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

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Version 2.0	23 August 2022	Biennial Review: Minor changes
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1. Purpose and Scope

This Standard Operating Procedure (SOP) details procedures to identify where a research passport may be required in order 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 access to identifiable patient data. If you will be delivering care, then an HRC will be required. See below.
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 his/her 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 are in place to confirm a researcher's responsibilities, accountability, 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 pre-engagement checks undergone with the NHS/Health and Social Care (HSC) organisation.

4. Procedure

4.1 Responsibilities

Individual named on Research Passport	• Responsible for ensuring 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. • Keeping 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.
Human Resources	• Responsible for undertaking 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.

4.2 When?

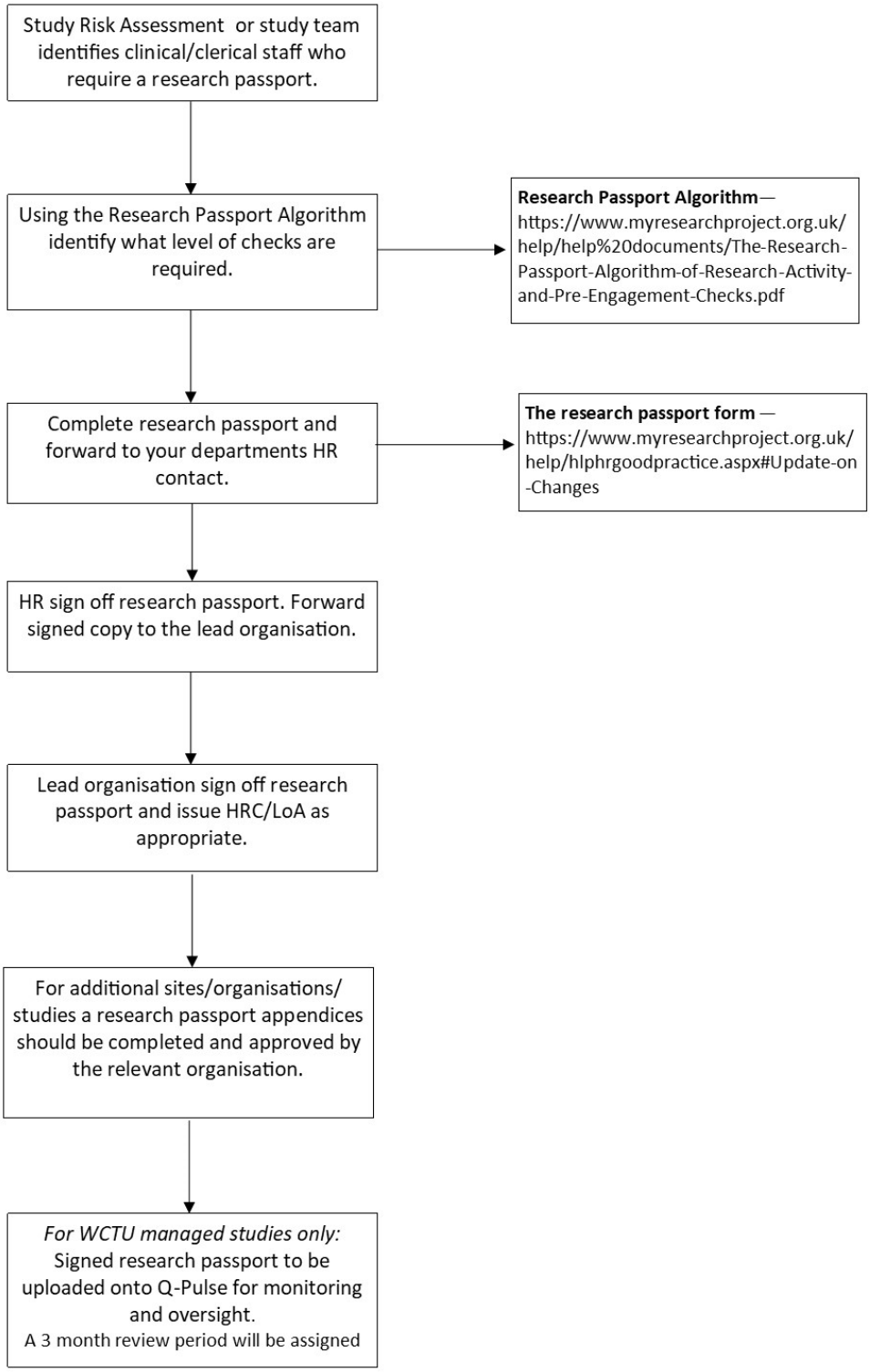
Research passports should be in place prior to an individual undertaking any activity at an NHS site/organisation, CCG, or where there will be contact with NHS patients or their data.

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

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.

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.

4.3 How?


Study Risk Assessment or study team identifies clinical/clerical staff who require a research passport.
Using the Research Passport Algorithm identify what level of checks are required.
Research Passport Algorithm— https://www.myresearchproject.org.uk/help/help%20documents/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf
Complete research passport and forward to your departments HR contact.
The research passport form — https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#Update-on-Changes
HR sign off research passport. Forward signed copy to the lead organisation.
Lead organisation sign off research passport and issue HRC/LoA as appropriate.
For additional sites/organisations/ studies a research passport appendices should be completed and approved by the relevant organisation.
For WCTU managed studies only: Signed research passport to be uploaded onto Q-Pulse for monitoring and oversight.
A 3 month review period will be assigned

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 on which you are working. 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 as long as the original research passport is in date and valid.

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.

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

Research Passport appendices are imbedded within the Research Passport Form. Each time you wish to add another appendix to your research passport you should use a copy of the relevant page indicating the appendix number in the box provided at the top of the page. To obtain approval for the appendices they should be sent to the new site/organisation/CCG/CRN, 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).

Please be aware that some CRNs and R&D offices will have a localised version of this appendix document – this will be notified to you during the approval process for that region.

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 uploaded onto the Q-Pulse Electronic Quality Management system as a new 'Active' document. An appropriate review date should be applied to the document record so that the holder of the Research Passport will be notified by Q-Pulse when renewals are required. The document 'author' and 'owner' set in the Q-Pulse document record, should be the individual that is the holder of the Research Passport. This will ensure reminders are sent to the appropriate person. The review date should be sufficient to allow adequate time for review and renewal.

List of abbreviations

CV	Curriculum Vitae
DBS	Disclosure and Barring Service
CCG	Clinical Commissioning Groups
CRN	Clinical Research Network
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
NHS	National Health Service
QA	Quality Assurance
R&D	Research & Development
R&IS	Research and Impact Services
SOP	Standard Operating Procedure
VAM	Variable Monthly
WCTU	Warwick Clinical Trials Unit