# CPFT Research Passports, Honorary Research Contracts and Letters of Access

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<th><strong>Author</strong></th>
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Signed on behalf of the Trust: …

Tracy Dowling, Chief Executive

Elizabeth House, Fulbourn Hospital, Fulbourn, Cambs CB21 5EF Phone: 01223 726789
### Version Control Sheet

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1. Scope

For use by;
- Researchers not employed by Cambridgeshire and Peterborough NHS Foundation Trust (CPFT)
- HEI substantive employers/students
- CPFT Research and Development (R&D) staff
- Trust Managers

2. Purpose

To provide clear and concise guidance for the local management of:
- The Research Passport (RP) system
- Honorary Research Contracts (HRC)
- Letters of Access (LoA)

3. Abbreviations

The meaning of abbreviations used within the document are listed in the table below.

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<td>CI</td>
<td>Chief Investigator</td>
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<td>CTIMP</td>
<td>Clinical Trial of an Investigational Medicinal Product</td>
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<td>CRN</td>
<td>Clinical Research Network</td>
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<td>DBS</td>
<td>Disclosure and Barring Service</td>
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<td>GCP</td>
<td>Good Clinical Practice</td>
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<td>HEI</td>
<td>Higher Education Institutions</td>
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<td>HR</td>
<td>Human Resources</td>
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<td>HRC</td>
<td>Honorary Research Contract</td>
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<td>ISA</td>
<td>Independent Safeguarding Authority</td>
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<td>LoA</td>
<td>Letter of Access</td>
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<td>NIHR</td>
<td>National Institute of Health Research</td>
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<td>OH</td>
<td>Occupational Health</td>
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<td>PI</td>
<td>Principal Investigator</td>
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<td>REC</td>
<td>Research Ethics Committee</td>
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<td>RP</td>
<td>Research Passport</td>
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<td>SLA</td>
<td>Service Level Agreement</td>
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4. Introduction

4.1 This SOP implements the Human Resources (HR) arrangements for researchers, introduced by the UK Clinical Research Collaboration (UKCRC) to streamline NHS Trust approval for access in the NHS by external researchers, and set out in the ‘Research in the NHS – HR Good Practice Resource Pack’ (http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx)

4.2 The UK Clinical Research Collaboration (UKCRC) is a partnership of organisations working to establish the UK as a world leader in clinical research, by harnessing the power of the NHS. The UKCRC is working to promote a streamlined regulatory and governance environment that facilitates high-quality clinical research while protecting the rights, dignity and safety of patients. As part of its activities, it has coordinated the development of a Good Practice Resource Pack to help the NHS and other research employers take a consistent approach to handling HR arrangements for those undertaking research in the NHS. All relevant documents are included in this document as appendices.

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

4.4 Duplication of pre-engagement checks and inappropriate use of honorary research contracts wastes considerable amounts of time and resource for both HEIs and NHS organisations.

4.5 Cambridgeshire and Peterborough NHS Foundation Trust (hereafter referred to as ‘the Trust’ or ‘CPFT’) is a partner in the NIHR Clinical Research Network (CRN) via its contract with CRN Eastern. The CRN’s Lead Research Management and Governance Manager is supporting Research and Development (R&D) managers across NHS organisations in order to adopt an approach to implementation that is as uniform as possible to reduce inconsistencies and ensure a smooth process for NHS access for researchers. Access for external researchers is implemented within the Trust according to national NIHR guidelines.

5. Aims and Objectives

5.1 The aim of this document is to provide clear and concise guidance for the local management of the Research Passport (RP) system and subsequent issue of honorary research contracts (HRC) and letters of access (LoA).
This document applies to all Research and Development (R&D) conducted by individuals whose substantive employment is external to the Trust. It is for use by Trust managers, external researchers (not employed by CPFT), HEI substantive employers/students, Human Resources and R&D Department Staff

5.2 The primary objective is the implementation of the Research Passports Scheme through the adoption of the Good Practice Resource Pack.

6. Definitions

6.1 The Research Passport (Appendix 1) is the standard form which provides information about a non-NHS researcher, including evidence of the pre-engagement checks that have already been conducted – to enable the NHS Trust/s hosting the research to issue an Honorary Research Contract or a Letter of Access (Non-NHS). The form is completed by the researcher and her/his employer, and validated by the host Trust. The validated Research Passport is presented to all other relevant NHS Trusts in order for an honorary research contract or Letter of Access (Non-NHS) to be issued rapidly.

6.2 The Honorary Research Contract is the standard contract between a researcher who has no contractual relationship with the NHS and wishes to conduct research in the NHS and the NHS trust hosting the research. It clarifies and confirms the accountability arrangements, including the policies, procedures and codes of conduct the researcher must abide by. An Honorary Research Contract is required as opposed to a Letter of Access when there is a possibility that the research activity may cause harm or impact on the treatment of service users.

6.3 The Letter of Access (Non-NHS) is the standard letter permitting access to service users, their data and/or Trust premises and confirming the responsibilities of a researcher who has no contractual relationship with the NHS and does not need an Honorary Research Contract.

6.4 The Letter of Access (NHS) is the standard letter permitting access to patients and confirming the responsibilities of a researcher who is either an employee of another NHS Trust or holds an Honorary Clinical Contract with another NHS Trust. Researchers may apply for this type of access using the NHS to NHS pro forma, see section 6.5.

6.5 Letter of Access Confirmation of pre-engagement checks form is the form which provides information about a NHS researcher - including evidence of the pre-engagement checks that have already been conducted – to enable the NHS Trust/s hosting the research to issue a Letter of Access. The form is completed by the researcher and her/his employer.
7. Roles and Responsibilities

7.1 Chief Executive/Medical Director
As accounting officer, the Chief Executive has overall responsibility for the effective implementation of this document. This responsibility is delegated to the Medical Director.

7.2 Medical Director
The Medical Director is responsible for the development, implementation, monitoring and review of this policy.

7.3 Clinical Effectiveness SubCommittee
The Clinical Effectiveness Subcommittee is responsible for the development, approval, implementation, monitoring and review of this policy.

7.4 The Research and Development (R&D) Team is responsible for:
- ensuring the implementation and the requirements outlined within this procedure are observed
- ensuring all divisions are made aware of the procedure.
- providing a single point of contact for externally employed researchers seeking to conduct research in the Trust
- assessing the need for a Research Passport, honorary research contract or Letter of Access (NHS) based on the individual’s employment status
- for non-NHS employees, assessing the need for an Honorary Research Contract or Letter of Access (Non-NHS) based on the nature of the proposed research project or programme
- assessing, in conjunction with HR, the need for pre-engagement checks based on the nature of the proposed research project or programme and also the appropriateness of pre-engagement checks already conducted by the researcher’s substantive employer
- requesting additional pre-engagement checks if required
- issuing Honorary Research Contracts and Letters of Access as appropriate
- training R&D staff within the Trust to ensure compliance with the Research Passports Policy
- maintaining an accurate record of Honorary Research Contract and/or Letters of Access (NHS and non-NHS) granted and sharing with relevant departments on a regular basis.

7.5 SERCO Employment Services are responsible for:
- providing advice on changing NHS legislative requirements

7.6 Human Resources Directorate is responsible for:
- providing advice on changing NHS legislative requirements
• supporting Trust employees in providing evidence to other NHS organisations hosting research as requests, such as completing the NHS to NHS proforma
• Researchers who are not clinically qualified and wish to undertake one or two days of observation of a research study may apply to CPFT HR outside of the main RP system.
• Where researchers are clinically qualified all access will need to be granted via the Trust’s Medical Staffing department.

7.7 Learning and Development Team is responsible for:
• advising Trust managers on induction and training requirements for staff with honorary contracts or letters of access
• supporting researchers in gaining access to their mandatory training requirements

7.8 Nominated NHS managers are responsible for:
• ensuring that study team members have the appropriate level of access for conducting research in the Trust.
• for ensuring that research staff receive reasonable instruction and follow relevant Trust policies.

8.0 General principles

8.1 The day to day management of the Research Passport System will be undertaken by the R&D Office.

8.2 The R&D Office will follow the Research Passport Algorithm as detailed in the NIHR HR Good Resource Pack. The algorithm provides clear guidance on the circumstances in which it is appropriate to issue an HRC or a LoA and the pre-engagement checks that must be evidenced.

8.3 All researchers must have the full support of either their substantive employer or place of study. Researchers approaching the Trust independently of their workplace/place of study will not be granted access to the Trust through the RP system.

8.4 Before issuing an HRC/LoA, the R&D Office will verify that an identified Trust manager is in place, who is to provide managerial supervision for the research activity.

8.5 Substantive employers will retain responsibility for other research activities that do not affect the Trust’s duty of care.
8.6 An HRC does not confer the right to access confidential information for research without explicit consent.

8.7 An HRC/LoA will not be issued for a period that will exceed the remainder of the life of the researcher's substantive employment contract.

8.8 All LoAs and HRCs issued will be signed by the Senior R&D Manager.

9. Who needs an honorary research contract/letter of access?

Those working in research within the NHS fall into a number of different categories (detailed below). In each of these categories, the RP system will be applied as follows;

(a) NHS employed researchers
Researchers already employed by another NHS organisation do not need to complete the RP application form and should not be issued with an HRC. Researchers in this group should complete the NHS to NHS Confirmation of Pre-engagement checks form and, together with their CV, submit to the R&D Office. An NHS to NHS LoA can then be issued.

(b) Honorary Clinical Academics
Researchers with substantive contracts with the University of Cambridge and honorary clinical NHS contracts are able to undertake research within the NHS organisation where they also perform their clinical duties. They do not therefore need an HRC.

Researchers in this group wishing to conduct research in another NHS organisation should be treated in the same way as NHS employed researchers (category ‘a’ above) and issued with an NHS to NHS LoA.

(c) Researchers with substantive university contracts and no other contractual arrangement with the NHS
Researchers in this group must complete a RP Application form. Contractual arrangements (i.e. issue of HRC or LoA) and pre-engagement checks will be dependent on the nature of the research activity. The R&D Office will use the NIHR RP algorithm to establish whether an HRC or LoA is appropriate and the pre-engagement checks that are required.
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. In such cases a researcher would be issued with an HRC.

When researchers conduct activities with no direct bearing on care, the vicarious liability for the actions of the individual rests with the substantive employer and thus an HRC is not required. In such circumstances a LoA would be issued to the researcher.

(d) Researchers with substantive employment contracts with charities, local government or other similar organisations
Arrangements for researchers within this group are similar to those in category ‘c’ above. However, where no local arrangements have been made to extend the RP system to the organisation, there will be no established method to share information about pre-engagement checks. In such cases and where it is deemed reasonable, the R&D Office may undertake appropriate pre-engagement checks and claim the costs for these from the substantive employer.

(e) Students
Undergraduate and postgraduate students are able to conduct research as part of a healthcare placement. A memorandum of understanding between the HEI and Trust will already be in place and as such the RP System should not be used.

Students are able to conduct research in the NHS other than through a healthcare placement. If students are:

- Clinically qualified but not supervised – the student must complete the RP Application form and be issued with either an HRC (if there is a direct bearing on care) or LoA. Under such arrangements, supervision will be by way of a CPFT Manager.

- Not clinically qualified and supervised – the student must be fully supervised by an NHS member of staff or HEI employee with an HRC at all times. An HRC for the student in this case may not be necessary.

- Not clinically qualified and not supervised – the student should complete the RP Application, with subsequent issue of an HRC or LoA as appropriate.

(f) Researchers undertaking observation only
Researchers who are not clinically qualified and wish to undertake one or two days of observation of a research study may apply to CPFT HR outside of the main RP system.
Where researchers are clinically qualified all access will need to be granted via the Trust’s Medical Staffing department.

(g) Work Experience
Researchers wishing to undertake a short period of work experience with a research team will need to contact CPFT HR directorate.

(h) Commercial researchers
Commercial researchers are not able to conduct research in the NHS through the RP system. Commercial research should be managed through a Service Level Agreement (SLA) between the commercial organisation and the Trust. SLAs may be study specific or applicable to all R&D approved studies that the company is involved in. Pre-engagement checks for each researcher must be completed and letter issued by the R&D Office to confirm access to the Trust.

(i) Support staff of researchers
Research support staff, such as administrators, should request access to CPFT via the RP system. Where the individual is an employee of an HEI or other organisation such as a charity the RP system can be applied as above. If the individual is self-employed or employed via a commercial organisation the RP system should not be used. In such cases an SLA with the research team may be more appropriate.

10. Pre-engagement Checks

General Principles

- In all cases standard pre-engagement checks must have been obtained and verified by an HR representative of the researcher’s substantive employer. These are detailed below but will include;
  - References
  - Right to work/study in the UK
  - ID with photograph
  - Evidence of qualifications
  - Exploration of any gaps in employment
  - Evidence of professional registration where applicable
Additionally, the RP algorithm clearly states under what circumstances OH or Disclosure and Barring Service (DBS) disclosure are applicable.

The substantive employer/place of study must fund the cost of all pre-engagement checks.

The R&D Office reserves the right to request sight of original pre-engagement checks or request additional pre-engagement checks from a researcher’s substantive employer should they be deemed necessary. The costs of any additional checks will be passed on to the substantive employer.

Pre-engagement checks must be signed off by the HR department of the substantive employer or place of study in the case of students, and not a departmental administrator or line manager.

Pre-engagement checks for temporary workers should be signed off by the substantive employer engaging the temporary worker and not the agency supplying them.

Pre-engagement checks from overseas should be translated and verified by an officially recognised translator.

If any pre-engagement check is deemed to be unsatisfactory the R&D Office will not issue a LoA/HRC. The reasons for this decision will be outlined in writing to the researcher, copied to their line manager and HR representative.

A researcher may appeal a decision not to issue an HRC/LoA because of unsatisfactory pre-engagement checks. This appeal must be made in writing to the Senior R&D Manager who will review the information before making a final decision. There are no further rights to appeal.

The Trust R&D Office must be informed of any changes regarding pre-engagement checks.

Disclosure and Barring Service (DBS, previously Criminal Records Bureau).

Where a researchers’ activity meets the definition of ‘Regulated Activity’¹, the researcher must provide evidence of a satisfactory DBS disclosure and appropriate barred list check.

The Trust will not issue an HRC or LoA to an individual researcher to undertake regulated activity who is known to be barred by the Independent Safeguarding Authority (ISA).

¹ See HR Good Practice Guide for a summary, or Schedule 4 of the Safeguarding Vulnerable Groups Act 2006 for a full definition of Regulated Activity
Furthermore, if the Trust suspends access to a researcher because they harmed or posed a risk to harm vulnerable groups the R&D Office has a legal obligation to inform the ISA. This will be done in conjunction with the HR department of the substantive employer.

The R&D Office will only require evidence of DBS in specific circumstances, as identified in the RP Algorithm.

In all circumstances where DBS clearance is applicable, the R&D Office will require the researcher’s original disclosure certificate and will determine if the disclosure is at an appropriate level. If this is not the case then a new DBS clearance will be requested.

**DBS certificates should be no more than 12 months old** and should have been requested by the substantive employer or by CPFT. If researchers are applying via the NHS to NHS pro forma, the DBS will need to be within 3 years of validity. DBS checks will be confirmed every three years.

Where a conviction, caution or reprimand is disclosed on a DBS disclosure certificate the Senior R&D Manager will complete a risk assessment. The outcome of this may be that the researcher is able to work in their planned research activity, able to do so with certain conditions or may have their application for an HRC/LoA turned down.

**Occupational Health (OH) clearance**

The Researcher’s activity will determine whether an OH clearance certificate is required by the R&D Office (as indicated by the RP Algorithm). In such cases the certificate must be provided with the completed RP Application form prior to issue of an HRC/LoA, and it must be within 12 months of issue.

The R&D Office will accept OH clearance given by another NHS organisation, provided that the clearance was at the level required by the research.

Where OH clearance is given by a non-NHS employer it will be acceptable provided that:

- the clearance was at the level required by the research and met the standards required in the NHS; and
- there is a policy in place requiring employees to notify their substantive employer about changes to their health status;

**ID/Right to work or study**

The R&D Office will follow guidelines laid out in the Trust’s Recruitment and Selection procedure with regard to acceptable documents to evidence ID and right to work.
• It is the responsibility of the substantive employer to undertake checks to the appropriate level.

• It is the responsibility of the substantive employer to ensure that the right to work/study remains in place for the duration of the HRC/LoA.

Professional Registration

• For research activity that requires the Researcher to have professional registration (such as Nursing and Midwifery Council or Health and Care Professions Council etc) it is the responsibility of the substantive employer to ensure that registration is in place and that the registration remains in place for the duration of the HRC/LoA.

• The R&D Office may, from time to time, audit professional registration and may suspend Trust access to any Researcher found not to have current registration with immediate effect.

References

• It is the responsibility of the substantive employer to ensure that appropriate references are sought for researchers.

• 2 references should be obtained, with both referees being able to show direct knowledge of the work performance of the individual and be able to comment on their suitability for the post. One referee should include the individual’s most recent line manager.

• For students a course tutor would be an acceptable alternative to the most recent line manager.

• References should not be accepted from relatives or from people writing solely in the capacity of friends.

Good Clinical Practice (GCP) training

Researchers undertaking Clinical Trials of Investigational Medicinal Products (CTIMPS) must provide the Trust’s Research and Development Department with written evidence that they have completed GCP training within the last two years before they start their research. All other researchers should complete GCP training at the earliest opportunity.

NHS to NHS pre-engagement checks

• Researchers employed by another NHS trust should complete the NHS to NHS confirmation of pre-engagement checks pro forma

• A representative from the HR department of the substantive employer should sign the form and submit to the R&D Office
11. **Process for applications for HRC/LoA**

General enquiries to the R&D Office are welcomed. The generic research passport email address (r&d@cpft.nhs.uk) should be used in all correspondence.

**Research Passports**

- All researchers not employed by an NHS Trust should complete sections 1, 2 and 3 of the RP application form.
- The researcher’s line manager or academic supervisor should complete section 4 to indicate the suitability of the individual for the specified research activity.
- An HR representative of the researcher’s substantive employer should complete section 5 of the application form, signing off all pre-engagement checks.
- The RP application form, CV and any additional documents (DBS/OH where applicable) should be sent to the R&D Office for validation. Section 6 provides a useful checklist.
- **The R&D Office** will complete section 7 where applicable and section 8 of the RP application form.
- The R&D Office will subsequently issue either a LoA or HRC as appropriate.
- Copies of the HRC/LoA will be provided to the substantive employer’s HR department and NHS manager. The original RP application form will be returned to the researcher, with a copy retained by the R&D office.

12. **Leavers**

The R&D office should be informed by the substantive employer if a researcher leaves before their contract end date.

13. **Short Term Extension Requests of less than 3 months**

- Subject to confirmation that there is no change in the research activities and no change in the researcher’s DBS or OH status (where applicable) we will issue a **one-off** short term extension to the HRC/LoA up to a period of 3 months.

- The extension will take the form of a letter sent to the researcher; a new HRC/LoA will not be issued.
• A copy of the letter issued will be sent to the researcher's line manager and the substantive employer's HR department.

14. Amendments to the research passport

• Amendments to the RP usually take the form of the following;
  o Additional research projects
  o Changes to research activity on the original project(s)
  o Personal details (including changes to DBS or OH status)

• Where the substantive employer changes, researchers cannot use the amendment process, even if they are working on the same research project. In such cases a new RP application must be made.

• Researchers whose line manager changes and/or research project changes, but where the employer remains the same should ask their new line manager to complete Section 4 of the RP application form and submit with an appendix page.

Any amendment should be recorded by the researcher on the appendix page of the original RP application and submitted to the R&D Office

• Where amendments are approved, the appendix page will be signed by the R&D office and returned to the researcher.

• The standard ‘acceptance of amendment letter’ will be sent to the researcher, with copies sent to the researcher’s line manager, HR department and nominated NHS Manager. There will be no additional LoA/HRC issued

• Where amendments are not approved, the researcher will need to submit a new RP application.

• The Senior R&D Manager’s decision regarding the acceptance or otherwise of amendments is final.

15. Suspension/withdrawal of an HRC or LoA

In cases where there is a suspected breach of Trust policy the Trust reserves the right to immediately suspend the HRC or LoA of an individual researcher as a precautionary measure pending investigation.

Suspension will be confirmed in writing by the R&D Manager, with copies to the researcher's line manager (or academic supervisor) and substantive HR department.
An investigation panel will conduct an investigation, and as a minimum should include a representative of the substantive employer as well as the Senior R&D Manager, or nominee of the Senior R&D Manager.

16. Complaints

Should a researcher (or associated party such as line manager, departmental administrator) have cause to be dissatisfied with any issue relating to the research passport process they should submit this in writing to the Senior R&D Manager in the first instance. Any further investigation will be led by the Senior R&D Manager.

Complaints will be responded to in writing within 14 days of the initial complaint. Where further investigations are necessary these will be undertaken and concluded as quickly as possible and within a reasonable timeframe.

17. Retention

Expired access letters and associated documents (including electronic versions) will be retained by R&D Department for 6 years following expiry and Copies of research passports and accompanying supporting documents will be retained for 6 years' after which time they can be destroyed in accordance with the Trust policy.

18. Monitoring

NIHR guidelines recommend that 10% of researchers submitting application forms are audited annually to ensure compliance with Trust policies.

- The R&D Office will conduct audits on a 12 monthly basis on a random sample of 10% of research passport holders.

- Two weeks notice will be given to researchers, their line manager and the substantive HR Dep’t of an audit of their RP paperwork.

- A copy of the audit findings will be provided to the researcher, their line manager and HR department of the substantive employer to highlight any missing information/inconsistencies.

- Problems identified should be reviewed within 8 weeks of the initial audit to ensure compliance.

- In the case of a lapse of NMC PIN registration or a researcher’s right to work/study in the UK the researcher’s access to CPFT may be temporarily
suspended.

- A report will be produced following each audit to draw together any common failings, identifying training needs or system failures. This report is intended for internal departmental use only.

- Compliance with this policy will be monitored using a risk-based approach and as agreed by the Clinical Effectiveness Subcommittee. Exceptions will be reported to the Quality and Healthcare Governance Committee as required.

19. Equality and Diversity

This document complies with the CPFT service equality and diversity policy.

20. Associated documents

A copy of Trust policies can be found on the Trust Intranet site or provided by the R&D department on request.

- Criminal Records Bureau Policy (DBS) [https://www.gov.uk/disclosure-barring-service-check/overview](https://www.gov.uk/disclosure-barring-service-check/overview)
- Corporate and Local Induction Policy
- Data Quality Policy
- Information Governance policies
- Recruitment and Selection Policy
- Mandatory Clinical Risk Assessment Policy
- Fraud policy Anti Fraud and Bribery policy

Appendix 1 RESEARCH PASSPORT ALGORITHM (External)
National Institute for Health Research. See: