Standard Operating Procedure

S29 – Letters of Access and The Research Passport Version No 5	
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It is the responsibility of all users of this SOP to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

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Full History			
Version	**Date**	**Author**	**Reason**
1.0	02/03/2012	Senior R&D Facilitator	New Policy
2.0	08/04/2014	SW PenCRN Assistant Manager	Revision to reflect significant changes in NIHR policy
3.0	02/02/2018	Senior R&D Facilitator	Updated into Trust Policy template
4.0	23/02/2021	Senior R&D Facilitator	Updated into new Trust Policy template
5	15/04/2024	Senior R&D Facilitator	Updated into new Trust Policy template and to reflect Trust merger (April 2022).

Associated Trust Policies/ Procedural documents:	S14 Honorary Contracts
Key Words:	Honorary Contracts Letters of Access Research Passport
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Contents

KEY POINTS OF THIS PROCEDURAL DOCUMENT:

This SOP describes the process for issuing Letters of Access (LOA) and outlines when the Research Passport (RP) should be applied for when researchers are undertaking research-related activity in the NHS/Trust. It also outlines when an Honorary Research Contract (HRC) is needed instead of a LOA.

The R&D Facilitator Team will ensure that the Research Passport or NHS to NHS proforma has been completed correctly, with supporting documents provided (CV and DBS if required) and relevant HR pre-engagement checks completed, prior to issuing a Letter of Access.

They will also ensure that a study has received 'Confirmation of Capacity & Capability' at site before issuing a Letter of Access.

Guidance and template documents for Researchers, R&D and HR Departments on Letters of Access can be found on the IRAS website: Research in the NHS: Human Resource (HR) Good Practice Resource Pack

1. INTRODUCTION

Research within the NHS can be undertaken by NHS or University / Higher Education Institution (HEI) staff, frequently requiring arrangements for staff to be able to work across a number of NHS organisations.

In accordance with the UK Policy Framework for Health and Social Care Research, UK Health Departments have coordinated the development of The 'HR Good Practice Resource Pack' to help the NHS and other research employers take a consistent approach to handling Human Resource (HR) arrangements for those undertaking research in the NHS.

The Royal Devon University Healthcare NHS Foundation Trust (hereafter called The Trust) has adopted procedures in line with the above guidance to enable researchers to gain access to the Trust to undertake research-related activity.

2. PURPOSE

This SOP describes the process for issuing Letters of Access (LOA) and outlines when the Research Passport (RP) should be applied for when researchers are undertaking research-related activity in the NHS.

3. SCOPE

This SOP should be read by anyone from a Higher Education Institution (HEI), or employed by another NHS Trust, wishing to undertake research within the Trust.

4. DEFINITIONS & ABBREVIATIONS

DBS	Disclosure and Barring Service
HEI	Higher Education Institution
HR	Human Resources
HRC	Honorary Research Contract
GOG	R&D Governance Oversight Group
LOA	Letter of Access
R&D	Research and Development
RP	Research Passport

5. DUTIES AND RESPONSIBILITIES OF STAFF

Researcher / Supervisor / Trust / University / HEI HR Department

- **University / Higher Education Institution (HEI) employed researchers** will be required to complete a RP: relevant sections of the form must be completed by the researcher's Supervisor and University/HEI HR Department OR for those already employed by the NHS, an NHS to NHS Confirmation of Pre-Engagement Checks form can be completed instead and signed off by the researcher's HR department.
- **Human Resources (HR)** will determine the level of DBS clearance required and request this (if applicable). They will also carry out pre-engagement checks including Occupational Health Clearance (if required).
- **Researcher** will be required to provide a copy of their CV and provide detail to Research and Development (R&D) as to what research-related activity they will be involved in.
- **R&D Facilitator Team** will ensure that all information has been completed correctly on the RP for University/HEI researchers, or NHS to NHS proforma for NHS researchers.

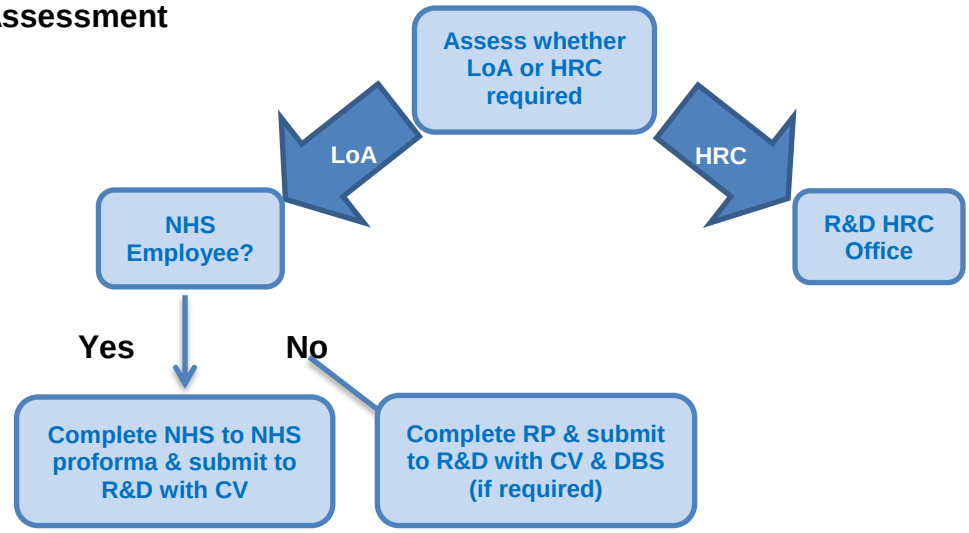
  They will check that the relevant pre-engagement checks have been requested by HR and determine whether a LOA or HRC should be issued depending on the nature of the research-related activity.

  They will ensure that a study has received 'Confirmation of Capacity & Capability' at the site before issuing a Letter of Access**.**

  Monthly reports will be run by the Senior R&D Facilitator to check LOA validity and assess the need for an extension. Expired LOAs will be checked against the study end dates on Edge. Where the study is still open, the Researcher will be contacted to confirm the need for the extension. Where an extension is required, HR evidence of the Researcher's new contract end date will be required prior to extending their LOA.

6. PROCEDURES

6.1 Assessment



The R&D Facilitator Team will assess whether the researcher requires a LOA or HRC. This is dependent on whether the researcher will have a direct bearing on clinical care. This could be direct contact with patients/service users, children or vulnerable adults and/or has a direct bearing on the quality of care and if access to patient data is required, but only if in NHS facilities. 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 those that foreseeably cause injury or loss to an individual to whom the organisation has a duty of care.

Researchers with substantive NHS employment contracts or Honorary Clinical Contracts e.g. Clinical Academics with one NHS organisation do not need additional HRCs to conduct research in other NHS organisations. Arrangements for substantive University employees with no NHS HRCs differ depending on whether or not research activities have a direct bearing on the quality of care.

The RP Algorithm available on the Integrated Research Application System (IRAS) website:

https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx can be used to assess when a LOA or HRC is required. LOAs are recommended for researchers working on projects with specified timeframes e.g. one year and HRCs for longer term studies or researchers working across multiple projects.

For further information on the issuing of HRCs refer to S14 Honorary Research Contracts.

6.2 Processing

6.2.1 In order to process a LOA for an NHS employee, the Trust must receive a copy of the following:

- NHS to NHS confirmation of pre-engagement checks form (completed by HR Department)
- CV (to check employment status and relevant training/qualifications)

6.2.2 In order to process a LOA for a University/Higher Education Institution, the Trust must receive a copy of the following:

- RP (with relevant sections completed by the institution's HR department and Supervisor)
- CV (to check employment status and relevant training/qualifications)
- DBS certificate

The R&D Facilitator Team will complete Section 8 on the RP Form and return a copy to the researcher with their issued LOA.

DBS certificates must be retained for the purpose of processing LOAs only. Original certificates should be returned to the researcher and any copies discarded.

6.3 Guidance and template documents for Researchers, R&D and HR Departments

6.3.1 The NIHR Research in the NHS: Human Resource (HR) Good Practice Resource Pack (also available on the IRAS website) describes the process for handling HR arrangements for researchers and provides a streamlined approach for confirming details of the pre-engagement checks they have undergone with the NHS.

6.3.2 Copies of Trust template letters (NHS and University/HEI templates) and issued LOAs can be found on the shared Drive J:/Research Passports and Letters of Access. LOA workflows are also completed against the study record on local database, EDGE and LOAs uploaded to the researcher's training record on the system.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the Royal Devon website shortly after having been released.

7.2 All staff whose activities are subject to this SOP must ensure that they take time to read and understand the content of this SOP.

7.3 If applicable, a training log within the Investigator Site File/Trial Master File must be completed to document that members of staff have read and understood the contents of this SOP.

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	R&D section of Research Passport form completed in full or NHS to NHS pre-engagement check completed/signed off.	Check section 8 completed of Research Passport form. Check completion and sign off of NHS to NHS proforma.
2.	DBS certificates for completed applications should be discarded.	Check that DBS received for application has been deleted from the R&D folder – J:/Research_Develop/ResearchPassports&LettersofAccess/IssuedLOAs
3.	Letter of Access workflow completed on Edge.	Check that a workflow has been created on EDGE for the researcher. This can be checked by running a workflow report on completed 'LOAs Study Specific – RP & NHS'.

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Royal Devon website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

Research in the NHS: HR Good Practice Resource Pack

UK Policy Framework for Health and Social Care Research