

Name	Procedure for the Implementation of the NHS Research Passport System.
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Background

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 procedures described in this document are taken from the [Research in the NHS – HR Good Practice Resource Pack](#).

Purpose

This SOP provides guidance and references to enable Research and Development Office staff and Human Resources Department staff to appropriately manage the Honorary Research Contract process for researchers who do not have a substantive contract with the National Waiting Times Centre Board.

Scope

The contents of this document apply to those individuals with the responsibility for the administration of the research project approval process:

- The Medical Director - the nominated NWTCCB Director with defined responsibility for research hosted by the Board.
- Clinical Directors – responsible for signing the **Authorisation required prior to R&D Approval** section (section 23) of the [NRES Site Specific Information form](#).
- The Research Manager – responsible for the continued development and administration of the R&D Approval process.
- Human Resources staff – responsible for all matters relating to employment contracts (honorary and substantive).

Responsible Personnel

Research Manager
Human Resources Manager (individual to be identified)

Abbreviations

GJNH	Golden Jubilee National Hospital
HR	Human Resources
HRC	Honorary Research Contract
NWTCB	National Waiting Times Centre Board
PI	Principal Investigator
R&D	Research and Development
SOP	Standard Operating Procedure

Procedure

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

1. Staff with substantive NHS employment contracts;
2. Researchers with a substantive university employment and an honorary NHS clinical contract, e.g. clinical academics;
3. Researchers with substantive university employment contracts and no honorary NHS clinical contract;
4. Researchers who are contracted to provide NHS services, e.g. GPs, who may or may not have a substantive university employment contract;
5. Researchers with substantive employment contracts with other employers, e.g. social workers;
6. University undergraduate or postgraduate students (some of whom may also have substantive NHS employment contracts);
7. Researchers in any of the above categories conducting research where the participants are NHS staff.

Essentially, the Research Manager reviews the [Site Specific Information \(SSI\)](#) form for each research project and advises the Human Resources department on the following two issues:

- The requirement for pre-employment checks. This is assessed using information contained within the SSI, the grid in [Appendix 1](#) and the information contained within [Appendix 2](#).
- The type of contract. This is detailed in [Appendix 2](#) however, in summary, the type of contract is dependant on present employment status: a Letter of Access is appropriate for researchers employed by, or who have Honorary Clinical Contracts with, the NHS. Honorary Research contracts are appropriate for researchers who have no contract status with the NHS (e.g. University employees).

The Human Resources department then carry out the pre-employment checks and, depending on the results, issue the Letter of Access or Honorary Research Contract.

Appendix 1: 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

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 60 of the Health and Social Care Act 2001 specify the very limited circumstances when identifiable patient information may be used for research without consent. The Patient Information Advisory Group considers such cases.
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.

Appendix 2: Research in the NHS – HR Good Practice Resource Pack

This appendix is taken directly from the above Resources Pack (Part 1: HR Good Practice, section 5, **Researchers in the NHS**).

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 [Appendix 1](#): 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 [Appendix 3](#): 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 [Appendix 4](#): 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.

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 [Appendix 1](#): 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 [Appendix 3](#): 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 [Appendix 4](#): 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.

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 [Appendix 1](#): 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.

a. **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 through the Research Passport system that arrangements are in place for handling access to identifiable patient data (see [Information governance and honorary research contracts](#));
- Arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Appendix 1](#): 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 [Appendix 5](#): 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.

b. 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 through the Research Passport system that arrangements are in place for handling access to identifiable patient data (see [Information governance and honorary research contracts](#));
- Arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Appendix 1](#): 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 [Appendix 6](#): 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.

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 **3b** 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 **3a** should be followed.

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.

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 through the Research Passport system that arrangements are in place for handling access to identifiable patient data (see [Information governance and honorary research contracts](#));
- Arrange for any additional pre-engagement checks required by the research activity to be undertaken (see [Appendix 1](#): 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 [Appendix 6](#): 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.

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 [Appendix 5](#): 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.**

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.

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.

Appendix 3: 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 Department
National Waiting Times Centre Board
Golden Jubilee National Hospital
Beardmore Street
Clydebank
G81 4HX

Insert 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.

We agree to accept that such checks as you consider necessary for the clinical activities of your staff have been carried out, where such checks are 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.

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

Director of Human Resources, National Waiting Times Centre Board

**cc: R&D Offices, National Waiting Times Centre Board
R&D Offices, Y NHS organisation**

Appendix 4: 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 Department
National Waiting Times Centre Board
Golden Jubilee National Hospital
Beardmore Street
Clydebank
G81 4HX

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 such checks as are necessary have been carried out by your employer and that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. This letter confirms your right of access to conduct research through the National Waiting Times Centre Board for the purpose and on the terms and conditions set out below. This right of access commences on **[insert date]** and ends on **[insert date]** unless terminated earlier in accordance with the clauses below.

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

You are considered to be a legal visitor to the National Waiting Times Centre Board premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through the National Waiting Times Centre Board, you will remain accountable to your employer **[insert employer]** but you are required to follow the reasonable instructions of your nominated manager **[insert Head of relevant NHS Department/research supervisor]** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation

by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with the National Waiting Times Centre Board policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with the National Waiting Times Centre Board 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 National Waiting Times Centre Board 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.

The National Waiting Times Centre Board 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

Director of Human Resources, National Waiting Times Centre Board

**cc: R&D office at the National Waiting Times Centre Board
HR department of the substantive employer (and provider of honorary clinical contract, where applicable)**

Appendix 5: 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 will not require access to confidential patient information or who do not require pre-engagement checks). It may be used for one project or a series of projects.

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

Human Resources Department
National Waiting Times Centre Board
Golden Jubilee National Hospital
Beardmore Street
Clydebank
G81 4HX

Date:

Dear *(insert name of researcher)*

Letter of access for research

This letter confirms your right of access to conduct research through the National Waiting Times Centre Board for the purpose and on the terms and conditions set out below. This right of access commences on **[insert date]** and ends on **[insert date]** unless terminated earlier in accordance with the clauses below.

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

The information supplied about your role in research at the National Waiting Times Centre Board 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 National Waiting Times Centre Board premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through the National Waiting Times Centre Board, you will remain accountable to your employer **[insert employer]** but you are required to follow the reasonable instructions of **[head of relevant NHS Department/research supervisor]** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation

by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with the National Waiting Times Centre Board's policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with the National Waiting Times Centre Board 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 National Waiting Times Centre Board 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.

The National Waiting Times Centre Board 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

Director of Human Resources, X NHS ORGANISATION

**cc: R&D office at the National Waiting Times Centre Board
HR department of the substantive employer**

Appendix 6: Example honorary research contract and letter

Human Resources Department
National Waiting Times Centre Board
Golden Jubilee National Hospital
Beardmore Street
Clydebank
G81 4HX

Date:

Dear *(insert name of researcher)*

Honorary research contract issued by the National Waiting Times Centre Board

I am pleased to offer you an honorary research contract in the National Waiting Times Centre Board. 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

Director of Human Resources, National Waiting Times Centre Board

cc: R&D Office, National Waiting Times Centre Board

HR department of the substantive employer

(A copy of the signed honorary research contract must be sent to the substantive employer/academic supervisor)

HONORARY RESEARCH CONTRACT BETWEEN

NHS
organisation(s): National Waiting Times Centre Board

AND

Name:
Employer:
OR Place of Study:
Report To:
(Principal Investigator/Head of
Department)

PERIOD of AGREEMENT

From: To:
OR
Fixed term years
contract for: months 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 Board named in this Agreement (“the Board”), 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 Board named in this Agreement (“the Board”), 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 Board provides healthcare services to NHS patients, including patients who are protected by the criminal record disclosure arrangements.

C. The Board and Researcher have entered into this agreement whereby the Researcher can have access to the Facilities of the Board 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 Board. 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 Board, employees of the Board or visitors to the Board.

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 Board 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 Board 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 Board including the Research Governance Framework, copies of which are available upon request.

3.3. The Researcher is required to co-operate with the Board 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 Board. 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 Board immediately. The Researcher must report any accident or injury, arising out of or in the course of her/his activities at the Board 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 Board.

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 Board 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 Board). Unauthorised disclosure could lead to prosecution under the terms of the Act.

5. Legal Claims

- 5.1. The Board agrees to indemnify the Researcher for any claims in negligence in respect of those patients of the Board to whom the Researcher provides care and treatment when performing duties in accordance with this Agreement.
- 5.2. The Board 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 Board 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 Board.
- 5.4. The Board accepts/accept no responsibility for damage to or loss of the Researcher's personal property.
- 5.5. The Board 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 Board 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 Board 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 Board or the Employer/Place of Study as part of any investigation of a complaint or of suspected misconduct.

7. Intellectual Property

The Board is required by the Scottish Government Health Department to protect and manage intellectual property arising from Research and Development funded by the NHS. The Board 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 Board, 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 Board 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 Board on relevant national databases and incorporated into the Annual Research Report of the Board. This Agreement will be subject to random checks as part of the research and development audit activity of the Board.

9. Duration and Termination

- 9.1. The Board, 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 Board 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 Board reserves/reserve the right to:
 - 9.3.1. Terminate the Agreement forthwith without notice and refuse the Researcher access to the Facilities of the Board; 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 Board; or
 - 9.3.3. Require that this Agreement is suspended subject to investigation by the Employer/Place of Study in conjunction with the Board. The Employer/Place of Study and the Board 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 Board agrees 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 Board 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 Board 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.