





For Use in:	Research		
Ву:	All staff		
For:	All staff involved in the conduct of research		
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SOP 004 Version 1

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing.

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## 2. Definitions of Terms Used / Glossary

CV	Curriculum Vitae
DoH	Department of Health
GCP	Good Clinical Practice
HEI	Higher Education Institutions
HR	Human Resources
HRC	Honorary Research Contract
IRAS	Integrated Research Application System
LoA	Letter of Access
NIHR	National Institute for Health Research
NNUHFT	Norfolk & Norwich University Hospitals NHS Foundation Trust
RGA	Research Governance Administrator
RP	Research Passport
R&D	Research and Development
SOP	Standard Operating Procedure

#### 3. Scope

This Standard Operating Procedure (SOP) describes the process for applying for a Research Passport in order to undertake research related activity at NNUHFT. This SOP is also relevant for NNUHFT staff wishing to undertake research related activity in other NHS Trusts.

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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#### 4. Introduction

The NHS Research Passport (RP) scheme is a UK-wide initiative introduced by the Department of Health (DoH) to streamline the process for non-NHS staff to obtain permission to carry out research in the NHS. It establishes a common system of preengagement 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 RP's, Honorary Research Contracts (HRC's) and Letters of Access (LoA's).

#### 5. Purpose

This SOP describes the process of completing the RP form in order to undertake research related activity at NNUHFT and is relevant for University staff wishing to undertake research and for staff members employed by NNUHFT to undertake research related activity in other NHS Trusts.

## 6. Who Needs a Research Passport?

Anyone coming to NNUHFT premises 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

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#### 7. Who does *NOT* need a Research Passport?

You do not need a Research Passport if:

You are a University student conducting research as part of your healthcare placement (e.g. Medical, Dental, Physiotherapy and Clinical Psychology students)

You have an Honorary Clinical Contract with an NHS Trust (e.g. Clinical Academics)\*

\*If you are in these categories, you will require an NHS to NHS Letter of Access

If you are not in any of the above categories and have no contractual relationship with the NHS, you will need a Research Passport in order to carry out research in the NHS.

#### 8. 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.

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.

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• To be followed where NHS staff want to undertake research within the NHS but *outside of their employing Trust*.

• This 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 preengagement checks proforma (available from the IRAS website, The HR Good Practice Resource Pack, Documents: The Research Passport) https://www.myresearchproject.org.uk

• The applicants employing HR department should complete the proforma, confirming contract of employment details.

 Researcher to submit proforma, research CV and GCP certificate with details of proposed research activities and how long they will need access to the site, to Research Governance Administrator (RGA) via RDoffice mailbox (Office.RD@nnuh.nhs.uk).

 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.

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#### 9. Research Passport Procedure

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

Sections 1-3 to be completed by the applicant.

After sections 1-3 are completed, section 4 to be completed and signed by applicant's line manager (if staff) or academic supervisor (if student).

Form to be submitted to HR department of the applicant's substantive employer or place of Registry if a student. Pre-engagement checks will be undertaken and section 5 of the form completed and signed.

Once section 5 completed RP form to be returned to applicant who will complete the checklist in section 6. RP and supporting documents (see local requirements) to be submitted to RGA (hard copies or scanned acceptable).

RGA will validate the RP and issue HRC or LoA as appropriate once the research study has confirmation of capacity & capability and send copy to applicant's HR department / Registry.

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### 10. Local Requirements / Additional Checks

Data Security Awareness training must be completed for all non-NHS applicants (details can be obtained from RGA).

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.

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 anonymised 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 identifiable staff data only	No	No	LoA (if in NHS facilities)
Researcher requires access to anonymised staff data only	No	No	LoA (if in NHS facilities)

Standard Operating Procedure for: Research Passports NNUH R&D SOP Number: SOP 004 Author/s: Caroline Stevens Author/s title: Research Governance Administrator

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# 11. Approval

Author:	Caroline Stevens		
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Signature:	Caroline Stevens		
Date:	07/05/2020		
Approved & Authorised NNUH:	Julie Dawson		
Role:	Research Services Manager		
Signature:	Julie Dawson		
Date:	13/05/2020		
Approved & Authorised UEA:	Sarah Ruthven		
Role:	Research Manager		
Signature:	Sarah Ruthven		
Date:	07/05/2020		

# 13. Reason for Update and Training Implication

This is a new SOP.

Update	Reason	Training Implication	Action
This is a new SOP	Gap analysis identified a gap in the compliance	Yes	Review of the SOP and completion of training matrix required

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