

SOP number	<b>52.005</b>	Version	<b>5.0</b>
Title	<b>Review of Research Passport and issuing of Honorary Research Contracts/Letters of Access</b>		

Prepared by Signature	Rozanne Suarez	Date
Approved by Signature	Melissa Robert	Date
Released by Signature	Chloë Cowan	Date

SOP category	NHS GG&C Hosted R&I			
Staff category				
<b>Staff Category</b>	<b>R</b>	<b>A</b>	<b>C</b>	<b>I</b>
Research & Innovation Systems & Operations Manager		X		
Research Co-ordinator	X			
Innovation Contracts Manager	X			
Research Facilitator	X			
Senior Research Administrator	X			
Innovation Project Manager				X
Information Officer				X

### 1. Scope

This procedure applies to NHS Greater Glasgow and Clyde (NHSGGC) R&I Department.

### 2. Purpose

The purpose of this SOP is to define the process of reviewing Research Passport Application Forms and issuing researchers with either an Honorary Research Contract (HRC) or Letter of Access (LoA).

### 3. Procedures

#### 3.1. Background

All those involved in research have a duty to ensure that they, and those they manage, are appropriately qualified, both by education and experience for the role they play in relation to research. The Research Passport system, launched nationally in October 2007, facilitates NHS review of Higher Education Institution (HEI) or charity employed researchers who require direct or indirect contact with Patients, their data, tissues or NHS staff.

The IRAS link below has the latest Research Passport guidance for applicants and issuing R&D offices:  
<https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx>

Please note that the HR Good Practice Resource Pack has been reviewed and updated in light of the Data Protection Act 2018 (DPA 2018) and the General Data Protection Regulation (GDPR) which came into force in the UK on May 2018.

The Chief Scientist Office recommended the implementation of the Research Passport system to the NHS and to HEIs with the effective date from 1 September 2008 (CEL (24) 2008).

R&I offices undertake assessment of local document sets for new study submissions (SOP 52.001 and SOP 52.002, Non-commercial and Commercially Sponsored respectively) where the research project will be hosted by the NHS organisation. This assessment includes review of the Principal Investigator (PI) and research team to ensure that they are appropriately qualified, experienced and hold a contract with the NHS. Research Passport contains information that the researcher is appropriately qualified and trained to undertake the research as well as evidence that the pre-engagement checks by the substantive HEI or registered charity employer are appropriate and have been concluded. Pre-engagement checks consist of Occupational health and Disclosure checks. There are levels of Disclosure: Basic, Enhanced and also membership of the PVG Scheme.

If the applicant's research activities involve working with protected groups as defined by the Safeguarding Vulnerable Groups Act 2006, membership of the PVG Scheme is required. This is a type of open-ended disclosure with no end date, where checks are reported back to the employer on an ongoing basis. As such, this type of disclosure can be more than 1 year old at the time of submission with the Research Passport.

There is *no need* make a fresh application to the PVG Scheme unless:

- The applicant has changed employer
- The applicant has changed name or address
- The applicant has changed their job role within the same organisation
- Their employer's organisation has changed its name

**n.b. It is the responsibility of the applicant to report any of these changes to R&I.**

The Research Passport facilitates sharing of personal information with NHS organisation(s) that are hosting the research. The NHS organisation will review the Research Passport and determine whether the researcher will be subsequently issued an HRC or LoA.

### **3.2. Identification and Confirmation of Research Passport requirement (Appendix A)**

#### **3.2.1. Identification of Researchers that require Research Passport**

The following criteria must be met to process a member of the research team through the Research Passport system:

- The research is hosted in the NHS **AND** they have no contractual relationship with the NHS but are substantively employed by an HEI or a registered charity

The research scenarios where a Research Passport is required are detailed in Appendix A.

The Senior/Research Administrator or Research Co-ordinator/Facilitator/Innovation Contracts Manager will determine whether a member of the research team has a contractual relationship with the NHS (Substantive or Honorary).

Contractual status of a researcher can be determined from a number of sources:

- Communication with PI or other member of research team prior to project submission
- Receipt of submission of a new study or an amendment to an active study
- Review of local documents
- Checking the NHSGGC global address book to establish if the applicant has a NHSGGC email address
- Review of CV (check name of Employer)
- Review list of researchers that have previously been issued or provided a copy of a Research Passport to the R&I office (common drive)
- Communication with HEI Human Resources (HR), HEI Student Registry, HEI Governance team or registered charity HR team

The Senior/Research Administrator will email the researcher stating the requirement for a Research Passport.

### **3.3. Review of Research Passport Application Form**

Completed Research Passport Application Forms are submitted to the R&I office as a Lead NHS Organisation or a receiving R&I department.

NHSGGC will be considered to be Lead NHS organisation under the following scenarios:

- NHSGGC have agreed to be Sponsor of the research project and is a research site
- The research project is Sponsored by another organisation and NHSGGC is the only site
- The research project is Sponsored by one of the Glasgow Universities and NHSGGC is a site

NHSGGC will be considered as the receiving R&I office when NHS GG&C is not the only participating site and another NHS organisation is the lead site.

#### **3.3.1. Process for acceptance and review of Research Passport Application Form**

The Substantive HEI employer or registered charity is responsible for ensuring that the pre-engagement checks are appropriate for that researcher and the research they will undertake in the NHS site. Documents submitted with the Research Passport Application Form can be submitted electronically, or sent as photocopies or originals.

### 3.3.1.1. Lead NHS Organisation:

The Senior/Research Administrators will ensure that the Research Passport is complete before passing to Research Co-ordinator/Facilitator for review. For NHSGGC-sponsored Innovation studies, these should be passed to the Innovation Contracts Manager for review. Senior/Research Administrator will check for the following:

- Sections 1 – 6 must be completed and signed by the Researcher and the HEI/registered charity
  - Where possible ensure that multi-project has been selected (rather than project specific), under 'Type of Research Passport'
  - For Project-Specific Research Passports *only*, the end date (Section 2) must not exceed the fixed term contract end date (Section 5). For Multi-Project Research Passports, the end date will always be 3 years from the date it is signed off by the Lead R&I Team, regardless of when the fixed term contract ends. The HRC/LoA will be valid until the end date of the fixed-term contract.
  - Accompanying evidence of pre-engagement checks to be submitted.
  - Employee's copy of Disclosure (Disclosure check must have been issued within the previous 12 months).
  - If the applicant is a member of the PVG Scheme (which incorporates ongoing checks), there is no need to apply for a fresh Disclosure unless they have:
    - Changed employer
    - Changed name or address
    - Changed their job role within the same organisation
    - Their employer's organisation has changed its name
- n.b. It is the responsibility of the applicant to report any of these changes to R&I.**
- Copy of Occupational health certificate stating 'fit' (there is no time limit on when the health check was issued) for researchers who will have direct patient contact.
  - CV
  - Evidence of training and qualifications may be provided. However, as these will be checked by the appropriate HEI/registered charity (Researcher qualification and training is a responsibility of the Substantive employer) this is not essential to be provided to the R&I office.

The Research Co-ordinator/Innovation Contracts Manager/Facilitator/Senior Administrator will check for the following:

- Researcher's activities detailed on the form should reflect the research activities listed in the local documents and the research proposal
- The Research Passport Application Form has been completed correctly
- The pre-engagement checks are appropriate for the Researcher and research activities within NHSGGC

The Research Co-ordinator/Facilitator/Senior Administrator will confirm whether the Research Passport Application Form is valid. If the form is not valid, see 3.3.2.

#### **3.3.1.2. Receiving R&I Office:**

The Research Administrator will ensure that the Research Passport is complete before passing to Research Co-ordinator for review. Research Administrators will check for the following:

- Sections 1 – 6 must be completed and signed by the Researcher and the HEI
- For Project-Specific Research Passports *only*, the end date (Section 2) must not exceed the fixed term contract end date (Section 5). For Multi-Project Research Passports, the end date will always be 3 years from the date it is signed off by the Lead R&I Team, regardless of when the fixed term contract ends. The HRC/LoA will be valid until the end date of the fixed-term contract.
- Sections 7 – 8 must be completed and signed by the Lead NHS Organisation (R&I Office or NHS HR).
- If section 7 is not required, the Lead NHS Organisation must state not applicable within this section.
- CV

The date of the Research Passport must have been completed by the HEI/registered charity within the previous 3 years.

The Research Co-ordinator/Facilitator/Senior Administrator will check for the following:

- Researcher's activities detailed on the form should reflect the research activities listed in the local documents and the research proposal
- The Research Passport Application Form has been completed correctly

The Research Co-ordinator/Facilitator/Senior Administrator will confirm whether the Research Passport Application Form is valid. If the form is not valid, see 3.3.2.

#### **3.3.2. Incomplete/incorrect Research Passport Application Form(s)**

The R&I office will only accept a completed and valid current version of the Research Passport Application Form. Incomplete or invalid applications (including completion of the incorrect version of the Research Passport Application Form) must be returned to the Researcher with instructions on how to complete or correct the Research Passport Application Form.

### **3.4. Completion of Research Passport Application Form**

#### **3.4.1. Completion as Lead NHS Organisation:**

The Research Co-ordinator/Innovation Contracts Manager/Facilitator/Senior Administrator will complete the Research Passport Application Form as Lead NHS organisation at sections 7 and 8.

Additional pre-engagement checks to be undertaken by the NHS Lead Organisation can be documented (if applicable). Section 7 will only be completed if the Research Co-ordinator/Innovation Contracts Manager/Senior Administrator has raised a concern with NHSGGC HR and it has been agreed that further checks are required. NHSGGC HR will complete this section if further checks are performed.

#### **3.4.2. Completion as Receiving NHS Organisation:**

The Research Co-ordinator/Facilitator/Senior Administrator will complete the Research Passport Application Form as Receiving NHS Organisation, Section 8 (receipt of valid Research Passport).

### **3.5. Verification of Research Passport Application Form**

Each complete and valid Research Passport must be verified as this check prevents the need for the researcher to present further evidence to confirm that they are the individual requiring a Research Passport.

#### **3.5.1. Verification as Lead NHS Organisation:**

The Research Administrator will email the HEI/registered charity HR individual that completed the pre-engagement checks section (Section 5) of the Research Passport Application Form to ensure that the researcher has been verified by the correct person.

#### **3.5.2. Verification as Receiving NHS Organisation:**

The Research Administrator will email the Lead NHS Organisation individual that completed Section 8 of the Research Passport Application Form to ensure that the Research Passport was approved by an appropriate individual (e.g. Lead NHS Organisation R&I office).

### **3.6. Issuing of HRC/LoA**

Once the Research Co-ordinator/Innovation Contracts Manager/Facilitator/Senior Administrator has confirmed that the Research Passport is valid, it will be confirmed whether the researcher will receive an HRC or LoA. The Research Co-ordinator/Innovation Contracts Manager/Facilitator/Senior Administrator must determine whether the Researcher's activities will, or will not, have a bearing on Patient care. This is determined from review of local documents and research proposal.

Activities may be deemed to have a direct bearing on quality of patient care if it will:

- influence decisions on the patient's access to care, care pathway of that patient or the type, quality of extent of prevention, diagnosis or treatment or illness OR
- cause injury or loss to patients to whom the organisation has a duty of care.

If the researcher is deemed to have a bearing on patient care then the Board will need to issue an HRC (Form 52.005A)(for further guidance please refer to Appendix A). The HRC will be signed by an R&I Manager.

If the researcher is deemed NOT to have a bearing on patient care then the Board will need to issue a LoA (Form 52.005B) (for further guidance please refer to Appendix A) The LoA will be signed by the Research Co-ordinator/Facilitator/Innovation Contracts Manager.

It is very important at this stage to remind everyone who has been issued with either a LOA or HRC, the serious consequences of breaching the Data Protection Act 2018 both for themselves and the Health Board. The penalty for a breach for the Health Board might be up to £500,000.

**Examples of research activities that will have a bearing on patient care and require the Board to issue an HRC:**

- Taking consent for an interventional research project
- Venepuncture, other biological samples
- Delivery of a psychological treatment such as Cognitive Behavioural Therapy
- Delivery of Physiotherapy
- Sports science – exercise
- Body measurements
- Eye tests
- Electrocardiography (ECG)
- Intima-Media Thickness (IMT)

**Examples of research activities which would not have a bearing on patient care and would require the Board to issue a LoA:**

- Data collection via questionnaires
- Focus groups which are not delivering an intervention
- Interviews where data is collected only and will not feed into the patient's care plan or decision making in the care of that patient.

For Project-Specific Research Passports, the end date of the HRC or LoA will match the end date of the listed study **OR** the contract end date; whichever is sooner.

For Multi-Project Research Passports, if the applicant has a fixed-term contract, the end date of the HRC or LoA will match this. If they have a permanent contract, the end date of the HRC or LoA will match the end date of the Research Passport.

### **3.7. Prior convictions/cautions**

In the scenario where the Research Co-ordinator/Facilitator/Senior Administrator has not received a clear Disclosure check, the Risk Scoring for Disclosure Purposes must be completed and a copy of this risk scoring document can be requested from NHSGGC HR. Prior convictions/cautions that receive a scoring of medium and above must be discussed with R&I Management. An R&I Manager will sign the Research Passport application form at Section 8.

### **3.8. Storage and Destruction of Documents**

Research Passport Application Forms that have been verified and completed by the Research Co-ordinator/Innovation Contracts Manager/Facilitator/Senior Administrator will be stored electronically in a central folder in the common drive. Copies of Disclosure and occupational health checks received by NHSGGC R&I office will be destroyed confidentially.

Electronic copies of the Research Passport Application Forms and paper copies of the HRC/LoA will not be stored past the end date of the documents. Electronic copies must be deleted and paper copies of the HRC/LoA will be destroyed confidentially.

### **3.9. Research Passport Amendments**

A Researcher who has previously been issued with an HRC or LoA may need to amend the original Research Passport, e.g. due to addition of research projects or change to research activities. Amendments to the Research Passport need to be documented in the Passport Appendix 'Amendments to Research Passport' table, each amendment will need to be signed by the Lead NHS Organisation.

#### **3.9.1. Change from project-specific to multi-project**

To amend a Research Passport from project-specific to multi-project:

- Researcher must submit an amendment to the project-specific Research Passport Application Form by completing relevant details of additional project in the Appendix to the application form to the Lead NHS Organisation (see section 3.3) for approval. An Appendix is completed per additional study.
- The amendment to the Research Passport must also be detailed in the 'Amendments to Research Passport' table in the Passport Appendix.
- The Lead NHS Organisation will need to ensure that the pre-engagement checks in place are still valid for this new activity. If so, the Lead NHS Organisation can convert the project-specific Research Passport to a multi-project Research Passport.
- The Researcher should be advised to inform the NHS organisations that also received the original Research Passport. The Receiving R&D office will update their study information to include the additional study(ies) or add the researcher to the study information.

Receiving R&I Office, as a new site, will need to review and process the Research Passport following sections 3.3.1.2 – 3.8.

#### **3.9.2. Change to Research Project end date or extension to Substantive employment contract**

To amend a Research Passport end date:

- The amendment to the Research Passport must also be detailed in the 'Amendments to Research Passport' table in the Passport Appendix and submitted to the Lead NHS Organisation.
- The Lead NHS Organisation will need to ensure that the pre-engagement checks in place are still valid for this extension.
- If the new end date will exceed the 3 year's time frame of the Research Passport, a fresh application for a new Research Passport must be submitted including all supporting documents.

Receiving R&I office will need to update the project information with the new end date and amend the issued HRC/LoA.



### **3.9.3. Change to researcher activities**

To amend Researcher activities:

- The Researcher will need to notify the Lead NHS Organisation of an amendment to the research activities they are undertaking
- The amendment to the Research Passport must also be detailed in the 'Amendments to Research Passport' table in the Passport Appendix
- The Lead NHS Organisation must review the pre-engagement checks to ensure that these are still valid or whether further checks are required
- The Lead NHS Organisation must confirm whether the new research activities will incur a change to the issued LoA or HRC, this will be dependent on whether the new research activities will/will not lead to a bearing on patient care
- The researcher will be advised to inform the NHS organisations that also received the original Research Passport of the new research activities.

Receiving R&I office will require a copy of the Appendix to attach with their copy of the Research Passport Application Form.

### **3.9.4. Change to substantive employer of researcher**

To amend Substantive employer:

- The Researcher will need to notify the Lead NHS Organisation that there has been a change in Substantive employer and whether they are continuing to support the same research project(s)
- The Researcher will need to complete a new Research Passport with the new employer and sections 3.3.1.1 – 3.8 should be followed.
- The Researcher will be advised to inform the NHS organisations that also received the original Research Passport.

Receiving R&I Office, will need to review and process the Research Passport following sections 3.3.1.2 – 3.8.

## **4. Referenced documents**

- CEL 24 (2008) – NHS Research Passports
- Research Passport Guidance:  
<https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx>
- SOP 52.001 – Obtaining NHS Management Approval, Non-Commercial Research
- SOP 52.002 – Obtaining NHS Management Approval, Commercial Research
- Form 52.005A – Honorary Research Contract
- Form 52.005B – Letter of Access
- Form 52.005C – Letter of Access (Staff Studies only)
- Form 52.005D – NHS to NHS Letter of Access

## **5. Related documents**

- UK Policy Framework for Health and Social Care

**6. Document history**

Version	Date	Description
1.0	07/03/2013	Release of first version
2.0	14/07/2016	Updated to template v1.4.
3.0	18/03/2020	Temp. change to Author and "Approved by". Minor changes to process (mostly typographical). Amended link to updated HR guidance pack. Version updated.
4.0	08/07/2021	Reference to Data Protection Act 2018 Coordinators assistant replaced with Research Administrators Addition of Senior Administrator next to Research Co-ordinator/Facilitator R&D replaced with R&I in SOP category, staff category and scope 5.3.1.2 and 5.5.2 removed senior administrator from first line
5.0	05/08/2024	Changes to 'Prepared by' and 'Approved by'. RACI index added. Clarification around Basic or Enhanced Disclosure vs PVG Scheme Membership. Addition of registered charity as well as HEI organisations. Clarification around duration of project-specific and multi-project research passports. Update to information about storing paper copies as we only keep electronic copies now.

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**APPENDIX A: Scenarios detailing requirement of Research Passport and issuing of HRC or LOA.**

Researcher Scenario	Research Passport to be completed YES/NO	Disclosure checks YES/NO	Occupational Health Check YES/NO	HRC or LoA to be issued (Form number)
Researcher employed by HEI/registered charity and will have indirect (inc virtual) contact with NHS patients with no bearing on patient care (e.g. telephone/Teams interviews)	YES	NO	NO	LoA (Form 52.005B)
Researcher employed by HEI/registered charity and will have indirect contact with NHS patients with bearing on patient care (e.g. providing remote delivery of intervention)	YES	NO	NO	HRC (Form 52.005A)
Researcher employed by HEI/registered charity and will have direct contact with NHS patients with no bearing on patient care (e.g. interviews, questionnaires, focus groups)	YES	YES	YES	LoA (Form 52.005B)
Researcher employed by HEI/registered charity and will have direct contact with NHS patients with bearing on patient care (e.g. delivery of intervention)	YES	YES	YES	HRC (Form 52.005A)

Researcher Scenario	Research Passport to be completed YES/NO	Disclosure checks YES/NO	Occupational Health Check YES/NO	HRC or LoA to be issued (Form number)
Researcher employed by HEI/registered charity and will have direct contact with patients via observation of NHS staff delivering questionnaires or taking samples. Confirmation has been received from NHS that researcher will be constantly supervised in clinical setting.	NO	NO	NO	LoA (Form 52.005B)
Undergraduate students undertaking research as part of healthcare placement.	NO	NO	NO	NO – confirmation must be received from NHS supervisor that the student will be supervised in the clinical setting.
Postgraduate students undertaking research with supervision, not clinically experienced and qualified.	NO	NO	NO	NO – confirmation must be received from NHS supervisor that the student will be supervised in the clinical setting.
Postgraduate students undertaking research, clinically experienced and qualified with no requirement for supervision e.g. MSc or PhD).	YES	YES	YES (if direct contact).	LoA (Form 52.005B) if no bearing on care  HRC (Form 52.005A) if bearing on care

Glasgow Clinical Trials Unit Standard Operating Procedure

Researcher Scenario	Research Passport to be completed YES/NO	Disclosure checks YES/NO	Occupational Health Check YES/NO	HRC or LoA to be issued (Form number)
Researcher employed (or registered as a student) by HEI/registered charity and will have direct contact with NHS staff in clinical setting (e.g. interviews, focus groups).	NO – single centre YES – multicentre	NO	NO	LoA (Form 52.005C)  Confirmation from HEI that the researcher is employed or registered as a student.  Confirmation from clinical department that they are aware of research study.
Researchers recruiting NHS Patients (past or present status) and research is NOT hosted by NHS (non-NHS sites, e.g. University)	NO	NO	NO	NO – NHS organisation does not retain a duty of care for any healthcare provision during the course of research by the non-NHS site hosting the research.
Commercially employed researchers in commercial studies (e.g. commercial research nurses)	NO	NO	NO	NO – no documents can be provided that can be construed as the NHS organisation accepting liability for their actions. Contract with the commercial organisation should be agreed to address issues relating to activities and suitability (pre-engagement checks) of commercial staff.
Trial Monitors	NO	NO	NO	NO – it is the responsibility of the sponsor for the actions of their trial monitors. Model agreements are considered to provide specific information relating to trial monitor activities.

Glasgow Clinical Trials Unit Standard Operating Procedure

Researcher Scenario	Research Passport to be completed YES/NO	Disclosure checks YES/NO	Occupational Health Check YES/NO	HRC or LoA to be issued (Form number)
Researchers substantively employed by NHS or hold Honorary Clinical Contract.	NO, complete NHS to NHS proforma	NO	NO	LoA (Form 52.005D)
Researcher will have access to Patient data (anonymised or identifiable) with no bearing on Patient care.	NO	NO	NO	LoA (Form 52.005B)
Researcher will have access to Patient data (anonymised or identifiable) with bearing on Patient care.	NO	NO	NO	HRC (Form 52.005A)