# STANDARD OPERATING PROCEDURE FOR RESEARCH & DEVELOPMENT
## Research Passports

<table>
<thead>
<tr>
<th>Version:</th>
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<tbody>
<tr>
<td>Name of originator/author:</td>
<td>Jane Carter, R&amp;D Manager</td>
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<td>Related Procedural Documents:</td>
<td>RNHRD Research Governance Policy RNHRD Research Passport Policy</td>
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## Document Audit Trail

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<tr>
<td>1.0</td>
<td>6/02/12</td>
<td>Jane Carter</td>
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Other relevant publications and associated documents

**NATIONAL:** NIHR Research in the NHS –HR Good Practice Resource Pack.

**LOCAL:** Standard Operating Procedure Research and Development – Research passports

RNHRD Pre employment checks Policy

RNHRD Research Governance Policy

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STANDARD OPERATING PROCEDURE FOR RESEARCH & DEVELOPMENT
Research Passports

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1.0 INTRODUCTION

1.1 Research within the NHS often relies on working in partnership with the Higher Education sector and is often undertaken by non-NHS staff, including staff employed by Higher Education Institutions (HEIs). This relationship calls for clear understanding about responsibility, accountability, patient safety, and duty of care. The Research Governance Framework requires all parties to be clear about responsibilities and liabilities. One of the ways this can be achieved is through appropriate use of honorary research contracts (HRCs).

1.2 The Research Passport system has been developed to:
   - provide a common approach towards issuing NHS honorary research contracts/Letters of Access.
   - provide a mechanism for assuring NHS organisations of the pre-engagement checks conducted on a researcher, thus reducing duplication of checks for researchers working across a number of NHS institutions (appendix 2).

1.3 The onus is 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.

1.4 The Research Passport (RP):
   - is the mechanism for non-NHS staff to obtain an HRC/Letter of Access when the research they propose to carry out is likely to impact on patient care.
   - is the document completed by researchers and their substantive HEI employer that lists the pre-engagement checks the HEI employer has carried out.
   - can be taken to more than one NHS organisation, so reducing the need for duplicate pre-engagement checks at multiple NHS organisations.

1.5 The 'Research in the NHS – Human Resources Good Practice Resource Pack'
http://www.nihr.ac.uk/files/Research%20Passport%20Current/HR_Good_Practice_Information_for_researchers_R+D_and_HR_staff_in_HEIs_and_the_NHS.pdf available via provides detailed advice for implementing the research passport system.

2.0 AIM

To describe the procedure within the Trust R&D Office for processing Research Passport applications (Appendix 1).

3.0 OBJECTIVES

This Standard Operating Procedure applies to all Trust R&D staff who have a responsibility for processing of research passport applications relating to research undertaken at the RNHRD.
4.0 DEFINITION OF RESEARCH PASSPORT

The Research Passport (RP):

- is the mechanism for non-NHS staff to obtain an HRC/Letter of Access when the research they propose to carry out is likely to impact on patient care.
- is the document completed by researchers and their substantive HEI employer that lists the pre-engagement checks the HEI employer has carried out.
- can be taken to more than one NHS organisation, so reducing the need for duplicate pre-engagement checks at multiple NHS organisations.

There are two types of RP:

- Project specific passport: required for researchers who will be involved with only one project over the course of three years
- Three year passport: required for researchers who will be working on a number of studies over the course of three years and have an ongoing research portfolio

5.0 RESPONSIBILITIES

5.1 Responsible Personnel

R&D Manager, RG Facilitator, HR Personnel

6.0 PRINCIPLES

6.1 The NHS organisation where the research will be undertaken will determine whether an honorary research contract is required. Whether an honorary research contract or Letter of Access is required or not, pre-engagement checks may be necessary (Appendix 2).

6.2 An honorary research contract is NOT required when the researcher has a substantive or honorary employment contract with an NHS organisation but a Letter of Access will be issued when confirmation from the NHS substantive employer provides evidence of pre-employment checks. However, additional pre-engagement checks may occasionally be required at the discretion of individual Trusts in order to undertake permitted research activities in NHS organisations.

6.3 Undergraduate and postgraduate students may conduct research as part of their health care placements. Students on health care placements should have appropriate pre-engagement checks conducted when they start their health care placement in the NHS. 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 Higher Education staff with honorary clinical or research contracts who themselves are covered by NHS indemnity.

6.4 An honorary research contract IS required when the researcher has no honorary or substantive contract with an NHS organisation, or where the planned activities of the researcher involve interacting with individuals in a way that has a direct bearing on the quality of their care.

6.5 A direct bearing on the quality of care suggests that the actions of researchers could foreseeably 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 (Appendix 2).

6.6 Where the researcher will have no direct bearing on the quality of patient care a Letter of Access will be issued on receipt of a valid research passport.

7.0 PROCEDURES

7.1 When researchers query the process for applying for a research passport/honorary research contract, the R&D Office or HR Department may send the following via e-mail:

> Individual researchers who do not have an honorary contract or a substantive post with an NHS organisation, e.g. employed solely by a University, must complete a research passport application form in order to obtain an honorary research contract. The passports are accessed via the link below, with guidance available from the research passports page.

> Application:  http://www.nihr.ac.uk/files/passportdocs/2passport.doc

> Research Passport Page

> http://nihr.ac.uk/systems_research_passports.aspx

> Each researcher must liaise with their employer’s HR department within the University or other external organisation in order to commence the process. The completed research passport and accompanying documentation (e.g. CRB check) must be submitted to the Trust R&D Office with the research study application. The research passport will be processed through the Trust R&D Office and the Trust HR department, and returned to the researcher prior to Trust R&D approval. The honorary research contract will be issued to the researcher with the final Trust R&D approval letter.

7.2 When the R&D Office receives a RP, the RG Facilitator will:
- Check that the project has R&D approval prior to reviewing any RP application or is in the application process.
- Check that sections 1 to 6* of the RP have been completed fully, and that any supporting documentation listed in section 6* has been provided (original copies).
- Check the requirements against the Research Passport algorithm to ensure that all appropriate checks have been carried out by substantive employers.
- Produce a standard letter/HRC to cover either project or 3 years, dated appropriately.
• The R&D Manager will sign off the RP if appropriate and issue HRC/Letter of Access
• The RG Facilitator/R&D Administrator will photocopy the RP, any supporting documentation and a copy of the signed HRC/Letter of Access and file in the R&D locked filing cabinet within a secure office, a copy of the RP and save an electronic copy into the ‘Research Passport’ folder.
• The RG Facilitator/R&D Administrator will return the RP and signed HRC/Letter of Access to the applicant and any supporting documentation.
• A copy of the HRC/Letter of Access will be forwarded to the Trust HR department.
• A copy of the HRC/Letter of Access and R&D approval letter will be forwarded to the researcher’s HR department.

8.0 RESOURCES

No additional resources have been identified as being required.

9.0 TRAINING

In house training will be provided for all relevant staff.

10.0 IMPLEMENTATION

The R&D Manager and RG Facilitator and Trust HR Department are all responsible for implementing this procedure.

11.0 AUDIT

11.1 Compliance
The Trust R&D Committee is responsible for overseeing the operational management of Research Governance and of providing assurance of robust Research Governance arrangements within the Trust.

11.2 Audit.
The Research Passports system will be audited on an annual basis.

11.2 Fit for Purpose.
It will be necessary for the Procedure to be evaluated for fitness for purpose. Feedback will be sought from individuals who have made use of the procedure.

12.0 DISTRIBUTION

The Procedure will be available on Public folders and the Trust intranet site.

13.0 REFERENCES

1. Research Governance Framework for Health and Social Care
14.0 APPENDICES

Glossary of Terms

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<thead>
<tr>
<th>C</th>
<th>CRB</th>
<th>Criminal Records Bureau</th>
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<td>HEI</td>
<td>Higher Education Institution</td>
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<tr>
<td></td>
<td>HR</td>
<td>Human Resources</td>
</tr>
<tr>
<td></td>
<td>HRC</td>
<td>Honorary Research Contract</td>
</tr>
<tr>
<td>L</td>
<td>LoA</td>
<td>Letter of Access</td>
</tr>
<tr>
<td>N</td>
<td>NHS</td>
<td>National Health Service</td>
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<td>R</td>
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<tr>
<td>S</td>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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Appendix 1: Procedure for Processing Research Passport Applications within R&D Office.

When a research passport (RP) is received in the R&D Office, the RG Facilitator/Administrator will:
- Check project database to ensure project has R&D approval or has been received and is awaiting approval

The RG Facilitator/Administrator will:
- Check that sections 1 to 6 of the RP have been completed fully, and that any supporting documentation listed in section 6 has been provided.
- Check the requirements against the Research Passport algorithm to ensure that all appropriate employment checks have been carried out by substantive employers.
- Check the RP Algorithm to decide if an Honorary Research Contract or a Letter of Access is required.

R&D Manager to sign off RP where appropriate, provided the project has Trust R&D approval in place.

If the project has already had R&D approval:
Send signed HRC/Letter of Access to the researcher.
Return the original RP, original supporting documents and 1 copy to the researcher.
1 copy of the HRC/Letter of access forwarded to RNHRD HR and 1 copy to the HR dept of the applicant.
File 1 copy in the research passport folder in the R&D office
Update the R&D Research Passport spreadsheet identifying issue/expiry date.

If the project has not yet had R&D approval:
File the Research Passport form/documentation in the R&D Office under Research projects pending folder in the R&D filing cabinet.
Await R&D approval

Project approval granted
Appendix 1: Research Passport Flow Chart

Researcher obtains passport from link below, and completes section 1-4 *
http://www.nihr.ac.uk/files/passportdocs/2passport.doc

Researcher provides University HR with Research Passport for completion of section 5* (or substantive employer)

Research Passport returned to Researcher who completes section 6*

Researcher sends passport to R&D Office with project application. Registered with R&D and original supporting documents

Passport assessed by R&D
R&D issue HRC or LoA and a copy is sent to HR.
Research Passport returned to researcher via Trust R&D

HRC/LoA issued to researcher once the study has received Trust R&D approval

Where the researcher is from a University, the Trust R&D Office will:
send letter to University HR department to confirm Trust R&D approval & HRC/LoA for the study.

*Section numbers may vary, as individual establishments may design their own RP application form.

Section 1 – Details of researcher
Section 2 – Details of research
Section 3 – Declaration by researcher
Section 4 – Suitability of researcher
Section 5 – Pre-engagement checks
Section 6 – Instructions to applicants
Section 7 – Additional pre-engagement checks
### APPENDIX 2: Honorary Research Contracts and Pre-engagement Checks

<table>
<thead>
<tr>
<th>Direct contact with patients/service users and direct bearing on the quality of care (not children or vulnerable adults)</th>
<th>Honorary Research Contract (HRC) necessary?</th>
<th>Made specifically aware of confidentiality?</th>
<th>Criminal Record Check necessary?</th>
<th>Occupational health clearance necessary?</th>
<th>HRC or LoA</th>
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<tbody>
<tr>
<td>Yes</td>
<td>Yes in HRC</td>
<td>Yes standard or enhanced</td>
<td>Yes</td>
<td>HRC</td>
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<tr>
<td>Direct contact with children or vulnerable adults and direct bearing on their quality of care</td>
<td>Yes</td>
<td>Yes in HRC</td>
<td>Yes standard or enhanced</td>
<td>Yes</td>
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<td>Direct contact with patients/service users but no direct bearing on the quality of care (e.g. observer)</td>
<td>No</td>
<td>Yes in Letter</td>
<td>Yes standard or enhanced</td>
<td>Yes</td>
<td>LoA</td>
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<tr>
<td>Indirect contact with patients/service users and direct bearing on the quality of their care (e.g. some types of telephone interviews)</td>
<td>Yes</td>
<td>Yes in HRC</td>
<td>Yes standard or enhanced</td>
<td>No</td>
<td>HRC</td>
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<td>Indirect contact with patients/service users but no direct bearing on the quality of their care (e.g. telephone interviews postal questionnaires)</td>
<td>No</td>
<td>Yes in letter</td>
<td>No</td>
<td>No</td>
<td>LoA</td>
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<td>Access with consent to identifiable patient data, tissues or organs with likely direct bearing on their quality of care.</td>
<td>Yes</td>
<td>Yes in HRC</td>
<td>No</td>
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<tr>
<td>Access with consent to identifiable patient data, tissues or organs but no direct bearing on the quality of their care.</td>
<td>No</td>
<td>Yes in Letter</td>
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<td>LoA</td>
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<tr>
<td>Access without consent to identifiable patient data, tissues or organs but no direct bearing on the quality of their care.</td>
<td>No</td>
<td>Yes in Letter</td>
<td>No</td>
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<td>Access to anonymised patient data, tissues or organs only (including by research staff analysing data)</td>
<td>No</td>
<td>Not necessary</td>
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<tr>
<td>Activity Description</td>
<td>Yes in Letter</td>
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<td>In Some Situations</td>
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<tr>
<td>Working on NHS premises (e.g. laboratory) only.</td>
<td>Yes in letter</td>
<td>No</td>
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<td>Direct contact with staff (e.g. interviews)</td>
<td>Yes in letter</td>
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<td>Access to identifiable staff data</td>
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