contract ends:</b>
<b>CRB check level:</b>	<input type="checkbox"/> Standard <input type="checkbox"/> Enhanced
<b>Checked for working with children?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Checked for working with vulnerable adults?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Date of Disclosure:</b>	<b>Ref no.:</b>
<b>Comments:</b>	
<b>Comments:</b>	

**Signed:**

**Date:**

<b>Print name:</b>	
<b>Post title/designation:</b>	
<b>Employers stamp:</b>	

## Appendix 7: Research Passport Application Form and Passport Appendix

[Completion guidelines available in *Research in the NHS – Human Resources Good Practice Resource Pack* Current version of Pack available at:  
[www.nihr.ac.uk/systems/Pages/systems\\_research\\_passports.aspx](http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx)]

### Research Passport Application Form

To be completed for all HEI staff (i.e. those with no substantive contract with the NHS) wishing to carry out research in an NHS organisation. This form and the attached documents will form your application for a Research Passport, Honorary Research Contract or Letter of Access, whichever is applicable to your role.

<b>Section 1 - Details of Researcher</b>				
<i>To be completed by Researcher</i>				
1.	Surname:		Prof <input type="checkbox"/> Dr <input type="checkbox"/> Mr <input type="checkbox"/> Mrs <input type="checkbox"/>	
	Forename(s):		<input type="checkbox"/>	
	Home Address:			
	Work Address/Place of Study:			
	Work Tel:	Mobile:	Email:	
2.	Date of birth:	Gender: Male <input type="checkbox"/> Female <input type="checkbox"/>		
	Ethnicity:	National Insurance number:		
3.	Professional registration details (if applicable): N/A <input type="checkbox"/>			
4.	Employer :		or place of study:	
	Name of School/Institute/Directorate:			
	Post or status held:			
<b>Section 2 - Details of Research</b>				
<i>To be completed by Researcher</i>				
5.	What type of Research Passport do you need? Project-specific <input type="checkbox"/> Three-year <input type="checkbox"/>			
	<i>If you will be conducting only one project please complete the details below. If you will be undertaking more than one project at any one time, please give details in the</i>			
	Project Title:			
	Project Timetable: Start Date:		End Date:	
	NHS organisation(s):	Dept(s):	Proposed research activities:	Manager in NHS
<b>Section 3 – Declaration by Researcher</b>				
<i>To be completed by Researcher</i>				

6.	Have you ever been refused an honorary research contract?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Have you ever had an honorary research contract revoked?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	If yes to either question, please give details:	
I consent to the information requested in this Research Passport (including attached documents) being processed and held by authorised staff of the NHS organisations where I will be conducting research.		
Signed:		Date:
<i>When Sections 1-3 have been completed, the researcher should forward the form to the appropriate person to complete Section 4.</i>		
<b>Section 4 - Suitability of Researcher</b>		
<i>To be completed by researcher's substantive employer, e.g. line manager, or academic supervisor</i>		
7.	Date employed:	Date contract ends:
	I am satisfied that the above named individual is suitably trained and experienced to undertake the duties associated with the research activities outlined in this Research Passport form.	
	Signed:	Date:
	Name:	Job Title:
	Organisation:	Department:
	Address:	
	Email:	
	<i>When Section 4 has been completed, the researcher should forward the form to the appropriate person to complete Section 5.</i>	
<b>Section 5 - Pre-engagement checks</b>		
<i>To be completed by the Human Resources department of the researcher's substantive employer or registry at place of study</i>		
8.	Can you confirm that a clear CRB Disclosure has been obtained for the above named individual, with no subsequent reports from the individual of changes to this record?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
		Comments:

<i>If yes, please provide details of the clear disclosure</i>	
Date of disclosure:	CRB Ref No.:
Type of disclosure: Standard <input type="checkbox"/>	Enhanced <input type="checkbox"/>
Checked for working with children	Yes <input type="checkbox"/> No <input type="checkbox"/>
Checked for working with vulnerable adults	Yes <input type="checkbox"/> No <input type="checkbox"/>
Organisation that requested disclosure:	
9. Have the pre-engagement checks described below been carried out with regard to the above-named individual?	
<ul style="list-style-type: none"> <li>▪ Employment/student screening: <ul style="list-style-type: none"> <li>○ ID with photograph</li> <li>○ two references</li> <li>○ verification of permission to work/study in the UK</li> <li>○ exploration of any gaps in employment</li> </ul> </li> </ul>	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
▪ Evidence of current professional registration	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
▪ Evidence of qualifications	Yes <input type="checkbox"/> No <input type="checkbox"/>
▪ Occupational health screening	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Signed:	Date:
Name:	Job Title:
Organisation:	Department:
Address:	
Email:	
<i>Please return the form to the researcher.</i>	

<b>Section 6 - Instructions to applicants</b>	
<i>To be completed by Researcher</i>	
<i>Please indicate which of the following documents are attached to this Research Passport:</i>	
Current curriculum vitae, including details of qualifications, training and professional registration (please use the template C.V. at <a href="http://www.rdforum.nhs.uk/docs/template_cv.doc">http://www.rdforum.nhs.uk/docs/template_cv.doc</a> )	Yes <input type="checkbox"/> No <input type="checkbox"/>
Researcher's copy of criminal record disclosure (if question 8 is answered Yes)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Evidence of occupational health screening	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

Appendix	Appendix numbers:  N/A <input type="checkbox"/>
----------	---

*Please send the completed form and original documents to the lead Research & Development office. The completed form and original documents will be returned to you. This package of documents will form your completed Research Passport. You may, where relevant, provide the Research Passport to other NHS organisations.*

**You must inform all NHS organisations that have received this Research Passport of any changes to the information supplied above. Failure to do so may result in withdrawal of your honorary research contract or letter of access. As part of the quality control procedures for the Research Passport, random checks on the accuracy of the information held on this Research Passport may be made.**

**Section 7**

**This section should be completed by Human Resources in the lead NHS organisation, only if additional checks are undertaken**

Having undertaken the necessary additional pre-engagement checks, I am satisfied that the above named researcher is suitable to carry out the duties associated with their research activity outlined in this Research Passport.

Signed:	Date:
Name:	Job Title:
Organisation:	Department:
Email:	

**Section 8 - For Office Use Only**

*This section should be completed by the NHS Research & Development office that received the initial application. The NHS Research & Development office must countersign and date retained photocopies of the documents. The grey section must be completed before returning the form to the applicant.*

CV reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Training?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Evidence of qualifications?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Appendix pages reviewed?	Numbers:
Registration details reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	Occupational health evidence reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Criminal record disclosure reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	Date of disclosure:	Certificate No:

Enter Electronic Staff Record Number (if issued):

Valid Research Passport issued: Project specific  Three-year

Signed:	Date:
---------	-------

Name:
-------

Date Honorary Research Contract/letter of access issued (*delete as appropriate*)

*This section should be completed by the NHS Research & Development office receiving the valid Research Passport. The NHS Research & Development office must countersign and date retained photocopies of the documents. The original Research Passport and documents should be returned to the applicant.*

CV reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Training?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Evidence of qualifications?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Appendix pages reviewed?	Numbers:
Registration details reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	Occupational health evidence reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Criminal record disclosure reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	Date of disclosure:	Certificate No:
		Checked Electronic Staff Record:	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

Signed:		Date:
Name:		
Date Honorary Research Contract/letter of access issued ( <i>delete as appropriate</i> )		

**Passport Appendix. List of projects and amendments**

Appendix Number:

If you are applying for a three-year Research Passport, please use this section to enter details of projects and activities that will be covered by this Research Passport. Once you have a complete Research Passport, you may add details of subsequent projects during the three years that this Research Passport is valid.

If you are applying for a project-specific Research Passport, but need to subsequently add further sites to the project, please enter the details below.

Whenever you add further details, the full Research Passport and accompanying documents must be submitted to the relevant NHS organisations.

Title:		Start Date:	End Date:
NHS organisation(s):	Dept(s):	Proposed research activities:	Manager in NHS organisation:

**Amendments to the Research Passport**

Please state what these are, e.g. they might be a change in name or employment details, or a change in research activities.

Please check with the NHS organisation where you are undertaking your research if you are unsure whether you will need a new Research Passport.

Date	Old Details	New Details	Office use only NHS R&D signature

**To add more projects please copy this page or download further blank pages.  
Each appendix page should be numbered.**

*For office use only:*

*A photocopy of the appendix should be retained whenever any amendments or additions to the appendix are made.*

## Appendix 8: Occupational Health Assessment Questionnaire

[This template taken from *Research in the NHS – Human Resources Good Practice Resource Pack* is the minimum standard expected. Current version of Pack available at: [www.nihr.ac.uk/systems/Pages/systems\\_research\\_passports.aspx](http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx)]

### Occupational Health Assessment Questionnaire

*This form contains confidential medical information and must not be copied or forwarded to anyone outside the occupational health service of the researcher's substantive employer/place of study. Only with the researcher's consent may any confidential information about the researcher be discussed with the occupational health service of NHS organisations where the researcher wishes to conduct research.*

The purpose of this health assessment is to ensure, so far as is possible, that you are fit for the research activities you will be undertaking in order to protect your own and others' health and safety.

Questions are asked about your past and present health, medical treatment and any impairment which may have implications for health and safety.

If you have any difficulties completing this form or wish to discuss any issues in a confidential setting please contact the occupational health department for advice.

Surname:		Prof <input type="checkbox"/> Dr <input type="checkbox"/> Mr <input type="checkbox"/> Mrs <input type="checkbox"/>
Forename(s):		Miss <input type="checkbox"/> Ms <input type="checkbox"/> Other <input type="checkbox"/>
Work Address/Place of Study:		
Tel:	Mobile:	Email:
Date of birth:	Gender: Male <input type="checkbox"/> Female <input type="checkbox"/>	

### BRIEF DESCRIPTION OF RESEARCH ACTIVITIES:

(This will enable our occupational health advisers to assess the health risk involved with your research)

1. During your research activity will you be involved in the following:	
a) Direct contact with patients/service users?	Yes <input type="checkbox"/> No <input type="checkbox"/>
b) Direct contact with children?	Yes <input type="checkbox"/> No <input type="checkbox"/>
c) Direct contact with vulnerable adults?	Yes <input type="checkbox"/> No <input type="checkbox"/>
d) Working with or direct contact with patient	Yes <input type="checkbox"/> No <input type="checkbox"/>

tissues/organs?	
2. Will you be undertaking exposure-prone procedures (EPP)*?	Yes <input type="checkbox"/> No <input type="checkbox"/>
3. Will you be at risk of exposure to blood-borne viruses?	Yes <input type="checkbox"/> No <input type="checkbox"/>

---

\* EPPs are those invasive procedures where there is a risk that injury to the worker may result in exposure of the patient's open tissues to the blood of the worker. These include procedures where the worker's gloved hands may be in contact with sharp instruments, needle tips or sharp tissues (e.g. spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times.

## VACCINATION HISTORY

Please give details of vaccinations and tests you have had. Where possible, give dates and results.

Immunisation History		
1a	Rubella vaccination (German measles)	Date:
1b	Rubella screening	Date:
		Result:
2a	Hepatitis B vaccinations	Date: (1)
		Date: (2)
		Date: (3)
2b	Hepatitis B booster	Date:
2c	Hepatitis B antibody screening	Date:
		Result:
3a	Heaf, Mantoux or Tine test (TB test)	Date:
3b	BCG (TB vaccination)	Date:
4	Polio booster	Date:
5	Tetanus booster	Date:
6	Varicella (chickenpox) screening	Date:
		Result:
7	Measles vaccination	Date:
8	Other	Date:

## DECLARATION OF HEALTH

1. Do you currently have any health problems, including psychological problems, or are you awaiting surgery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2. Are you presently receiving any prescribed medication, treatment or therapy except contraception?	Yes <input type="checkbox"/> No <input type="checkbox"/>
3. How many days off sick have you had over the past two years?	
4. Do you have any health or psychological condition that may affect your ability to perform the proposed research activity?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5. Do you have any health condition caused or made worse by work?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6. Do you have any disability or other health condition not mentioned above that may require additional help or support to perform the research activity?	Yes <input type="checkbox"/> No <input type="checkbox"/>

If you have answered 'yes' to any of the above, please give details including dates and how it affects you now. Continue on a separate sheet if necessary.

Question	Further details

## DECLARATION

The information in this form is true and complete. I agree that any deliberate omission, falsification or misrepresentation in the form may be grounds for rejecting this application and/or subsequent disciplinary action.

I consent to relevant health information about me being shared between the occupational health service of my employer/place of study and the occupational health service of any NHS organisations where I wish to undertake research activities. I hereby agree to inform the occupational health service of my employer/place of study and of any NHS organisations where I will be conducting research activities of any changes in my health circumstances that may affect my ability to perform the research activity.

I understand my responsibility to notify the occupational health service of my employer/place of study and of any NHS organisations where I will be conducting research activities if I think I have had significant exposure to, or am carrying, a serious communicable condition such as Hepatitis B, Hepatitis C or HIV and to follow advice from a consultant in occupational health or another suitably qualified colleague about treatments and/or modifications to my practice.

I understand the importance of routine infection-control procedures, including the importance of hand hygiene, appropriate use of protective clothing and compliance with local policies in the NHS organisations where I wish to undertake research activities.

Signed:	Date:
---------	-------

## **Appendix 9: HRC Cover Letter and HRC**

[Taken from *Research in the NHS – Human Resource Good Practice Resource Pack*.

Human Resources Department

Date:

Dear *(insert name of researcher)*

### **Honorary research contract issued by The Newcastle upon Tyne Hospitals NHS Foundation Trust**

I am pleased to offer you an honorary research contract in **[The Newcastle upon Tyne Hospitals NHS Foundation Trust]**. I should be grateful if you would sign the attached three contracts, keep one yourself and return the other two to **[insert address]**. We will send a copy of the contract to your substantive employer.

The contract if accepted by you begins on **[insert date]** and ends on **[insert date]** unless terminated earlier in accordance with the clauses in the contract. Please note that you cannot start the research until the Principal Investigator has received a letter from us giving permission to conduct the project.

We will not reimburse any expenses you incur in the course of your research unless we have agreed to do so by prior arrangement. Similarly, we accept no responsibility for damage to or loss of personal property.

Your Research Passport may be subject to random checks carried out by us within the lifetime of the project. The information it contains must therefore remain up to date and accurate.

If your circumstances change in relation to your health, criminal record, professional registration or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform your employer through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Once you have signed and returned two of the attached contracts, you should contact the Human Resources/Research & Development Department **[delete as appropriate]** of this organisation, who will arrange for you to be issued with an ID badge.

Yours sincerely

### **Senior HR Manager/HR Manager Recruitment**

**cc: Research & Development office, The Newcastle upon Tyne Hospitals NHS Foundation Trust**

**Human Resources Department of the substantive employer**

## Honorary Research Contract

***A copy of the signed honorary research contract must be sent to the substantive employer/academic supervisor. Where relevant, "Trust" or "PCT" should be replaced by "Board"***

<b>HONORARY RESEARCH CONTRACT BETWEEN</b>	
<b>The Newcastle upon Tyne Hospitals NHS Foundation Trust</b>	
<b>AND</b>	
Name: Employer: OR Place of Study: Report To: (Principal Investigator/Head of Department)	
<b>PERIOD of AGREEMENT</b>	
From:	To:
OR	
Fixed term _____ years contract for: _____ months	Effective Date:
<b>SIGNATURES</b>	
Researcher:	Date:
Name:	
On behalf of the NHS organisation(s)	Date:
Name:	

## **Whereas**

A. The Researcher named in this Agreement (“the Researcher”) is employed by the employing organisation named in this Agreement (“the Employer”) to undertake research, during the course of which the Researcher requires access to the Trust(s) named in this Agreement (“the Trust(s)”), their premises, patients, their clinical samples, and clinical and personal information (“the Facilities”). Where independent contractors and their premises are involved with research activity, the Agreement is issued by the host PCT on behalf of the independent contractors.

## **OR**

The Researcher named in this Agreement (“the Researcher”) is studying at the place of study named in this Agreement (“the Place of Study”) to undertake research, during the course of which the Researcher requires access to the Trust(s) named in this Agreement (“the Trust(s)”), their premises, patients, their clinical samples, and clinical and personal information (“the Facilities”). Where independent contractors and their premises are involved with research activity, the Agreement is issued by the host PCT on their behalf of the independent contractors.

B. The Trust(s) provide healthcare services to NHS patients, including patients who are protected by the criminal record disclosure arrangements.

C. The Trust(s) and Researcher have entered into this agreement whereby the Researcher can have access to the Facilities of the Trust(s) to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation, subject to the conditions below.

### **1. Status**

The title and status of this Honorary Research Contract does not create an employment relationship and attracts no remuneration from the Trust(s). Its award will be subject to: a satisfactory criminal record disclosure if the research includes the categories of patients who are included in the criminal record disclosure arrangements of the Trust; confirmation of registration with the GMC or other appropriate professional body if the Researcher is required to maintain such professional registration; and confirmation that the Researcher’s health does not constitute a risk to patients of the Trust(s), employees of the Trust(s) or visitors to the Trust(s).

### **2. Reporting Arrangements**

The Researcher shall report to the Principal Investigator/Head of Department named in this Agreement whilst conducting research under this Agreement.

### **3. Policies and Procedures**

3.1. The terms and conditions of employment of the Researcher including applicable policies and procedures are determined by the Employer and the Researcher will be carrying out duties at the Trust(s) in accordance with the contract of employment with the Employer

## **OR**

The rules governing the Researcher's period of study including applicable policies and procedures are determined by the Place of Study and the Researcher will be carrying out duties at the Trust(s) in accordance with those rules.

- 3.2. In carrying out research under the terms of this Agreement, the Researcher agrees to act at all times in accordance with the policies and procedures of the Trust(s) including the Research Governance Framework, copies of which are available upon request.
- 3.3. The Researcher is required to co-operate with the Trust(s) in discharging relevant duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of himself/herself and others while on the premises of the Trust(s). The Researcher must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and the premises as is expected of any other contract holder and must act appropriately, responsibly and professionally at all times.
- 3.4. The Researcher agrees to accept any variation to this Agreement necessitated by changes to research and development guidance issued by the Department of Health.
- 3.5. In the event of sickness or unavoidable absence, the Researcher must notify her/his line manager and/or the Trust(s) immediately. The Researcher must report any accident or injury, arising out of or in the course of her/his activities at the Trust(s) and make appropriate records and statements as required
- 3.6. Adverse events or incidents arising from the research should be reported immediately in compliance with the policies of the Trust(s).

#### **4. Confidentiality**

Information concerning the Facilities is confidential and must not be disclosed under any circumstances. The Researcher must treat all material connected with her/his presence in the Trust(s) in accordance with the NHS Confidentiality Code of Practice and the Data Protection Act 1998 (which covers information concerning individuals stored in any systems belonging to the Trust(s)). Unauthorised disclosure could lead to prosecution under the terms of the Act.

#### **5. Legal Claims**

- 5.1. The Trust(s) agrees/agree to indemnify the Researcher for any claims in negligence in respect of those patients of the Trust(s) to whom the Researcher provides care and treatment when performing duties in accordance with this Agreement.
- 5.2. The Trust(s) takes/take no responsibility for any claims against the Researcher arising from her/his negligent acts or omissions in undertaking agreed programmes of research using the Facilities of the Trust(s) where these are covered by warranties or conditions of any third party contracts signed by the Employer/Place of Study.
- 5.3. The Researcher is therefore advised either to ensure that the Employer/Place of Study maintains adequate indemnity arrangements or, if not, maintains membership

of her/his medical defence organisation or has other professional indemnity arrangements in place before starting to use the Facilities of the Trust(s).

- 5.4. The Trust(s) accepts/accept no responsibility for damage to or loss of the Researcher's personal property.
- 5.5. The Trust(s) accepts/accept no legal liability in respect of any decision it/they may take to terminate this contract pursuant to section 9 below.

## **6. Complaints and misconduct**

- 6.1. The Researcher should raise any complaints against the Trust(s) with the Employer/Place of Study.
- 6.2. Complaints or allegations against the Researcher will be dealt with in accordance with the policies and procedures of the Employer/Place of Study. Partnership between the Trust(s) and the Employer/Place of Study will be assured.
- 6.3. The Researcher agrees to comply with any requests for data, information or documents from the Trust(s) or the Employer/Place of Study as part of any investigation of a complaint or of suspected misconduct.

## **7. Intellectual Property**

The Trust(s) is/are required by the Department of Health to protect and manage intellectual property arising from Research and Development funded by the NHS. The Trust(s) has/have arrangements in place with the Employer/Place of Study relating to ownership and exploitation of intellectual property. All intellectual property outputs from the Researcher's research activity in the Trust(s), both commercially and non-commercially exploitable, should be declared to the Research and Development office of this NHS organisation for our records, e.g. peer-reviewed papers or patents.

## **8. Audit**

The Researcher agrees that all research undertaken by him/her may be subject to audit and/or monitoring. The Trust(s) will ensure that all data, records and other materials are kept confidential. The Researcher also agrees that the information about her/his research activity may be listed by the Trust(s) on relevant national databases and incorporated into the Annual Research Report of the Trust(s). This Agreement will be subject to random checks as part of the research and development audit activity of the Trust(s).

## **9. Duration and Termination**

- 9.1. The Trust(s), the Researcher or the Employer/Place of Study may request that this Agreement is reviewed in order to confirm the Researcher's status as a Researcher.
- 9.2. Subject to 9.3 below, the Trust(s) reserves/reserve the right to terminate this Agreement upon giving one month's written notice.
- 9.3. In the event that the Researcher fails to comply with the requirements of this Agreement, the Trust(s) reserves/reserve the right to:

- 9.3.1. terminate the Agreement forthwith without notice and refuse the Researcher access to the Facilities of the Trust(s); or
  - 9.3.2. require the Researcher to submit to an agreed training programme as a condition of being allowed to continue to have access to the Facilities of the Trust(s); or
  - 9.3.3. require that this Agreement is suspended subject to investigation by the Employer/Place of Study in conjunction with the Trust(s). The Employer/Place of Study and the Trust(s) will endeavour to complete the investigation within 20 working days and the Researcher will be notified regarding termination or reinstatement of the contract.
- 9.4. The Trust(s) agrees/agree that no later than five working days prior to terminating the Agreement in accordance with 9.2 or 9.3 above, it will inform the Employer/Place of Study of its intention to do so.
- 9.5. The Trust(s) reserves/reserve the right to exclude the Researcher at any time from its premises for whatever reason, pending a decision upon whether it wishes to terminate this Agreement.
- 9.6. It is the obligation of the Researcher to disclose any mitigating circumstances that may affect the Agreement such as a change in criminal record, registration, employment or occupational health status.
- 10.** The Researcher warrants that she/he has the relevant skills and expertise to undertake the research for which she/he is permitted to use the Facilities of the Trust(s) and is supported through suitable professional development programmes or training by the Employer/Place of Study or research sponsor, to ensure that she/he is suitable to undertake research.

## **Appendix 10: Letter of Access 1 – For researchers who do not require an HRC**

[Taken from *Research in the NHS –Human Resources Good Practice Resource Pack*]

*Standard letter (or annexe to letter giving NHS permission for research) to confirm responsibilities of researchers who do not require an honorary research contract (including researchers who will not require access to confidential patient information or who do not require pre-engagement checks). It may be used for one project or a series of projects.*

*The letter should be sent to the researcher and copied to the substantive employer. This letter is not required for those issued with an honorary research contract.*

Human Resources Department

Date:

Dear *(insert name of researcher)*

### **Letter of access for research**

This letter confirms your right of access to conduct research through The Newcastle upon Tyne Hospitals NHS Foundation Trust for the purpose and on the terms and conditions set out below. This right of access commences on **[insert date]** and ends on **[insert date]** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at The Newcastle upon Tyne Hospitals NHS Foundation Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to The Newcastle upon Tyne Hospitals NHS Foundation Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through The Newcastle upon Tyne Hospitals NHS Foundation Trust], you will remain accountable to your employer **[insert employer]** but you are required to follow the reasonable instructions of **[head of relevant NHS Department/research supervisor]** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with The Newcastle upon Tyne Hospitals NHS Foundation Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with The Newcastle upon Tyne Hospitals NHS Foundation Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on The Newcastle upon Tyne Hospitals NHS Foundation Trust premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice ([www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf](http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf)) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

The Newcastle upon Tyne Hospitals NHS Foundation Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

**Senior HR Manager/HR Manager Recruitment**

**cc: R&D office, The Newcastle upon Tyne Hospitals NHS Foundation Trust  
Human Resources Department of the substantive employer**

## Appendix 11: Letter of Access 2 – For NHS researchers

[Taken from *Research in the NHS – Human Resources Good Practice Resource Pack*].

*Standard letter (or annexe to letter giving NHS permission for research) to confirm responsibilities of NHS employees or staff with an honorary clinical contract with an NHS organisation. It may be used for one project or a series of projects.*

*The letter should be sent to the researcher and copied to the substantive employer.*

Human Resources Department

Date:

Dear *(insert name of researcher)*

### Letter of access for research

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is responsible for ensuring such checks as are necessary have been carried out. This letter confirms your right of access to conduct research through The Newcastle upon Tyne Hospitals NHS Foundation Trust for the purpose and on the terms and conditions set out below. This right of access commences on **[insert date]** and ends on **[insert date]** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to The Newcastle upon Tyne Hospitals NHS Foundation Trust premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through The Newcastle upon Tyne Hospitals NHS Foundation Trust, you will remain accountable to your employer **[insert employer]** but you are required to follow the reasonable instructions of your nominated manager **[insert Head of relevant NHS Department/research supervisor]** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with The Newcastle upon Tyne Hospitals NHS Foundation Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with The Newcastle upon Tyne Hospitals NHS Foundation Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on The Newcastle upon Tyne Hospitals NHS Foundation Trust premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice ([www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf](http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf)) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

The Newcastle upon Tyne Hospitals NHS Foundation Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

### **Senior HR Manager/HR Manager – Recruitment**

**CC:** Research & Development office, The Newcastle upon Tyne Hospitals NHS Foundation Trust  
Human Resources department of the substantive employer (and provider of honorary clinical contract, where applicable)

**THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST**  
**IMPACT ASSESSMENT – SCREENING FORM A**

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Policy Title:	Research passport Scheme	Policy Author:	Karen Pearce – Senior HR Manager (Projects)
		Yes/No?	You must provide evidence to support your response:
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of the following: (* denotes protected characteristics under the Equality Act 2010)	No	Policy applies to all employees of the Trust. It is underpinned by Trust's overriding policy on Equal Opportunities
	• Race *	No	}
	• Ethnic origins (including gypsies and travellers)	No	}
	• Nationality	No	}
	• Gender *	No	}
	• Culture	No	As above
	• Religion or belief *	No	}
	• Sexual orientation including lesbian, gay and bisexual people *	No	}
	• Age *	No	}
	• Disability – learning difficulties, physical disability, sensory impairment and mental health problems *	No	}
	• Gender reassignment *	No	}
	• Marriage and civil partnership *	No	}
2.	Is there any evidence that some groups are affected differently?	No	There was no evidence to support any group was affected differently
3.	If you have identified potential discrimination which can include associative discrimination i.e. direct discrimination against someone because they associate with another person who possesses a protected characteristic, are any exceptions valid, legal and/or justifiable?	No	As above
4(a).	Is the impact of the policy/guidance likely to be negative? <i>(If "yes", please answer sections 4(b) to 4(d)).</i>	No	
4(b).	If so can the impact be avoided?	NA	
4(c).	What alternatives are there to achieving the policy/guidance without the impact?	NA	
4(d).	Can we reduce the impact by taking different action?	NA	

<b>Comments:</b>	<b>Action Plan due (or Not Applicable):</b>
------------------	---

Name and Designation of Person responsible for completion of this form: ..... Karen Pearce – Senior HR Manager (Projects) ..... Date: ..... 05/01/2011 .....

Names & Designations of those involved in the impact assessment screening process: ..... The Employment Policies and Procedures Consultative Group .....

.....  
 (If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)