

Standard Operating Procedure R&D/SOP010

Research Passports, Honorary Research Contracts and Letters of Access

1. Scope

For use by;

- Researchers not employed by CUH
- HEI substantive employers/place of study
- R&D HR Office

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. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

Common abbreviations and definitions can be found in CCTU/INF001 Common Abbreviations and Definitions.

3.1. Definitions

Research Passport System	A means of ensuring appropriate HR arrangements are put in place where a researcher is required to deliver research activity at CUH but is not employed by CUH.
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3.2. Abbreviations

Abbreviation	Meaning
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CUH	Cambridge University Hospitals
CRN	Clinical Research Network
DBS	Disclosure and Barring Service (previous Criminal Records Bureau)
GCP	Good Clinical Practice
HEI	Higher Education Institutions
HRA	Health Research Authority
HRC	Honorary Research Contract
ISA	Independent Safeguarding Authority

LoA	Letter of Access
NIHR	National Institute of Health Research
OH	Occupational Health
PI	Principal Investigator
REC	Research Ethics Committee
RP	Research Passport
SLA	Service Level Agreement

4. Undertaken by

- External researchers and their substantive employers
- R&D HR Office

5. Items Required

- NIHR RP Algorithm
- Research passport application form (where researcher is not an NHS employee)
- NHS to NHS confirmation of pre-engagement checks pro forma (where researcher is an NHS employee)
- CV template

All items can be downloaded via

<http://www.cuh.org.uk/cms/research-and-development/for-researchers/setting-project/hr-and-research-passports/research-passport-system>

6. Summary of Significant Changes

General update.

7. Process

The following sections provide a description of the processes to be followed when implementing this document's procedures.

7.1. General principles

- The day to day management of the Research Passport System will be undertaken by the R&D HR Office, referring to the guidelines detailed in the NIHR HR Good Resource Pack
- All researchers must have the full support of either their substantive employer or place of study
- Before issuing an HRC/LoA, the R&D HR Office will verify that an identified Trust manager, who is to provide managerial supervision for the research activity, is in place
- Substantive employers will retain responsibility for other research activities that do not affect the Trust's duty of care

- An HRC does not confer the right to access confidential information for research without explicit consent
- 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
- All LoA issued will be signed by the BRC/R&D Manager and all HRCs signed by an appropriate NHS Senior Manager in addition to the R&D Manager
- HRCs for research nurses require the signature of a named Divisional Lead Nurse at CUH who will act as the professional line of report

7.2. Who needs a research passport?

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

(a) NHS employed researchers

- Researchers in this group should complete the NHS to NHS Confirmation of Pre-engagement checks form and submit to the R&D HR Office
- An NHS to NHS LoA can then be issued

(b) Honorary Clinical Academics

- Researchers with substantive university contracts and NHS honorary **clinical** contracts are able to undertake research within the NHS organisation where they also perform their clinical duties. They do not therefore need an HRC. Honorary Clinical Contracts are issued through the Trust's Medical Staffing Department.
- 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 or visitor agreements 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
- 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

- 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 HR 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
 - 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 CUH outside of the main RP system
- A LoA for observation will be granted at the discretion of the R&D HR Manager
- Where researchers are clinically qualified all access will need to be granted via the Trust's Medical Staffing department

(g) Work experience

- For researchers wishing to undertake a short period of work experience with a research team the R&D HR department will follow the process set out by the Work Experience team and not the RP system
- The work experience applicant must fill out the Work Experience Application form and will be issued a Work Experience Contract on this basis

(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
- Pre-engagement checks for each researcher must be completed and letter issued by the R&D HR Office to confirm access to the Trust

7.3. Application for an HRC or LoA

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

7.3.1. 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 HR Office for validation. Section 6 provides a useful checklist
- The R&D HR Office will complete section 7 where applicable and section 8 of the RP application form
- The R&D HR Office will subsequently issue either a LoA or HRC
- Copies of the HRC/LoA will be provided to the substantive employer's HR department and line manager. The original RP application form will be returned to the researcher, with a copy retained by the R&D HR office
- The R&D HR Office will provide a copy of the ID application form where appropriate, enabling the individual to apply for an ID badge and access to specific areas of the Trust. This should be completed and submitted to the relevant Trust department by the researcher and their host NHS manager.
- The R&D HR Department will provide information directly to the Trust's Workforce Information Department regarding the details of all researchers who have been issued with a LoA or HRC. This information will allow the researcher to be added to the Trust's Workforce system, subsequently enabling access to IT systems

7.3.2. NHS to NHS confirmation of 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 HR Office
- An NHS to NHS LoA will be issued, with copies being sent to the line manager and substantive employer's HR department

7.4. Pre-engagement checks

7.4.1. 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
- In addition to these checks OH clearance and/or standard or enhanced DBS disclosure may also be required
- The substantive employer/place of study must fund the cost of all pre-engagement checks
- The R&D HR 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 HR 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 BRC/R&D Manager who will review the information before making a final decision. There are no further rights to appeal
- The Trust R&D HR Office must be informed of any changes regarding pre-engagement checks

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

- Where a researcher's activity meets the definition of 'Regulated Activity', 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 ISA
- Furthermore, if the Trust suspends access to a researcher because they harmed or posed a risk to harm vulnerable groups the R&D HR 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 HR Office will only require evidence of DBS in specific circumstances, as outlined in the HR Good Practice Resource Pack
- In all circumstances where DBS clearance is applicable, the R&D HR 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 CUH
- Where a conviction, caution or reprimand is disclosed on a DBS disclosure certificate the R&D HR 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

7.4.3. Occupational Health (OH) clearance

- The Researcher's activity will determine whether an OH clearance certificate is required by the R&D HR Office (as outlined in the HR Good Practice Resource Pack). In such cases the certificate must be provided with the completed RP Application form prior to issue of an HRC/LoA.
- The R&D HR 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;

7.4.4. ID/Right to work or study

- The R&D HR 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

7.4.5. 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 HR 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

7.4.6. 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

7.4.7. Good Clinical Practice (GCP) training

- Researchers undertaking Clinical Trials of Investigational Medicinal Products (CTIMPS) must provide the Trust's Research and Development Department with 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

7.5. Leavers

- The R&D HR Office should be informed by the substantive employer if a researcher leaves before their contract end date
- The Trust's Workforce Information Department will be notified of a leaver by the R&D HR Department
- Researchers will automatically be removed from the Workforce Information System at the expiry of their LoA or HRC

7.6. Extensions

- National RP guidance does not allow for extensions of an RP and subsequent HRC/LoA. However in the HEI environment a researcher's employment may be of limited tenure. Therefore local discretion may be applied as follows;

- Where a researchers' limit of tenure has been extended they may submit a request to extend their LoA/HRC via the appendix page of their research passport
- With the exception of short term extensions (see below) no LoA/HRC will be extended beyond the period by which the initial validated research passport becomes 3 years old, or where applicable the DBS disclosure becomes 3 years old
- The R&D HR Office will undertake a risk assessment to assess the request and to establish what additional pre-engagement checks are necessary. This will automatically include in all circumstances;
 - Written confirmation from the HR dep't of an extension to a fixed term contract
 - Evidence of right to work/study in the UK (passport or birth certificate)

And where applicable;

- Written confirmation of evidence of continued professional registration
- Written confirmation from the researcher that there have been no changes to their OH status since the initial check
- Written confirmation that there have been no changes to the researcher's DBS status
- The R&D HR Office reserves the right to request any additional pre-engagement checks as required
- Once a research passport has become 3 years old it must be re-submitted, following the initial application process (a renewal)
- Where amendments are approved, the appendix page will be signed by the R&D HR Office and returned to the researcher
- A new LoA/HRC will be issued with the new date of expiry. In the case of HRC's this must be re-signed by all parties named.
- The R&D HR Manager's decision on whether to accept an extension is final.
- Where an extension is not agreed, the researcher must submit a new RP application form

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) the R&D HR Department 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

7.7. Amendments

- Amendments to the RP usually take the form of the following;
 - Additional research projects
 - Changes to research activity on the original project(s)
 - 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 HR Office.
- The R&D HR Office will complete a risk assessment to assess the amendment and either approve the amendment or request further information/pre-engagement checks
- Where amendments are approved, the appendix page will be signed by the HR Manager 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 R&D HR Manager's decision regarding the acceptance or otherwise of amendments is final

7.8. Audit

- NIHR guidelines recommend that 10% of researchers submitting application forms are audited annually to ensure compliance with Trust policies
- 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 professional registration or a researcher's right to work/study in the UK the researcher's access to CUH 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

7.9. Monitoring of contract end dates

- Whilst individual researchers must take responsibility for the validity of their own research passport, the R&D HR office will endeavour to contact researchers' and their line managers around 3 months prior to expiry of their HRC/LoA
- Researchers who do not confirm their status will have their IT access to the Trust and ID access badge suspended once their contract expires

7.10. Suspension/withdrawal of HRC/LoA

- In cases where there is a suspected breach of CUH policy, or if the individual is suspended by their substantive employer, the Trust reserves the right to immediately suspend the HRC or LoA of the individual researcher as a precautionary measure pending investigation
- Suspension will be confirmed in writing by the R&D HR 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 R&D HR Manager, or nominee of the R&D HR Manager

7.11. Trust ID badge

- It is the responsibility of the manager of the host department to ensure that the HRC/LoA holder is supplied with an identification badge which should be worn at all times for access and security purposes
- The manager must ensure that the expiry date of the contract is entered onto the ID badge application form
- The ID badge must clearly state that the wearer is an honorary research contract/ letter of access holder

7.12. 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 R&D HR Manager in the first instance
- Any further investigation will be led by the BRC/R&D Manager, with the support of the R&D HR 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

7.13. Retention of documents

- 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 HR destruction schedule

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness

As part of routine monitoring visits audit and inspection

b. Standards/Key Performance Indicators

This process forms part of a quality management system. Documents are reviewed every two years

9. References

NIHR, 2013, HR Good Practice Guide.

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

NIHR, 2013, HR Good Practice Guide.

10. Associated Documents

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

This SOP incorporates the key principles of the following documents:

- Research in the NHS – NIHR HR Good Practice Resource Pack
- <https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm>
- CUH staff immunisation and infection screening policy.
- CUH recruitment and selection procedure.
- CUH Data protection policy
- CUH Scientific Misconduct policy
- CUH Fraud policy
- CUH Information Governance Code of Conduct

11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

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