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Standard Operating Procedure for JRO Administration of Research Passports

JRO SOP 7

SOP ID Number	Version Number	Effective Date	Review Date
JRO SOP 7	5	19/09/2023	19/09/2026
Author: Name and Job Title	Ummulkheir Ayub, JRO Quality Assurance Manager		
Reviewed by; Name and Job Title:	Pushpsen Joshi, JRO Research Management and Governance Team Manager Shamimul Islam, JRO Operational Manager		
Target Audience	Joint Research Office, Researchers		
Please check this is the latest version of the SOP on the Joint Research Office website: www.ucl.ac.uk/joint-research-office			

Revision Chronology			
Version	**Effective Date**	**Reasons for Change**	**Author**
JRO RMG RSS SOP-07 version 1	23/04/2012	First version including NIHR RSS Framework.	Wendy Fisher
JRO RMG SOP 7 Version 2 (*unpublished*)	21/04/2014	The second version removed mention of Royal Free London NHS Foundation Trust because they merged with Barnet & Chase Farm on the 1st July 2014 and therefore produced their own suite of SOPs. The Research Management and Governance Team structure changed in 2012. The review timeframe was revised to every 3 years and the key criteria for inclusion in the audit checklist were outlined. Therefore the SOP was updated to include these changes.	Emma Prowse, JRO Operations Administrator
JRO SOP 7 Version 3	24/04/2018	In the third version references to ESR have been removed, as records are no longer kept on ESR. References to the Criminal Records Bureau (CRB) have been replaced with the U.K Disclosure and Barring Service (DBS). An updated JRO Operations team email address has been provided. The whole document has been updated to reflect current DoH and UCL Research Passport guidance and templates, and stipulations for researchers whom don't require honorary research contracts. SOP has also been updated to the current JRO SOP template.	Katie Osborn, JRO Operations Administrator
JRO SOP 7 Version 4	11/11/2019	The SOP has been updated in line with release of the May 2019 edition of the HR Good Practice resource pack. Detail has been summarized, and charts and tables inserted to improve clarity. Researchers have been added as an audience to this SOP. Information regarding UCLH Epic training and relevant UCLH contact details has been added. Links and references have also been updated.	Arti Kara, Research Audit & Quality Officer Mona Hassan, Research Quality & Safety Manager.
JRO SOP 7 Version 5	19/09/2023	Updated author and review by sections.	Ummulkheir Ayub, Quality Assurance Manager

1. ACRONYMS

DBS	Disclosure and Barring Service
DoH	Department of Health
Epic	UCLH Electronic Health Records System
ESR	Electronic Staff Record
GCP	Good Clinical Practice
HEI	Higher Education Institute
HR	Human Resources
HRC	Honorary Research Contract
JRO	Joint Research Office
LoA	Letter of Access
NHS	National Health Service
NIHR	National Institute for Health Research
PO	Portfolio Officer
QA	Quality Assurance
R&D	Research & Development
RM&G	Research Management & Governance
SOP	Standard Operating Procedure
UCL	University College London
UCLH	University College London Hospitals NHS Foundation Trust

2. DEFINITIONS

Research Passport System	The process that an applicant goes through in order to obtain a Honorary Research Contract or Letter of Access. The process provides evidence of the pre-engagement checks undertaken on a Researcher in line with NHS Employment Checks standards.
Research Passport Form	The document used to collect the information required to issue a HRC or LoA for Higher Education Institute employee with no contractual arrangement with the NHS organisation where they plan to undertake research. Each Research Passport Form is specific to one research study.
Honorary Research Contract	The document which defines the terms and conditions applicable to a Higher Education Institute employee with no contractual arrangement with the NHS organisation where they plan to undertake research which has a direct bearing on the quality of patients' care.
Letter of Access	The document which confirms the extension of NHS terms of employment for an NHS employee undertaking research in another NHS organisation or replaces an HRC where a Higher Education Institution employee with no contractual arrangements with the NHS but the access to patients has no direct bearing on the quality of their care.
Higher Education Institute	University or College employing the researcher who wishes to undertake research within the NHS where there is no existing contractual arrangement in place.

NHS to NHS Proforma	The document used to collect the information required to issue a LoA to an existing NHS employee undertaking research in an NHS site different to where their employment contract is held.

3. JRO POLICY

Standard Operating Procedures (SOPs) are written working practice documents detailing routine procedures that must be followed to perform a given task.

All SOPs produced from the JRO must be used in conjunction with local NHS Trust and UCL policies and procedures.

The JRO represents UCL and UCLH as the Sponsor and UCLH as a participating site. The JRO is responsible for research management and governance processes as sponsor and host site representative. The JRO SOPs will provide the quality system to fulfil these requirements.

This SOP complies with the U.K Policy Framework for Health and Social Care Research 2017 (3rd edition, 2017) and its subsequent amendments, Good Clinical Practice as outlined by the EU Clinical Trials Regulation 2001/20/EC and the HR Good Practice Resource Pack (May 2019 edition) published by the National Institute for Health Research (NIHR) and hosted on IRAS Help.

4. BACKGROUND

Research is an integral component of NHS activity, and is often undertaken in collaboration with by NHS staff not directly employed by the host NHS organisation, or by non-NHS staff, particularly researchers employed by universities. The U.K Policy Framework for Health and Social Care Research require all parties involved in undertaking research within the NHS to be clear about responsibilities. This is achieved through using appropriate HR procedures. The *HR Good Practice Resource Pack*[1], has been developed by the National Institute for Health Research (NIHR and Department of Health and Social Care, in conjunction with the UKCRC partners and stakeholder organisations.

The Resource Pack describes the Research Passport system, which offers a standard approach to issuing NHS honorary research contracts (HRCs) to those who have no employment contract with the NHS, and who need to undertake their research activities in the NHS. The Resource Pack also provides clear guidance regarding good HR practice for those who already have a contractual relationship with the NHS (i.e. those with either a substantive employment contract or honorary clinical contract) and who need to undertake their research activities across several NHS organisations. Subject to specific local arrangements, the principles of the Resource Pack can be applied to other researcher groups (e.g. employers of social care researchers) who need to access NHS facilities for their research, whether this is done through a Research Passport, or through a normal NHS contract.

[1] https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#HR-Good-Practice-Resource-Pack

5. PURPOSE AND SCOPE

This SOP describes the JRO's methods for processing Research Passports (and information on HR arrangements) for individuals conducting research in the NHS, specifically University College Hospitals NHS Foundation Trust (UCLH). The scheme applies to:

a. All researchers who **do not** hold a substantive employment contract with this NHS organisation,
b. All researchers with a substantive NHS contract of employment who need to undertake their research in a **different NHS site**.

The NHS Research Passport scheme is a UK-wide initiative introduced by the Department of Health and Social Care to streamline the process for non-NHS staff to obtain permission to conduct research within the NHS. It establishes a common system of pre-engagement checks which confirm to NHS Employment Check Standards, so that they are transferrable across NHS Trusts. A HRC covers all research activity as per the protocol and UCLH Confirmation of Capacity and Capability. It is specific to the applicant and cannot be shared by the whole research team. A HRC does not confer the right of access to confidential information for research without explicit informed consent. The Research Passport itself is a package of documents completed by Researchers with their substantive employer and then validated by the first NHS R&D office, who will then issue a HRC or Letter of Access (LoA), as appropriate. It usually contains:

- A completed Research Passport Application Form
- Researcher's CV
- Evidence of pre-engagement checks completed by the substantive employer, such as a DBS and Occupational Health (OH) check

When completed, it can be taken to other NHS organisations, thus removing the need for duplicate checks.

NHS HRCs apply to single NHS sites only, and are research project-specific. If there is a change of Principal Investigator for a non-CTIMP study, a non-substantial amendment is required. If there is a change of Principal Investigator for a CTIMP study, a substantial amendment is required. For any other research team changes, such as the addition of a new research fellow, no amendments are required[2]. However, the study IRAS form must be updated and reauthorized where necessary, and the appropriate site and R&D office informed. A HRC or LoA must also be in place if they are not already employed by UCLH. Separate Research Passport applications will need to be made to the R&D departments of additional NHS sites, and for different research projects. This SOP and the JRO does NOT cover other R&D department/HEI arrangements for Research Passport applications. Please contact the relevant R&D departments concerned.

Additional Examples of researchers who DO require an HRC or LoA:

- Researchers already issued with an HRC/LoA at another NHS site, who wish to conduct research activity at UCLH. Their original validated Research Passport application should be submitted to uclh.jro-communications@nhs.net. The JRO Operations team will review and issue either the HRC or LoA, as appropriate. No additional checks are required, as the existing pre-engagement checks remain acceptable to UCLH.

[2] https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx#Activities-not-notified-NHS-HSC

- Researchers already issued with an HRC/LoA, whose research activities have altered significantly since original approval (e.g. moving to a position where their research involves direct contact with children where previously they worked only with adults) or a direct impact on care, where previously there was none, the individual will need to complete the latest version of the Research Passport Form. If changes only relate to occupational health requirements, the appropriate additional checks should be undertaken and the existing Research Passport Form updated as described in the Resource Pack and new details provided to all host sites.
- Existing NHS staff (including clinical academics) outside of UCLH: the substantive employer remains wholly responsible for ensuring that requisite pre-engagement checks have been undertaken. Researchers should therefore only complete the *NHS to NHS proforma* (signed confirmation that their substantive employer has completed required checks), Research CV, and confirmation of UCLH Confirmation of Capacity & Capability to the JRO Operations team. They will be issued with an NHS to NHS LoA.

Researchers who do NOT require an Honorary Research Contract:

- Researchers with substantive NHS employment contracts (the NHS has existing mechanisms for these staff to work across NHS organisations)
- Researchers whom are independent contractors (e.g. GP) or employed by an independent contractor
- Researchers who already hold an Honorary Clinical Contract with UCLH e.g. clinical academics (these researchers have joint NHS/university posts which enable them to conduct clinical duties, including research, and to work across NHS organisations through the existing NHS systems).
- Researchers conducting research where the participants are NHS staff
- The researcher is a student on a healthcare placement. Students will not be given access to UCLH's electronic health record system, EPIC.

Staff not covered by the Research Passport Process:

- Commercial research staff should not be given a research passport, or be issued with an honorary research contract or letter of access or any other document that could be construed as indicating that the NHS organisation is accepting liability for their actions. Commercial research staff should contact the UCLH Honorary Contracts team for advice on how to proceed: uclh.honorarycontracts@nhs.net.

- UCLH should not extend HRCs to independent contractors if they are conducting research as part of their NHS practice (e.g. GPs permitted to conduct research).

- Independent contractors who undertake research under a separate contract with the NHS will be dealt as appropriate to the individual circumstances (e.g. issued with either HRC, LoA, NHS to NHS LoA, etc.).

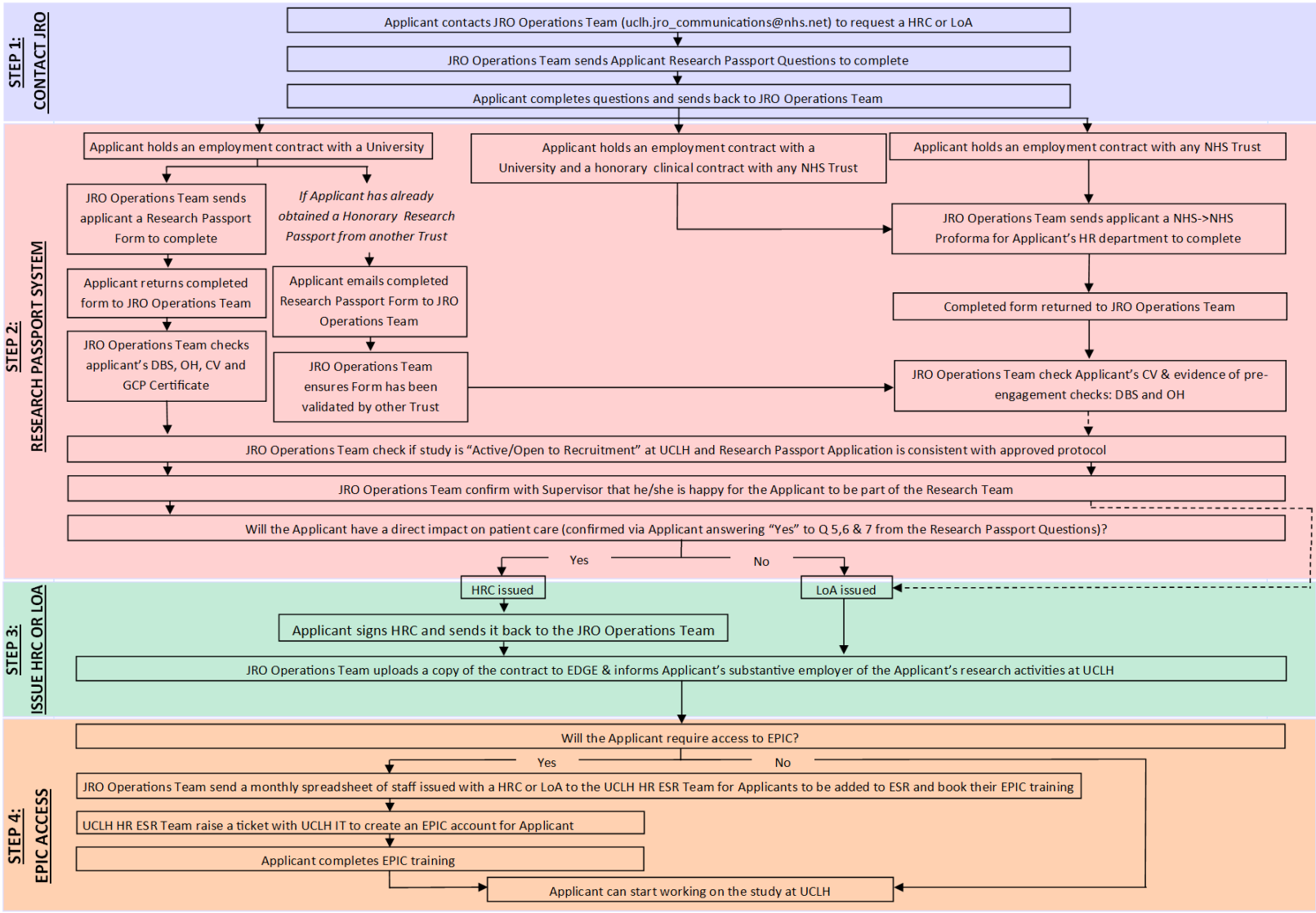
Researchers are advised to contact the JRO Operations team for guidance at the earliest opportunity, via uclh.jro-communications@nhs.net.

6. RESPONSIBLE PERSONNEL AND THEIR DUTIES

	Responsible Person	Summary of duties
1	Researcher applicant	• Complete all necessary Research Passport application forms and pre-engagements checks, and provide necessary ID documentation to JRO Operations Team.
2	JRO Operations Team	• Validate and complete section 8 of the Research Passport application Form • Photocopy the completed form and attachments • Record the details of the HRC or LoA onto the JRO Research Passports spreadsheet • Liaise with JRO Portfolio Officer and check R&D Management Database to confirm researcher application is valid and associated with an approved research project ('Active', where UCLH Confirmation of Capacity & Capability has been issued) • Issue the HRC or LoA • Re-issue HRC or LoA following expiration/changes, upon confirmation and request from researcher • Informs UCLH HR in order for an ESR and Epic accounts to be created.
3	JRO Portfolio Officer	• Confirms to JRO Operations team that a research passport application is valid, and associated with a recognised, approved UCLH research project.
4	Quality Assurance Team	• Provides support to JRO Operations Team in regards to any deviations from processes, missing/incorrect information, escalations.
5	UCLH queries	• UCLH honorary contracts: uclh.honorarycontracts@nhs.net • UCLH electronic health records system (Epic) Research Add-on training: Research staff can book their Research Add-on training via their UCLH Learning Portal account (created once after an HRC/LoA has been issued and ESR account created), or by contacting the team via uclh.induction@nhs.net or calling ext. 77447

All staff applying for a HRC or LoA may additionally require access to UCLH's electronic health records system, Epic, in order to conduct and record research activities. The JRO will ascertain this during the application process.

7. PROCEDURE



Pre-Engagement Checks for Applicants who will have direct patient contact (adapted from "Research in the NHS – HR Good Practice Resource Pack", version 1.3, September 2012 as published by the NIHR)

	ACTIVITY EXAMPLES	CRIMINAL RECORD CHECK REQUIRED?	OCCUPATIONAL HEALTH CLEARANCE REQUIRED?	HRC or LoA
DIRECT PATIENT CONTACT	Researcher is a healthcare professional[2] providing healthcare[3] to an adult and/or child	Yes, if undertaking regulated activity: enhanced DBS & appropriate barred list check	Yes	HRC
	Researcher provides healthcare to an adult and/or child under the direction or supervision of a healthcare professional	Yes, if undertaking regulated activity: enhanced DBS & appropriate barred list check	Yes	HRC
	Researcher provides personal care to an adult or child OR Researcher is a social care worker providing social work which is required in connection with any healthcare or social services to an adult who is a client or potential client	Yes, if undertaking regulated activity: enhanced DBS & appropriate barred list check	Yes	HRC
	Researcher undertakes the following unsupervised: teach, train, instruct, care for or supervise children, or provide guidance/advice on well-being	Yes, if done regularly then this is defined as regulated activity: enhanced DBS & appropriate barred list check	Yes	HRC
	Researcher has opportunity for any form of contact with children in the same Children's Hospital but is not providing healthcare or other types of regulated activity and has no direct bearing on the quality of care	Yes, if done regularly: enhanced DBS only	Yes	LoA
	Researcher has direct contact to persons in receipt of healthcare services in the course of their normal duties but is not providing healthcare or other types of regulated activity and has no direct bearing on the quality of care	Yes, standard DBS only	Yes	LoA

Pre-Engagement Checks for Applicants who will have indirect/no patient contact (adapted from "Research in the NHS – HR Good Practice Resource Pack", version 1.3, September 2012 as published by the NIHR)

	ACTIVITY EXAMPLES	CRIMINAL RECORD CHECK REQUIRED?	OCCUPATIONAL HEALTH CLEARANCE REQUIRED?	HRC or LoA
INDIRECT/NO PATIENT CONTACT	Researcher has indirect contact with patients or service users e.g. some types of telephone interviews, but is not providing healthcare or other types of regulated activity	No	No	LoA
	Researcher requires access to **identifiable** patient data derived from health records, tissues or organs with a likely bearing on quality of care	No	Yes, only if working with tissues or organs in NHS facilities	HRC
	Researcher requires access to **identifiable** patient data derived from health records, tissues or organs with no likely bearing on 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
	Researcher is working on NHS premises e.g. laboratory only with 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)

Please note: For studies involving identifiable patient data, applicants may be asked for a DBS at the discretion of the JRO. This will be judged on a study-by-study basis.

8. IMPLEMENTATION & TRAINING

Staff following this SOP shall confirm they have read and understood the procedures outlined above by completing their relevant signature log as a record of acknowledgement.

9. PUBLICATION & COMMUNICATION

This SOP is authorised and published on the JRO website: http://www.ucl.ac.uk/jro. The latest version of the SOP will be made available on the JRO website and EDGE UCLH SOP Store. The electronic versions maintained here are the controlled copies; therefore, staff are encouraged to frequently review that they have the most up to date copies.

The original fully signed master copy is stored in a designated binder within the JRO and maintained by the JRO Research Quality & Safety team.

10. TEMPLATES ASSOCIATED WITH THIS DOCUMENT

	Document	Stored
1.	Research Passport Application Form (Version 4.0,02/04/2019)	https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#HR-Good-Practice-Resource-Pack
2.	Research in the NHS: Human Resource (HR) Good Practice Resource Pack, including: - Flowchart 1: RP Research at a single site - Flowchart 2 RP research at more than one site - Flowchart 3 NHS to NHS arrangements **The Research Passport** - The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks - Passport FormResearch Passport form appendix - NHS to NHS confirmation of pre-engagement checks - Instructions for completing the Research Passport form CV template	https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#HR-Good-Practice-Resource-Pack
3.	UCL Research Passport form	https://www.ucl.ac.uk/human-resources/research-passport-and-letter-access-procedure

11. REFERENCES

JRO Website
http://www.ucl.ac.uk/joint-research-office

HR Good Practice Resource Pack:

https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#HR-Good-Practice-Resource-Pack

UCL Research Passports process:
https://www.ucl.ac.uk/human-resources/research-passport-and-letter-access-procedure

Disclosure Barring Service:
https://www.gov.uk/government/organisations/disclosure-and-barring-service/about

U.K Policy Framework for Health and Social Care Research (V3.3, 07/11/2017 Edition):
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

International Conference on Harmonisation Good Clinical Practice: E6 (R2)
https://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html

12. SIGNATURE PAGE

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