

Standard Operating Procedure

Title: **STUDY TEAM – Issue of an Honorary Research Contract**

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|---|--------------------|---------------------|
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1. BACKGROUND

What is the Honorary Research Contract?

Honorary Contracts are a tool used by the NHS to ensure that non-NHS researchers (who therefore do not have a paid contract with an NHS body) are contractually bound to take proper account of the NHS duty of care and to follow the requirements of research governance at every stage in the conduct of their research. In turn, the issuing of an Honorary Contract ensures that non-NHS researchers are covered, like NHS staff, by NHS indemnity (HSG(96)48). Thus honorary contracts offer protection to the NHS, researchers and to the participants in research.

The ultimate sanction a Trust holds within an Honorary Agreement is to withdraw the rights of access conferred by the agreement, prevent the researcher from accessing NHS facilities to conduct their research and disassociate itself with the person concerned. The responsibility for initiating disciplinary procedures lies with substantive employers.

Who should have an Honorary Research Contract?

The Research Governance Framework states unequivocally that care organisations must ensure that non-NHS employed researchers hold honorary NHS contracts where appropriate (appendix I) and that there is clear accountability and understanding of who is responsible for what. The Department of Health has issued further guidance on who should hold Honorary Contracts.

The status of the research team and the details of the research project will be screened at the notification stage, by the R&D Lead to identify whether or not any Honorary Contracts are required.

How will an Honorary Contract be obtained?

The **Research Passport** is a document that researchers complete to apply for an Honorary Research Contract (HRC). The Research Passport aims to provide assurances from the substantive employer (usually a university) to the NHS organisation about the applicant (university employee). The document confirms that an agreed list of pre-engagement checks have been carried out on the applicant (see p26 Research in the NHS-HR Good practice resource Pack V1.1 January 2009 available from the R&D office). The processing of the **Research Passport form** (appendix II) is undertaken by one lead NHS organisation. The details may then be provided to other NHS organisations covered by the remit of the completed passport.

The Research Passport system:

Places the onus on the researcher and the researcher's substantive employer to provide and verify the necessary information regarding the researcher's suitability to carry out research in the NHS;

Ensures that the appropriate accountability is in place;

Avoids unnecessary duplication of checks;

Increases efficiency in the issue of HRCs;

Allows NHS organisations to easily audit and share information;

Gives NHS organisations' HR departments assurances that the appropriate pre-engagement checks have been carried out.

2. PURPOSE

This Standard Operating Procedure (SOP) describes the process for issuing an HRC and/or the processing of a Research Passport with accompanying Letter of Access for Research within the Wirral University Teaching Hospital NHS Foundation Trust.

3. OTHER RELATED PROCEDURES

Research Passport (Appendix II)

Issue of Letter of Access for research (appendix III)

Trust Requirements (appendix V)

4. WHEN

Honorary Research Contracts (HRCs) should be issued in accordance with the national guidance (see table Appendix IV - from Research in the NHS-HR Good practice resource Pack V1.1 January 2009). Overuse places inappropriate liability on the NHS Organisations (Wirral University Teaching Hospital NHS Foundation Trust).

If an NHS substantive contract or an honorary clinical contract is with an NHS organisation the researcher does not need an HRC to conduct research in another NHS organisation. In this case the Research Governance Lead will, on proof of employment, issue a Letter of Access for Research.

If there are no NHS contracts an HRC is issued only if the research activities involve interacting with individuals in a way that has a direct bearing on the quality of care. HRCs do not provide a mechanism for access to confidential patient information without consent.

When researchers conduct activities with no direct bearing on the quality of care, vicarious liability for the actions of the individual rests with the substantive employer and a HRC should not be issued.

Whether an HRC is issued or not the Trust should make arrangements for the appropriate management and or supervision of the researcher by the persons with either a substantive or honorary contract with the NHS organisations concerned.

5. WHO

Requests for an honorary contract should be made to the R&D office who will identify researchers who need to be issued with a contract. The Research Passport Application form will need to be filled in and submitted to the R&D Office.

6. HOW

The researcher applies to the NHS organisation for R&D approval for permission to conduct the research through the normal processes – NIHR CSP. The application is screened by the R&D leads to determine if a HRC is required at the initial application.

The NHS R&D office provides a Research Passport form and specifies the Information required for the Research Passport, e.g. standard CRB disclosure (see pre-engagement checks below).

The researcher completes the Research Passport form and requests the appropriate signatures and documents needed as evidence of the relevant checks from the substantive employer's HR department.

The researcher presents their Research Passport along with accompanying documents to the NHS R&D office.

A CV, Occupational Health Screen, evidence of professional registration are included and checked by the R&D lead.

If the researcher lacks the necessary R&D experience/qualification the PI is notified as to suitability.

A HRC is drawn up and three copies (One for the Office, One for the researcher, and one for the substantive employer) are issued for signature by the R&D/RMG Lead.

Once returned the HRC is issued with the appropriate accompanying letter.

The passport is returned with the original CRB to the researcher with the Appropriate letter (Appendix IV)

A copy of the HRC is sent to the substantive employer.

Notice of the issue is recorded in the database.

The original Research Passport is returned to the researcher.

The HRC is issued when permission to conduct the research is granted by the NHS organisation. Additional sites are covered by a letter of access.

The Research Passport is either project-limited (less than three years), or for a Three year maximum duration if the researcher is working on a number of projects. The processing of a Research Passport form by an NHS organisation should not take longer than two weeks if all appropriate pre-engagement checks have been conducted.

Depending on the nature of the substantive employment and the proposed research, additional checks may be required and additional time will be taken before the HRC can be issued.

Pre-engagement checks

The R&D office should consider the type or degree of pre-engagement checks (e.g. CRB and 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. Generally 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.

All those who will have access to or contact with patients as part of their normal duties are required to provide a standard CRB disclosure. Individuals whose work will regularly involve care, training, supervising or sole charge of children under 18 or vulnerable adults are required to provide an enhanced CRB disclosure. For childcare posts meeting the appropriate criteria for a 'regulated position', a check under the Protection of Children Act list (PoCA check) is also required.

A CRB disclosure carries no period of validity. However, the frequency of checks needs to balance risk with use of resources. Within the Office an initial application will accept a recent CRB with the application (within one year of

the application). Individuals holding HRCs should have a CRB check at the start of their honorary engagement. This need not be repeated for the duration of the HRC 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 may affect a CRB check. If a new PoCA check is required a new disclosure must be obtained.

The R&D office will take the following action:

It is standard procedure to check researchers' CV and professional registration (if appropriate). Where research may involve contact with children or service users with learning disabilities or mental-health difficulties, such as CRB disclosure and occupational health screening. An occupational health check form should suffice for research with limited patient contact.

From 12 October 2009 all individuals working with vulnerable adults and children will have to be registered with the Independent Safeguarding Authority (ISA) before they work. This will be incorporated into the Trust Requirements (Appendix V) for researchers working in the relevant areas from 12 October 2009

Each project will need to be taken on a case-by-case basis ensuring that the checks are commensurate with the scale of the research and potential risk to which the Trust is exposed by agreeing to host that research. It is not appropriate for the Trust to investigate every research proposal in the same depth regardless of risk. Checks should relate to the individual role that the researcher will assume within the Trust when conducting their research. Hence any decision on what pre-employment screening should be carried out may take into account factors such as:

- The time physically spent within the organisation
- Degree of contact with patients
- Contact with vulnerable patients such as children or people with learning disabilities
- Whether or not the project involves non-NHS staff undertaking procedures that impinge on the care of patients where they may not have the skills to undertake that task safely.

Honorary Contract records

R&D will store the honorary contracts. A copy will be placed in the researcher's project folder and the information will be stored electronically on a database. Upon termination of the contract the honorary employee should be required to return Trust property as appropriate including ID badges.

Appendix I Honorary Research Contract
(A copy of the signed honorary research contract must be sent to the substantive employer/academic supervisor)

| | |
|--|-----------------|
| 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

- 9.4. The Trust(s) agrees/agree that no later than five working days prior to terminating the Agreement in accordance with 9.2 or 9.3 above, it will inform the Employer/Place of Study of its intention to do so.
 - 9.5. The Trust(s) reserves/reserve the right to exclude the Researcher at any time from its premises for whatever reason, pending a decision upon whether it wishes to terminate this Agreement.
 - 9.6. It is the obligation of the Researcher to disclose any mitigating circumstances that may affect the Agreement such as a change in criminal record, registration, employment or occupational health status.
- 10.** The Researcher warrants that she/he has the relevant skills and expertise to undertake the research for which she/he is permitted to use the Facilities of the Trust(s) and is supported through suitable professional development programmes or training by the Employer/Place of Study or research sponsor, to ensure that she/he is suitable to undertake research.

Appendix II 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: |

When Sections 1-3 have been completed, the researcher should forward the form to the appropriate person to complete Section 4.

Section 4 - Suitability of Researcher

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

| | | |
|----|---|-------------|
| 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: | |

When Section 4 has been completed, the researcher should forward the form to the appropriate person to complete Section 5.

Section 5 - Pre-engagement checks

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

| | | |
|----|---|--|
| 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? | |
| | Employment/student screening: <ul style="list-style-type: none"> o ID with photograph o two references o verification of permission to work/study in the UK o exploration of any gaps in employment | Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| | ▪ Evidence of current professional registration | Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| | ▪ Evidence of qualifications | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| | ▪ Occupational health screening | Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| | Signed: | Date: |
| | Name: | Job Title: |
| | Organisation: | Department: |
| | Address: | |
| | Email: | |

Please return the form to the researcher.

| 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: |
|-------|------------|

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|---------------|-------------|
| Organisation: | Department: |
|---------------|-------------|

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|--------|
| Email: |
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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"/> |
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| | |
|---------|-------|
| 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.

Appendix III Letter of Access for Research
(On Trust standard headed paper)

Clinical Trials Unit
C Block North
Arrowe Park Hospital
Arrowe Park Road
Upton. Wirral
CH49 5PE

Tel: 0151-604-7311
Website: <http://www.whnt.nhs.uk>

Our ref:
Address

Date:

Letter of access for research

Title of project:

Start date:to be reviewed

Dear ,

This letter confirms your right of access to conduct research through Wirral University Teaching Hospital NHS Foundation Trust (WUTH) for the purpose and on the terms and conditions set out below. This right of access commenced on2009 and ends on2009 unless terminated earlier in accordance with the clauses below. You have a right of access to conduct the above research.

The information supplied about your role in research at WUTH 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 WUTH 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 WUTH, you will remain accountable to your employer but you are required to follow the reasonable instructions ofin this NHS organisation or those given on h... 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 WUTH policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with WUTH 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 WUTH 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.

WUTH 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 Letter of Access changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

R&D Co-ordinator or Manager

CC:

Appendix IV Research in the NHS-HR Good practice resource Pack V1.1 Part 2 January 2009 available from the R&D office **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 |

For Research Passport System requirements and to confirm the type of pre-engagement check required, please see Table - page 47 - of the document NIHR Research passport:

Appendix V

Wirral University Teaching Hospital NHS Foundation Trust. Research Passport System: Trust Requirements.

Revised following discussion 11 February 2009 with Pauline Fitzgerald, Anthony Kenna, Dr Rod Owen and Carol Eames **P1 of 2**

| GROUP | Researcher activity | Researchers: Higher Educational Institute, NHS Staff & Research Network and Others |
|--------------|---|---|
| 1 | Interventional patient contact and more than eight weeks at the Trust | Enhanced CRB Trust occupational health check. (OHC) <i>If allied health professional copy of employers OHC.</i> Mandatory training* Induction *** (if advised by R&D) Trust Code of Confidentiality & signed agreement |
| 2 | Less than eight weeks at the Trust WITHOUT continuous supervision | As above (Group 1) but with Mandatory training** Induction*** (if advised by R&D) |
| 3 | Less than eight weeks at the Trust WITH continuous supervision | Trust Code of Confidentiality & signed agreement CTU/R&D to inform HR of requirement for continuous supervision |
| 4 | More than eight weeks at the Trust No direct patient contact. Group 2 Includes staff as research participants | Standard CRB Mandatory training* Induction*** (if advised by R&D) Trust Code of Confidentiality & signed agreement |
| 5 | Less than eight weeks at the Trust No direct patient contact | Trust Code of Confidentiality & signed agreement |

Research Passport System: Trust Requirements. P2 of 2

Identity Badge: All Researchers are required to wear a hospital ID badge; available from The Education Centre. Badge request made on-line by C Eames. Researcher applies for badge at mandatory training session.

* Mandatory training to include Health And Safety, Medicine Management, Annual CPR For Nursing And Allied Health Professionals, Fire, Manual Handling, Child Protection.

**Mandatory training to include Health & Safety, Fire, Manual Handling - and Medicine Management for Nursing and Allied Health Professionals.

***Trust Induction when appropriate to Researcher/Trust requirements, as per Trust policy.

Mandatory training will be arranged via email from CTU with details of researcher and researcher group (above) to Anthony Kenna in L&D Department

Research start and end dates to be included on letter of access for research. Researcher to inform Trust if dates change. Network employees for review after 3 years.

CV: Professional body/employer check: to be confirmed before letter of access completed.

Exceptions procedure – if urgent need – with follow-up to ensure CRB etc. Individual Exceptions to be discussed with Jill O'Callaghan for opinion/advice.

The researcher's manager will be required to complete the Requests for Exceptions Approval form.

From 12 October 2009 all individuals working with vulnerable adults and children will have to be registered with the Independent Safeguarding Authority (ISA) before they work. This will be incorporated into the Trust Requirements for researchers working in the relevant areas from 12 October 2009