UNIVERSITY OF WARWICK

STANDARD OPERATING PROCEDURE 38

Research Passports, Letters of Access (LOA) and Honorary Research Contracts (HRCs)

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1 Purpose and Scope

To identify where a research passport may be required to obtain a LoA or an HRC and to detail the procedures for obtaining, maintaining and renewing a valid Research Passport.

All members of the research team, including lay representatives, regardless of whether they are employed or working on a voluntary basis should consider whether a research passport is required for the work completed.

This SOP applies to UoW staff, students, volunteers and other individuals undertaking research activities on behalf of University-sponsored studies who may require a Research Passport, Letter of Access or Honorary Research Contract.

2 Acronyms

CV	Curriculum Vitae
DBS	Disclosure and Barring Service
GCP	Good Clinical Practice
HR	Human Resources
HRA	Health Research Authority
HRC	Honorary Research Contract
HSC	Health and Social Care
ICG	Integrated Care Group
IRAS	Integrated Research Application System
LoA	Letter of Access
NIHR	National Institute for Health and Care Research
NHS	National Health Service
QA	Quality Assurance
RDN	NIHR Research Delivery Network
R&D	Research & Development
R&IS	Research and Impact Services
SOP	Standard Operating Procedure
TM/TC	Trial Manager/Trial Coordinator
WCTU	Warwick Clinical Trials Unit

3 Definitions

NHS Organisation	Hospital, ambulance, mental health, social care, and primary care services provided by the NHS.
Research Passport	The mechanism for non-NHS staff to obtain an HRC or LOA when they propose to carry out research in the NHS.
Research Passport Appendix	A method to add additional locations e.g. NHS sites/organisations/ICGs, or additional work to the existing Research Passport. [E.g. a researcher may have an appendix for each geographical location within a study, or an appendix for different studies.]
LOA	Required when researchers are not employed by an NHS organisation and the research involves patient contact or accessing personal identifiable data. NB Organisations may request this for interviews with staff.

HRC	Required when researchers are not employed by an NHS organisation and the research activity has a direct bearing on the quality of patient care. This may include delivering care.
UK Policy Framework for Health and Social Care Research	Sets out principles of good practice in the management and conduct of health and social care research in the UK. Details can be found on the HRA website.

4 Background

Research passports confirm a researcher's responsibilities and accountability regarding patient safety and duty of care. The UK Policy Framework for Health and Social Care Research requires all parties undertaking research within the NHS to be clear about responsibilities and liabilities. One of the ways in which this can be achieved is through using HR procedures and research passports appropriately.

Guidance on Research Passports is available via the IRAS website. The HR Good Practice Resource Pack contains information and documentation to support the process for handling HR arrangements for researchers and provides a streamlined approach for confirming details of the required pre-engagement checks with the NHS organisation(s).

WMS also provides guidance for researchers.

The research passport system provides:

- One set of checks on a researcher conducting research in the NHS e.g. Disclosure Barring Service (DBS) checks and Occupational Health clearance.
- One standard form completed by the researcher and their employer, and validated by an NHS organisation
- A Research Passport which is presented to all the relevant NHS organisations.

5 Responsibilities

Individual named on Research Passport	• Ensure a research passport is in place for the scope of work, before work commences and for the duration of the study. • Keep NHS organisations informed of any relevant changes [E.g. employment status, professional registration status, criminal record checks]. Failure to do so may result in termination of the individual's HRC or LoA. • Ensure renewals are instigated in a timely way.
HR	• Undertake checks associated with the Research Passport application and provide sign off for staff that are not employed through Unitemps (see below).
Unitemps	• For Unitemps staff, Unitemps provide authorisation for an application if provided with section 5 of the research passport form and the associated documentation to check.
TM/TC	• Support researchers in obtaining the required approvals and maintaining study records. Responsibility for holding a valid Research Passport, LoA or HRC remains with the individual researcher.
NHS organisation	• Review the research passport and issue the HRC/LoA in line with the Research Passport Algorithm

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6 When

A valid research passport should be in place prior to an individual undertaking any research activity at an NHS organisation or where there will be contact with NHS patients or their data.

At the study outset, it should be identified whether any members of the team, require a research passport - this can be done via IRAS, using the HR Good Practice Resource Pack.

Research Passports should be updated as new roles and responsibilities are taken on by members of the team or if the work being completed changes.

For studies where outgoing participant telephone calls will be made by University of Warwick staff, the NIHR RDN or the site's R&D office should be consulted as to whether a research passport is required.

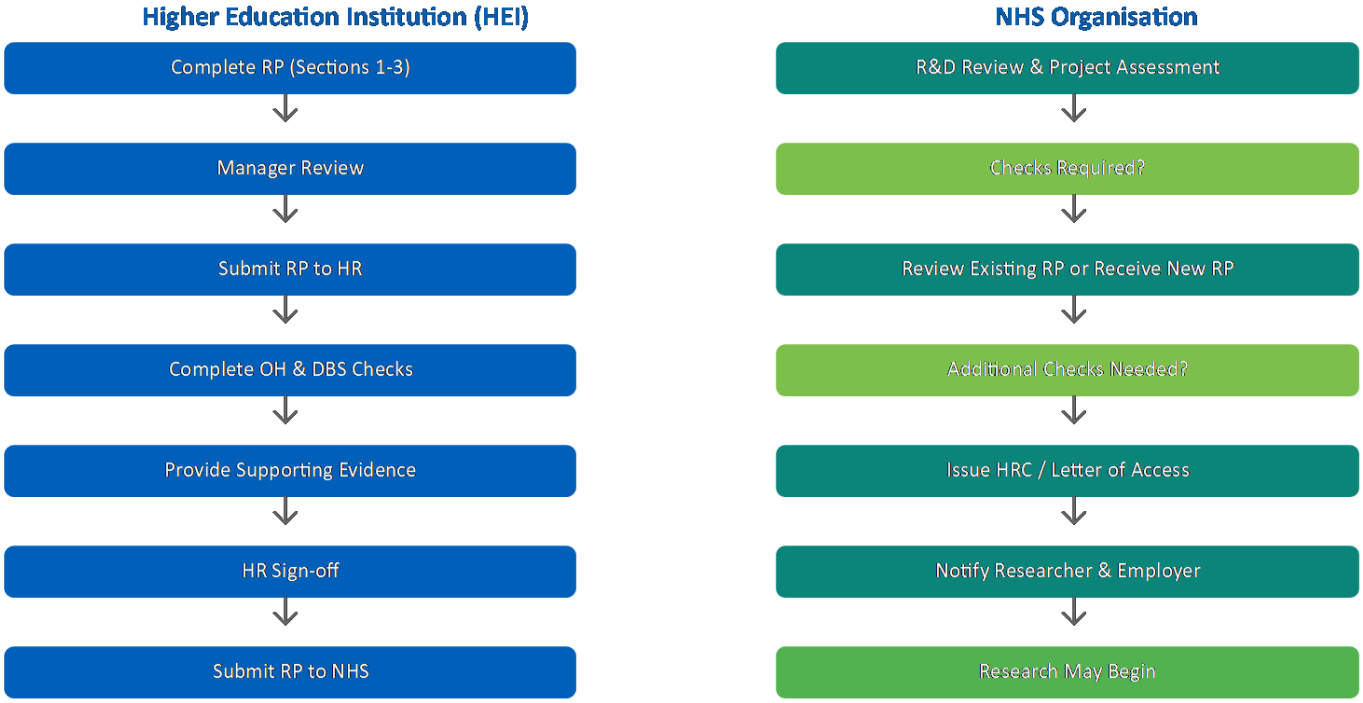
It is the responsibility of the researcher and team to check requirements following the guidance in the HR Good Practice Resource Pack and confirm which checks are needed.

7 How

7.1 Application Process

Research Passports are generally valid for three years based on the date of application. A start and end date must be added. Note the dates relate only to the validity of the research passport. Any appendices may have different end dates.

When applying for a Research Passport 'project specific' or 'multi project can be selected.' Regardless of the dates on any appendices or LoA, the documents can only be deemed valid if the original research passport is in date and valid.



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7.2 Adding projects to a Research Passport

Additional Research Passport appendices should be considered when:

- New organisations are introduced
- Staff will be completing work in a new organisation
- The scope of work changes

Appendices are embedded within the Research Passport Form. When another appendix is required, a copy of the relevant page indicating the appendix number in the box provided at the top of the page should be used. To obtain approval for the appendices they should be sent to the new organisation along with the following documents:

- Fully signed Research Passport
- Supporting documents as applicable (CV, GCP certificate, DBS certificate, Occupational Health clearance. Proof of registration may also be required).

If another project needs to be added to a Research Passport as an appendix and a higher DBS clearance level is required as per the algorithm, then a new passport needs to be issued.

The key triggers for a new DBS check for individuals working under a valid research passport are when:

- Researchers have never had a criminal record check before and are moving to a position that now requires them to have a check. The level of check is dependent on the role.
- Responsibilities of their research role have changed, and they require a higher level of check, or a check against one or both barred lists.

Appendices will need approval from the site/organisation/region before the work can begin.

Some RDNs and R&D offices will have a localised version of this appendix document – this will be notified to the applicant during the approval process for that region.

N.B. Arrangements differ in Northern Ireland. Researchers should seek advice from the study sponsor and relevant NHS organisation.

7.3 Research Passports Renewal

Researchers should begin renewal applications at least three months before expiry. Where required, updated DBS or Occupational Health clearances must be obtained. Responsibility for maintaining a valid Research Passport rests with the individual researcher.

Consideration should be given to Research Passport management when a study ends or when staff holding a Research Passport leave their post.

For WCTU staff, the valid research passport should be saved within personal development records with the expiry date clearly visible. It is the individual's responsibility to ensure renewals are obtained.

7.4 Exclusions to the Research Passport

The following are not covered by the Research Passport but may be required to complete different processes to undertake research in the NHS. Advice should be sought through NIHR RDN or relevant R&D office before any research is conducted.

- Staff members employed by an NHS organisation*
- Independent contractors (e.g. GP) or those employed by an independent contractor
- Staff members with an honorary clinical contract with NHS Trust e.g. clinical academics*.

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- Students on a healthcare placement.

*Researchers with a substantive NHS contract, or an honorary clinical contract with one NHS organisation do not need additional honorary research contracts to conduct research in other NHS organisations. Additional pre-engagement checks may be required. NHS organisations should accept the NHS to NHS proforma confirmation of pre-engagement checks from the researcher's substantive employer as evidence that the appropriate clearances are in place and inform the researcher's substantive employer of their activities in their organisations by issuing the NHS to NHS Letter of Access.

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