RDSOP12 Research Passport – Issue of Honorary Research Contracts and Letters of Access

Greater Manchester Mental Health NHS Foundation Trust

Document Summary: To make all NHS/university staff involved in the preparation, administration and issue of Research Passports aware of how this must be carried out. This includes instructions for NHS and non-NHS Applicants. This SOP is in accordance with the National Guidance issued by the National Institute for Health Research (NIHR)/Health Research Authority (HRA).

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Target Audience: Trust-wide, Research Community, Internal and External Researchers

Consultation: R&I Office, research community and R&I Committee members

Approval Committee: R&I Committee

Cross Reference Document(s): Research Approval Policy All Trust R&I SOPs

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1. Introduction

1.1 Background

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

The UK Policy Framework for Health and Social Care Research (2017) require all parties undertaking research within the NHS to be clear about responsibilities, liabilities, patient safety and duty of care. One of the ways this is achieved is through using HR procedures appropriately.

The substantive employer retains the primary accountability and liability for the actions of their researchers. Once NHS organisations have confirmed capacity and capability for research to take place at their sites that affects their legal duty of quality and common law duty of care, they then accept vicarious liability for harm due to clinical negligence.

All staff involved with the preparation, administration and approval of Research Passports, issue of Honorary Research Contracts and Letters of Access on behalf of GMMH must refer to this SOP and to the National HRA Guidance on Research Passports, accessible via the Integrated Research Application Service (IRAS) HR Good Resource Pack. All forms are available on the website (via https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx).

1.2 The Research Passport System

The Research Passport is a form which enables non-NHS employers to share pre-engagement information about their researcher with NHS organisations hosting the researcher’s activity.


Once the Research Passport form is validated, the host NHS organisation can issue an Honorary Research Contract (HRC) or Letter of Access (LoA) depending on the nature of the research activity. The Research Passport is usually valid for a three-year period.

2. Purpose

To make all NHS/university staff involved in the preparation, administration and issue of Research Passports aware of how this must be carried out. This includes instructions for NHS and non-NHS Applicants. This SOP is in accordance with the National Guidance issued by the NIHR & Health Research Authority.
3. Roles and Responsibilities

3.1 Duties within the Organisation

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R&I SOPs are available to research staff so that SOPs can be distributed appropriately. Current SOPs can be found on the R&I website: https://www.gmmh.nhs.uk/standard-operating-procedures-sops-and-guidance-documents

It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure that up-to-date copies of SOPs are filed in the Investigator Site File and are available to research staff.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example, those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Trust R&I SOP it is the responsibility of the CI or PI to resolve these with the R&I Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

3.2 Specific Responsibility to this SOP

Principal Investigator/Study Coordinator: To recognise individuals who are not contracted to the Trust and initiate a Research Passport application if appropriate.

The Applicant: To complete the Research Passport proforma and obtain all necessary signatures/authorisations required and to sign an HRC (if applicable) with the Trust confirming adherence to Trust rules and policies or to receive a Letter of Access.

Research Support Co-ordinator (or Proxy): To adhere to the guidance set out in this procedure. Advise researchers on the process, receive and check documents submitted, prepare HRC or LoAs, obtain signatures, return documents to researcher, and record and monitor on the Researcher Register.

Head of R&I Office: To ensure that this procedure has been correctly followed by the R&I Office team and sign the Research Passport proforma and HRC/LoA on behalf of the Director of HR and Corporate Services for the Trust.

Trust HRC signatories (Head of R&I or Initiation & Delivery Manager): To ensure that the HRC/LoA is completed correctly prior to signing the contract or letter.
4. Details of Procedure

4.1 Who needs to apply for an Honorary Research Contract or Letter of Access and submit a Research Passport?

Who doesn’t need to apply for a Research Passport?

- Those employed by an NHS organisation
- Independent contractors (e.g. GPs) or employed by an independent contractor
- Those having an honorary clinical contract with the NHS (e.g. clinical academics)
- Undergraduate students of the University of Manchester who are covered by the Memorandum of Understanding with the University.
- Higher Education (HE) students on formal healthcare placements.
- Medical students who will be supervised within clinical settings by an NHS employee or HE staff member with an Honorary Clinical or Honorary Research Contract.
- Volunteers with no employer and who are not students cannot complete a Research Passport as there is no-one to take responsibility. These volunteers would need to apply for a Volunteer Honorary Contract via the Trust’s volunteer service: www.gmmh.nhs.uk/volunteering
- If the project is not classified as research as per Health Research Authority standards.

Whether an HRC/LoA is required or not, each applicant must be reviewed and assessed in terms of their normal role, relevant experience, supervision and pre-employment checks required as outlined in the Research Passport Algorithm; see https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

Those who MAY need an HRC/LoA:

- Non-GMMH NHS Contract holders.
- Non-NHS employed Researchers, including:
  - HE substantive employee
  - HE student not on a formal healthcare placement.
  - Volunteers with an honorary contract from the university and no NHS or other employer (the Research Passport would be completed via the university).

4.2 Application Process

For non-GMMH NHS researchers an NHS-NHS Confirmation of Pre-Engagement Checks form is completed by the employing Trust and a Letter of Access is issued (see Section 4.5 below).

For non-NHS researchers a Research Passport will be needed and, if appropriate, an Honorary Research Contract or Letter of Access will be issued. Where a Research Passport application is appropriate, researchers must complete and submit the
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Research Passport form for authorisation to their employer, line manager and then to the Trust for review and signature.

Research Passport Form and Guidance

The Research Passport form and guidance are available in electronic format via the R&I Office or directly from the IRAS website: https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

The Research Passport form must be submitted to the R&I Office with:
- The original DBS (if applicable), within 6 months of issue
- Evidence of occupational health screening (if applicable)
- An up-to-date CV, including relevant training undertaken

Completion of the Research Passport Form

The Principal Investigator/Study Coordinator will initiate the completion of the Research Passport form with the applicant.

The Research Passport must be completed up to and including Section 6. This includes signatures by the applicant, by the line manager and by HR representatives from the employer of the applicant. Section 7 is completed by the Trust issuing the first HRC/LoA.

Appendices should be completed when there are a number of studies, or additional studies/revisions required after the Research Passport has been issued.

The completed Research Passport with original documents should be forwarded to the Research Support Co-ordinator in the R&I Office at the Trust.

Approval of Research Projects

All Research Passport applications will refer to one or more research projects. These projects must have received confirmation of capacity and capability by the Trust prior to issue of an HRC/LoA and prior to any research activities commencing on Trust premises (see Research Conduct Policy).

Validation of the Application

If the Research Passport is completed correctly, signed as instructed on the form, and is accompanied by the enclosures (as required), this is a valid submission and can be processed. Otherwise, the R&I Office will notify the applicant as soon as possible and request additional information as required.

Issue of Honorary Research Contract/Letter of Access

Once a valid application is received, the application is processed usually within five working days. It is usual to issue a Letter of Access so that the employer retains liability for the non-NHS researcher. Only if there is a direct (or possibly direct) bearing on care (e.g. the researcher is performing an intervention) will an HRC be issued. In almost all other circumstances an LoA will be issued.
If an HRC is to be issued, two copies of the HRC with covering letter will be sent to the applicant, who must sign both copies and return one to the R&I Office to file.

An HRC will not become active until the valid Research Passport application has been reviewed, a signed HRC issued and the applicant has returned a signed copy. Appropriate Trust signatories for the HRC/LoA are the Head of R&I Office or senior R&I Managers.

If an LoA is to be issued the letter will be signed by an appropriate Trust signatory, scanned and emailed electronically to the applicant. All original application documents and the signed LoA will be posted via Recorded Delivery to the applicant.

4.3 Pre-Employment Checks

Refer to the Research Passport Algorithm for a summary of the pre-employment checks required (e.g. DBS and occupational health) when conducting different types of research activity: https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

Occupational Health Clearance

For non-NHS employed researchers, where occupational health screening is required, this must be arranged with the employer’s Occupational Health (OH) department.

NHS employees must have received appropriate OH checks on employment, unless deemed inappropriate by the HR Advisor, and this check would normally suffice (refer to Section 4.5).

Disclosure and Barring Service (DBS) Checks

A clear, valid DBS (within 6 months of issue) is required at the level specified in the Research Passport Algorithm (see link above).

The original DBS must be enclosed with the Research Passport application (dated within 6 months of the NHS organisation issuing an HRC or LoA).

The original DBS must be seen by the Research Support Co-ordinator and this is returned with the Research Passport application pack to the researcher with the HRC or LoA. Information may only be shared between organisations with the consent of the applicant.

Students on Healthcare Placements

Students must provide an appropriate level of DBS disclosure when they start working in the NHS, although the level of supervision must be taken into account if their role has changed.
4.4 Accepting a Research Passport issued by another Trust

Research Passports used to obtain an HRC/LoA at another Trust

These must be submitted to the new Trust with the following:

- A copy of the Research Passport form (authorised by the R&I Lead)
- A copy of fully signed HRC or copy of LoA issued by lead Trust
- A current CV
- A completed Research Passport Appendix outlining details of the project, the local supervisor/collaborator and the applicant’s role in the project

Processing a Request

The Research Passport form must be reviewed by the Research Support Co-ordinator to ascertain the level of DBS check and confirm that OH checks were carried out. The checks must be appropriate to the level of involvement of the applicant in the project at GMMH.

If the researcher does not have the appropriate DBS check, the applicant must apply for one through their employer.

If pre-employment checks are satisfactory the Research Support Co-ordinator will issue the applicant with the reciprocal agreement for access to the Trust.

4.5 Researchers holding an NHS Contract with another Trust (Substantive or Honorary Clinical)

These researchers do not require an Honorary Research Contract and must not be processed using a Research Passport. The HR Department (or R&I Office) of the employing NHS Trust should complete an NHS-to-NHS Confirmation of Pre-Engagement Checks form on behalf of the staff member and forward directly to the Research Support Co-ordinator at GMMH to process. This confirms their NHS status and expiry date if on a fixed term contract.

If the level of access required differs from the employee’s usual role, i.e. they have not received DBS or enhanced DBS then the applicant may be required to apply for an enhanced DBS check, and/or undergo additional occupational health checks, or may be required to undergo additional training and/or supervision.

Once a valid application is received and the checks are deemed satisfactory after review, a Letter of Access will be issued to the applicant and copied to their employer.

4.6 Review, Renewal and Expiration

The maximum duration of a Research Passport is three years. If a researcher requires a Research Passport for longer than this, a repeat application should be completed and the relevant checks should be re-assessed. This is in line with the advice on arrangements for highly mobile NHS staff groups, where criminal record and other appropriate checks should be undertaken at three-yearly intervals.
Applicants must start their renewal application at least two months prior to the expiry date (a notification will be sent by the R&I Office prior to expiry). The applicant must contact the R&I Office to confirm if they will need their HRC or LoA extending. Please note this must correlate with the expiration of a research project. The applicant must reapply for DBS and OH when a new Research Passport is completed and processed and as required by the guidance.

5. Researcher Register

The purpose of the Researcher Register is to maintain a current list of all external researchers working on Trust-approved studies. The register is on an Excel spreadsheet and contains the following fields:

- Name
- Type of contract issued
- Start and end date of contract
- Which Portfolio and/or non-Portfolio studies the researcher is working on
- Job title
- Employer
- Usual base
- Email address

The Research Support Co-ordinator will maintain the spreadsheet in the R&I Office and record details when HRCs/LoAs are issued or renewed. These details will be kept in line with the Trust’s Information Governance Policy.

6. References and Bibliography

UK policy framework for health and social care research (2017)

Human Resource (HR) Good Practice Resource Pack