



*National Institute for
Health Research*

Research in the NHS – HR Good Practice Resource Pack

Acknowledgements

The Research Passport system was first developed in Greater Manchester by a partnership of NHS organisations and the University of Manchester. A pilot project was undertaken in selected areas across the UK in 2006/7. The evaluation of the pilot and development work with a wide range of stakeholders has led to the issue of *Research in the NHS – HR Good Practice Resource Pack*.

The purpose of the resource pack is to inform NHS and Higher Education organisations of a common approach towards issuing NHS honorary research contracts. *Research in the NHS – HR Good Practice Resource Pack* describes the Research Passport system. This new system will ensure that researchers obtain the correct checks to satisfy NHS organisations prior to undertaking research in the NHS.

This resource pack sets out guidance and good practice standards. **It is for individual NHS bodies to satisfy themselves as to the process used to carry out criminal record and other checks on honorary researchers. If an NHS body is in any doubt about such checks it should take such action as it considers necessary to confirm them.**

It is intended that we consult regularly on how *Research in the NHS – HR Good Practice Resource Pack* is functioning in order to make any necessary changes. Review of the resource pack will be taken forward by the UK Clinical Research Collaboration.

I am grateful to all the organisations listed below and to the numerous individuals who have provided input and feedback on this resource pack.

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

Dr Janet Messer
On behalf of the UKCRC Working Group

Please note this document has been formatted for double-sided printing.

Version Control

Version 1.1 January 2009

Page/ Section	Text change	Reason
Acknowledgements	List of bodies involved moved into text Authorship more clearly attributed to UKCRC	To clarify their role in the development of the guidance To clarify ownership of document
Page 3 – Section 5.1	Text changed: “An honorary research contract does not confer the right of access to confidential information for research without explicit consent.”	Clarity
Page 6 - Section 4	Text changed: “An honorary research contract does not confer the right of access to confidential information for research without explicit consent.”	Clarity
Page 8 – Section 5.1.2 and 5.1.3	Text changed: “ensure that arrangements are in place for handling access to identifiable patient data” Text deleted: Link to “Information governance and honorary research contracts” removed	To clarify that systems for confidentiality arrangements extend beyond the Research Passport system This section is currently under review
Page 10 – Section 5.4	Text changed: “ensure that arrangements are in place for handling access to identifiable patient data” Text deleted: Link to “Information governance and honorary research contracts” removed	To clarify that systems for confidentiality arrangements extend beyond the Research Passport system This section is currently under review
Page 16 - Section 4	Text changed: “An honorary research contract does not confer the right of access to confidential information for research without explicit consent.”	Clarity
Page 19 – Section 5.3.1	Text changed: “ensure that arrangements are in place for handling access to identifiable patient data” Text deleted: Link to “Information governance and honorary research contracts” removed	To clarify that systems for confidentiality arrangements extend beyond the Research Passport system This section is currently under review
Page 20 – Section 5.3.2	Text changed: “ensure that arrangements are in place for handling access to identifiable patient data” Text deleted: Link to “Information governance and honorary research contracts” removed	To clarify that systems for confidentiality arrangements extend beyond the Research Passport system This section is currently under review
Page 21 – Section	Text changed:	To clarify that systems for

5.6	<p>“ensure that arrangements are in place for handling access to identifiable patient data”</p> <p>Text deleted: Link to “Information governance and honorary research contracts” removed</p>	<p>confidentiality arrangements extend beyond the Research Passport system</p> <p>This section is currently under review</p>
Page 26 – footnote 4	<p>Text changed: <i>“In England and Wales, regulations under Section 251 of the NHS Act 2006, as amended, specify the very limited circumstances when researchers may use identifiable patient information without consent.”</i></p>	<p>To reflect updated regulations, and the transfer of the function of the Patient Information Advisory Group to the National Information Governance Board</p>
Page 67	<p>Text deleted: ...”who will not require access to confidential patient information or”...</p>	<p>To clarify that the letter of access should be used where honorary research contracts are not required</p>
Page 67	<p>Text deleted: ...”such checks as are necessary have been carried out by your employer and that”...</p> <p>Text inserted: “Your employer is responsible for ensuring such checks as are necessary have been carried out.”</p>	<p>To clarify that responsibility for ensuring appropriate checks have been carried out is retained by employer</p>
Page 69	<p>Text changed: “You are responsible for ensuring that such checks as you consider necessary for the clinical activities of your staff have been carried out, and we require you to undertake the necessary checks.”</p> <p>Text inserted: “We agree to accept the checks undertaken by you, in order to enable your employee(s) to undertake research activities in this NHS organisation.”</p>	<p>To clarify that responsibility for ensuring appropriate checks have been carried out is retained by employer</p>
Page 85	<p>Text deleted: “An unauthorised person is anyone who does not need to have access to the patient information in order to provide care to that individual.”</p>	<p>To clarify that level of access to confidential information should be defined by job role</p>
Page 88	<p>Text changed: “You should always ensure that a secure system for transferring care records (or other personal information that identifies individuals) between sites is used, referring to any guidance that your organisation issues.”</p>	<p>To reflect updated guidance on security arrangements from the Department of Health</p>
Page 95	<p>Text changed: “An honorary research contract does not confer the right of access to confidential information for research</p>	<p>Clarity</p>

	without explicit consent.”	
Page 98 – Section 5.3	Text deleted: “e.g. access to confidential information”	Example removed as applies to a range of activities
Page 98 – footnote	Text changed: “The requirement for explicit consent applies to research unless disclosure is justified exceptionally in the public interest or has support in law in England and Wales under section 251 of the NHS Act 2006, as amended. Guidance relating to confidentiality and consent in research should be consulted for further details.”	To reflect updated regulations, and the transfer of the function of the Patient Information Advisory Group to the National Information Governance Board
Page 99 – Section 7	Section removed	This section is currently under review
Page 101 – footnote 4	Text changed: <i>“In England and Wales, regulations under Section 251 of the NHS Act 2006, as amended, specify the very limited circumstances when researchers may use identifiable patient information without consent..”</i>	To reflect updated regulations, closure of Patient Information Advisory Group and formation of National Information Governance Board
Page 102 – Information governance and honorary research contracts	Section removed	This section is currently under review

Contents

Part 1 - HR Good Practice

Summary for Higher Education Institutions and the NHS	1
Information for research support and HR staff in Higher Education Institutions	5
HEI Flowchart	13
Information for HR staff in NHS organisations	15
NHS Flowchart	24
Pre-engagement checks and honorary research contracts	26

Part 2 - The Research Passport

The Research Passport – information for researchers	27
Research Passport	35
The Research Passport – information for HE and NHS staff	41

Part 3 - Frequently Asked Questions

Frequently Asked Questions – HR good practice	47
Frequently Asked Questions – The Research Passport	51

Part 4 - Example documents

Example honorary research contract and letter	57
Example letter of access for researchers who do not require an honorary research contract	65
Example letter of access for NHS researchers	67
Example letter of agreement between NHS organisations	69
Example letter for joint arrangements	71
Example occupational health assessment questionnaire	73
Example occupational health assessment request	77
Example occupational health evidence	81
Example confidentiality code of conduct	83
Example confidentiality agreement between researcher and GP practice	93

Part 5 - Background information

Honorary research contracts: principles and legal requirements	95
Information governance and honorary research contracts	102
Links	103

Summary for Higher Education Institutions and the NHS

1 Introduction

Research is an integral part of NHS activity.

- It identifies innovative ways of preventing, diagnosing and treating illness.
- It provides information on the costs, effectiveness and broader impact of health technologies.
- It provides the evidence base for the organisation, management and delivery of healthcare services to increase the quality of patient care, ensure better patient outcomes and contribute to improved population health.

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 Higher Education institutions. This relationship calls for clear understanding about responsibility, accountability, patient safety and duty of care. The Research Governance Frameworks published by the UK health departments require all parties undertaking research within the NHS to be clear about responsibilities and liabilities. One of the ways this is achieved is through appropriate use of honorary research contracts.

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 a good practice resource pack to help the NHS and other research employers take a consistent approach to handling Human Resources (HR) arrangements for those undertaking research in the NHS.

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

- a Research Passport system, which provides a mechanism for assuring NHS organisations of the pre-engagement checks conducted on a researcher; and
- other standardised procedures for handling the HR arrangements for researchers.

The Research Passport system and associated procedures have been developed in parallel with the development of other arrangements across the UK to streamline the arrangements for obtaining permission from NHS organisations to undertake research.

2 Background

- There has previously been no clear, practical, national guidance on the situations in which honorary research contracts are required. NHS organisations have issued honorary research contracts in accordance with policies determined locally, based on a variable interpretation of the legal and employment requirements, and diverse assessment of risks.
- Researchers who need to work across a number of NHS organisations have needed to obtain multiple honorary research contracts, each involving a variety of pre-engagement checks.

3 Impact

- Inconsistency and the lack of clear guidance about the requirement for honorary research contracts have meant that they have been issued inappropriately in parts of the NHS. Where they have been underused, this has resulted in lack of clarity about liability. Where they have been overused, this has not only wasted the resources and time of HR, Research and Development (R&D) departments and researchers themselves, but has also placed inappropriate liability on NHS organisations.
- Duplication of pre-engagement checks and inappropriate use of honorary research contracts wastes considerable amounts of time and resource for both HE and NHS organisations. Frustration with inconsistent approaches can harm working relationships.

4 Responsibilities under the Research Governance Frameworks

Higher Education Institutions (HEIs), as employers of researchers, are responsible for:

- developing and promoting a high quality research culture in their organisation;
- ensuring that their staff are supported in, and held to account for, the professional conduct of research;
- ensuring compliance with all relevant employment and health and safety legislation; and
- ensuring that they are able to compensate anyone harmed as a result of negligence on the part of staff and others for whom they have liability.

Healthcare organisations are responsible for:

- the quality of care of participants to whom they have a duty of care;
- being aware of all research undertaken in their organisation, or involving participants, organs, tissue or data obtained through the organisation; and
- ensuring there is clear accountability and understanding of responsibilities for research involving external partners.

5 Research in the NHS – HR Good Practice Resource Pack

5.1 Summary

The resource pack is provided through a dedicated website that provides information targeted appropriately, for those involved in implementing and using the system. For more information see <http://www.ukcrc.org/researchpassport.aspx>.

- Researchers with a substantive employment contract with one NHS organisation do not need an honorary research contract to conduct research in another NHS organisation. NHS organisations can accept an existing NHS contract of employment, but additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations.
- Researchers with an honorary clinical contract with one NHS organisation do not need additional honorary research contracts to conduct research in other NHS organisations. Additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations.
- Researchers with no contractual relationship with the NHS require an honorary research contract only if the planned activities of the researcher involve interacting with individuals in a way that has direct bearing on the quality of their care, i.e. the researcher could foreseeably directly affect the type, quality or extent of prevention,

diagnosis or treatment of illness or foreseeably cause injury or loss to patients or service users to whom the NHS organisation has a duty of care.

- Substantive employers retain responsibility for other research activities that do not affect the NHS organisation's duty of care.
- An honorary research contract does not confer the right of access to confidential information for research without explicit consent.
- Researchers who do not require an honorary research contract may require additional pre-engagement checks to undertake permitted research activities in NHS organisations.
- Decisions on requirements for pre-engagement checks, induction and training rest with NHS organisations but should be commensurate with the role of the researcher, the type of research and the duty of care.
- There should be a system at local level for identification and local managerial control/supervision of all individuals carrying out research in or through the NHS.

5.2 Solutions provided by the resource pack

- Clear guidance on the requirement for honorary research contracts and pre-engagement checks, underpinned by sound legal principles.
- A Research Passport (held by a specific researcher for a specific project or type of project, and specific duration) that clarifies which pre-engagement checks the researcher's employer has conducted, and whether other NHS organisations have accepted these checks.
- A standard procedure for use where researchers do not require an honorary research contract.

5.3 Benefits of the resource pack

- Clarifies accountability and responsibility for researchers in the NHS, resulting in increased patient safety and improved risk management.
- Provides clear HR processes, resulting in more efficient work processes.
- Minimises duplication of activity, resulting in better use of resources.
- Facilitates research within the NHS, resulting in faster study set-up.
- Supports HEI quality assurance of the activities of research staff.

5.4 Key success factors for introducing and implementing the resource pack

- Collaboration and building trust between partner HEIs and NHS organisations.
- Agreement and documentation of the roles of different individuals/departments/organisations.
- Effective communication between research support and HR departments.
- Provision of information and support to researchers.
- Development of clear policies and procedures within organisations.

6 Actions required

NHS organisations and HEIs are encouraged to:

- accept the principles in this good practice resource pack;
- co-operate in the use of this good practice resource pack;
- put in place processes and policies in accordance with this good practice resource pack; and
- inform researchers about local mechanisms to operate this good practice resource pack.

This resource pack has been developed with help from

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

Information for research support and HR staff in Higher Education Institutions

1 Introduction

Research is an integral part of NHS activity.

- It identifies innovative ways of preventing, diagnosing and treating illness.
- It provides information on the costs, effectiveness and broader impact of health technologies.
- It provides the evidence base for the organisation, management and delivery of healthcare services to increase the quality of patient care, ensure better patient outcomes and contribute to improved population health.

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 Higher Education institutions. This relationship calls for clear understanding about responsibility, accountability, patient safety and duty of care. The Research Governance Frameworks published by the UK health departments require all parties undertaking research within the NHS to be clear about responsibilities and liabilities. One of the ways this is achieved is through using honorary research contracts appropriately.

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 a good practice resource pack to help research employers and the NHS take a consistent approach to handling Human Resources (HR) arrangements for those undertaking research in the NHS.

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

- a Research Passport system, which provides a mechanism for assuring NHS organisations of the pre-engagement checks conducted on a researcher; and
- other standardised procedures for handling the HR arrangements for researchers.

The Research Passport system and associated procedures have been developed in parallel with the development of other arrangements across the UK to streamline the arrangements for obtaining permission from NHS organisations to undertake research.

2 Benefits of the resource pack

- Clarifies accountability and responsibility for researchers in the NHS, resulting in increased patient safety and improved risk management.
- Provides clear HR processes, resulting in more efficient work processes.
- Minimises duplication of activity, resulting in better use of resources.
- Facilitates research within the NHS, resulting in faster study set-up.
- Supports HEI quality assurance of the activities of research staff.

3 The Research Governance Frameworks

The Research Governance Frameworks published by the UK Health Departments make clear that appropriate allocation of responsibility, and hence a clear understanding of liability, is fundamental to good overall governance of research. This approach helps everyone work

together to manage the risks, so that the research can go ahead safely, even in difficult settings.

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

The good practice resource pack clarifies the areas of responsibility, and hence liability, of NHS organisations and HEIs in relation to researchers. Neither NHS organisations nor HEIs should take responsibility for issues that are outside their ability to discharge fully.

The guide describes the communication between an NHS organisation and the HE substantive employer of a researcher that is necessary to fulfil the overall governance arrangements. The system also relies on good internal communication within organisations between HR, research support and academic management functions. Organisations will need to agree internal mechanisms for allocating responsibility for the activities described in this guidance.

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

- Researchers with a substantive employment contract with one NHS organisation do not need an honorary research contract to conduct research in another NHS organisation. NHS organisations can accept an existing NHS contract of employment, but additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations.
- Researchers with an honorary clinical contract with one NHS organisation do not need additional honorary research contracts to conduct research in other NHS organisations. Additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations.
- Researchers with no contractual relationship with the NHS require an honorary research contract only if the planned activities of the researcher involve interacting with individuals in a way that has a direct bearing on the quality of their care, i.e. the researcher could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to patients or service users to whom the NHS organisation has a duty of care.
- Substantive employers retain responsibility for other research activities that do not affect the NHS organisation's duty of care.
- An honorary research contract does not confer the right of access to confidential information for research without explicit consent.
- Researchers who do not require an honorary research contract may require additional pre-engagement checks to undertake permitted research activities in NHS organisations.
- Decisions on requirements for pre-engagement checks, induction and training rest with NHS organisations but should be commensurate with the role of the researcher, the type of research and the duty of care.

There should be a system at local level for identification and local managerial control/supervision of all individuals carrying out research in or through the NHS.

5 Researchers in the NHS

Staff employed by HEIs who conduct research in the NHS may be either:

- i) researchers with no contractual relationship with the NHS; or
- ii) researchers with a substantive Higher Education contract and an honorary NHS contract, e.g. clinical academics; or
- iii) researchers who are also clinicians contracted to provide NHS services, e.g. GPs.

In addition, undergraduate and postgraduate students in HEIs may conduct research in the NHS.

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

5.1 Researchers with no contractual relationship with the NHS

Such researchers may conduct research activity in the NHS of two types:

- activities that have a direct bearing on the quality of care; or
- activities with no direct bearing on the quality of care.

Activities that could have a direct bearing on the quality of care are those that could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to an individual to whom the NHS organisation has a duty of care (see [Pre-engagement checks and honorary research contracts](#)).

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

When researchers conduct activities with no direct bearing on the quality of care, the vicarious liability for the actions of the individual rests with the substantive employer, and **an honorary research contract should not be issued by the NHS organisation.**

In both cases it is important that the NHS organisation where the research is being undertaken make arrangements for the appropriate management and/or supervision of the researcher by an individual or individuals with either a substantive or honorary contract with the NHS organisation concerned.

5.1.1 The Research Passport

The NHS organisation where the research will be undertaken will determine whether an honorary research contract is required. Whether an honorary research contract is required or not, pre-engagement checks may be necessary (see [Pre-engagement checks and honorary research contracts](#)). Pre-engagement checks should be documented in the Research Passport. Detailed information on completing and administering the Research Passport is provided separately (see [The Research Passport - information for HE and NHS staff](#)).

HEIs may wish to support researchers in completing the Research Passport before other preparations for a research project begin, to minimise delays during study start-up. The Rehabilitation of Offenders Act 1974 and the Police Act 1997 set out the circumstances in which criminal record disclosures may be obtained and the level of disclosure required for

particular posts. It is, therefore, not possible to request a criminal record disclosure until those conditions are met.

The Research Passport relies on a requirement of the researcher to notify her/his employer and the NHS organisations where she/he is conducting research of any changes to health, criminal record, professional registration or any other circumstance that may impact on her/his suitability to conduct research. HEIs should provide systems for researchers to declare this information, and should set in place arrangements for monitoring and ensuring compliance with this requirement. HEIs may wish to reserve the right to conduct random checks on criminal records.

5.1.2 Researchers conducting activities with no direct bearing on the quality of care

The NHS organisation hosting the research should:

- ensure through the Research Passport system that appropriate pre-engagement checks have been completed (see [The Research Passport - information for HE and NHS staff](#));
- ensure that arrangements are in place for handling access to identifiable patient data;
- arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Pre-engagement checks and honorary research contracts](#));
- make arrangements for appropriate management and supervision of the research activity;
- issue a letter outlining the researcher's responsibilities to the NHS organisation, copying it to the researcher's employer (see [Letter of access for researchers who do not require an honorary research contract](#));
- give permission for the research.

The HE substantive employer should:

- share information about its employee through the Research Passport system with the NHS organisation hosting the research;
- ensure through contracts, codes of conduct, training and disciplinary arrangements that staff using confidential information in research understand and exercise a duty of confidentiality;
- maintain records of the research activity of its employee.

5.1.3 Researchers conducting activities that will have a direct bearing on the quality of care

The NHS organisation hosting the research should:

- ensure through the Research Passport system that appropriate pre-engagement checks have been completed (see [The Research Passport - information for HE and NHS staff](#));
- ensure that arrangements are in place for handling access to identifiable patient data;
- arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Pre-engagement checks and honorary research contracts](#));
- make arrangements for appropriate management and supervision of the research activity;
- issue an honorary research contract, copied to the researcher's employer (see [Example honorary research contract](#));
- give permission for the research, which should include confirmation of NHS Indemnity for clinical negligence through NHS schemes.

The HE substantive employer should:

- share information about its employee through the Research Passport system with the NHS organisation hosting the research;
- ensure through contracts, codes of conduct, training and disciplinary arrangements that staff using confidential information in research understand and exercise a duty of confidentiality;
- maintain records of the research activity of its employee.

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

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

Clinical academics do not need an honorary research contract in order to undertake research in the partner NHS organisation where they undertake their clinical duties. This will be covered by their honorary clinical contract. **When clinical academics wish to conduct research in other NHS organisations, this should be covered by an agreement between the NHS organisation where the clinical academic undertakes clinical duties, and the NHS organisation in which it is proposed to undertake research. This is the same as for staff with substantive NHS contracts, for whom honorary research contracts are not required.**

In accordance with the recommendations of the Follett Report, universities and NHS organisations responsible for medical education and research are expected to have joint strategic planning arrangements, with joint subsidiary mechanisms responsible for human resource policies and procedures for staff with academic and clinical duties.

The NHS organisation hosting the research should:

- liaise with the NHS organisation providing the honorary clinical contract to ensure that appropriate pre-engagement checks are in place (see [NHS Employers – Occupational Health Smart Cards](#));
- arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Pre-engagement checks and honorary research contracts](#));
- check whether an appropriate agreement is in place between the organisations, or confirm arrangements by letter to the NHS organisation issuing the honorary clinical contract (see [Example letter of agreement between NHS organisations](#));
- make arrangements for appropriate management and supervision of the research activity;
- inform the NHS organisation issuing the honorary clinical contract about the individual's proposed research (see [Example letter of access for NHS researchers](#));
- give permission for the research, which should include confirmation of NHS Indemnity for clinical negligence through NHS schemes.

The NHS organisation issuing the honorary clinical contract should:

- share information about its staff member with the HR department of the NHS organisation hosting the research (see [NHS Employers – Occupational Health Smart Cards](#));
- confirm acceptance of the arrangements set out by the NHS organisation hosting the research;
- maintain records of the research activity of its employee;
- ensure the university employer is aware, through agreed partnership arrangements, about the research activity of its employees.

5.3 Researchers who are contracted to provide NHS services

Researchers with substantive university employment contracts who are also Independent Contractors (e.g. GPs) may wish to undertake research involving patients outside their routine clinical practice. Where such a researcher, in her/his capacity as a university employee, is conducting activities that will have a direct bearing on the quality of care, the individual will be accountable to the NHS organisation where the research is being undertaken for this activity. **An honorary research contract should be issued to the individual by the NHS organisation to clarify and confirm this accountability.** The arrangements described in section 5.1.3 should be used. Where such a researcher, in her/his capacity as a university employee, is conducting activities that will not have a direct and foreseeable impact on the duty of care, the arrangements described above in 5.1.2 should be followed.

5.4 Undergraduate or postgraduate students

Undergraduate and postgraduate students may conduct research as part of their healthcare placements. A memorandum of understanding between the HEI and the NHS organisation will be in place for healthcare placements. This should confirm the accountability arrangements between the organisations. Students on healthcare placements should have appropriate pre-engagement checks conducted when they start their healthcare placement in the NHS (see [NHS Employers safer recruitment guidance](#)). Any research conducted as part of healthcare placements should come within the existing arrangements for such students. Students should be supervised within clinical settings by NHS employees or HE staff with honorary clinical or research contracts who themselves are covered by NHS Indemnity. Therefore, **students conducting research as part of their healthcare placements should not be issued with honorary research contracts by the NHS organisation.**

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

Where a postgraduate student is appropriately clinically qualified and experienced, direct supervision is not appropriate and the student must be issued with an honorary research contract by the NHS organisation if the research will have a direct bearing on the quality of care.

Pre-engagement checks on students should be arranged by the HEI through an appropriate department, e.g. Registry. Student projects may occasionally take place across more than one NHS organisation, in which case information about pre-engagement checks may be shared using the Research Passport system.

The NHS organisation hosting the research should:

- ensure that appropriate pre-engagement checks are in place through the Research Passport system (see [The Research Passport - information for HE and NHS staff](#));
- ensure that arrangements are in place for handling access to identifiable patient data;
- arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Pre-engagement checks and honorary research contracts](#));
- make arrangements for appropriate management and supervision of the research activity;

- issue an honorary research contract, where required, copied to the student's HEI (see [Example honorary research contract](#));
- give permission for the research, which should include confirmation of NHS Indemnity for clinical negligence through NHS schemes.

The student's HEI should:

- ensure through codes of conduct and training that students using confidential information in research understand and exercise a duty of confidentiality;
- maintain records of the research activity of its students;
- maintain supervision of the academic aspects of the student's research activity.

In any of the above situations, where NHS staff are undertaking a course of study that includes a research component, e.g. a nurse undertaking a PhD, arrangements available for NHS staff should be used.

5.5 Researchers conducting research where the participants are NHS staff

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

The NHS organisation hosting the research and employing the participants should:

- make arrangements for appropriate management and supervision of the research activity;
- ensure that the NHS organisation's duties towards its employees are met, e.g. the requirements of the Data Protection Act relating to personal information about its employees;
- issue a letter outlining the researcher's responsibilities, copied to the researcher's employer (see [Example letter of access for researchers who do not require an honorary research contract](#));
- give permission for the research, which should include confirmation of indemnity for harm to employee participants through NHS schemes.

The HE substantive employer should:

- ensure that staff using confidential information in research understand and exercise a duty of confidentiality through contracts, codes of conduct, training and disciplinary arrangements;
- maintain records of the research activity of its employee.

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

5.6 Research hosted by organisations outside the NHS

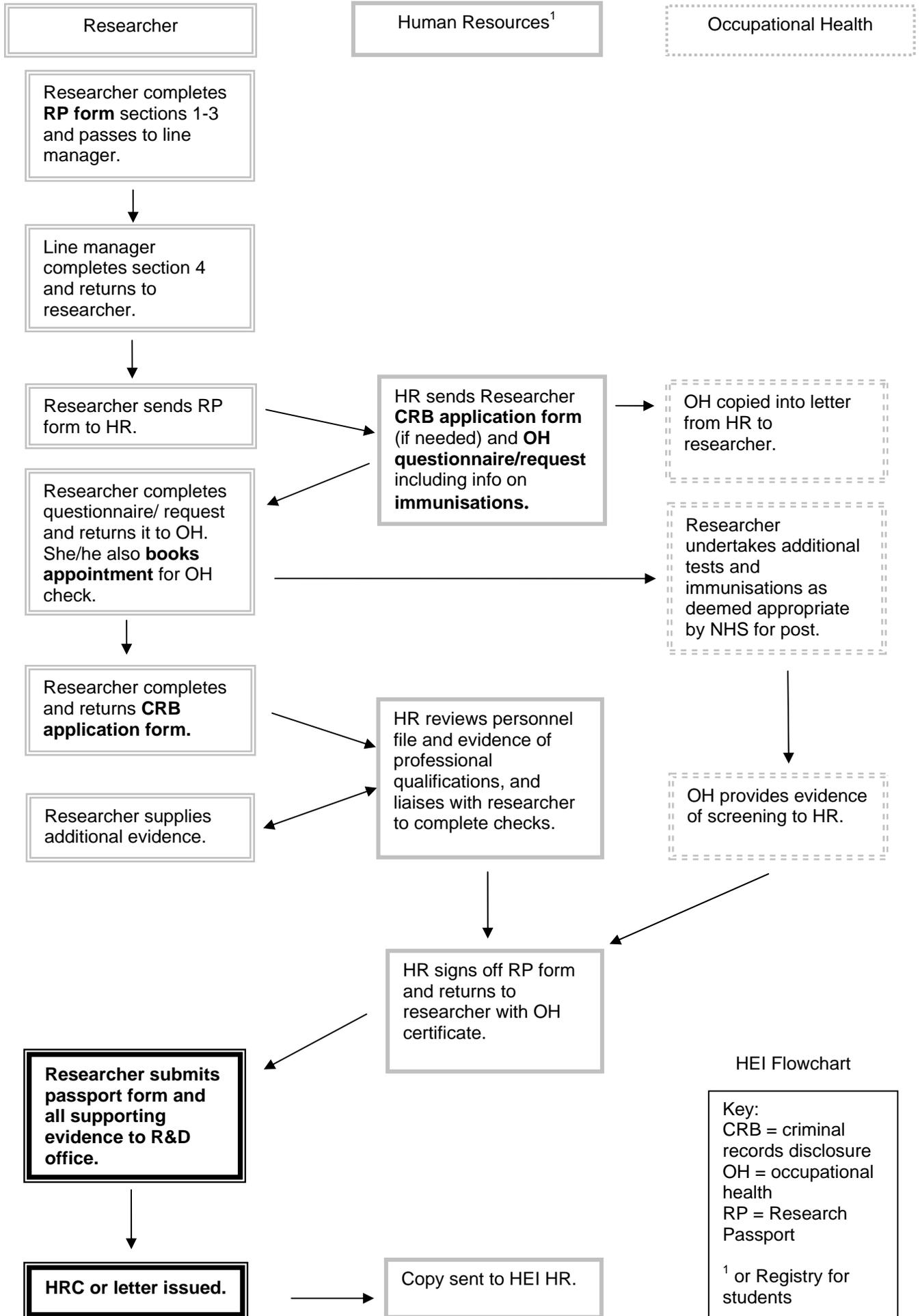
Participants in research may sometimes be identified by virtue of their past or present status as patients or service users of an NHS organisation, e.g. where potential participants are

identified from medical records by a clinical care team, but the research is then conducted by a separate organisation.

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

This resource pack has been developed with help from

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



Information for HR staff in NHS organisations

1 Introduction

Research is an integral part of NHS activity.

- It identifies innovative ways of preventing, diagnosing and treating illness.
- It provides information on the costs, effectiveness and broader impact of health technologies.
- It provides the evidence base to inform the organisation, management and delivery of healthcare services to increase the quality of patient care, ensure better patient outcomes and contribute to improved population health.

Research activity raises a number of HR management issues for NHS organisations. Research within the NHS is often undertaken by non-NHS staff, particularly researchers employed by universities. This raises issues about responsibility, accountability, patient safety and duty of care. Research is also frequently undertaken across a number of NHS organisations and requires arrangements for both NHS and non-NHS staff to work across those organisations. The Research Governance Frameworks published by the UK health departments require all parties undertaking research within the NHS to be clear about responsibilities and liabilities. One of the ways this is achieved is through using honorary research contracts appropriately.

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 a good practice resource pack to help the NHS and other research employers take a consistent approach to handling Human Resources (HR) arrangements for those undertaking research in the NHS.

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

- a Research Passport system, which provides a mechanism for assuring NHS organisations of the pre-engagement checks conducted on a researcher; and
- other standardised procedures for handling the HR arrangements for researchers.

The Research Passport system and associated procedures have been developed in parallel with the development of other arrangements across the UK to streamline the arrangements for obtaining permission from NHS organisations to undertake research.

2 Benefits of the good practice resource pack

- Clarifies accountability and responsibility for researchers in the NHS, resulting in increased patient safety and improved risk management.
- Provides clear HR processes, resulting in more efficient work processes.
- Minimises duplication of activity, resulting in better use of resources.
- Facilitates research within the NHS, resulting in faster study set-up.
- Supports HEI quality assurance of the activities of their research staff.

3 The Research Governance Frameworks

The Research Governance Frameworks published by the UK Health Departments make clear that appropriate allocation of responsibility, and hence a clear understanding of liability,

is fundamental to good overall governance of research. It helps everyone work together to manage the risks, so that the research can go ahead safely, even in difficult settings.

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

The good practice resource pack clarifies the areas of responsibility, and hence liability, of NHS organisations and HEIs in relation to researchers. Neither NHS organisations nor HEIs should take responsibility for issues that are outside their ability to discharge them fully.

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

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

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

- Researchers with a substantive employment contract with one NHS organisation do not need an honorary research contract to conduct research in another NHS organisation. NHS organisations can accept an existing NHS contract of employment, but additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations.
- Researchers with an honorary clinical contract with one NHS organisation do not need additional honorary research contracts to conduct research in other NHS organisations. Additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations.
- Researchers with no contractual relationship with the NHS require an honorary research contract only if the planned activities of the researcher involve interacting with individuals in a way that has a direct bearing on the quality of their care, i.e. the researcher could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to patients or service users to whom the NHS organisation has a duty of care.
- Substantive employers retain responsibility for other research activities that do not affect the NHS organisation's duty of care.
- An honorary research contract does not confer the right of access to confidential information for research without explicit consent.
- Researchers who do not require an honorary research contract may require additional pre-engagement checks to undertake permitted research activities in NHS organisations.

- Decisions on requirements for pre-engagement checks, induction and training rest with NHS organisations but should be commensurate with the role of the researcher, the type of research and the duty of care.

There should be a system at local level for identification and local managerial control/supervision of all individuals carrying out research in or through the NHS.

5 Researchers in the NHS

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

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

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

5.1 Staff with substantive NHS employment contracts

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

Where NHS staff wish to conduct research activities within GP practices or through other independent contractors, a joint arrangement between the employing NHS organisation and the PCT is sufficient. **An honorary research contract issued by the PCT is not required.**

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

The NHS organisation hosting the research should:

- check the individual's employment status in the CV supplied by the applicant as part of the application for permission to conduct the research at that site;
- liaise with the employing NHS organisation to ensure that appropriate pre-engagement checks are in place (see [NHS Employers – Occupational Health Smart Cards](#));
- arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Pre-engagement checks and honorary research contracts](#));

- check whether an appropriate agreement is in place between the organisations, or confirm arrangements by letter to the NHS organisation providing the employment contract (see [Example letter of agreement between NHS organisations](#));
- make arrangements for appropriate management and supervision of the research activity;
- inform the employing NHS organisation about its employee's proposed research (see [Example letter of access for NHS researchers](#));
- give permission for the research, which should include confirmation of indemnity for clinical negligence through NHS schemes.

The NHS employer should:

- with the permission of the employee, share information about its staff member, with the HR department of the NHS organisation hosting the research (see [NHS Employers – Occupational Health Smart Cards](#));
- agree arrangements with the NHS organisation hosting the research;
- maintain records of the research activity of its employees.

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

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

Clinical academics do not need an honorary research contract in order to undertake research in the partner NHS organisation where they undertake their clinical duties. This will be covered by their honorary clinical contract. **When clinical academics wish to conduct research in other NHS organisations, this should be covered by an agreement between the NHS organisation where the clinical academic undertakes clinical duties, and the NHS organisation in which it is proposed to undertake research. This is the same as for staff with substantive NHS contracts, for whom honorary research contracts are not required.**

In accordance with the recommendations of the Follett Report, universities and NHS organisations responsible for medical education and research are expected to have joint strategic planning arrangements, with joint subsidiary mechanisms responsible for human resource policies and procedures for staff with academic and clinical duties.

The NHS organisation hosting the research should:

- liaise with the NHS organisation providing the honorary clinical contract to ensure that appropriate pre-engagement checks are in place (see [NHS Employers – Occupational Health Smart Cards](#));
- arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Pre-engagement checks and honorary research contracts](#));
- check whether an appropriate agreement is in place between the organisations, or confirm arrangements by letter to the NHS organisation issuing the honorary clinical contract (see [Example letter of agreement between NHS organisations](#));
- make arrangements for appropriate management and supervision of the research activity;
- inform the NHS organisation issuing the honorary clinical contract about the individual's proposed research (see [Example letter of access for NHS researchers](#));
- give permission for the research, which should include confirmation of NHS Indemnity for clinical negligence through NHS schemes.

The NHS organisation issuing the honorary clinical contract should:

- share information about its staff member with the HR department of the NHS organisation hosting the research (see [NHS Employers – Occupational Health Smart Cards](#));
- confirm acceptance of the arrangements set out by the NHS organisation hosting the research;
- maintain records of the research activity of its employee;
- ensure the university employer is aware, through agreed partnership arrangements, about the research activity of its employees.

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

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

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

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

In both cases it is important that the NHS organisation where the research is being undertaken makes arrangements for the appropriate management and/or supervision of the researcher by an individual or individuals with either a substantive or honorary contract with the NHS organisation concerned.

5.3.1 Researchers conducting activities with no direct bearing on the quality of care

The NHS organisation hosting the research should:

- ensure through the Research Passport system that appropriate pre-engagement checks have been completed (see [The Research Passport - information for HE and NHS staff](#));
- ensure that arrangements are in place for handling access to identifiable patient;
- arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Pre-engagement checks and honorary research contracts](#));
- make arrangements for appropriate management and supervision of the research activity;
- issue a letter to the researcher outlining her/his responsibilities to the NHS organisation, copying it to the researcher's employer (see [Letter of access for researchers who do not require an honorary research contract](#));
- give permission for the research.

The HE substantive employer should:

- share information about its employee through the Research Passport system with the NHS organisation hosting the research;

- ensure through contracts, codes of conduct, training and disciplinary arrangements that staff using confidential information in research understand and exercise a duty of confidentiality;
- maintain records of the research activity of its employee.

5.3.2 Researchers conducting activities that will have a direct bearing on the quality of care

The NHS organisation hosting the research should:

- ensure through the Research Passport system that appropriate pre-engagement checks have been completed (see [The Research Passport - information for HE and NHS staff](#));
- ensure that arrangements are in place for handling access to identifiable patient data;
- arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Pre-engagement checks and honorary research contracts](#));
- make arrangements for appropriate management and supervision of the research activity;
- issue an honorary research contract, copied to the researcher's employer (see [Example honorary research contract](#));
- give permission for the research, which should include confirmation of NHS Indemnity for clinical negligence through NHS schemes.

The HE substantive employer should:

- share information about its employee through the Research Passport system with the NHS organisation hosting the research;
- ensure through contracts, codes of conduct, training and disciplinary arrangements that staff using confidential information in research understand and exercise a duty of confidentiality;
- maintain records of the research activity of its employee.

5.4 Researchers who are contracted to provide NHS services

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

Where Independent Contractors undertake research on patients outside their routine clinical practice, their personal professional defence arrangements may not extend to cover such research activities. NHS Indemnity arrangements specifically do not extend to Independent Contractors (or their staff) while they are working under contract for services to the NHS. **Therefore, issuing an NHS honorary research contract to this group of researchers does not bring them under the ambit of NHS Indemnity arrangements.** Independent Contractors may be employed by an NHS organisation under certain circumstances, in which case NHS Indemnity arrangements would apply in the same way as for other NHS staff (see [Indemnity Arrangements within Primary Care](#)).

Researchers with substantive university employment contracts who are also Independent Contractors (e.g. GPs) may wish to undertake research involving patients outside their routine clinical practice. Where such a researcher, in her/his capacity as a university employee, is conducting activities that will have a direct bearing on the quality of care, the individual will be accountable to the NHS organisation where the research is being undertaken for this activity. **An honorary research contract should be issued to the**

individual to clarify and confirm this accountability. The arrangements described in section 5.3.2 should be used. Where such a researcher, in her/his capacity as a university employee, is conducting activities that will not have a direct and foreseeable impact on the duty of care, the arrangements described above in 5.3.1 should be followed.

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

The arrangements for researchers conducting research within the NHS who are employed by local government, charities or other organisations are similar to those described above for university-employed staff. However, except where local arrangements have been made to extend the Research Passport system between NHS organisations and other partners, there will be no established method to share information from employers about pre-engagement checks. Where there are no local arrangements to enable sharing of information about pre-engagement checks to take place, NHS organisations hosting research may themselves need to undertake appropriate checks on researchers and claim the costs of such checks from the employer or research funder.

5.6 Undergraduate or postgraduate students

Undergraduate and postgraduate students may conduct research as part of their healthcare placements. A memorandum of understanding between the HEI and the NHS organisation will be in place for healthcare placements. This should confirm the accountability arrangements between the organisations. Students on healthcare placements should have appropriate pre-engagement checks conducted when they start their healthcare placement in the NHS (see [NHS Employers safer recruitment guidance](#)). Any research conducted as part of healthcare placements should come within the existing arrangements for such students. Students should be supervised within clinical settings by NHS employees or HE staff with honorary clinical or research contracts who themselves are covered by NHS Indemnity. Therefore, **students conducting research as part of their healthcare placements do not require honorary research contracts.**

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

Where a postgraduate student is appropriately clinically qualified and experienced direct supervision is not appropriate and the student must have an honorary research contract if the research will have a direct and foreseeable impact on the duty of care.

Pre-engagement checks on students should be arranged by the HEI through an appropriate department, e.g. Registry. Student projects may occasionally take place across more than one NHS organisation, in which case information about pre-engagement checks may be shared using the Research Passport system.

The NHS organisation hosting the research should:

- ensure that appropriate pre-engagement checks are in place through the Research Passport system (see [The Research Passport - information for HE and NHS staff](#));
- ensure that arrangements are in place for handling access to identifiable patient data;
- arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Pre-engagement checks and honorary research contracts](#));

- make arrangements for appropriate management and supervision of the research activity;
- issue an honorary research contract, where required, copied to the student's HEI (see [Example honorary research contract](#));
- give permission for the research, which should include confirmation of NHS Indemnity for clinical negligence through NHS schemes.

The student's HEI should:

- ensure through codes of conduct and training that students using confidential information in research understand and exercise a duty of confidentiality;
- maintain records of the research activity of its students;
- maintain supervision of the academic aspects of the student's research activity.

In any of the above situations, where NHS staff are undertaking a course of study that includes a research component, e.g. a nurse undertaking a PhD, the arrangements for NHS staff undertaking research should be used.

5.7 Researchers conducting research where the participants are NHS staff

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

The NHS organisation hosting the research and employing the participants should:

- make arrangements for appropriate management and supervision of the research activity;
- ensure that the NHS organisation's duties towards its employees are met, e.g. the requirements of the Data Protection Act relating to personal information about its employees;
- issue a letter to the researcher outlining her/his responsibilities, copied to the researcher's employer (see [Example letter of access for researchers who do not require an honorary research contract](#));
- give permission for the research, which should include confirmation of indemnity for harm to employee participants through NHS schemes.

The substantive employer should:

- ensure that staff using confidential information in research understand and exercise a duty of confidentiality through contracts, codes of conduct, training and disciplinary arrangements;
- maintain records of the research activity of its employee.

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

5.8 Research hosted by organisations outside the NHS

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

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

5.9 Ongoing management of HR arrangements for researchers

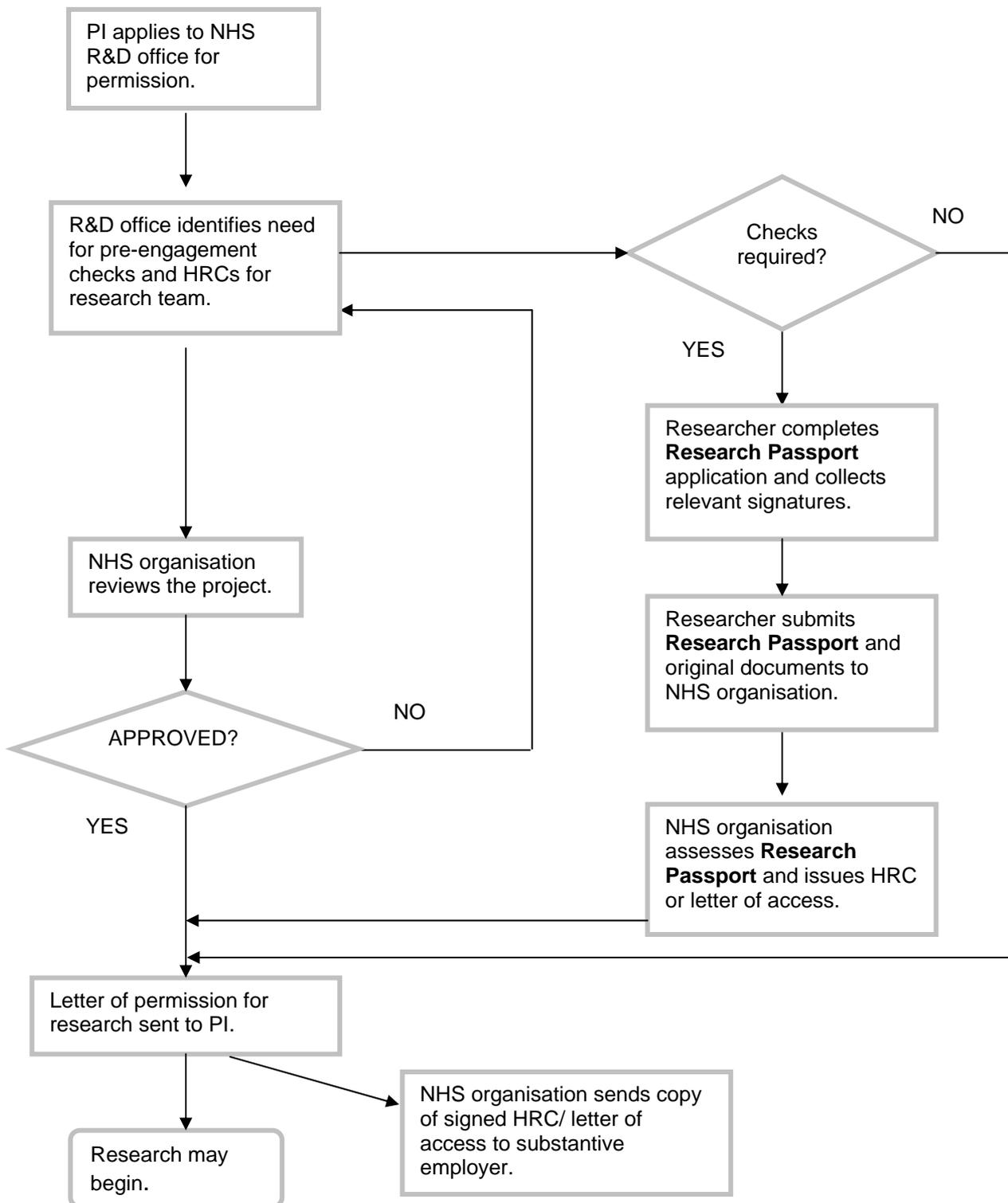
The staff involved in research in NHS organisations may frequently change during the course of a research project. Internal systems must be set up to ensure that changes to research teams are notified by Principal Investigators and the necessary arrangements (as described above) are put in place. The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

This resource pack has been developed with help from:

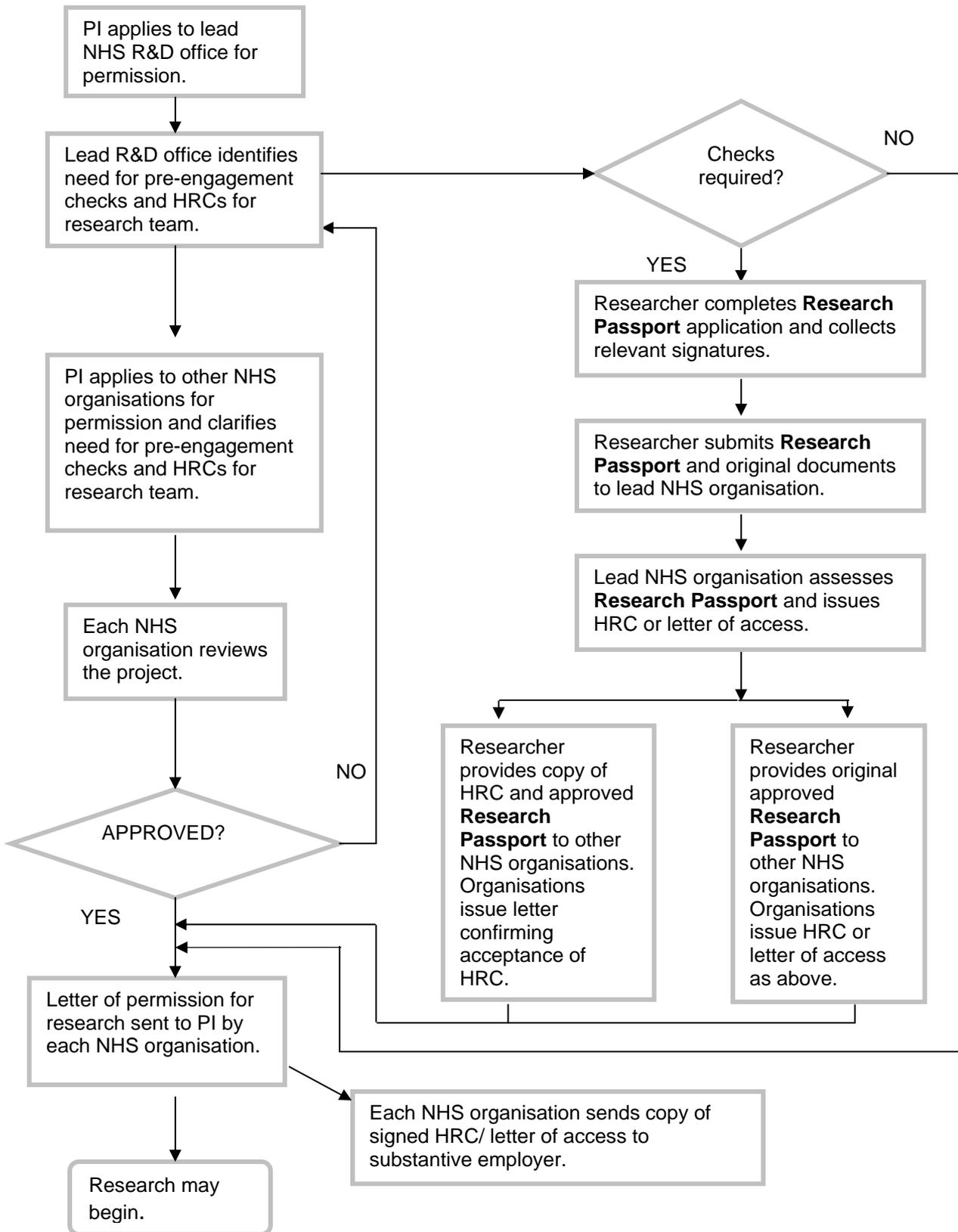
- The UK Health Departments
- NHS R&D Forum
- NHS Employers
- UK Clinical Research Collaboration (UKCRC)
- UK Clinical Research Network (UKCRN)
- Universities UK
- Universities and Colleges Employers Association (UCEA)
- Association of Research Managers and Administrators (ARMA)
- Medical Schools Council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

NHS Flowchart

Research at a single site



Research at more than one site



Key:
HRC = honorary research contract

Pre-engagement checks and honorary research contracts

A “direct bearing on the quality of care” suggests that the actions of researchers could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to an individual to whom the organisation has a duty of care.

	Honorary research contract (HRC) necessary ¹ ?	Made specifically aware of confidentiality?	Criminal record check necessary? ²	Occupational health clearance necessary?
Direct contact with patients/service users and direct bearing on the quality of their care (not children or vulnerable adults)	Yes	Yes, in HRC	Yes, standard or enhanced ³	Yes
Direct contact with children or vulnerable adults and direct bearing on the quality of their care	Yes	Yes, in HRC	Yes, standard or enhanced ³	Yes
Direct contact with patients/service users but no direct bearing on the quality of their care (e.g. observer)	No	Yes, in letter	Yes, standard or enhanced ³	Yes
Indirect contact with patients/service users and direct bearing on the quality of their care (e.g. some types of telephone interviews)	Yes	Yes, in HRC	Yes, standard or enhanced ³	No
Indirect contact with patients/service users but no direct bearing on the quality of their care (e.g. telephone interviews, postal questionnaires)	No	Yes, in letter	No	No
Access with consent to identifiable patient data, tissues or organs with likely direct bearing on the quality of their care	Yes	Yes, in HRC	No	No
Access with consent to identifiable patient data, tissues or organs but no direct bearing on the quality of their care	No	Yes, in letter	No	No
Access without consent ⁴ to identifiable patient data, tissues or organs but no direct bearing on the quality of their care	No	Yes, in letter	No	No
Access to anonymised patient data, tissues or organs only (including by research staff analysing data)	No	Not necessary ⁵	No	No
Working on NHS premises (e.g. laboratory) only	No	Yes, in letter	No	In some situations
Direct contact with staff (e.g. interviews)	No	Yes, in letter	No	No
Access to identifiable staff data	No	Yes, in letter	No	No
Access to anonymised staff data only	No	Not necessary ⁵	No	No

A simplified version of this table is provided [elsewhere](#) in the Resource Pack.

¹ Applies only to researchers with no contractual relationship with the NHS

² Students who have access to patients in the course of their normal duties will require a CRB check.

³ The level of supervision should be taken into account when determining whether an enhanced or standard disclosure is required. A check under the Protection of Children Act/ Protection of Children (Scotland) Act list may also be required. The host trust will advise on the criterion for the post applied for.

⁴ In England and Wales, regulations under Section 251 of the NHS Act 2006, as amended, specify the very limited circumstances when researchers may use identifiable patient information without consent.

⁵ Specific reference to confidentiality is not necessary if access will only be to anonymised information, but the standard references to confidentiality in letters should be retained as general guidance.

The Research Passport – information for researchers

What is the Research Passport?

- One set of checks on a researcher conducting research in the NHS.
- One standard form for each researcher.
- The form is completed by the researcher and her/his employer, and validated by an NHS organisation.
- The completed Research Passport is presented to all the relevant NHS organisations.
- No duplication of checks.
- Faster study start-up.

Who does not need a Research Passport?

You will not need a Research Passport or an honorary research contract if:

- you are employed by an NHS organisation; or
- you are an independent contractor (e.g. GP) or employed by an independent contractor; or
- you have an honorary clinical contract with the NHS (e.g. clinical academics); or
- you are a student who will be supervised within clinical settings by an NHS employee or HE staff member with an honorary clinical or research contract; or
- the research you are doing does not require any checks or honorary research contract.

Who needs a Research Passport?

If you are not in any of the above categories and you have no contractual relationship with the NHS, you *may* need a Research Passport. Check the table on the next page to see which checks you will need and whether you will also need an honorary research contract. A Research Passport may be project-specific or may be valid for a period of three years for a number of projects.

How do I get a Research Passport?

- Read the attached guidance for completing the Research Passport form.
- Complete sections 1-3 of the Research Passport form.
- Ask your line manager (or other authorised person) to complete section 4.
- Take your form to your HR department to complete section 5.
- You may need to complete occupational health assessments, and/or a criminal record disclosure application, and/or provide additional documents.
- Your HR department will sign off the form and return it to you.
- Take the completed Research Passport form with attachments to the lead NHS organisation.
- Once the form has been authorised by one NHS organisation it becomes a valid Research Passport that you can provide to other NHS organisations.
- If you are a student please ask the Registry at your place of study to complete the form, not the HR department.

The Principal Investigator must apply for permission to conduct the research in the NHS organisation. The Research Passport does not remove the need to apply to the NHS organisation for permission or to apply for ethical review.

What type of pre-engagement check is needed?

This table only applies to researchers who may need a Research Passport. Highlighted activities require a Research Passport.

The NHS organisation hosting the research will confirm:

- if you require a Research Passport;
- if you require an honorary research contract; and
- which checks you need.

Type of research activity researcher will be conducting	Honorary research contract necessary?#	Criminal record check necessary?+	Occupational health clearance necessary?
Direct contact with patients/service users and providing prevention, diagnosis or treatment of illness (not children or vulnerable adults)	Yes	Yes, standard or enhanced*	Yes
Direct contact with children or vulnerable adults and providing prevention, diagnosis or treatment	Yes	Yes, standard or enhanced*	Yes
Direct contact with patients/service users but not providing prevention, diagnosis or treatment (e.g. observer)	No	Yes, standard or enhanced*	Yes
Indirect contact with patients/service users and providing prevention, diagnosis or treatment (e.g. some types of telephone interviews)	Yes	Yes, standard or enhanced*	No
Indirect contact with patients/service users but not providing prevention, diagnosis or treatment (e.g. some telephone interviews, postal questionnaires)	No	No	No
Access to identifiable patient data, tissues or organs with likely impact on prevention, diagnosis or treatment	Yes	No	No
Access to identifiable patient data, tissues or organs with no likely impact on prevention, diagnosis or treatment	No	No	No
Access to anonymised patient data, tissues or organs only (including by research staff analysing data)	No	No	No
Working on NHS premises (e.g. laboratory) only	No	No	In some situations
Direct contact with staff (e.g. interviews)	No	No	No
Access to identifiable staff data	No	No	No
Access to anonymised staff data only	No	No	No

Notes

- ID badges should be issued by each NHS organisation where researchers will have face-to-face contact with patients or staff.
- Clinicians must be fully registered with an appropriate professional body and be a member of a recognised medical defence organisation which provides them with appropriate professional indemnity for the research activity.

Where an honorary research contract is not required, a letter of access will be provided.

+ Students who have access to patients in the course of their normal duties will require a criminal record check.

* The level of supervision should be taken into account when determining whether an enhanced or standard disclosure is required. A check under the Protection of Children Act/ Protection of Children (Scotland) Act list may also be required - the NHS organisation will advise on the criterion for the post applied for.

Important information about the Research Passport

Before you can be considered for appointment in a position of trust within the NHS, each NHS organisation needs to be satisfied about your character and suitability.

The law requires the NHS to promote equality of opportunities and to treat all applicants for positions fairly and on merit regardless of age, disability, gender, race, ethnic origin, nationality, religion, belief, or sexual orientation. The NHS shall not discriminate unfairly against applicants on the basis of any criminal conviction or other information declared.

Prior to making a final decision concerning your application, each NHS organisation should discuss with you any information declared by you that it believes has a bearing on your suitability for the position. If any information is not raised with you, this is because the NHS organisation believes that it should not be taken into account. In that event, you remain free to discuss any of that information or any other matter that you wish to raise. As part of assessing your application, the NHS organisation will take into account any relevant criminal record and other information declared.

In accordance with the Data Protection Act 1998 you are advised that your personal data will be processed by each NHS organisation to which you submit the Research Passport. In completing and submitting the Research Passport you are deemed to have given consent to processing personal data about you. Processing includes: holding, obtaining, recording, using, sharing and deleting information. The Data Protection Act 1998 defines 'sensitive personal data' as including ethnic origin, physical or mental health, commission or alleged commission of offences and any proceedings for any offence committed or alleged to have been committed.

The information that you provide in this Research Passport will be processed in accordance with the Data Protection Act 1998, and may also be used for the purpose of determining your application for this position. It may also be used for the purpose of enquiries in relation to the prevention and detection of fraud. Once a decision has been made concerning your appointment, for successful applicants the Research Passport will be retained on their personal file; if unsuccessful, the Research Passport will be destroyed one month after receipt of the application. This form will be kept securely and in confidence, and access to it will be restricted to designated persons within the NHS organisation who are authorised to view it as a necessary part of their work.

While conducting research in the organisation, all researchers should comply with NHS organisation policies relating to safety and confidentiality. These may include the following:

- incident reporting;
- research governance;
- misconduct and fraud;
- data storage and handling.

Section 1 - Details of Researcher

To be completed by Researcher

Question 1. Please state your name and contact details.

Question 2. Please provide basic details about your identity. This information is used to complete the Electronic Staff Record (the NHS HR system).

Question 3. If you are registered with a professional body please give details.

Question 4. Details of your substantive employer or, for students, place of study should be given. Please give your job title or type of study (e.g. undergraduate). **NB NHS organisations need to be informed of any changes in employment.**

Section 2 - Details of Research

To be completed by Researcher

Question 5. There are two types of Research Passport: the project-specific Research Passport and the three-year Research Passport.

- The project-specific Research Passport is for researchers who will be involved with only one project over the course of three years. If this is the case please provide details in this section.
- The three-year Research Passport is for researchers who will be working on a number of studies over the course of three years and have an ongoing research portfolio. Please give details in the Appendix instead of completing this section. You may add as many Appendix pages as required. Please number each Appendix page. You should update the Appendix with any new studies and present the updated Research Passport to all relevant NHS R&D offices before commencing the new project.

Either here or in the Appendix, as appropriate, please provide the title, and the start and end dates of the project. The start date should be when you plan to be involved in the study at the first site, and the end date should be when you plan to complete your involvement in the study at the last site. Please list the NHS organisation(s) and department(s) where you will be working. Describe very briefly what activities you will be undertaking, e.g. prescribing medicine, taking blood, conducting behavioural therapy etc. If you know who will manage or supervise you or be responsible for your conduct in the NHS organisation, e.g. the Principal Investigator, please insert her/his name.

If you subsequently find that you need to conduct a study in additional NHS organisations, the details should be added in the Appendix, and the Research Passport should be submitted to the relevant NHS organisation(s).

Section 3 - Declaration by Researcher

To be completed by Researcher

Question 6. Please tell us if you have ever been refused an honorary research contract or had it revoked by an NHS organisation and the reasons for it. Disclosing this information does not necessarily mean that you will be turned down in your application for an honorary research contract or letter of access this time, but it could be that particular training needs have to be addressed by the NHS organisation where you plan to undertake research or your substantive employer.

The Research Passport system relies on information about you in the Research Passport being shared with relevant NHS organisations instead of being duplicated by each NHS organisation. You are required to consent to this information being shared.

Section 4 - Suitability of Researcher

To be completed by researcher's substantive employer, e.g. line manager, or academic supervisor

Question 7. This section should be completed by an appropriate manager from your employer who is responsible for ensuring that you are suitably trained, qualified and experienced to carry out the research. It could be your line manager or head of department. For students, your academic supervisor should complete this section.

Training should be commensurate with the nature of the research study and the research environment. Please ask the Principal Investigator or Chief Investigator for the study about your training needs in relation to Good Clinical Practice, data protection, use of equipment etc.

Section 5 - Pre-engagement checks

To be completed by the HR department of the researcher's substantive employer or registry at place of study

This section is for the Human Resources (HR) department of your substantive employer to complete and sign. For student projects, the registry or admissions department should be able to give assurance of identity and qualifications.

Question 8. Your employer/place of study needs to confirm that you have a criminal record disclosure with no convictions or police information listed. The criminal record disclosure should have been obtained in the last six months. Alternatively, a criminal record disclosure obtained in the last year may be used, as long as your employer/place of study has a system for requiring you to declare any changes to your criminal record. Details of the disclosure should be provided. Your employer/place of study will not be asked to pass on any information in your criminal record disclosure. Your original copy of the disclosure (not a photocopy) should be provided when you submit the Research Passport to the NHS R&D office.

If you have not had a criminal record disclosure conducted in the appropriate time scale, you should arrange for a criminal records disclosure to be obtained through your employer/place of study.

If any convictions or police information have been reported in your disclosure, the NHS organisation receiving the Research Passport will need to request a criminal record disclosure. This is to ensure that it has relevant and up-to-date information on which to base decisions about issuing an honorary research contract.

Overseas staff/students should endeavour to have the necessary documents to show they do not have any previous convictions in their country of origin. The CRB overseas helpline can provide information on specific countries (0870 010 0450).

Question 9. Your employer/place of study must confirm that it completed checks with regard to identity, professional registration status and certificates of qualifications prior to employing/admitting you. It must also verify that you have had occupational health screening and are fit to carry out the research activities you plan to undertake. Your employer or, where appropriate, your place of study should provide written evidence of completion of the following checks:

- employment screening:
 - ID with a photograph;
 - two references;
 - verification of permission to work/study in the UK;

- exploration of gaps in employment;
- occupational health screening;
- evidence of professional registration;
- evidence of qualifications.

Section 6 - Instructions to applicants

To be completed by Researcher

You are now ready to complete your Research Passport application. Indicate here which documents you have attached. If you do not require a criminal record disclosure or occupational health screening for the research activities you will be conducting, you should tick “Not Applicable”. If you have completed any Appendices, please give the numbers, otherwise tick “Not Applicable”.

Submitting the Research Passport

When you have completed the form, obtained all the relevant signatures and collected the relevant documents to accompany your application, you should submit the Research Passport application to the R&D office at the lead NHS organisation where you wish to undertake your research. The lead NHS organisation may be the R&D office that is nearest to you, or the one that you originally approached about the project. You should provide original copies of all documents. The R&D office will complete the shaded sections of the form and take a photocopy for its records. The original Research Passport form and documents will be returned to you. Your honorary research contract or letter of access can now be issued to you by the NHS organisation.

The NHS organisation will take copies of the Research Passport and attachments for its records to provide an auditable system. Please note that, in accordance with criminal record disclosure guidance, photocopies of criminal record disclosures are not retained.

Once the shaded part of Section 8 has been completed and the form and documents have been returned to you, you have a complete Research Passport. This Research Passport will be valid for the duration of the project or for three years, as indicated in Section 8. You should keep it safe so that you can use it to apply to any other NHS organisation for an honorary research contract or letter of access.

In some cases it may be necessary to undergo additional screening in one NHS organisation because of the nature of the environment where you will be carrying out research. For example, if you are working with immune-compromised individuals you may have to undergo additional screening in line with the policy of the department in which you will be undertaking research. **The R&D office will let you know if you need to have additional checks. Please add the written evidence of these checks to the attachments to your Research Passport.** If any additional checks are undertaken by an NHS organisation, this will be documented in Section 7.

To obtain an honorary research contract or letter of access from another NHS organisation listed on your Research Passport, you should submit the valid Research Passport (with the shaded sections completed) and the original documents to the R&D office at that NHS organisation. As before, a photocopy will be taken and an honorary research contract or letter of access issued.

Appendix

Please ensure that you keep your Research Passport up to date. You should inform any NHS organisation where you are conducting research of any change in details, e.g.

employment status, registration status, criminal record etc. Any failure to do so may result in termination of your honorary research contract or letter of access. Additions and amendments to the Research Passport appendix should be countersigned by the relevant R&D office. The R&D office will take a photocopy of any amendments and additions to the Research Passport. You should check that you do not need additional pre-engagement checks if you are taking on an entirely new research activity.

Research Passport

Please refer to the guidance notes before completing the form.

Section 1 - Details of Researcher <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):		Miss <input type="checkbox"/> Ms <input type="checkbox"/> Other <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:	
	Post or status held:			
Section 2 - Details of Research <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 Appendix.</i>			
	Project Title:			
	Project Timetable: Start Date: End Date:			
	NHS organisation(s):	Dept(s):	Proposed research activities:	Manager in NHS organisation:
Section 3 – Declaration by Researcher <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>				

Section 4 - Suitability of Researcher																								
<i>To be completed by researcher's substantive employer, e.g. line manager, or academic supervisor</i>																								
7.	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>																								
Section 5 - Pre-engagement checks																								
<i>To be completed by the HR department of the researcher's substantive employer or registry at place of study</i>																								
8.	Can you confirm that a clear criminal record 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"/>																							
<i>If yes, please provide details of the clear disclosure</i>																								
Date of disclosure: _____																								
Type of disclosure: _____																								
Organisation that requested disclosure: _____																								
9.	Have the pre-engagement checks described below been carried out with regard to the above-named individual?																							
<table border="1"> <tr> <td> <ul style="list-style-type: none"> ▪ Employment/student screening: <ul style="list-style-type: none"> ○ ID with photograph ○ two references ○ verification of permission to work/study in the UK ○ exploration of any gaps in employment ▪ Evidence of current professional registration ▪ Evidence of qualifications ▪ Occupational health screening </td> <td> <table border="0"> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td>N/A <input type="checkbox"/></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td>N/A <input type="checkbox"/></td> </tr> </table> </td> </tr> </table>		<ul style="list-style-type: none"> ▪ Employment/student screening: <ul style="list-style-type: none"> ○ ID with photograph ○ two references ○ verification of permission to work/study in the UK ○ exploration of any gaps in employment ▪ Evidence of current professional registration ▪ Evidence of qualifications ▪ Occupational health screening 	<table border="0"> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td>N/A <input type="checkbox"/></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td>N/A <input type="checkbox"/></td> </tr> </table>	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"/>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
<ul style="list-style-type: none"> ▪ Employment/student screening: <ul style="list-style-type: none"> ○ ID with photograph ○ two references ○ verification of permission to work/study in the UK ○ exploration of any gaps in employment ▪ Evidence of current professional registration ▪ Evidence of qualifications ▪ Occupational health screening 	<table border="0"> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td>N/A <input type="checkbox"/></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td>N/A <input type="checkbox"/></td> </tr> </table>	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"/>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <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"/>																							
Yes <input type="checkbox"/>	No <input type="checkbox"/>																							
Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>																						
Yes <input type="checkbox"/>	No <input type="checkbox"/>																							
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>																								

Section 6 - Instructions to applicants	
<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 http://www.rdforum.nhs.uk/docs/template_cv.doc)	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 R&D 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 HR 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 R&D office that received the initial application. The NHS R&D 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 <input type="checkbox"/> Three-year <input type="checkbox"/>			
Signed:	Date:		
Name:			
Date Honorary Research Contract/letter of access issued (<i>delete as appropriate</i>)			

This section should be completed by the NHS R&D office receiving the valid Research Passport. The NHS R&D 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.*

The Research Passport – information for HE and NHS staff

This section should be read in conjunction with the information for HEIs and for NHS HR staff in the resource pack, and the guide for researchers on completing the Research Passport. It provides specific information for HEIs on completing the Research Passport, and for NHS organisations on reviewing the Research Passport.

What is the Research Passport?

The Research Passport provides a mechanism for pre-engagement information about a researcher to be shared with relevant NHS organisations in which the applicant will be conducting research. The Research Passport provides:

- clear guidance on the relevant checks required;
- a robust process to document the checks; and
- clear principles that enable NHS organisations to rely on those checks for the duration of the Research Passport.

Who does not need a Research Passport?

Researchers will not need a Research Passport or an honorary research contract if:

- they are employed by an NHS organisation; or
- they are an independent contractor (e.g. GP) or employed by an independent contractor; or
- they have an honorary clinical contract with the NHS (e.g. clinical academics); or
- they are a student who will be supervised within clinical settings by an NHS employee or HE staff member with an honorary clinical or research contract; or
- the research they are doing does not require any checks or honorary research contract.

Please read other sections of the resource pack for further information on handling the arrangements for researchers in the above categories.

Who needs a Research Passport?

Researchers who are not in any of the above categories, and have no contractual relationship with the NHS, *may* need a Research Passport. Not all types of research activity require a Research Passport. The table at the end of this document provides guidance on the pre-engagement checks that should be carried out in particular research situations, and whether or not an honorary research contract is required. Please note that not all researchers involved in a particular project will be conducting the same research activities and so there may be different requirements for different members of a research team.

A Research Passport may be project-specific or may be valid for a period of three years for a number of projects. Once the checks have been completed and a valid Research Passport has been issued, the checks may be relied upon for the duration of the Research Passport.

The Principal Investigator must also apply for permission to conduct the research in the NHS organisation. The Research Passport does not remove the need to apply to the NHS organisation for permission or to apply for ethical review.

Completing the Research Passport

The Research Passport needs to be completed by a number of parties. The relevant pre-engagement checks and authorisations should be completed with input from the following departments.

For students who require a Research Passport:

- the academic supervisor, and
- the Registry (or equivalent department), and
- the occupational health service.

For employees:

- the researcher's manager, and
- the HR department, and
- the occupational health service.

Types of Research Passport

There are two types of Research Passport: the project-specific Research Passport and the three-year Research Passport.

- The project-specific Research Passport is for researchers who will be involved with only one project over the course of three years.
- The three-year Research Passport is for researchers who will be working on a number of studies over the course of three years and have an ongoing research portfolio.

For researchers who require a three-year Research Passport, details of the initial projects should be entered in the Appendix. Subsequent projects during the duration of validity of the Research Passport may be added to the Appendix at a later stage. The complete Research Passport is presented to the relevant NHS organisations. As long as there is no substantial difference in the requirements for pre-engagement checks for the research activities for the subsequent projects, the original checks may be relied upon and no additional checks need be undertaken.

Additional appendix pages should be added as required, each appendix being numbered sequentially. The appendices reviewed in the initial application should be noted in Section 8. Review of further appendices should be noted in the amendments section at the end of the Research Passport.

Suitability of the Researcher

Employers should agree appropriate internal policies for appropriate signatories for Section 4. The signatory should be someone who would normally be recognised as responsible for overseeing the appropriate training, experience and suitability of the employee. This may be a line manager or head of department. For students, it may be the academic supervisor. Confirming suitability does not place individual liability on the signatory. The action of confirming suitability forms part of the core responsibilities of employers and academic institutions.

Criminal Record Disclosures

Criminal record disclosures may only be requested in line with the relevant legislation. When a researcher plans to conduct research activities that will require a criminal record disclosure (see the table at the back of this section), the employer/place of study may arrange for the disclosure to be obtained.

Criminal record disclosures do not carry a period of validity. Therefore, HEIs are recommended to establish mechanisms to require employees/students who have undergone a criminal record disclosure to declare any subsequent changes in their criminal record to the HEI. Where such arrangements are in place, criminal record disclosures obtained in the year prior to completion of the Research Passport application may be used. Where such arrangements are not in place, only criminal record disclosures obtained in the previous six months are deemed to be appropriate.

HEIs will not be asked to pass on any details in criminal record disclosures. Researchers should provide their own original copy (not a photocopy) with their Research Passport.

HEIs should establish disciplinary arrangements to accompany any requirement of employees to declare changes to their criminal record. For students, such requirements should be included in codes of conduct. HEIs may wish to consider monitoring such arrangements, e.g. through spot checks.

Employment/student screening

It is expected that normal arrangements within HEIs will have included obtaining two references and verification of permission to work/study in the UK. Where this forms part of routine practice in an HEI, these checks may be confirmed as having been conducted on an applicant, and do not need to be repeated.

It is recognised, however, that exploration of gaps in employment and confirmation of identity may not routinely be carried out by HEIs in the same way as expected of NHS organisations. HEIs are asked to check for gaps in employment/study of more than six months in the past three years. Where this has not been done previously, the HEI should arrange for the applicant's C.V. to be checked. Confirmation of identity includes determining that the individual's identity is genuine and relates to a real person, and establishing that the individual owns and is rightfully using that identity. Applicants should provide:

- a document containing the individual's photograph, such as a passport or UK driving licence, and
- a document providing the individual's current address, such as a utility bill, a bank statement or the most recent council tax bill.

In addition, where possible, electronic databases such as electoral roll information should be searched to verify identity.

HEIs should familiarise themselves with the following guidance on pre-employment screening for the NHS, in order to develop systems that comply with NHS requirements:

- Safer Recruitment guidance, NHS Employers, <http://www.nhsemployers.org>
- *A Good Practice Guide on Pre-employment Screening*, Centre for the Protection of National Infrastructure, <http://www.cpni.gov.uk/Docs/Pre-employmentscreening.pdf>

Occupational health assessment

The occupational health service for the HEI should confirm, so far as is possible, that the individual is fit for the research activities she/he will be undertaking, in order to protect the health and safety of the researcher and others.

The Department of Health recommends checks for tuberculosis disease/immunity and the offer of hepatitis B immunisation, with post-immunisation testing of response, and the offer of

tests for hepatitis C and HIV as standard health clearance checks for new healthcare workers. For those who will perform exposure-prone procedures (EPPs) for the first time, additional health clearance should also be undertaken. Additional health clearance means being non-infectious for HIV, hepatitis B and hepatitis C. The purpose of this guidance is to restrict those with blood-borne viruses from working in those clinical areas where their infection might pose a risk to patients in their care.

New healthcare workers include: healthcare workers new to the NHS; healthcare workers moving into training or posts involving exposure-prone procedures for the first time; and healthcare workers returning to the NHS, depending on the activities they have been engaged in while away. The Research Passport system, in line with existing systems, places an ongoing obligation on researchers to seek professional advice about the need to be tested if they have been exposed to a serious communicable disease.

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 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. Laboratory test results required for clearance for performing EPPs must be derived from an identified, validated sample.

If additional vaccinations are required, these should be identity validated.

HEIs should familiarise themselves with the following guidance on occupational health screening for the NHS, in order to develop systems that are compliant with NHS requirements.

Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers, Department of Health,
http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=140873&Rendition=Web

Immunisation against infectious disease - "The Green Book", Department of Health,
http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254

HEIs may be able to use their local NHS Plus occupational health services to undertake health checks and clearance on their behalf (<http://www.nhsplus.nhs.uk>).

Reviewing the Research Passport

NHS organisations should consider the type and/or degree of pre-engagement checks that are required, ensuring that these are commensurate with the role of the researcher, the type of research and the duty of care. Where a researcher is not able to provide evidence of appropriate checks in the Research Passport, the decision whether or not to issue an honorary research contract or letter of access should take account of the above factors and be made following discussion with the applicant and her/his employer.

NHS Employers (<http://www.nhsemployers.org>) and the UK health departments offer further guidance and advice on issues relating to those working within the NHS as employees, honorary staff, contractors, students or volunteers.

What type of pre-engagement check is needed?

This table only applies to researchers who may need a Research Passport. Highlighted activities require a Research Passport.

Type of research activity researcher will be conducting	Honorary research contract necessary?#	Criminal record check necessary?+	Occupational health clearance necessary?
Direct contact with patients/service users and providing prevention, diagnosis or treatment of illness (not children or vulnerable adults)	Yes	Yes, standard or enhanced*	Yes
Direct contact with children or vulnerable adults and providing prevention, diagnosis or treatment	Yes	Yes, standard or enhanced*	Yes
Direct contact with patients/service users but not providing prevention, diagnosis or treatment (e.g. observer)	No	Yes, standard or enhanced*	Yes
Indirect contact with patients/service users and providing prevention, diagnosis or treatment (e.g. some types of telephone interviews)	Yes	Yes, standard or enhanced*	No
Indirect contact with patients/service users but not providing prevention, diagnosis or treatment (e.g. some telephone interviews, postal questionnaires)	No	No	No
Access to identifiable patient data, tissues or organs with likely impact on prevention, diagnosis or treatment	Yes	No	No
Access to identifiable patient data, tissues or organs with no likely impact on prevention, diagnosis or treatment	No	No	No
Access to anonymised patient data, tissues or organs only (including by research staff analysing data)	No	No	No
Working on NHS premises (e.g. laboratory) only	No	No	In some situations
Direct contact with staff (e.g. interviews)	No	No	No
Access to identifiable staff data	No	No	No
Access to anonymised staff data only	No	No	No

Notes

- ID badges should be issued by each NHS organisation where researchers will have face-to-face contact with patients or staff.
- Clinicians must be fully registered with an appropriate professional body and be a member of a recognised medical defence organisation which provides them with appropriate professional indemnity for the research activity.

Where an honorary research contract is not required, a letter of access will be provided.

+ Students who have access to patients in the course of their normal duties will require a criminal record check.

* The level of supervision should be taken into account when determining whether an enhanced or standard disclosure is required. A check under the Protection of Children Act/ Protection of Children (Scotland) Act list may also be required - the NHS organisation will advise on the criterion for the post applied for.

Frequently Asked Questions – HR good practice

1. Doesn't all research have the potential to impact on the NHS duty of care?

Any research may have a long-term impact on care within the NHS, by virtue of the evidence produced when the research is complete. However, the impact on duty of care which dictates the requirement for an honorary research contract relates only to the research activity being conducted in or through, i.e. hosted by, the NHS organisation during the course of conducting the research protocol or proposal. The duty of care therefore applies to research activity of a researcher conducting research in or through an NHS organisation that involves direct interaction with patient care. The patient care may be prevention, diagnosis or treatment of illness.

If foreseeable negligent harm arising from the research activities described in the research protocol occurred, the NHS organisation would be vicariously liable if the activities were conducted with the permission of the NHS organisation. The honorary research contract confirms that accountability of the NHS organisation.

2. Shouldn't we issue an honorary research contract to all researchers to make sure that we have a way of controlling their activities so that we minimise the risk to the NHS?

The Department of Health previously advised that researchers who do not have a paid contract with an NHS body, but whose research involves NHS staff or patients, their organs, tissue or data, must have an honorary contract with an NHS body. The advice was withdrawn some years ago when it was acknowledged that this description was misleading.

The Research Governance Frameworks make clear that appropriate allocation of responsibility, and hence liability, is fundamental to good overall governance of research. HEIs must accept their responsibilities as employers of researchers, because it is only the employer that can be responsible ultimately for ensuring the suitability of the individual in terms of training, experience and conduct.

HEI substantive employers must retain accountability and liability for the actions of researchers that are outside the core responsibility of NHS organisations, i.e. actions that do not relate to the legal duty of quality and the common law duty of care of the NHS organisation. NHS organisations should not lay claim to responsibility, and hence liability, for issues that are outside their ability to fully discharge.

HEIs as employers are responsible for ensuring that staff conducting research within the NHS are appropriately trained in handling identifiable patient information, and that disciplinary arrangements are in place for handling breaches of confidentiality.

The resource pack describes the communication channels between the NHS organisation and the substantive employer that should be put in place to ensure the overall governance arrangements.

3. Where the resource pack indicates that researchers don't require an honorary research contract, isn't the suggested letter equivalent to an honorary contract anyway?

The resource pack suggests using letters to make accountability arrangements clear and includes a number of examples. By using the appropriate example letter, the NHS

organisation avoids falling into the trap of accepting responsibility for activities for which it should not be held responsible.

4. Where do the liabilities lie for students conducting research projects in the NHS which do not have a direct bearing on the quality of care?

Universities fulfil their responsibilities for quality assurance of the design of research initiated by their students through the academic supervisor.

NHS Indemnity covers any harm to participants as a result of clinical negligence, whether caused by students or staff. Honorary research contracts and supervision arrangements are part of the process of minimising risk and having clear accountability.

5. For researchers making frequent visits but who do not require an honorary research contract, are there any issues about cover for compensation for injury etc to them while on site? Are they covered in the same way as any other visitor to the site?

Researchers without honorary research contracts are covered in the same way as other visitors. Researchers with honorary research contracts are not provided with additional cover for injury etc compared to researchers without honorary research contracts. The role of the honorary research contract is to clarify the role of the researcher in relation to participants in research.

6. Why are clinical academics treated in the same way as NHS staff?

Clinical academics are a specific group of individuals who hold “joint appointments” across NHS and HE organisations in order to conduct clinical activity, teaching and research in an integrated way across the organisations. The Follett report¹ clearly outlined the joint arrangements that should be in place for managing these staff. Other researchers employed by universities, and not holding “joint appointments” should not be assumed to be accountable to NHS organisations in the same way as clinical academics.

The intention in the resource pack of using the specific term “honorary research contract” as distinct from “honorary contract” is that honorary research contracts relate to research activity only and do not cover accountability arrangements for wider activity including non-research clinical activity.

7. The resource pack mentions agreements on research between partner NHS organisations and HEIs. Are there any templates?

The NHS R&D Forum has published guidance for developing partnership agreements between the NHS and Universities (<http://www.rdforum.nhs.uk/library.htm#university>).

8. Should the processing of Research Passports and honorary research contracts in NHS organisations be conducted by R&D office staff or HR staff?

The Research Passport system does not rely on any one department fulfilling particular activities, although timely and efficient processing requires good communication and agreed

¹ A Review of Appraisal, Disciplinary and Reporting Arrangements for Senior NHS and University Staff with Academic and Clinical Duties, A report to the Secretary of State for Education and Skills, by Professor Sir Brian Follett and Michael Paulson-Ellis, September 2001 <http://www.dfes.gov.uk/follettreview/>

systems between the departments. It is therefore for local agreement within an NHS organisation how responsibility for tasks should be allocated, depending upon the resource and expertise available. In England, the new Comprehensive Local Research Networks of the National Institute for Health Research will adopt the Research Passport as standard practice, and develop working procedures with their local partners.

9. What happens about research that will last longer than three years?

The maximum duration of a Research Passport is three years. If a researcher requires a Research Passport for longer than this, a repeat application should be completed and the relevant checks should be re-assessed. This is in line with the advice on arrangements for highly mobile NHS staff groups, where criminal record and other appropriate checks should be undertaken at three-yearly intervals.

10. Which university departments should provide advice on and sign the Research Passport application: HR or research support?

The Research Passport has been devised to support research. In research-active organisations such support will typically be accessed by researchers through the Research (or Pre-award) Office. There is, however, an important role for HEI HR departments in assuring NHS organisations' HR of the pre-engagement checks undertaken.

The Research Passport relies on good communication between HR and research support in both the HE and NHS sectors.

Frequently Asked Questions – The Research Passport

1. How does the Research Passport system fit with guidance about portability of criminal record checks?

Portability refers to the re-use of a disclosure. The Research Passport uses a single system to provide pre-engagement information to several NHS organisations. The application form is completed by the applicant and her/his substantive employer. One criminal record check is performed as part of the single process for a number of NHS organisations, and a specific project or type of project. The Research Passport provides a mechanism to set aside the requirement for a new check by each NHS organisation.

The CRB issued a revised Portability Framework in November 2006. The CRB Portability Framework indicates that an individual taking up more than one position requiring a criminal record check may be able to avoid making duplicate applications to the CRB. The document includes details of the limitations and risk management that should be taken into account in adopting this approach. These have been incorporated into the Research Passport guidance. For full details see http://www.crb.gov.uk/PDF/CRB_DIP016-Portability_Eng.pdf.

NHS Employers has given advice to NHS organisations on handling criminal record checks for particular staff groups such as students, trainees, agency workers and locums, which provides a balanced and proportionate approach to meeting NHS organisations' responsibilities. The provision for researchers is in accordance with advice for doctors in training whereby, if there is evidence that a researcher has had a criminal record check by her/his employer or another NHS organisation within the previous three years, then the requirement for the checks to be repeated can be set aside. The exception to this would be if the research post requires a PoCA check, in which case a new criminal record disclosure must be obtained regardless of when the last check was carried out.

The Research Passport system places an obligation on researchers to inform both the employer and any relevant NHS organisations about any changes to their criminal record.

The Research Passport system provides additional assurances from the substantive employer to the NHS organisation and establishes a clear ongoing communication channel between the employer and the NHS organisation to address any future issues.

2. Our NHS organisation's policy is that we should not accept criminal record disclosures over 6 months old. Does the Research Passport disregard this policy?

Within the NHS, provision has been made for students, trainees and highly mobile staff, whereby the requirement for repeat checks on each new appointment has been set aside. The Research Passport system is in accordance with the provision for doctors in training. Once a criminal record check has been performed it is relied on for either the duration of the project or for up to three years (depending on the type of Research Passport issued).

Once an individual has had a criminal record check conducted and has been issued with a Research Passport and a letter of access or honorary research contract, she/he is required to inform the employer and the organisation(s) with whom she/he is conducting research of any change that affects the status of her/his criminal record. Therefore when the researcher produces her/his Research Passport documents when she/he needs to approach a new NHS organisation, the new organisation does not need to repeat the checks, even if the check was conducted more than 6 months ago.

3. Does this guidance comply with CRB/Disclosure Scotland guidance about handling of disclosures? What happens if a criminal conviction or police information is disclosed?

The Research Passport requires the substantive employer who requested the criminal record check to confirm whether or not a criminal record disclosure with no convictions or other police information has been obtained. Where the employer confirms that there is no information revealed in the disclosure, the applicant should then provide her/his own copy of the disclosure document to the NHS organisation. In providing her/his own copy, the applicant consents to the sharing of that information.

When a standard disclosure is obtained, the information obtained in the check will be included on the individual's copy of the disclosure document.

When an enhanced disclosure is obtained, some information may only be provided to the registered organisation that requested the disclosure, and will not be copied to the individual. It is therefore not appropriate to rely only on the individual's copy of the disclosure. NHS organisations may, therefore, wish to contact the counter signatory named on the front of the criminal record check to verify the information provided in the Research Passport. The counter signatory can, however, only confirm whether or not any additional information is given. The content of that information may not be shared by the employer with anyone.

Information provided in a disclosure is therefore not passed from the employer to an NHS organisation and CRB¹ guidance is adhered to.

If the response on the application form indicates that no clear criminal record disclosure has been obtained, this may be because convictions or police information were reported in the disclosure, or because no criminal record disclosure has been obtained. The NHS organisation should clarify with the employer/place of study whether a disclosure was obtained. If a disclosure was obtained and the employer/place of study confirmed that it was not clear, the NHS organisation should ensure that a new criminal record disclosure is obtained with relevant and up-to-date information. The new criminal record disclosure may be requested by the employer or the NHS organisation.

4. What should an HEI employer do if a criminal record check on an existing employee discloses a criminal conviction?

The employer would need to deal with each such case on an individual basis. The employer would need to assess whether the convictions on the disclosure were relevant to the work of the employee and then make an assessment as to how appropriate it would be to permit the individual to do that work. This assessment would be in addition to any NHS organisation's decision to issue an honorary research contract or letter of access. If the conviction is likely to have an impact on the individual's research activity generally then contractual issues may arise and legal advice should be sought.

The same principles would apply if a researcher declared a change in her/his criminal record after a criminal record check had been completed. The NHS organisation would need to make an assessment whether to withdraw the honorary research contract or letter of access or whether to put in place additional supervision arrangements.

¹ References to CRB also apply to Disclosure Scotland

5. How long are criminal record checks valid?

A criminal record check carries no formal period of validity. Information revealed through a criminal record check only reflects the information that was available at the time of its issue. A person's criminal record or other relevant information may subsequently change. Employers can, however, require employees to inform them of any change in their criminal record during the course of their employment, backed by appropriate disciplinary measures.

6. Some places now ask for enhanced disclosure for all who will have unsupervised access. Should we indicate that all who want honorary research contracts should get an enhanced disclosure?

The Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975 and the Police Act 1997 set out the circumstances in which criminal record disclosures may be obtained and the level of disclosure required for particular posts. NHS organisations cannot request criminal record checks of researchers who only require access to personal data (e.g. patient records)². All organisations and individuals receiving enhanced and standard disclosure information must comply with the obligations set out in a Code of Practice and explanatory guide to ensure that the information is used appropriately and fairly and that people are not unjustly discriminated against. It is an offence under Sections 113 and 115 of the Police Act 1997 to apply for a disclosure in respect of a post which does not warrant it³.

Ultimately, each NHS organisation has to decide whether the activities of a researcher meet the requirements for a standard or enhanced check.

7. Do we need to get researchers to complete declaration forms in addition to viewing their criminal record disclosures?

No. The information supplied by the employer, in addition to the evidence provided in the Research Passport, is deemed to provide sufficient assurance about the individual.

8. Where does liability lie in relation to the checks conducted by the substantive employer?

The Police Act 1997 includes specific provision that no proceedings shall lie against the CRB⁴ by reason of an inaccuracy in the information made available or provided to the CRB. Organisations requesting criminal record checks would be able to argue that no liability rests with the organisation, as long as that organisation had not knowingly made a false declaration on the application form and had complied with all guidance issued by the CRB, including the Code of Practice.

If the information revealed by the criminal record check is disputed by the applicant, the CRB has a procedure in place to resolve issues about accuracy. Where a dispute is raised, the decision to issue an honorary research contract should not be made until the investigation is completed.

The responsibility for complying with the CRB's Code of Practice rests with each individual recipient of the criminal record check. For further details about these obligations please read the Codes of Practice (http://www.crb.gov.uk/PDF/code_of_practice.pdf and

² <http://www.nhsemployers.org/restricted/downloads/download.asp?ref=647&hash=303ed4c69846ab36c2904d3ba8573050>

³ <http://www.opsi.gov.uk/acts/acts1997/1997050.htm#aofs>.

⁴ References to CRB also apply to Disclosure Scotland

<http://www.disclosurescotland.co.uk/PDF/CODE%20OF%20PRACTICE%20-%202007%20EDITION.pdf>).

In relation to the remaining checks conducted by the substantive employer, as required by the Research Passport system, the substantive employer is responsible for ensuring that they adhere to good employment practice.

This Research Passport system sets out guidance and good practice standards. It is for individual NHS bodies to satisfy themselves about the process used to carry out criminal record and other checks on researchers. If an NHS body is in any doubt about such checks, it should take such action as it considers necessary to confirm them.

Complaints or allegations against the researcher will be dealt with in accordance with her/his substantive employer's policies and procedures. The NHS organisation and the employer must work in collaboration in handling such incidents.

9. Why doesn't the Research Passport application request references?

The Research Passport system does not require references from researchers as the substantive employer signs off the form and the employer will normally have checked references as part of standard pre-employment procedures. NHS organisations will want to be satisfied that the researcher is suitably qualified and experienced for the research she/he is to undertake and this should be indicated in the C.V. supplied. The standard format of C.V. requested in the Research Passport application covers this.

10. What is meant by a verified reference? Do substantive employers need to check qualifications with the awarding body or accept that any certificate(s) provided by the applicant are authentic?

A verified reference means that references were taken up when the individual was appointed by the Higher Education Institution (HEI) and this is confirmed by the HEI HR department in completing the Research Passport form.

Substantive employers are expected to follow good employment practice to satisfy themselves that the individual has attained the qualifications that she/he has claimed.

11. Do substantive employers need to check with the professional body to ensure that the applicant is currently registered or simply accept that the applicant is still registered with the stated body?

Where an HEI is employing someone who is required to be a registered professional, the HEI would be expected to check that the individual is registered. However, registration may lapse or be discontinued. The substantive employer should, therefore, check current professional registration when completing the Research Passport form. The registration should be valid, in date and without any restrictions to undertake the research in question.

12. What information on occupational health checks should be expected from the substantive employer?

The substantive employer should provide the researcher with written evidence of the health checks conducted. A record of vaccinations should be included.

The document should include workplace issues that the NHS organisation needs to be aware of, e.g. reasonable adjustments to meet the needs of individuals with disabilities. Where there are potential confidentiality issues, the document should explain that other

issues will need to be discussed directly with occupational health at the NHS organisation, with the applicant's consent.

13. Who bears the cost of the checks required for the Research Passport?

For individuals employed by a Higher Education Institution or enrolled as a student, who are expected to undertake research as part of their role, the costs of checks should be borne by the HEI. Wherever possible, costs should be built into grant applications.

14. Sometimes researchers employed by a university will conduct research with NHS organisations a long way from their university and their only contact with participants is one visit. Where the activity will require pre-engagement checks to be completed, how do we handle viewing the original criminal record disclosure or conducting occupational health checks that cannot be completed by the employer?

Where it would be difficult for a researcher to present her/his Research Passport to the NHS organisation in person, there are two options:

- the researcher may post the documents and request that they be posted back when they have been processed (using appropriate secure postage); or
- the Research Passport can be processed based on photocopies as long as the issuing of the honorary research contract or letter of access is conditional upon the NHS organisation viewing the original documents prior to the researcher conducting the research activity.

In some situations, it may not be possible for an employer to conduct occupational health checks for a particular research activity (e.g. where specific vaccinations are required, or a discussion with the applicant is necessary). If the NHS organisation is distant from the employer, it may be necessary to process the Research Passport without finalising this information. The issue of the honorary research contract or letter of access would then be conditional upon the NHS organisation ensuring that satisfactory occupational health checks have been completed prior to the researcher conducting the research activity. Alternatively, it may be possible in some situations for the researcher to have the necessary occupational health procedures conducted through a more local NHS organisation.

Example honorary research contract and letter

Human Resources Directorate

Date:

Dear *(insert name of researcher)*

Honorary research contract issued by X NHS organisation

I am pleased to offer you an honorary research contract in **[insert NHS organisation]**. 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 HR/R&D Department **[delete as appropriate]** of this organisation, who will arrange for you to be issued with an ID badge.

Yours sincerely

X
Director of Human Resources, X NHS ORGANISATION

cc: R&D office at X NHS organisation
HR department of the substantive employer

(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”.)

HONORARY RESEARCH CONTRACT BETWEEN	
NHS organisation(s):	AND
Name:	
Employer:	
OR Place of Study:	
Report To: (Principal Investigator/Head of Department)	
PERIOD of AGREEMENT	
From:	To:
OR Fixed term contract for: months years	Effective Date:
SIGNATURES	
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; 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.

Example letter of access for researchers who do not require an honorary research contract

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 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 Directorate

Date:

Dear *(insert name of researcher)*

Letter of access for research

This letter confirms your right of access to conduct research through **[Insert NHS organisation]** 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 **[Insert NHS organisation]** 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 **[Insert NHS organisation]** 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 **[Insert NHS organisation]**, 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 **[Insert NHS organisation]** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **[Insert NHS organisation]** 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 [**Insert NHS organisation**] 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 (<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.

[**Insert NHS organisation**] 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

X
Director of Human Resources, X NHS ORGANISATION

cc: R&D office at X NHS organisation
HR department of the substantive employer

Example letter of access for NHS researchers

For researchers with substantive employment or an honorary clinical contract with an NHS organisation

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 Directorate

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 **[Insert NHS organisation]** 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 **[Insert NHS organisation]** 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 **[Insert NHS organisation]**, 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 **[Insert NHS organisation]** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **[Insert NHS organisation]** 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 [**Insert NHS organisation**] 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 (<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.

[**Insert NHS organisation**] 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

X

Director of Human Resources, X NHS ORGANISATION

**cc: R&D office at X NHS organisation
HR department of the substantive employer (and provider of honorary clinical contract, where applicable)**

Example letter of agreement between NHS organisations

To permit NHS employees or staff with an honorary clinical contract (e.g. clinical academics) with one NHS organisation to conduct research in another NHS organisation-

Standard letter from an NHS organisation hosting research to the NHS employer or provider of an honorary clinical contract. It may be used for one project or a series of projects.

Human Resources Directorate
X NHS organisation

Date:

To Human Resources Directorate, Y NHS organisation

This letter is to confirm the arrangement between this NHS organisation and **[insert Y NHS organisation]** whereby your employees are permitted to conduct research in this NHS organisation. Such staff do not require an honorary research contract with this NHS organisation.

We offer a right of access to your staff to conduct research in this organisation in accordance with the clauses below.

Your staff have a right of access to conduct such research as is confirmed in writing in the letter of permission for research from this NHS organisation.

You are responsible for ensuring that such checks as you consider necessary for the clinical activities of your staff have been carried out, and we require you to undertake the necessary checks commensurate with the activities your staff will be conducting in this NHS organisation. We will require you to conduct additional checks if the research activities of your staff in this NHS organisation differ substantially from the current clinical activities of your staff. We agree to accept the checks undertaken by you, in order to enable your employee(s) to undertake research activities in this NHS organisation.

Your staff are considered to be legal visitors to the premises of this NHS organisation. They 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 them and this NHS organisation, in particular that of employees.

While undertaking research through this NHS organisation, your staff will be accountable to you as their employer but they will be required to follow the reasonable instructions of an appropriate head of department or supervisor 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 the right of access, your staff are required to co-operate fully with any investigation by us in connection with any such claim and to give all such assistance as may reasonably be required by us regarding the conduct of any legal proceedings.

Your staff must act in accordance with our policies and procedures, which are available to them upon request, and the Research Governance Framework.

Your staff are required to co-operate with us in discharging our 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 themselves and others while on our premises. Your staff 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 they must act appropriately, responsibly and professionally at all times.

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

We will not indemnify your staff 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 your staff and/or you as the substantive employer.

We accept no responsibility for damage to or loss of the personal property of your staff.

We may terminate the right of your staff to attend at any time either by giving seven days' written notice to them or immediately without any notice if they are in breach of any of the terms or conditions described to them or if they commit any act which we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to our interests and/or business or if they are convicted of any criminal offence.

We will inform you when any of your employees wishes to conduct research in this NHS organisation. Your staff must inform us of any changes to their circumstances in relation to their health, criminal record, professional registration or any other aspect that may impact on their suitability to conduct research. Your staff must also inform us of any change to their role in research in this NHS organisation.

Yours sincerely

X
Director of Human Resources, X NHS ORGANISATION

cc: R&D offices, NHS organisations X and Y

Example letter for joint arrangements

Letter from an NHS organisation accepting a researcher's existing Honorary Research Contract and forming a second honorary research contract with the researcher, where joint arrangements for issuing honorary research contracts have been agreed

Human Resources Directorate

Date:

Dear *(insert name of researcher)*

Existing Honorary Research Contract issued by Y NHS Organisation

Thank you for submitting a copy of your honorary research contract with **[insert Y NHS organisation]** and your Research Passport. I am pleased to offer you an honorary research contract in **[insert X NHS organisation]** on the same terms as the above contract except as detailed below. Please accept this letter as confirmation of such an arrangement.

The contract if accepted by you will commence 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 for the research project has received a letter from us giving permission to conduct the project.

Amendments to the existing honorary research contract issued by **[insert Y NHS organisation]** are as follows,

- While undertaking research through **[Insert X NHS organisation]**, you will remain accountable to your employer **[insert employer]** but you will 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.
- We will not reimburse any expenses you incur in the course of your research unless by prior arrangement we have agreed to do so. 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 this NHS organisation within the lifetime of the project. The information it contains must therefore be accurate and remain up to date.
- 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.

Yours sincerely

X

Director of Human Resources, X NHS ORGANISATION

**cc: R&D office at X NHS organisation
HR department of the substantive employer**

Example 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 tissues/organs?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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	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:
---------	-------

Example occupational health assessment request

If the researcher has previously completed a health self-assessment questionnaire for her/his substantive employer/place of study that is appropriate to the research activities to be performed, this form may be used to provide additional details to inform the occupational health assessment of the researcher by the 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.

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:		
Work 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 tissues/organs?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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	Other	Date:

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:
---------	-------

Example occupational health evidence

Name of researcher:	
Employer or place of study:	

The occupational health department should complete the information below about the applicant. This document will be made available to HR and research support staff in the employing organisation and in those NHS organisations where the applicant will be undertaking research. It should not contain confidential information without the consent of the applicant. In signing this form, the researcher consents to the sharing of relevant health information between occupational health staff of her/his employer and occupational health staff of those NHS organisations where she/he wishes to undertake research to inform the assessment of her/his suitability to conduct research within the NHS.

Any questionnaire, checklist or other document used in conducting an occupational health assessment must not be attached to this document or passed to any NHS organisation.

Please confirm which occupational health assessments have been carried out in respect of the applicant.

- Occupational health self-assessment questionnaire including physical conditions, psychological conditions, current workplace adjustments Yes No
- Interview with occupational health staff Yes No
- Medical examination by occupational health staff Yes No

Has an occupational health assessment confirmed that there are no health-related matters that could affect the health and safety of the applicant or others within the NHS?

Yes No

Is the applicant cleared for exposure-prone procedures? Yes No N/A

If no to either of the above, it may be necessary for occupational health staff in those NHS organisations where the applicant wishes to undertake research to discuss health-related information with the occupational health staff of the substantive employer.

Contact details of occupational health staff:

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

VACCINATION HISTORY

Please enter dates of vaccinations.

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:
		Scar Seen: Yes/ No/ Not checked
4	Polio booster	Date:
5	Tetanus booster	Date:
6	Varicella (chickenpox) screening	Date:
		Result:
7	Other	Date:
Occupational Health Comments:		

To be completed by the researcher before including this document in the Research Passport:

I consent to the information in this document being shared with relevant staff in the NHS for the purposes of ensuring my suitability to conduct research within the NHS. In addition, I consent to the sharing of relevant health information between my employer and those NHS organisations where I wish to undertake research to inform the assessment of my suitability to conduct research within the NHS.

Name:	
Signed:	Date:

Example confidentiality code of conduct

1 BACKGROUND

All NHS organisations work to a Code of Conduct for handling patient-identifiable information. Working to the same Code of Conduct helps ensure a more unified approach across NHS organisations to the way NHS staff handle, store, transfer and work with patient information. This also helps ensure compliance with the Data Protection Act 1998 <http://www.ico.gov.uk>.

The Health Service holds large amounts of confidential information about you, members of your family, friends, and colleagues; but the vast majority of this information will be about strangers, most of whom you are unlikely to meet. This information is classed as patient-Identifiable information. The information belongs to the patients. Their information should be treated with as much respect and integrity as you would like others to treat your own information. It is your responsibility to protect that information from inappropriate disclosure and to take every measure to ensure that patient-identifiable information is not made available to unauthorised persons.

This Code of Conduct on confidentiality, which is mandatory for all NHS organisations, aims to clarify the principles that govern all use of patient-identifiable information and to ensure that certain practices are adhered to. None of these practices is onerous and they should already be in everyday use. This document restates them as an expectation of how systems should be maintained.

The Code of Conduct is about promoting best practice and continuing improvement in the use of personal health information as an integral part of patient care. Involving patients in decisions about their healthcare information and how it is used is also integral to improving patient confidence in their health services.

Protection of personal health information is part of good practice, and is underpinned by the common law duty of confidentiality, the implementation of the Data Protection Act 1998, Codes of Professional Practice, and the Human Rights Act 1998.

Breaches of confidentiality are a serious matter. Non-compliance with this code may result in disciplinary action being taken. No employee shall knowingly misuse any information or allow others to do so.

NHS organisations are registered under the Data Protection Act 1998, and careless or deliberate misuse of patient-identifiable information may result in that organisation, and in some cases the individual concerned, being prosecuted under the Act.

2 AIM OF THE DOCUMENT

This document seeks to provide a code of conduct for all staff conducting research, which will ensure the confidentiality of patient-identifiable information at all times.

Scope

The code relates only to patient-identifiable information as defined within the Caldicott Principles, the Data Protection Act 1998 and the NHS Information Governance Toolkit.

Disciplinary and legal implications

Generally, there are four main areas of law which constrain the use and disclosure of confidential information. These are briefly described below but are covered in more detail in the document, Confidentiality: NHS Code of Practice, 2003.

The Data Protection Act 1998 (DPA)

The DPA is designed to control the use, storage and processing of personal data in whatever format - especially where there is a risk to personal privacy. Patients and staff should be aware that their information will be stored and processed on a computer.

Common law of confidentiality

Although not written in statute, the principle of the common law of confidentiality states that information confided should not be used or disclosed further, except as originally understood by the confider, or with her/his subsequent permission. In other words, if you are told something in confidence, you are not at liberty to disclose the information without permission.

Human Rights Act 1998

The Human Rights Act establishes the right to respect for private and family life. Current understanding is that compliance with the Data Protection Act and the common law of confidentiality should satisfy Human Rights requirements.

Administrative law

Administrative law governs the actions of public authorities to ensure that they operate within their lawful powers. In other words, the authority must possess the power to carry out what it intends to do and is particularly relevant to the issue of patient consent.

What do you do if in doubt about handling patient-identifiable information?

Each NHS organisation has a Caldicott Guardian of patient information. If you are in doubt regarding the handling of patient-identifiable information, ask the advice of your manager or, if necessary, contact the Caldicott Guardian for your organisation to ask for clarification.

Users' rights

Patients and families have a right to believe and expect that private and personal information given in confidence will be used for the purposes for which it was originally given, and not released to others without their consent. Everyone in the NHS must safeguard the integrity and confidentiality of, and access to sensitive information.

3 DEFINITIONS

What is Patient-identifiable information?

"All items of information which relate to an attribute of an individual should be treated as potentially capable of identifying patients and hence should be appropriately protected to safeguard confidentiality". (Caldicott Committee: Report on the review of patient-identifiable information, 1997)

These items include:

Surname	Forename
Initials	Address
Date of birth	Other dates (e.g. death, diagnosis)
Postcode	Occupation
Sex	NHS number
National Insurance number	Ethnic group
Local identifier (e.g. hospital or GP practice number)	

or a combination of these pieces of information.

Who is an unauthorised person?

Your job role, or level of access to a computer system, provides you with a level of authority to access information. Do not assume that all your work colleagues are authorised to see the same information that you are. Even if they are in a more senior role to you - if they do not need to know the information, they do not need to have it. If you are in doubt as to whether you should share the information with one of your colleagues, seek the advice of your manager or the Caldicott Guardian.

In certain instances, an NHS body or member of staff may have a statutory responsibility to pass on patient information.

- The NHS has a statutory obligation to notify the government of certain infectious diseases for public health purposes, e.g. measles, mumps, meningitis, tuberculosis, but not HIV/AIDS.
- Births and deaths must also be notified.
- Limited information is shared with health authorities and public health departments to assist with the organisation of national public health programmes, e.g. breast screening, cervical smear tests and childhood immunisation.
- Do not access patient information for anything other than your official duties, as misuse of the computer system will result in disciplinary action. It is not acceptable for staff to access their own records, or those of relatives, friends, or neighbours on their behalf. Staff and patients have rights of access to their own health and personnel records but this access should only be allowed in accordance with the guidance of the Data Protection Act 1998. The appropriate manager or Practice Manager within each organisation will be able to provide details.
- Patient-identifiable information must not be used in training, testing systems or demonstrations without explicit consent.

What is meant by the transfer of patient-identifiable information?

The transfer of patient-identifiable information, by whatever means, can be as simple as:

- taking a document and giving it to a colleague;
- making a telephone call;
- sending a fax;
- passing on information held on computer, for example confidential clinical information held on patient records.

In all cases, however simple or complicated, the Caldicott Principles (Figure 1) must be adhered to in order to ensure that patient-identifiable information is not disclosed inappropriately.

Figure 1 Caldicott Principles

1. **Justify the purpose.**
2. **Don't use patient-identifiable information unless it is absolutely necessary.**
3. **Use the minimum necessary patient-identifiable information.**
4. **Access to patient-identifiable information should be on a strict need to know basis.**
5. **Everyone should be aware of their responsibilities.**
6. **Understand and comply with the law.**

4 ENSURING CONFIDENTIALITY

Physical security

Room access – Patient-identifiable information should not be left unattended. However, where this can be justified, consideration should be given to restricting room access.

If the room can be locked without compromising patient care (e.g. where the patient information is unlikely to be needed by non key-holders), then it should be locked.

Work areas - Identifiable, confidential information should always be held securely. In any area which is not secure, and which can be accessed by a wide range of people (including possibly the public), such information should be put/locked away immediately after it has been finished with. Where it is impractical for this to be achieved, access to the work area must be restricted. Examples of this latter situation are:

- where work is being undertaken simultaneously on samples from a number of patients in a laboratory or clinical area that only laboratory or clinical staff may enter;
- where reports are dictated on a number of patients seen within a clinic in a reporting/medical office that only medical staff may enter;
- where a computer screen is angled to deny unauthorised viewing of confidential data.

Safeguarding information

- Never leave patient-identifiable information around for others to find.
- Wherever possible, avoid taking confidential information away from your work premises. Where this is necessary in order to carry out your duties (e.g. home visit to a patient), you must keep the information secure and make every effort to ensure that it does not get misplaced, lost or stolen.

Remember - you are bound by the same rules of confidentiality while away from your place of work as when you are at your desk.

- When disposing of paper-based information, ensure that it is shredded. Never put confidential information directly into a general waste paper bin or recycling bin. If your NHS organisation has a designated confidential waste destruction programme, you

must follow the requirements of that programme which can be checked with your head of department.

- Work diaries can hold a great deal of personal information and should be kept secure when not in use. Precautions should be taken when transporting your work diary to ensure it is in your care at all times. Remember to hand back any work diaries if you no longer need them for your job.
- Do not take personal notes or pocket books containing patient-identifiable information away from your place of work. If the information is no longer required, it should be disposed of appropriately. If the information is required for an ongoing purpose, it should be locked securely away. All personal notes and pocket books containing patient-identifiable information must be handed back to your manager if you no longer need them for your job.
- If documents containing patient information come into your possession and you are not the intended recipient, you should either forward these to the named person for action or storage or, if there is no named person, to your Caldicott Guardian. If you identify any document containing patient information, such as letters or clinical results, you should make every effort to decrease the possibility of these being seen by inappropriate persons by obscuring or turning them over; case notes or nursing notes left open should be closed. Wherever possible, these documents should be filed and locked away.
- Adopt a clear desk policy.

Patient-identifiable information left unattended

- Caution should be exercised at all times when working with patient-identifiable information.
- Only have the minimum information necessary on your desk for you to carry out your work. Any other related information should be put away securely, preferably locked away.
- Do not walk away from your work area leaving any documents exposed for unauthorised persons to see.

Information transfer

It is imperative that the utmost care is exercised when transferring patient-identifiable information. To this end written documents as well as fax machines and email should be used with care. When internal courier post or public mail is used, it is essential to confirm that the addressee details are correct. The basic rule is that in all circumstances where patient-identifiable data is shared, by whatever method, the items transferred should be restricted to a minimum. Only essential items of information should be included. Other items should be omitted or blocked out before transmission.

When transferring paper notes which contain patient-identifiable information, make sure "CONFIDENTIAL" is marked in a prominent place on the front of the envelope. Ensure that the address of the recipient is correct and clearly stated, using the following format:

- Name;
- designation (job title);

- department;
- organisational address.

Write a return address on the back of the envelope (if using a plain envelope).

If patient-identifiable information is to be sent in carrier (internal) envelopes, the envelope must be sealed and marked "CONFIDENTIAL". Internal mail should still be properly named and addressed, e.g. not just to "Mary from Maternity".

Do not pass documents containing patient-identifiable information to other colleagues by leaving them on a secretary's desk or in an "IN" tray. Always ensure that patient-identifiable information is in a sealed envelope addressed to the recipient and clearly marked "CONFIDENTIAL".

Transfer between hospital sites, clinics, community bases etc.

You should always ensure that a secure system for transferring care records (or other personal information that identifies individuals) between sites is used, referring to any guidance that your organisation issues.

Only authorised personnel may assist in the transfer of patient records where an office, department or practice is moving premises from one site to another. This must be done under the guidance of an authorised employee/employees of the relevant organisation.

Transfer between departments on site

Where an organisation has in place an internal system for transferring confidential information (e.g. routine portering transfer), this may be used to transport records between departments. Alternatively, appropriate special arrangements may need to be made for information required urgently (e.g. non-routine portering transfer). In either situation, the information must be correctly packaged and labelled as detailed earlier. Depending upon circumstances, it may be more appropriate and expedient to transport the information personally. If this is the preferred option, do not leave any information visible inside the car; ensure that it is locked away securely in the boot.

It is not appropriate for unpackaged information to be handed to another person for delivery simply because she/he is going to the destination department.

If you have any specific questions regarding transferring patient records, contact the assigned Records Manager or line manager in your organisation for further guidance.

Indiscreet conversations

- Ensure you cannot be overheard by unauthorised people when making sensitive telephone calls, during meetings, and when you are having informal discussions with colleagues about confidential information. In these situations, if you do not need to identify a patient by name, do not do so.
- Consideration needs to be given to the siting of an answer phone to ensure that recorded conversations cannot be overheard or otherwise inappropriately accessed.
- During team meetings/briefings (or visits to nursing homes) when a patient's details are being discussed, staff should bear in mind that they might be overheard by other people in the same room. While it is appreciated that it is difficult to manage confidentiality in situations like these, staff are expected to be aware of the possible problems and do all they can to respect the patient's rights.

- It is not appropriate to discuss personal information in hallways, corridors or stairways or any other public place where you might be overheard.
- When speaking to a patient or carer on the telephone, confirm the caller's identity or ring back. If in doubt, ask for confirmation in writing, or by fax.

Inappropriate sending of faxes

When sending faxes that contain patient-identifiable information try to use a designated Safe Haven fax wherever possible. A designated Safe Haven is a place where a fax containing confidential information can be sent safely in the knowledge that procedures are in place at the other end to ensure its security. NHS organisations are adopting the principle of Safe Havens, and every effort should be made to use them wherever possible. If you are faxing to a non-Safe Haven fax, the procedures below should be followed.

- Telephone first to inform the recipient that you are faxing confidential information.
- Ask if she/he could wait by the fax machine whilst you send it.
- Ask if she/he could telephone to acknowledge receipt.
- Always double check that you have keyed in the right number before hitting the "send" key.
- Numbers used regularly should be programmed into your fax machine, so decreasing the possibility of keying in the wrong number.

Safeguarding electronic computer information

The security and confidentiality of information held on computer must be maintained at all times.

- Never leave a computer logged on to a system and unprotected. Always protect the system (e.g. log off or use a password-protected screensaver) when you have finished or stop using it for a period. Always log off when you have finished. Failure to do this not only leads to a risk of unauthorised access to patient information, but you will be held responsible for any actions associated with your sign-on.
- Do not walk away from your work area and leave patient-identifiable information on your screen for unauthorised persons to see. If you need to leave your desk, you should protect the system (e.g. log off or use a password-protected screensaver).
- Where it is necessary for patient-identifiable information to be stored on your computer, ensure that it is stored in a secure way with password protection.
- Always remove your Smartcard from your computer (if using one to access systems) when leaving your workstation.
- Do not keep any patient-identifiable information longer than necessary. Delete personal files you do not need to keep and if the information is stored on diskette, tape or CD, ensure that it is clearly labelled and locked away. When the information held is no longer required, the diskette, tape, or CD must be reformatted, erased or destroyed in accordance with the relevant section of the IT Security Policy. Further advice on the retention of information can be found in the Records Retention and Disposal Policy.
- Computer users should remember that when deleting files they may be moved to a "recycle bin". Therefore, the recycle bin should be emptied on a regular basis. If in doubt, check with your IT Department or Systems Manager.
- Passwords are the keys that provide access to information; you must not disclose your network password to anyone under any circumstances. Never write your password down as this could be seen by other users, and always change your password when prompted. It is recommended that passwords should be a minimum

of 6 characters and be a mixture of letters and numbers, i.e. using 5 instead of S, 1 instead of l, etc.

- Turn off your computer at the end of the working day unless it is needed to work unattended, e.g. for print-outs.
- Never use anyone else's code and password, even to be helpful. Never, as a manager, ask anyone to use another's password for convenience. If it is absolutely necessary, (e.g. to access information when a patient or other person is in danger and the owner of the password cannot be found), contact the IT Department or Systems Manager.
- Destruction and /or disposal of computers, or parts thereof, must be carried out by your IT Department or Systems Manager. This will ensure that all information is stripped from the computer and disposed of using the correct procedures. You should not remove or relocate computers without first checking with your IT Department or Systems Manager.

If you use a portable computer outside your place of work ensure that:

- you have the authority to take equipment off-site;
- you have permission to transfer patient-identifiable information off site;
- your computer is password-protected to BIOS level which will be set by the IT department which provides the portable;
- you store back-ups securely and complete them regularly whilst using portables;
- databases are encrypted;
- keep anti-virus software up to date – see the IT department or Systems Manager for assistance if necessary;
- all equipment is locked away when not in use;
- every effort is taken to prevent loss or theft of your computer;
- you do not leave your computer in your car.

Use of the email system

Email encryption

The NHS Information Authority advises that email should be regarded as insecure unless full encryption is available at both ends of the transmission path.

Wrongly addressed

An email address that is incorrect poses a very real threat to the security of information. Messages can be addressed to the wrong person by mistake e.g. recipient with a similar name. There have been several high-profile cases of sensitive documents being sent to the wrong recipient with highly publicised consequences.

Forwarded email

The same degree of care should be taken in entering the address details when forwarding email messages to others.

Virus infection

Viruses and other malicious software can be attached to messages. These can cause infections in other systems and delay or prevent the transfer of messages. It is, therefore, important to maintain anti-virus software to minimise disruption of services.

Acceptable clinical email

The NHS encrypted email system should be used for clinical communications between NHS organisations. It is recommended that local policies and procedures are implemented at both ends of the communications path to ensure that:

- clinical information is clearly marked;
- emails are clearly addressed to the right people;
- browsers are safely set up so that, for example, passwords are not saved and temporary internet files are deleted on exit;
- the receiver is ready to handle the information in the right way;
- information sent by email will be safely stored and archived as well as incorporated into patients' records;
- there is an audit trail to show who did what and when;
- there is adequate fall-back and fail-safe arrangements in place in case of difficulties in transmission;
- information is not saved or copied onto any PC or medium that is "outside the NHS".

It is not acceptable practice to send clinical information by email without having these safeguards in place. Other email is considered insecure and must not be used to transmit sensitive patient-identifiable information.

See appendix 1 for an example of the recommended procedure for sending email.

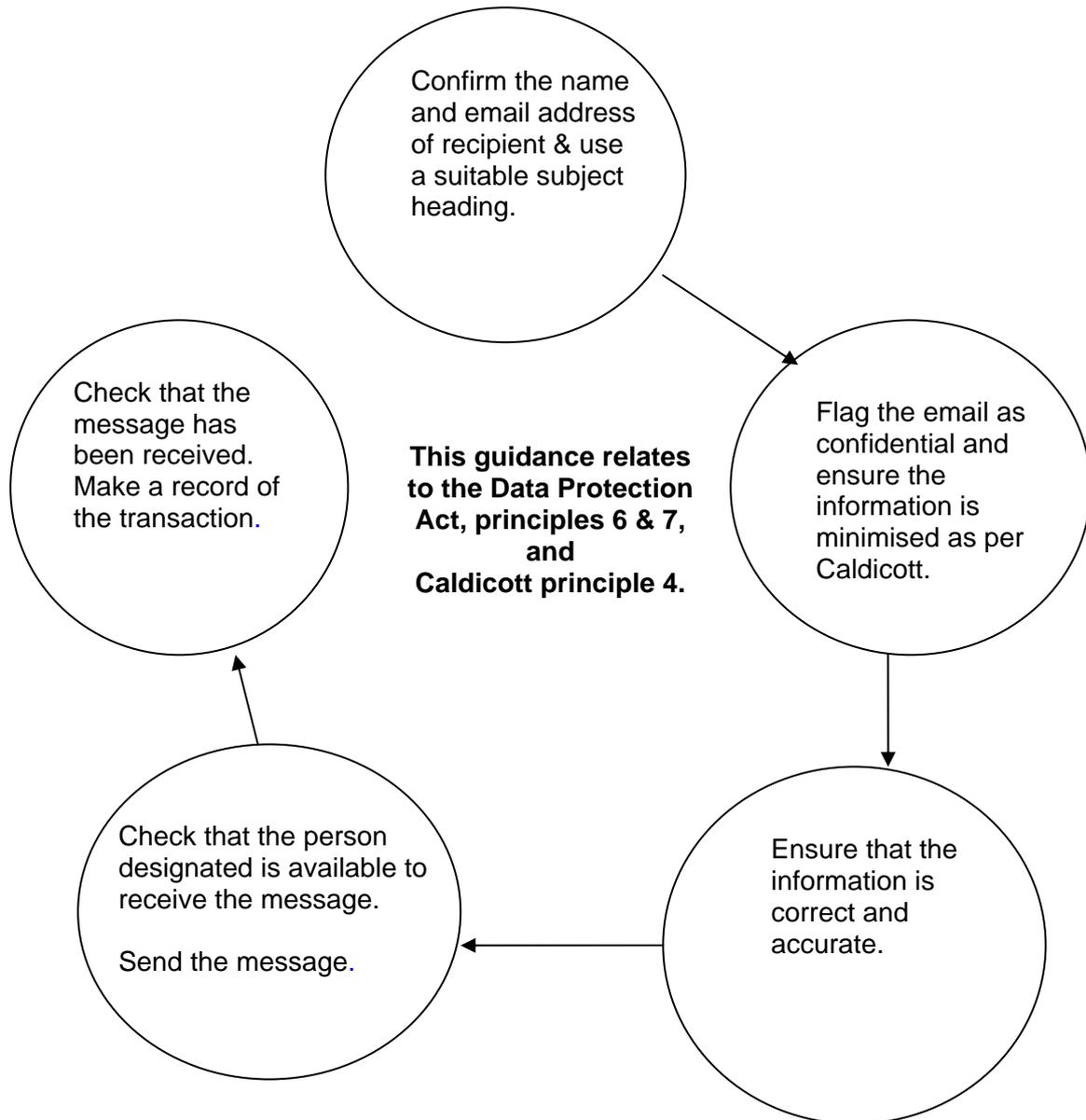
You are responsible for the content of your emails. Ensure that:

- patient-identifiable information is not sent via the internet; as this is not a secure system;
- you only use NHS addresses that are contained in NHS address books;
- you do not disclose your network password to anyone;
- you remember to log out of the system when you are leaving your computer.

Appendix 1

Procedure for sending email

When sending patient-identifiable information via email use the following procedure



Example confidentiality agreement between researcher and GP practice

GP Practices may wish to use a confidentiality agreement in addition to the clauses relating to confidentiality in any letter or honorary research contract issued by a Primary Care Organisation (PCT/LHB/Health Board.).

Name of Researcher:

GP Practice:

Project Title:

I, the undersigned, acknowledge, understand and agree to adhere to the following conditions of access.

Insert details of dataset fields and other information to be accessed in course of research

- I will maintain the privacy and confidentiality of all accessible project data and understand that unauthorised disclosure of personal/confidential data is an invasion of privacy and may result in disciplinary, civil, and/or criminal actions against me.
- I will not disclose data or information to anyone other than those to whom I am authorised to do so.
- I will access data only for the purposes for which I am authorised explicitly. On no occasion will I use project data, including personal or confidential information, for my personal interest or advantage, or for any other business purposes.
- I will comply at all times with the practice's data security policies and confidentiality code of conduct.
- I am informed that the references to personal, confidential and sensitive information in these documents are for my information, and are not intended to replace my obligations under the Data Protection Act 1998.
- I understand that where I have been given access to confidential information I am under a duty of confidence and would be liable under common law for any inappropriate breach of confidence in terms of disclosure to third parties and also for invasion of privacy if I were to access more information than that for which I have been given approval or for which consent is in place.
- Should my employment be terminated or my work in relation to the project discontinue for any reason, I understand that I will continue to be bound by this signed Confidentiality Agreement.

Researcher Signature:

Date:

GP/Practice Manager's Name:

GP/Practice Manager's Signature:

Date:

Honorary research contracts: principles and legal requirements

This document should be read in conjunction with the relevant Research Governance Framework and the appendix at the end of the document. For information relating to independent contractors, see also the NHS R&D Forum's document *Indemnity Arrangements within Primary Care*.

Summary:

- Researchers with a substantive employment contract with one NHS organisation do not need an honorary research contract to conduct research in another NHS organisation. NHS organisations can accept an existing NHS contract of employment, but additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations.
- Researchers with an honorary clinical contract with one NHS organisation do not need additional honorary research contracts to conduct research in other NHS organisations. Additional pre-engagement checks may occasionally be required. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations.
- Researchers with no contractual relationship with the NHS require an honorary research contract only if the planned activities of the researcher involve interacting with individuals in a way that has a direct bearing on the quality of their care, i.e. the researcher could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to patients or service users to whom the NHS organisation has a duty of care.
- Substantive employers retain responsibility for other research activities that do not affect the NHS organisation's duty of care.
- An honorary research contract does not confer the right of access to confidential information for research without explicit consent.
- Honorary research contracts do not provide a mechanism for access to confidential patient information without consent. Access to confidential patient information, either with patient consent or statutory support, does not require an honorary research contract.
- Researchers who do not require an honorary research contract may require additional pre-engagement checks to undertake permitted research activities in NHS organisations.
- Decisions on requirements for pre-engagement checks, induction and training rest with NHS organisations but should be commensurate with the role of the researcher, the type of research and the duty of care.
- There should be a system at local level for identification and local managerial control/supervision of all individuals carrying out research in or through the NHS.

1 Duty of care and duty of quality

- 1.1 Duty of care is the common law obligation to exercise a level of care towards an individual, as is reasonable in all the circumstances, to avoid injury to that individual or his property.
- 1.2 Once NHS organisations have given permission for research that affects their legal duty of quality and common law duty of care, they are then vicariously liable for clinical negligence and other negligent harm to individuals to whom they owe a duty of care. In general, NHS organisations have a duty of care to patients, service users and visitors. The liability for a breach of that duty is based upon the relationship of the

parties, the negligent act or omission and the reasonable foreseeability of loss to that individual.

- 1.3 There is a legal duty on each NHS organisation to put and keep in place arrangements for the purpose of monitoring and improving the quality of healthcare provided by and for that organisation. Healthcare means services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness; and the promotion and protection of public health.
- 1.4 NHS Indemnity covers negligent harm to patients and volunteers taking part in research that has been authorised by an NHS organisation. NHS Indemnity covers the actions of staff in the course of their employment and other researchers including clinical academic staff with honorary clinical contracts and those conducting clinical research, when the NHS organisation owes a duty of care to the person harmed.
- 1.5 NHS organisations are not liable for the actions of researchers that will not foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to an individual to whom the organisation has a duty of care.
- 1.6 The Research Governance Frameworks require researchers not employed by any NHS organisation who interact with individuals in a way that has direct bearing on the quality of their care to hold an NHS honorary contract.
- 1.7 When individuals who are patients or service users of an NHS organisation take part in research that is not hosted by or through that NHS organisation, e.g. by a university or in a private facility, the NHS organisation does not retain a duty of care for any healthcare provision by the external body¹. Where the participants were referred by the NHS organisation, the NHS organisation should have systems in place for ensuring the suitability of referrals.

2 Substantive employment

- 2.1 Employment can be described as performing work for the benefit of an employer (i.e. to fulfil its role and purpose) for remuneration. This arrangement is formalised through a legal contract in which the employer and employee agree on roles and responsibilities. This employer is described as the substantive employer.
- 2.2 Substantive employers are vicariously liable for any negligent acts committed by their employees during the course of their employment. Malpractice claims against staff employed by the NHS (i.e. other than independent contractors) are managed by the NHS employer and the costs borne by the NHS organisation (usually through a scheme, e.g. the Clinical Negligence Scheme for Trusts²).
- 2.3 Staff with a substantive contract with one NHS organisation may wish to conduct research in another NHS organisation. This research will form part of their NHS duties and should be covered by a letter of agreement between the NHS organisations. An honorary research contract with the other NHS organisation would not be required. Additional pre-engagement checks may still be required if the requirements of the NHS organisation hosting the research are different from those of the substantive NHS organisation. If an individual will be conducting research

¹ External body here does not refer to Independent Sector Treatment Centres, as such providers treating NHS patients benefit from the referring PCT's CNST membership

² For an explanation of NHS indemnity in relation to independent contractors see the statement published by the NHS R&D Forum (see links section).

regularly across a number of NHS organisations, e.g. as part of a research network, the contractual arrangements should be agreed across the relevant NHS organisations through a framework agreement. The NHS organisation where the research is being conducted should notify the substantive NHS employer of each project that the researcher is involved in.

3 Clinical academics

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

4 Honorary research contracts

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

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

- 5.1 An honorary research contract is only required when the research could have a foreseeable and direct impact on patient care. A foreseeable and direct impact on patient care means situations where the actions of a researcher could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to an individual to whom the organisation has a duty of care. In other situations, e.g. if the need for an intervention is revealed during the course of a research interview with a patient, an honorary research contract is not required. However, researchers should still ensure that appropriate arrangements are in place for situations where care interventions may become

necessary, and these arrangements should be explained in the participant information sheet.

- 5.2 Where an individual conducting research is not performing any activities that might have a direct and foreseeable impact on patient care, the vicarious liability for the actions of the individual should be retained by the substantive employer, and an honorary research contract is not appropriate. This is similar to the situation applying to other individuals who work for the benefit of their substantive employer but who conduct work within or involving an NHS organisation, e.g. regulatory inspectors. Inappropriate use of honorary contracts could potentially transfer to the NHS organisation liability that should be retained by the substantive employer, with damaging consequences for the NHS organisation.
- 5.3 Where an honorary research contract is not appropriate, an individual may still be conducting activities which should meet specific legal, ethical or regulatory standards. The requirement of an individual to conduct activities to an appropriate standard will be met through:
- ethical review of the project, and
 - patient consent where required³, and
 - permission from the relevant NHS organisation, and
 - registration with a statutory regulatory professional body, where relevant, and
 - a letter from the NHS organisation outlining the researcher's responsibilities, copied to the researcher's employer.
- 5.4 There should be a system at local level for identification and local managerial control/supervision of all individuals carrying out research in or through the NHS.
- 5.5 NHS Indemnity for clinical negligence can also provide cover in the event of negligence by staff conducting research with NHS permission but who do not require honorary research contracts, if the NHS organisation has a duty of care to the person harmed. Consideration should be given, in any contract or agreement between the NHS organisation and the substantive employer, to the NHS having the right to recover losses should they arise. It should be noted that this eventuality would be unlikely if the systems for issuing honorary research contracts outlined in this document are in place.

6 NHS staff as research participants

- 6.1 All employers have a common law duty of care for the health, safety and welfare at work of all their employees. Where research involves NHS employees as participants, the duty of care of the NHS organisation to its employees is non-delegable and the NHS organisation will always be liable, regardless of who employs the researcher. Research using NHS staff as participants should be subject to ethical review, and permission must be obtained from the staff member's NHS organisation. Where the individual conducting the research is not substantively employed by the NHS organisation, an honorary research contract will not affect accountability or liability and is therefore not appropriate. When NHS employees participate in research outside work, their participation is outside the NHS employer's duty of care, even if their participation makes use of knowledge or experience gained as a result of their employment.

³ The requirement for explicit consent applies to research unless disclosure is justified exceptionally in the public interest or has support in law in England and Wales under section 251 of the NHS Act 2006, as amended. Guidance relating to confidentiality and consent in research should be consulted for further details.

7 Confidentiality

This section is currently under review.

8 Pre-engagement checks

- 8.1 NHS organisations should consider the type and/or degree of pre-engagement checks (e.g. criminal record, occupational health) and the extent of subsequent induction or training that is required, ensuring that these are commensurate with the role of the researcher, the type of research and the duty of care. Pre-engagement checks may still be required for researchers who do not need an honorary research contract. NHS Employers (<http://www.nhsemployers.org>) and the UK health departments offer further guidance and advice on issues relating to those working within the NHS as employees, honorary staff, contractors, students or volunteers.
- 8.2 All individuals working within the NHS are required to disclose anything that might compromise their position, such as a recent conviction.
- 8.3 GMC-registered medical practitioners in England and Wales conducting research in hospitals may make use of the Occupational Health Smart Card which is being rolled out across the NHS. The cards record pre-employment check data securely such as GMC-registration status, contractual details, criminal record checks and occupational health and immunisation records for doctors who move from one NHS organisation to another.
- 8.4 Occupational health clearance is required for those who will interact directly with patients as part of their normal duties. Where health clearance has been obtained from an NHS organisation, and the individual retains a substantive employment contract with that organisation, the individual is responsible for ensuring that occupational health details are up to date. An occupational health check from an HEI might be suitable for the NHS environment in which a researcher will be working, and therefore may not need to be repeated.
- 8.5 All those who will have access to or contact with patients as part of their normal duties are required to provide a standard criminal record disclosure. Individuals whose research will regularly involve care, training, supervising or sole charge of children under 18 or vulnerable adults are required to provide an enhanced criminal record disclosure. In England and Wales, for research activities in childcare meeting the appropriate criteria for a 'regulated position', a check under the Protection of Children Act list (PoCA check) is also required. Separate PoCA checks must be conducted for each 'regulated position' an individual undertakes. In Scotland, for research activities in childcare meeting the appropriate criteria for a 'regulated position', applications for disclosures should request a check against the list of individuals Disqualified from Working with Children (DWCL) in accordance with the Protection of Children (Scotland) Act 2003 (POCSA).
- 8.6 In Scotland, individuals may also apply for a basic disclosure, which is the lowest level of disclosure and is available to anyone for any purpose, on payment of the appropriate fee. It contains details of convictions considered unspent under the Rehabilitation of Offenders Act 1974 or states that there are no such convictions. This type of disclosure is only issued to the applicant. It is not job-specific or job-related and may be used more than once.

- 8.7 All GPs have to provide an enhanced disclosure in order to provide services to the NHS.
- 8.8 Students on healthcare placements should provide an appropriate level of criminal record disclosure before starting their healthcare placement in the NHS, which takes account of the level of supervision to be given.
- 8.9 A criminal record disclosure carries no period of validity. Risk and use of resources need to be balanced when deciding the frequency of checks required. Individuals holding honorary research contracts should have a criminal record check at the start of their honorary engagement. This need not be repeated for the duration of the honorary research contract unless the details of the individual's research activity change and a higher level of disclosure is required or the individual's circumstances change in a way that might affect a criminal record check.

Appendix: Pre-engagement checks

A “direct bearing on the quality of care” suggests that the actions of researchers could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to an individual to whom the organisation has a duty of care.

	Honorary research contract (HRC) necessary ¹ ?	Made specifically aware of confidentiality?	Criminal record check necessary? ²	Occupational health clearance necessary?
Direct contact with patients/service users and direct bearing on the quality of their care (not children or vulnerable adults)	Yes	Yes, in HRC	Yes, standard or enhanced ³	Yes
Direct contact with children or vulnerable adults and direct bearing on the quality of their care	Yes	Yes, in HRC	Yes, standard or enhanced ³	Yes
Direct contact with patients/service users but no direct bearing on the quality of their care (e.g. observer)	No	Yes, in letter	Yes, standard or enhanced ³	Yes
Indirect contact with patients/service users and direct bearing on the quality of their care (e.g. some types of telephone interviews)	Yes	Yes, in HRC	Yes, standard or enhanced ³	No
Indirect contact with patients/service users but no direct bearing on the quality of their care (e.g. telephone interviews, postal questionnaires)	No	Yes, in letter	No	No
Access with consent to identifiable patient data, tissues or organs with likely direct bearing on the quality of their care	Yes	Yes, in HRC	No	No
Access with consent to identifiable patient data, tissues or organs but no direct bearing on the quality of their care	No	Yes, in letter	No	No
Access without consent ⁴ to identifiable patient data, tissues or organs but no direct bearing on the quality of their care	No	Yes, in letter	No	No
Access to anonymised patient data, tissues or organs only (including by research staff analysing data)	No	Not necessary ⁵	No	No
Working on NHS premises (e.g. laboratory) only	No	Yes, in letter	No	In some situations
Direct contact with staff (e.g. interviews)	No	Yes, in letter	No	No
Access to identifiable staff data	No	Yes, in letter	No	No
Access to anonymised staff data only	No	Not necessary ⁵	No	No

A simplified version of this table is provided [elsewhere](#) in the Resource Pack.

¹ Applies only to researchers with no contractual relationship with the NHS

² Students who have access to patients in the course of their normal duties will require a CRB check.

³ The level of supervision should be taken into account when determining whether an enhanced or standard disclosure is required. A check under the Protection of Children Act/ Protection of Children (Scotland) Act list may also be required. The host trust will advise on the criterion for the post applied for.

⁴ In England and Wales, regulations under Section 251 of the NHS Act 2006, as amended, specify the circumstances when identifiable patient information may be used for research without consent.

⁵ Specific reference to confidentiality is not necessary if access will only be to anonymised information, but the standard references to confidentiality in letters should be retained as general guidance.

Information governance and honorary research contracts

This section is currently under review.

Links

- A Good Practice Guide on Pre-employment Screening, Centre for the Protection of National Infrastructure, <http://www.cpni.gov.uk/Docs/Pre-employmentscreening.pdf>
- A Review of Appraisal, Disciplinary and Reporting Arrangements for Senior NHS and University Staff with Academic and Clinical Duties, A report to the Secretary of State for Education and Skills, by Professor Sir Brian Follett and Michael Paulson-Ellis, September 2001
<http://www.dfes.gov.uk/follettreview/>
- Confidentiality and Disclosure of Information: General Medical Services (GMS), Personal Medical Services (PMS), and Alternative Provider Medical Services (APMS) Code of Practice, Department of Health, 2005
<http://www.dh.gov.uk/assetRoot/04/10/73/04/04107304.pdf>
- Confidentiality: NHS Code of Practice, Department of Health, 2003
<http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf>
- Confidentiality: Protecting and providing information, General Medical Council, 2004
<http://www.gmc-uk.org/guidance/current/library/confidentiality.asp>
- CRB Disclosures in the NHS – April 2007, NHS Employers
<https://www.nhsemployers.org/practice/safer-recruitment.cfm>
- Data Protection Act 1998
<http://www.opsi.gov.uk/acts/acts1998/19980029.htm>
- Disclosure Scotland
<http://www.disclosurescotland.co.uk>
- Equality and Human Rights in the NHS: a guide for NHS boards, Department of Health, 2006
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_062906
- Guidance Note on Research Governance and Honorary Contracts, Chief Scientist Office, 2004
<http://www.sehd.scot.nhs.uk/cso/Publications/ResGov/Guidance/Honorary%20contracts%20guidance.doc>
- Health and Social Care Act 2008
http://www.opsi.gov.uk/acts/acts2008/pdf/ukpga_20080014_en.pdf
- Health and Social Care (Community Health and Standards) Act 2003
<http://www.opsi.gov.uk/acts/acts2003/20030043.htm>
- Human Rights Act 1998
<http://www.opsi.gov.uk/ACTS/acts1998/19980042.htm>
- Indemnity arrangements within Primary Care – who is responsible for what?, NHS R&D Forum, 2005
http://www.rdforum.nhs.uk/workgroups/primary/indemnity_arrangements.doc

- National Health Service Act 2006
http://www.opsi.gov.uk/acts/acts2006/pdf/ukpga_20060041_en.pdf
- NHS indemnity arrangements for handling clinical negligence claims against NHS staff, HSG (96)48, Department of Health, 1996
http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/HealthServiceGuidelines/HealthServiceGuidelinesArticle/fs/en?CONTENT_ID=4018270&chk=0Hc10u
- Occupational Health Smart Card, NHS Employers
<http://www.nhsemployers.org/practice/smart-cards.cfm>
- Personal Information in Medical Research, MRC Ethics Series, 2000 (updated 2003)
<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002452>
- Protection and Use of Patient Information, HSC 2000/09, NHS Executive, 2000
<http://www.dh.gov.uk/assetRoot/04/01/21/72/04012172.pdf>
- Research Governance Frameworks
http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/Researchgovernance/DH_4002112
- Research in the NHS: indemnity arrangements, Department of Health, 2005
<http://www.dh.gov.uk/assetRoot/04/12/52/84/04125284.pdf>
- Research: The role and responsibilities of doctors, General Medical Council, 2002
<http://www.gmc-uk.org/guidance/current/library/research.asp>
- Responsibilities, liabilities and risk management in clinical trials of medicines, Department of Health and Universities UK, 2004
http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/Researchgovernance/DH_4082518
- Safer recruitment guidance, NHS Employers
<http://www.nhsemployers.org>
- Use and Disclosure of Health Data, Guidance on the Application of the Data Protection Act 1998, Information Commissioner 2002
http://www.ico.gov.uk/upload/documents/library/data_protection/practical_application/health_data_-_use_and_disclosure001.pdf

