STANDARD OPERATING PROCEDURE 38
Research Passports, Letters of Access (LOA) and Honorary Research Contracts (HRCs)

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Revision Chronology:	Effective date:	Reason for change:
Version 3.0	8 November 2024	Biennial Review: Updates to text for clarification of processes. Section headers, application flowcharts and exclusions section added.
Version 2.0	23 August 2022	Biennial Review: Minor changes
Version 1.0	23 April 2020	N/A new SOP

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1. Purpose and Scope

This Standard Operating Procedure (SOP) details procedures to identify where a research passport may be required to obtain a Letter of Access (LOA) or an Honorary Research Contract (HRC) where it is required for researchers undertaking research in the NHS. The SOP also details the procedures to maintain a valid Research Passport

All members of the clinical research team, including lay representatives, research, clinical and clerical staff regardless of whether employed on a contract, Variable Monthly (VAM) Payroll, Unitemps or are working on a voluntary basis should consider whether a research passport is required for the work being completed on behalf of the study.

2. Definitions

NHS Organisation	Hospital, ambulance, mental health, social care, and primary care services provided by the NHS.
Research Passport	A Research Passport is 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/Clinical Commissioning Groups (CCGs), or additional work to the existing Research Passport. *For example, a researcher may have a separate appendix for each geographical location within a study, or a separate appendix for different studies.*
Letter of Access (LOA)	Required when researchers are not employed by an NHS organisation in either a substantive or honorary way and their research involves patient contact or accessing identifiable patient data for research purposes. If the applicant will be delivering care, then an HRC will be required.
Honorary Research Contract (HRC)	Required when researchers are not employed by an NHS organisation in either a substantive or honorary way and their 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. Full details can be found on the Health Research Authority (HRA) website

3. Background

A Research Passport is the mechanism by which non-NHS staff can obtain an HRC or LOA to enable them to carry out research in the NHS and on NHS premises. The research passport system provides:

- one set of checks on a researcher conducting research in the NHS e.g. Disclosure Barring Service (DBS) checks
- 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; and
- faster study start-up.

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 published by the UK Department of Health and Social Care 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 Human Resources (HR) procedures and research passports appropriately.

There is extensive guidance on Research Passports in the 'Research in the NHS HR Good Practice Resource Pack' available via the Integrated Research Application System (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/Health and Social Care (HSC) organisation.

WMS also provides guidance for researchers in higher education institutions who need to undertake their research within the NHS which also includes details of the pre-engagement checks required.

4. Procedure

4.1 Responsibilities

Individual named on Research Passport	• Ensure an up-to-date research passport is in place for the work being completed on a study before work commences and for the duration of the study. • Keep NHS sites/organisations/CCGs, informed of any changes that might be relevant, for example employment status, professional registration status or 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.
Human Resources (HR)	• Undertake the checks associated with the Research Passport application and to provide sign off on the application for staff that are not employed through Unitemps.
Unitemps	• For staff employed through Unitemps, Unitemps can provide authorisation for an application if provided with section 5 of the research passport form and the associated documentation to check.
Trial Managers/Coordinators	• Assist individuals with obtaining approvals from NHS sites and organisations, however ultimate responsibility lies with the individual completing the work to ensure the correct HRC/LoA are in place prior to completing any work at each site/organisation.

NHS sites	• Review the individual's research passport and issue the HRC/LOA in line with The Research Passport Algorithm, prior to any research being conducted.

4.2 When?

Research passports should be in place prior to an individual undertaking any research activity at an NHS site/organisation, CCG, or where there will be contact with NHS patients or their data.

At the beginning of a study during the risk assessment it should be identified whether any members of the team, both clinical and professional support services, require a research passport - this can be done by using Table 1 in 'The Research Passport Algorithm of Research Activity and Pre-Engagement Checks' document. The current version of the document is available via the IRAS help pages on HR Good Practice Resource Pack

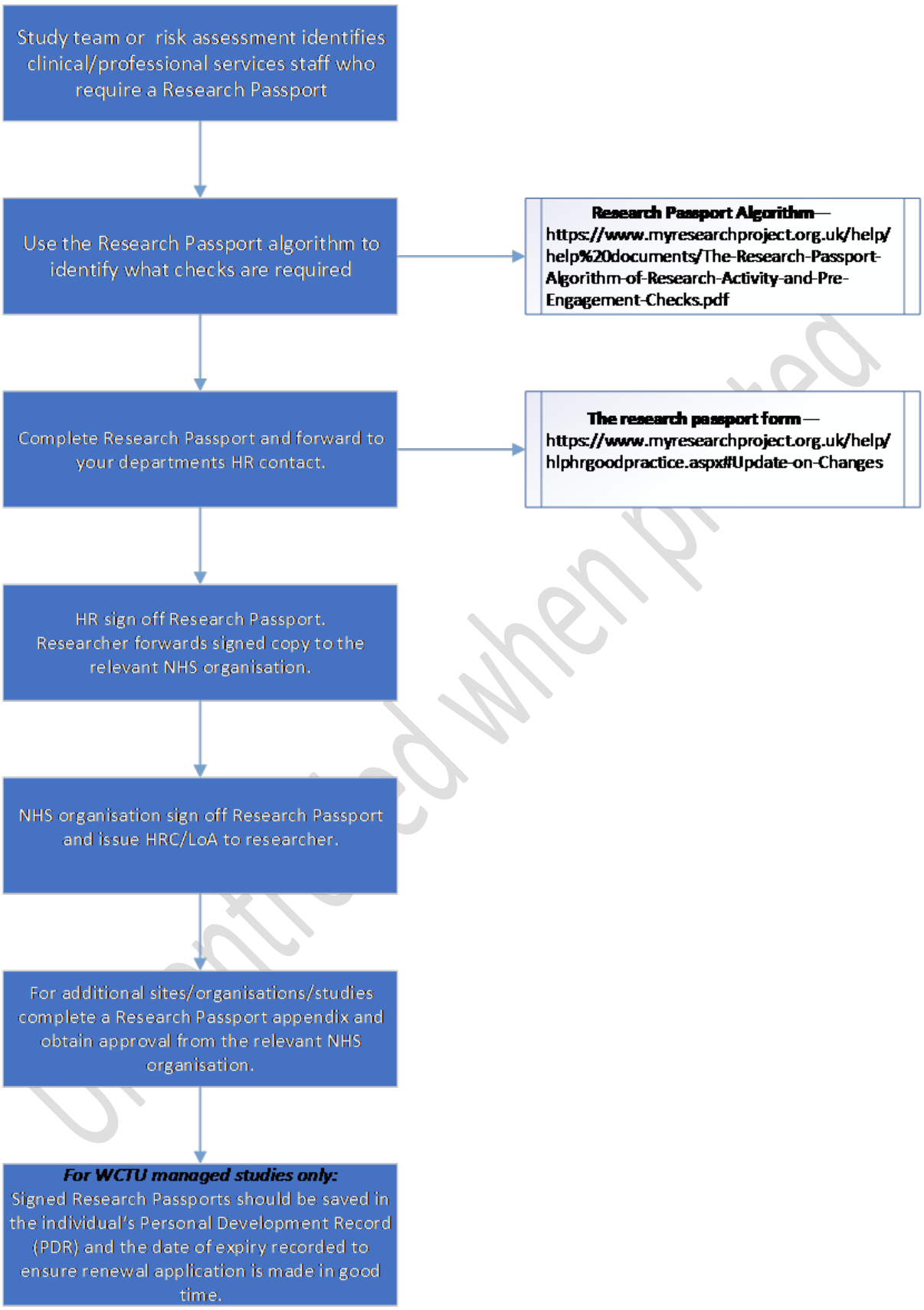
Research Passports should be updated as new roles and responsibilities are taken on by members of the team or if the work being completed changes. If this happens, the Research Passport Algorithm should be consulted.

Please note: For studies where outgoing participant telephone calls will be made by a University of Warwick member of staff, the NIHR Research Delivery Network (RDN) or R&D office for the NHS site should be consulted as to whether a research passport is required for such activity.

It is the responsibility of the researcher/team intending to undertake such research to check requirements following the guidance in the HR Good Practice Resource Pack (link above) and speak to the relevant RDN/NHS teams to confirm which checks are needed (e.g. DBS) to obtain the correct documentation.

4.3 How?

4.3.1 Application Process

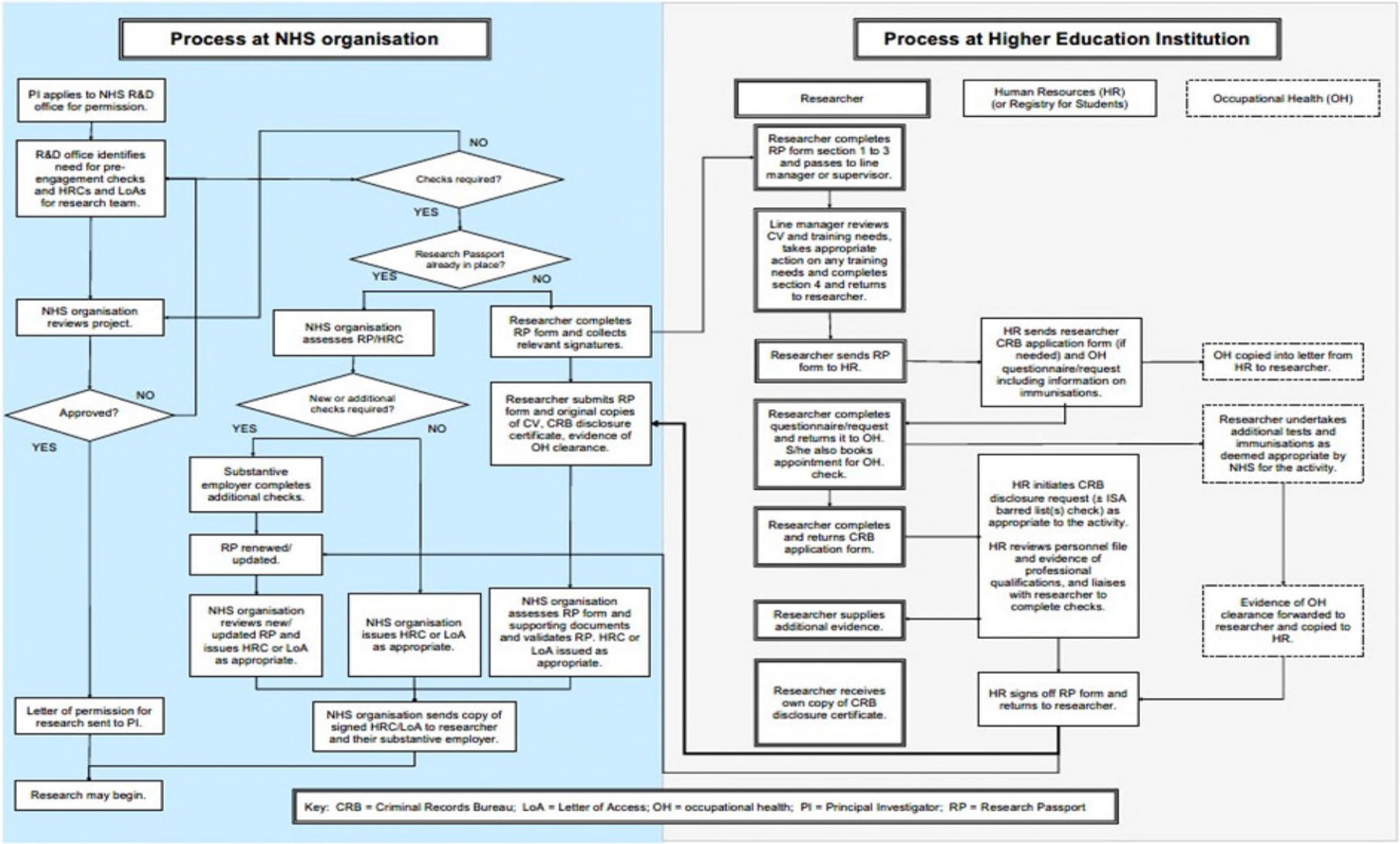


Research Passports are generally valid for a period of **three years** based on the date of application. In section two of the Research Passport, a start and end date for the three years that the Research Passport will be valid must be added, regardless of the research study. Note that the three years stated

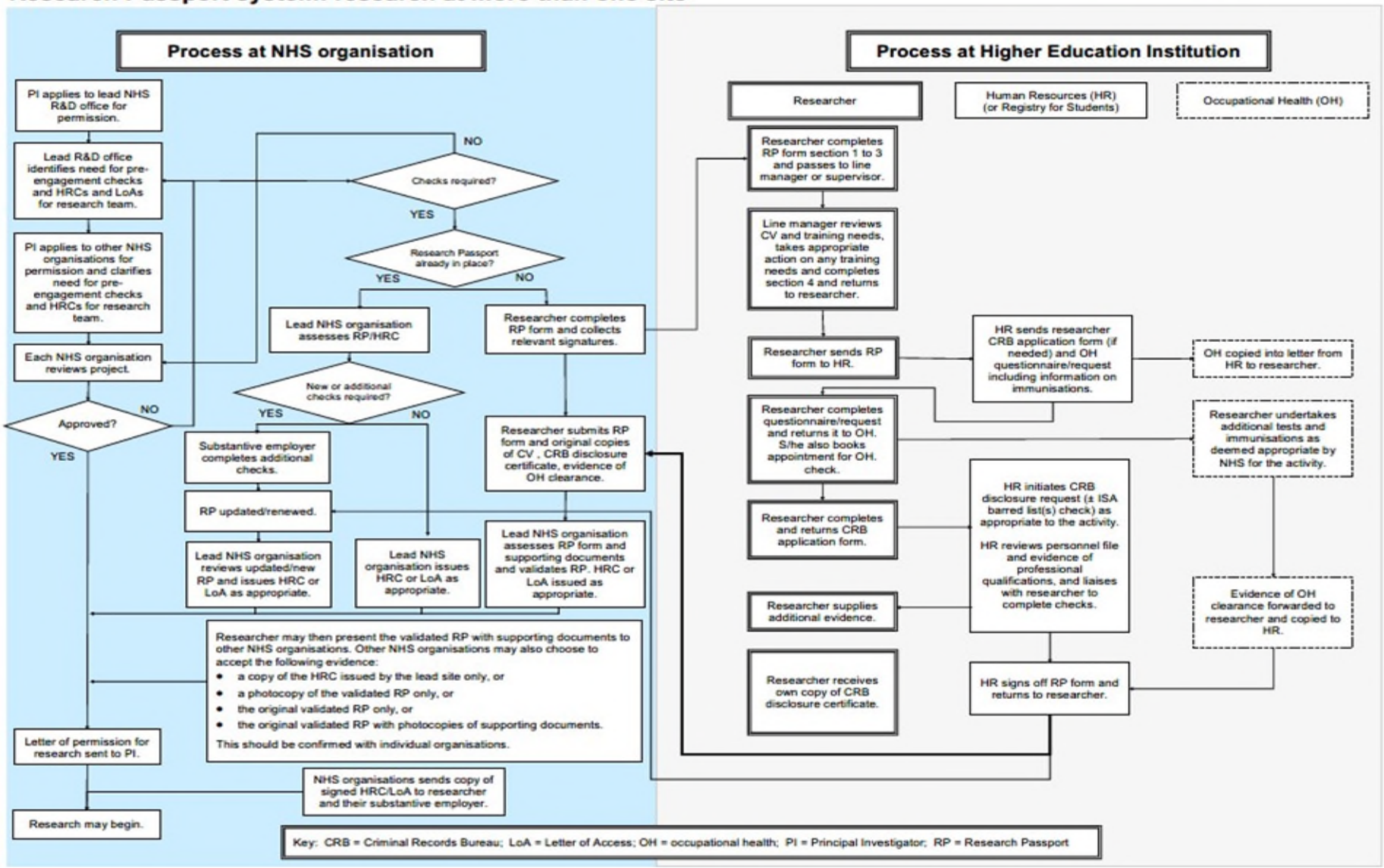
in section two are the dates which relate only to the validity of the research passport; any appendices and the study may have different end dates.

When applying for a Research Passport you can select either 'project specific' or 'multi project.' With both it is crucial to remember that 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.

Research Passport system: research at one site



Research Passport system: research at more than one site



4.3.2 Adding projects to a Research Passport

Additional Research Passport appendices should be considered when:

New sites/regions/CCGs are brought on board	Staff will be completing work in a new site/region/CCG	If the work being completed changes	Prior to new work on a study being undertaken

Research Passport appendices are embedded within the Research Passport Form. Each time another appendix to a research passport 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 site/organisation/CCG/RDN, etc. along with the following documents:

- Fully signed Research Passport
- Supporting documents as applicable (CV, Good Clinical Practice (GCP) certificate, DBS certificate, Proof of registration).

If another project needs to be added to a Research Passport as an appendix *and* a higher Disclosure and Barring Service (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:

- the researcher has 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.
- the responsibilities of their research role have changed, and they require a higher level of check, or a check against one or both barred lists.

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

Please be aware that 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. There is no Research Passport system in Northern Ireland (NI). For studies sponsored by an institution in NI, the study sponsor will need to coordinate any applications from staff who are required to work in NHS premises.

4.3.3 Research Passports Renewal

It is good to practice to allow at least three months prior to the end date of the current research passport to apply for a new/extended research passport and associated NHS organisation approvals. Some researchers will be required to complete a DBS and/or an Occupational Health review before the new/extended research passport can be approved. It is important to factor in sufficient time to conduct these processes.

For members of staff in WCTU, once a research passport has been obtained it should be saved in your Personal Development Folder (PDR) with the expiry date clearly visible. It is the individual's responsibility to ensure renewals are obtained in a timely way.

4.3.4 Exclusions to the Research Passport

The following groups of staff 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 Research Delivery Network (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*.
- 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 occasionally 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.*

List of abbreviations

CV	Curriculum Vitae
DBS	Disclosure and Barring Service
CCG	Clinical Commissioning Groups
GCP	Good Clinical Practice
HR	Human Resources
HRA	Health Research Authority
HRC	Honorary Research Contract
HSC	Health and Social Care
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
VAM	Variable Monthly
WCTU	Warwick Clinical Trials Unit