# Research Passports

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|---|---|
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## 1 Introduction

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 Research within the NHS is often undertaken by NHS staff not directly employed by the host NHS organisation, or by non-NHS staff e.g., researchers employed by universities.

1.3 Research passports provide evidence that the researcher is appropriately qualified and trained to undertake the research at each host site and document the required pre-engagement checks (e.g., occupational health checks, disclosure checks).

## 2 Purpose

2.1 The purpose of this SOP is to outline the process of reviewing a Research Passport application and issuing researchers with either an Honorary Research Contract (HRC) or a Letter of Access (LoA) to undertake research within NHS Lothian.

## 3 Scope

3.1 This procedure applies to all NHSL research governance and administration staff involved in the processing of research passport applications.

3.2 This procedure also applies to researchers, who already have a contractual relationship with the NHS or who are required to apply, and to students who are clinically supervised.

## 4 Responsibilities

4.1 All those who require direct or indirect contact with patients, their data/tissue or NHS staff, have a duty to ensure that they and those they manage are appropriately qualified both by education and experience.

4.2 Applicants are responsible for completion and submission of Research Passport applications forms to the ACCORD office.

4.3 ACCORD administration staff, including the R&D Administration Team Manager, are responsible for the initial logging and checking and storing of the submitted application.

4.4 The Higher Education Institution (HEI) employer is responsible for ensuring pre-engagement checks are conducted appropriately.

4.5 The R&D Administration Team Manager, Research Governance Officer, or delegate is responsible for reviewing the complete Research Passport application (including amendments) and determining whether an HRC or LoA is issued. This task can be delegated to the R&D Coordinator, Research Governance Officer or the R&D Amendments Officer.

4.6 The Head of Research Governance for NHSL, or designee, is responsible for signing the HRC or LoA letter. This task can be designated to the Principal R&D Manager or the Deputy R&D Director.

## 5 Procedure

### 5.1 Identification of the Requirement for a Research Passport

5.1.1 When necessary, the Administrator or Research Governance Officer (SOP GS001 R&D Governance Review of Non-Commercial Studies) will check the contractual status of a researcher, to determine whether a research passport is required, using the following sources:

- Communication with the Principal Investigator (PI) prior to project submission
- Receipt of a new study submission or an amendment to an active study
- Review of localised Organisation Information Document (OID)
- Review of CV (check name of employer)
- Review list of researchers that have previously provided a Research Passport to the R&D office
- Communication with HEI Human Resource (HR)

5.1.2    If the Researcher holds a substantive employment contract or honorary clinical contract with another NHS organisation, they do not require a Research Passport and must complete a NHS to NHS pro-forma on letterhead of the Board or Trust where the individual is employed, and submit this to the ACCORD office.

5.1.3    If the NHS to NHS pro-forma is not on letterhead, it will still be accepted if it is received directly from the relevant HR team. If the pro-forma is received directly from the applicant, the R&D Administration Team Manager, or designee, will contact the relevant HR person named on the pro-forma.

5.1.4    If a research passport is required, the researcher will complete a Research Passport application and submit this to the ACCORD office.

5.1.5    Applications can be submitted electronically (Loth.accord@nhs.scot) or sent as hard photocopies or originals.

5.1.6    See Appendix 1 for guidance on whether a research passport application is required.

**5.2    Application Receipt**

5.2.1    On receipt of an application, the Administrator, or designee, will complete the Research Passport Checklist (GS006-F01), and add the applicants name to the Administration team research passport spreadsheet (located on the NHSL R&D shared drive).

5.2.2    The Administrator, or designee, will ensure the passport application is valid and check the application for the following:

- Sections 1-6 are completed and signed by the researcher and HEI HR
- Supporting documents submitted
- Disclosure or PVG scheme membership (issued within 3 years)
- Occupational Health Fit Slip (issued within 3 years)
- Dated Curriculum Vitae (within two years)
- Up-to-date Good Clinical Practice (GCP) training certificate (if research is a Clinical Trial of an Investigational Medicinal Product (CTIMP))

5.2.3    The Administrator, or designee, will create an e-folder in the NHSL R&D shared drive for the named applicant.

5.2.4    The Administrator, or designee, will return incomplete or invalid applications to the researcher with instructions on how to complete correctly.

5.2.5    Once deemed acceptable, the Administrator, will pass the complete application to the R&D Administration Team Manager, or designee, for review.

**5.3    Lead NHS Organisation Application Review**

5.3.1    When the Research Passport application is submitted to the ACCORD Office as the Lead NHS Organisation (i.e., NHSL sponsor, single site or sponsored by one of the Edinburgh Universities), the R&D Administration Team Manager, or designee, will check the following:

- The Researcher has detailed their activities on the project on the form
  The Research Passport application has been completed correctly
- The end date of research passport does not exceed the fixed term contract
- The pre-engagement checks are appropriate

5.3.2    The R&D Administration Team Manager, or designee, will confirm the validity of the Research Passport Application Form as Lead NHS Organisation and complete sections 7-8 for a new application, which may include additional pre-engagement checks if required.

**5.4    Receiving R&D Office Review**

5.4.1    NHSL will be considered the receiving R&D office when NHSL is not the only participating site, and another NHS Organisation is the lead.  The Administrator, or designee, will ensure that sections 7-8 of the application have been completed and signed-off by the Lead NHS Organisation.  The Research passport application must have been completed within the previous 3 years.

5.4.2    The R&D Administration Team Manager, or designee will complete the Research Passport Application Form as Receiving NHS Organisation, section 8 (receipt of valid Research Passport).

5.4.3    As the previous pre-engagement checks will have been completed by the Lead NHS Organisation, it is not necessary for the receiving R&D office to check these documents.

5.4.4    If not previously provided, the R&D Administration Team Manager, or designee will e-mail the PI/line manager of the researcher to ensure that they have been verified by the correct person for access to a project.

**5.5    Issuing HRC/LoA**

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Document No: GS006 v5.0
Effective Date: 11 NOV 2024

5.5.1    Once review of the application is complete, the R&D Administration Team Manager, or designee, will confirm whether the researcher will receive an HRC or LoA, date the application and generate either the HRC or LoA.

5.5.2    If the researcher is deemed to have a bearing on patient care, then the Board will issue an HRC.   The HRC will be signed, by the NHSL Head of Research Governance, or designee.

5.5.3    If the researcher is deemed NOT to have a bearing on patient care, then the Board will issue a LoA.  The LoA will be signed by the NHSL Head of Research Governance, or designee.

5.5.4    See Appendix 2 for examples of research activities having or not having a bearing on patient care.

5.5.5    The Administrator, or designee, will ensure that the end date of an HRC or LoA is the shortest of the contract end date, study end date, and Research Passport end date. The Research Passport is valid for a maximum of 3 years.

5.5.6    The Administrator, or designee, will date the Research Passport to match the date of issue of the HRC or LoA.

5.5.7    The Administrator, or designee, will issue the HRC or LoA to the researcher by email.

**5.6    Prior Convictions/Cautions**

5.6.1    In the scenario where the researcher has not received a clear Disclosure check, the R&D Administration Team Manager, or designee, will reject the application.

**5.7    Storage of Documents**

5.7.1    The Administrator, or designee, will store complete Research Passport Application Forms electronically in the named applicant folder on the NHSL R&D shared drive.

5.7.2    The Administrator, or designee, will return any original hard copies of applications.

**5.8    Research Passport Amendments**

5.8.1    A researcher, who has previously been issued with an HRC or LoA, may need to amend the original Research Passport, examples of amendments include:

- Change from project-specific to multi-project

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Document No: GS006 v5.0
Effective Date: 11 NOV 2024

- Change to Research Project end date or extension to substantive employment contract
- Change to research activities

5.8.2    Amendments to the Research Passport need to be documented in the Passport Appendix table of the original Research Passport Application Form, each amendment will need to be signed by the Lead NHS Organisation.

5.8.3    The R&D Administration Team Manager, or designee, will review amendments and will sign the table in the appendix.

5.8.4    If there is a change of research activity, the R&D Admin Team Manager, or designee, will ensure the pre-engagement checks are still valid.  If pre-engagement checks are no longer valid, the R&D Administration Team Manager, or designee will complete section 8 again.  The R&D Administration Team Manager, or designee will confirm whether the new research activities will incur a change to the issued HRC/LoA.

5.8.5    The receiving R&D Office will review and process the Research Passport application following sections 5.2 – 5.5 and will require a copy of the Appendix to attach with their copy of the Research Passport Application Form, and update any project information to reflect changes.

5.8.6    If there is a change to the substantive employer of a researcher, a new Research Passport application must be submitted to the R&D Office.

**5.9      Renewing an Expired Research Passport**

5.9.1    A Research Passport is only valid for a maximum of 3 years.  Once expired, the researcher will complete a new Research Passport application and submit this to the R&D Office.

5.9.2    The procedure for review and issue of HRC or LoA will be the same as detailed in sections 5.1-5.8.
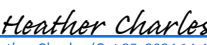
# 6      References and related documents

- IRAS HR Good Practice Research Pack
  https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx
- CSO NHS Research Passports (CEL (24) 2008)
  http://www.msg.scot.nhs.uk/wp-content/uploads/Circulars/CEL's/CEL2008_24.pdf
- GS006-F01 Research Passport Checklist

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## 7 Document History

| Version Number | Effective Date | Reason for Change |
|---|---|---|
| 1.0 | 29 MAR 2016 | New SOP. |
| 2.0 | 28 MAR 2018 | Clarified HRC/LoA no longer issued by post and replaced by email. |
| 3.0 | 05 JUN 2019 | Updated to include relevant changes following the implementation of the UK Local Information Pack (05 June 2019) and references updated. |
| 4.0 | 19-Sep-22 | Updates to ACCORD staff responsibilities in section 4. Section 5.8.6 added to confirm that a change to the substantive employer of a researcher, will require a new Research Passport application to be submitted to the R&D Office. Appendices updated to clarify that access to TRAK will also require HRC. Minor administrative changes throughout. |
| 5.0 | 11 NOV 2024 | Minor administrative changes made to SOP and Research Passport Checklist (GS006-F01 - now v3.0). Both documents moved to new ACCORD template. |

## 8    Approvals

| Sign | Date |
|------|------|
| *Kenneth Scott*<br>Kenneth Scott (Oct 25, 2024 14:26 GMT+1)<br><br>AUTHOR: Kenneth Scott, NRS Generic Review Manager, NHS Lothian, ACCORD | Oct 25, 2024 |
| *Heather Charles*<br>Heather Charles (Oct 25, 2024 14:44 GMT+1)<br><br>APPROVED:  Heather Charles, Head of Research Governance, NHS Lothian, ACCORD | Oct 25, 2024 |
| *[signature]*<br>Gavin Robertson (Oct 25, 2024 13:26 GMT+1)<br><br>AUTHORISED:  Gavin Robertson, QA Coordinator, NHS Lothian, ACCORD | Oct 25, 2024 |

## 9    Appendix 1

### 9.1    Scenarios detailing requirement of Research Passport and issuing of HRC or LoA

| Form | Substantive Employer | | | | | |
|------|------|------|------|------|------|------|
| | **HEI Substantive Employee** | **HEI Substantive Employee with Honorary Clinical NHS Contract** | **HEI Student** | **HEI Student on a formal healthcare placement** | **NHS Substantive Employee** | **Commercial Researcher** |
| **Is a Research Passport needed?** | Yes | No | Yes | No | No | No |
| **HRC** | Yes[1] | No | Yes[1] | No | No | No |
| **LoA** | Yes[2] | No | Yes[2] | No | No | No |
| **NHS to NHS Proforma** | No | Yes[3] | No | No | Yes[3] | No |

[1] Research activities will have a bearing on patient care (if indirect contact with NHS patients i.e. telephone interviews then disclosure checks & occupational health checks are not required), when access to TRAK is to be provided, or if an NHS email address is required

[2] Research activities will NOT have a bearing on patient care, also applies to researchers who will have direct contact with NHS staff in a clinical centre for multicentre projects only.

[3] NHS to NHS confirmation of pre-engagement checks covers all types of research. On receipt of a proforma, a LoA will be issued.

# 10    Appendix 2

## 10.1    Scenarios of activities having or not having a bearing on patient care

**Examples of research activities that have a bearing on patient care and will require an HRC;**

- Taking consent for an interventional research project
- Taking biological samples
- Delivery of psychological treatment such as Cognitive Behavioural Therapy
- Delivery of physiotherapy
- Eye tests
- Electrocardiography (ECG)
- Access to TRAK
- NHS email address required

**Examples of research activities that will NOT have a bearing on patient care and will require a LoA;**

- Data collection via questionnaires
- Focus groups
- Interviews where data is collected only and will not be fed into the patient's care plan

# GS006 Research Passports v5.0

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