

## SOP 004 Research Passports &amp; NNUH Access

<b>For Use in:</b>	Research
<b>By:</b>	All staff
<b>For:</b>	All staff involved in the conduct of research
<b>Division responsible for document:</b>	Research & Development
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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### 2. Definitions of Terms Used / Glossary

CV	Curriculum Vitae
FT	Foundation Trust
GCP	Good Clinical Practice
HEI	Higher Education Institute
HR	Human Resources
HRC	Honorary Research Contract
IRAS	Integrated Research Application System
LoA	Letter of Access
LTS	Learning & Teaching Service
NHS	National Health Service
NIHR	National Institute for Health Research
NNUH	Norfolk & Norwich University Hospitals
PGR	Post-Graduate student
R&D	Research and Development
RGA	Research Governance Administrator
RP	Research Passport
SOP	Standard Operating Procedure
UG	Undergraduate student

### 3. Objectives

To describe the process for applying for a Research Passport in order to undertake research related activity at NNUH NHS Foundation Trust.

### 4. Scope

This SOP has been developed in accordance with the national NIHR 'Research in the NHS: Good Practice Resource pack' which can be found on the IRAS website <https://www.myresearchproject.org.uk>

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The NHS Research Passport (RP) scheme is a UK-wide initiative to streamline the process for non-NHS staff to obtain permission to carry out research in the NHS. It establishes a common system of pre-engagement checks which conform to NHS Employment Check Standards so that they are transferrable across NHS Trusts.

Research at NNUHFT is often undertaken in partnership with other NHS Trusts and with Higher Education Institutions (HEI). Current national guidelines call for a clear understanding about responsibility, accountability, patient safety and duty of care in relation to research. This can be achieved through the use of Research Passports (RP), Honorary Research Contracts (HRCs) and Letters of Access (LoAs).

### 5. Purpose

This SOP describes the process of completing the RP form in order to undertake research related activity at NNUHFT and is also relevant for University staff wishing to undertake research.

### 6. Who needs a research passport?

A research passport is needed by:

- Anyone coming to NNUHFT to undertake research activity that involves Trust patients, their tissues, samples or data, with no contractual relationship with the NHS. This includes:
  - University employees
  - Students conducting research which is **not** part of a healthcare placement

A research passport is **not** needed if:

- You have a substantive contract of employment with the NHS\*
- You have an Honorary Clinical Contract with a NHS Trust (e.g. Clinical Academics\*)
- You are an University student conducting research as part of your healthcare placement (e.g. Medical, Dental, Physiotherapy and Clinical Psychology students)

\*If you are in these categories, you will require a NHS-to-NHS Letter of Access (see section 7 below)







### 7. NHS to NHS arrangements

The NHS to NHS LoA gives permission for the applicant to have access to the NHS site which hosts the research project.

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The researcher's substantive employer remains fully responsible for undertaking and updating his / her pre-engagement checks.

The research host site can accept the researcher's existing relationship with the NHS.

	To be followed where NHS staff want to undertake research within the NHS but <i>outside their employing Trust</i> .
	The process allows Trusts to share pre-engagement checks to prevent the duplication of checks by multiple Trusts.
	Download and complete the NHS to NHS confirmation of pre-engagement checks proforma (available from the IRAS website, The HR Good Practice Resource Pack, Documents: The Research Passport) <a href="https://www.myresearchproject.org.uk">https://www.myresearchproject.org.uk</a>
	The applicant's employing HR department should complete the proforma, confirming contract of employment details.
	Researcher to submit proforma, research CV and GCP certificate (where required – see SOP 002) with details of proposed research activities and how long they will need access to the site, to the NNUH Research Governance Administrator (RGA) via the RDoffice mailbox (Office.RD@nnuh.nhs.uk).
	The RGA issues NHS to NHS LoA to the researcher and sends a copy to their HR department once the study has confirmation of capacity & capability.

### 8. Procedure NNUH

The Research Passport application form can be obtained from the IRAS website <https://www.myresearchproject.org.uk>

- a) Sections 1-3 to be completed by the applicant.
- b) Section 4 to be completed and signed by the applicant's line manager (if staff) or academic supervisor (if student).
- c) Section 5 to be completed by the HR department of the applicant's substantive employer or place of Registry if a student (e.g. LTS for UGs and PGR service for post-graduate students)
- d) Applicant to complete the checklist in Section 6 and send the RP and supporting documents (see local requirements below) to the RGA at NNUH via email to [Office.RD@nnuh.nhs.uk](mailto:Office.RD@nnuh.nhs.uk)
- e) The RGA to validate the RP and issue an HRC or LoA as appropriate once the research study has confirmation of capacity & capability and send a copy to applicant's HR department / Registry.

### 9. Local requirements

- Data Security Awareness training must be completed for all non-NHS applicants. Level 1 is required and is accessed via link <https://portal.e-lfh.org.uk/Register>. Email the provider ([enquiries@e-lfh.org.uk](mailto:enquiries@e-lfh.org.uk)) once registered to request access to the course if an .ac.uk suffix does not provide automatic access to the course.

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- A signed and dated research CV must be provided, dated within the last 2 years (*template available from IRAS website, The HR Good Practice Resource Pack, Documents: The Research Passport*) <https://www.myresearchproject.org.uk>
- GCP training certificate dated within last 2 years must be provided if required - please see SOP 002 Good Clinical Practice.
- DBS and Occupational Health Clearance may be required. The only times DBS and Occupational Health Clearance will **not** be required are under the following circumstances...

Activity	Criminal record check necessary? <sup>3</sup>	Occupational Health Clearance Necessary?	LOA or HRC
Researcher has indirect contact with patients or service users but is not providing healthcare or other types of regulated activity and has no direct bearing on the quality of care (e.g some types of telephone interview).	No	No	LoA
Researcher requires access to <b>identifiable</b> patient data derived from health records, tissues or organs with a likely direct bearing on the quality of care	No	Yes, only if working with tissues or organs in NHS facilities	HRC
Researcher requires access to <b>identifiable</b> patient data derived from health records, tissues or organs with no direct bearing on the quality of care	No	Yes, only if working with tissues or organs in NHS facilities	LoA
Researcher requires access to <b>anonymised</b> patient data derived from health records, tissues or organs only (including by research staff analysing data)	No	Yes, only if working with tissues or organs in NHS facilities	LoA (only if reviewed in NHS facilities)
Researcher is working on NHS premises (e.g. laboratory) only (no access to identifiable data)	No	Yes, only if working with tissues or organs in NHS facilities	LoA
Researcher requires direct contact with staff only but no access to patients (e.g. staff interviews)	No	No	LoA (if in NHS facilities)
Researcher requires access to <b>identifiable</b> staff data only	No	No	LoA (if in NHS facilities)
Researcher requires access to <b>anonymised</b> staff data only	No	No	LoA (if in NHS facilities)

## 10. References and Related Documents

### References



ICH GCP E6 / SI 2004/1041

### SOP No.      SOP Title

SOP 002      Good Clinical Practice

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### 11. Approval

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### 12. Reason for new version and Training Implication

This SOP replaces the previous version number V1

Changes made	What changes have been made to the contents of the document
Reason	<ul style="list-style-type: none"> <li>• New layout</li> <li>• Revision in procedure</li> <li>• Changes to GCP requirements;</li> <li>• Adding email contact for applications;</li> <li>• Adding Data Security Training information</li> </ul>
Training Implication	<b>No</b>
Actions required	<ul style="list-style-type: none"> <li>• NA</li> </ul>