St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)
Research Passports

SOP ID number:	JRESGOVSOP0020	**Effective Date:**	24/06/2019
Version number and date:	V4.0 24/06 /2019	**Review Date:**	24/06/2021
Author:	Subhir Bedi	**Title:**	Head of Research Governance and Delivery
Approved by:	Mark Cranmer, Director of the JRES.	**Date:**	24/06/2019
Signature of Authoriser			

This is a controlled document.
The master document is posted on the JRES website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JRES website for the most recent version.
They may print off this document for training and reference purposes.

SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	New SOP	Lucy H H Parker
V2.0	New logo, new Trust name, update of links	Deborah McCartney
V3.0	Re-structuring of process. Addition of appendices	Subhir Bedi
V4.0	Update to JRES name Update to national HRC guidelines- GDPR and IRAS Update to signatories and reporting individuals	Subhir Bedi

Associated JRES documents

SOPs	WPDs	Docs	LOGs
-	JREOWPD0020 "General Research Definitions"	-	-

Contents

1. Background

The Research Passport procedure is the process by which researchers can obtain an honorary research contract (HRC) or a Letter of Access (LoA). The procedure enables researchers to complete a single set of documents in order to be able to access a single or multiple NHS sites, smoothing out the process of obtaining permission to attend NHS sites.

The system was devised by the National Institute for Health Research (NIHR) and allows all parties undertaking research in the NHS to have clearly defined responsibilities and liabilities as laid out in the UK policy framework for health and social care research. The current source of information is the HR Good Practice (Resource Pack): Information for Researchers, R&D and HR staff in the NHS and HEIs. (www.nihr.ac.uk)

The guiding principles for the system are to ensure that legal liability is clear, should research activity have adverse incidents. To ensure that non-NHS researchers are bound, contractually, to ensure NHS duty of care and to ensure that they follow research governance and regulations, and that most importantly, research participants are protected.

The system can be used by researchers taking part in studies which could have a foreseeable or direct impact on patient care and clearly defines what documentation and checks in-house that should be undertaken without duplicating the checks made by another NHS organisation.

"The research passport" is a single set of a standard form and associated documents. These documents include identity checks, Occupational Health (OH) clearance, Disclosure and Barring Service (DBS), (formerly Criminal Record Bureau) checks etc. The form will detail what needs to be included with your application,

The Research Passport form and more details can be found at the IRAS website https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

The above link also contains any other document that may need to be completed.

Please note: The Research Passport does not guarantee access to an NHS organisation but is the mechanism by which investigators *apply* for access.

It is important that the link above is used to fill out the form as NHS organisations can only accept the latest version of the form and if an older version is used, it will be refused.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.
The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT).

3. Scope

This SOP describes the process for completing the forms necessary for a Research Passport in order to undertake research related activity in the NHS. This SOP is relevant for SGUL and SGHFT staff wishing to undertake research related activity both in SGHFT and other NHS trusts.

4. Definitions

For general research management related acronyms refer to "General Research Definitions" working practice document (JREOWPD0020).

5. Responsibilities

This SOP is for all researchers intending to conduct research at SGHFT who do not have a SGHFT contract or those SGUL or SGHFT researchers who wish to conduct research at a different NHS organisation. It is that researcher's responsibility to ensure that he/she has the correct documentation to cover their activity. This SOP also outlines what documentation a researcher should expect to receive from either the JRES at St George's or from another NHS Trust.
For the purpose of this the Governance Team will include the Research Governance and Facilitation Officers, Clinical Research Associates, Research Development and Governance Manager and Research Development and Delivery Manager who have all been delegated responsibility to process Research Passports under this SOP.

6. Procedure

The researcher must first assess what activity will be undertaken. The NIHR have outlined a number of researcher „types“ and an algorithm to support the identification of the type of activity theresearcher will be undertaking and what level of review is required – see appendix.

6.1 NHS Organisation Access Arrangements and Confirmation of Capacity and Capability

For all research studies Confirmation of Capacity and Capability (C&C) is requested from the Trust unless specified otherwise by the Health Research Authority (HRA). Assessment of Capacity and Capability is led by the Research Governance Team and commences upon confirmation of receipt of a Valid Research Application (VRA). The VRA should include an application for an HRC/RP/LoA where appropriate.

During the assessment of C&C, the Research Governance Team are responsible for checking that HRC/RP/LoA arrangements are in place or have been initiated. Please refer to Appendix 8.1 for a summary of the contractual arrangements required for individuals wishing to undertake research in the Trust. Appendix 8.2 provides a sumamry of researcher activity with associated pre-emplyment check requirements.
An overview of applying for a RP/HRC/LoA is described in the following sections. Further detailed information about this can be found in the “HR Good Practice Resource Pack, HR Good Practice: Information for researchers, JRES/R&D and HR staff in Higher Education Institutions and the NHS”.

6.2 NHS to NHS Letter of Access

Where researchers have either a substantive employment contract or an honorary clinical contract with one NHS organisation an HRC is not required in order to undertake research in another NHS organisation. The JRES, on behalf of the Trust, will accept the NHS to NHS Proforma as confirmation of preengagement checks from the researcher's substantive employer HR department as evidence that the appropriate clearances are in place and inform the researcher’s substantive employer of her/his activities in their organisations by issuing the NHS to NHS LoA.

6.2.1 Obtaining an NHS to NHS Letter of Access from the Trust (for accsess outside of SGHFT)

Substantive employees of the Trust who require a NHS to NHS LoA to carry out research in another NHS Trust should download and complete the NHS to NHS confirmation of pre-engagement checks Proforma which can be found at: https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

This should then be dated and sent along with a current CV, to their NHS HR representative who should be in a position to sign the form as the 'employer's representative' and return it to the applicant. The applicant should then submit this completed form to all NHS Trusts in which an NHS to NHSLoA is required for that study.

6.2.2 JRES actions upon receipt of a NHS to NHS Letter of Access form (external researcher to accsess SGHFT)

Upon receipt of a completed NHS to NHS confirmation of pre-engagement checks Proforma:

1. The Research Governance Team member will confirm that the Proforma has been completed correctly and has been dated.
2. If the application is complete the Research Governance team member will draft the NHS to NHS LoA for signature by the Head of Research Governance and Delivery(HRGD) or Director of the JRES in their abence. Template documents located in I:\Investigators_Research Passports\Template Docs
3. A copy of the LoA and NHS Proforma will be sent to the researcher, their SGHFT nominated manager(s) and substantive HR signed on the NHS Proforma.
4. An e-copy of the complete Proforma together with the NHS to NHS LoA will be placed in

the Honorary Contract / Letter of Access File which is held in the shared drive Under Investigators/Research Passportsand Record of all HRCs and LoAs issued spreadsheet is updated

6.3 The Research Passport (RP)

Researchers with no contractual relationship with the NHS require an honorary research contract only if the planned activities of the researcher involve interacting with patients in a way that has a direct bearing on the quality of their care, i.e. the researcher could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to patients or service users to whom the NHS organisation has a duty of care.

An algorithm of defined HRC and pre-engagement activity can be found in Appendix 8.2 and at https://www.myresearchproject.org.uk/help/help%20documents/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf

6.3.1 Applying for a RP

A RP can be issued for the duration of a single research project.or the researchers can apply for a three year RP for multiple studies.
These studies must be defined in the passport. Additions or amendments to the studies approved in a three year RP must be agreed with the substantive employer (who will decide if any new checks are needed) and the amended RP counter signed by each R&D Office in each participating NHS Trust.

Researchers should :

1 Complete sections 1-3 of the downloadable RP Form
2 . Ask their line manager or other authorised person to complete section 4.
3. Take the form to their employing HR department to complete section 5.
4. Complete occupational health assessments, and /or a barring and disclosure service application, and/or provide additional documents as determined by the HR department. The HR department will sign off the form once all of the checks have been completed and return it to the researcher.
5. Take the completed RP Form with attachments to the lead NHS organisation to be validated by completing the first part of section 8 and receive letter/confirmation of validation.
6. Provide the validated RP to NHS Trust when making a site application

6.3.2 JRES responsibilities (when SGHFT Trust is the Lead NHS Organisation)

1. The Research Governance Team member will, on behalf of the lead NHS organisation, assess the research Passport Form and supporting documents. It is the responsibility of the substantive employer to undertake additional checks as may be required.
2. The DBS check should have been obtained in the last 6 months. Alternatively, a DBS check obtained in the 12 months may be used, as long as the applicant's employer has a system for requiring the applicant to declare any changes to criminal record. Details of the disclosure should be provided.
3. The Research Governance team member will validate the RP by completing the first part of section 8 of the form
4. For the purpose of SGHFT accses, Research Governance Team member will complete the final part of section 8 (Date HRC/LoA issued) and draft an HRC/ LoA for authorisation by the HRGD or Director of the JRES depending on level of acivity to be conducted by the external research within SGHFT (see appendix 8.2)
5. The JRES will forward the original signed copy to the applicant, and email a copy to the applicants substantive employment organisation and SGHFT HR.
6. A copy of the completed RP Form and issued LoA/HRC is retained in the RP Folder held on the shared drive under Investigators/_Research Passportsand Record of all HRCs and LoAs issued spreadsheet is updated

6.3.3 JRES responsibilities (when SGHFT is the not the Lead NHS Organisation)

1. If an external researcher requires access to support a study, on presentation of a RP authorised by another Trust: Research Governance Team member will check that the first part of section has been correctly completed.
2. Research Governance Team member should determine the level of activity to be conducted by the external researcher within SGHFT to determine if a HRC or a LoA is to be issued (refer to Appendix 8.2)
3. The Research Governance Team member will then complete the second part of section 8 on behalf of the Trust and draft a HRC or LoA for authorisation by for authorisation by the HRGD or Director of the JRES
4. The JRES will forward the original signed copy to the applicant, and email a copy to the applicants substantive employment organisation and SGHFT HR.
5. A copy of the completed RP Form and issued LoA/HRC is retained in the Research Passport Folder held on the shared drive under Research Passports and Record of all HRCs and LoAs issued spreadsheet is updated.

Please note, in all eventualities, DBS certificates and or Occupational Health evidence should not be retained by the JRES beyond the validation of the RP (where SGHFT is Lead NHS Organisation). Where SGHFT is not Lead NHS Organisation these documents are not required as validation has been provided by another (Lead) NHS organisation.

For all HRC and LoA, external nurses/midwives and or research coordinators are accountable to the Head of Research Nursing as well as any study specific Principle Investigators (if applicable). All Clinical Research Network (CRN) South London Flexible Delivery Staff (FDS) are accountable to the Head of Research Nursing solely.

6.4 Applying for an Honorary Contract (non-Research Passport)

For research activity taking place at the Trust and where applicants without a substantial employment contract with a HEI and or honorary clinical contract (NHS organisation) they are unable to apply for a RP an application for an HRC from the Trust. A formal honorary application may be made to Trust HR. Contact the SGHFT HR for further information.

7. References

- HR Good Practice: Information for Researchers, R&D and HR staff in the NHS and HEIs (Resource pack) https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx
- UK policy framework for health and social care research v3.3 07/11/17

8. Appendices

8.1 Summary of forms of contractual arrangement available for individuals undertaking research in the NHS

Table 1: Summary of forms of contractual arrangement available for individuals undertaking research in the NHS

Forms of contractual arrangement that can be issued to cover research activity	Substantive Employer							
	(1) HE Substantive Employee	(2) Substantive HE with Honorary Clinical NHS Contract (Clinical Academic)	(3) HE Student on a formal healthcare placement	(4) HE Student NOT on a formal healthcare placement	(5) NHS Substantive Employee	(6) Independent Contractor e.g. GP (providing NHS services under contract))	(7) Commercial Researcher	(8) Commercial Researcher under contract to HE (non-commercial research)[5]
HRC	YES[6]	NO	NO	YES[6]	NO	NO	NO	YES[6]
LoA accepting an HRC	YES[7]	NO	NO	YES[7]	NO	NO	NO	YES[7]
LoA (no HRC required)	YES[8]	NO	NO	YES[8]	NO	NO	NO	YES[8]
NHS to NHS LoA	NO	YES[9]	NO	NO	YES[9]	NO	NO	NO
Service Level Agreement	NO	NO	NO	NO	NO	NO	YES[10]	NO
Healthcare Placement Agreement	NO	NO	YES	NO	NO	NO	NO	NO
Is a Research Passport needed?	YES[11]	NO[12]	NO	YES[11]	NO[12]	NO	NO	MAYBE[13]

5 Applies only to HEs contracting researchers to undertake research funded and sponsored by non-commercial bodies

6 Appropriate where the Trust owes a duty of care to research participants and the researcher's activity will have a direct impact on patient care.

7 Appropriate where the Trust owes a duty of care to research participants and the researcher's activity will have a direct impact on patient care and the researcher already holds an HRC with another NHS organisation.

8 Appropriate where the Trust owes a duty of care in respect of the research activity and the researcher's activity has no direct impact on care but involves access to NHS patients, data or facilities.

9 Covers all types of research activity i.e. direct and indirect impact on patient care, where the researcher has a contractual relationship with the NHS.

10 HR issues should be addressed in a service level agreement unless covered by Trial Agreement e.g. Data Monitors

11 Yes, where evidence of pre-engagement checks are required

12 NHS to NHS proforma confirmation of pre-engagement checks should be used for those with an existing substantive or honorary clinical NHS contract.

13 Yes, to facilitate sharing of pre-engagement checks

RP001 - Good Practice: Information for researchers, R&D and HR staff in HEIs and the NHS
Research in the NHS: HR Good Practice Resource Pack

8.2 Research Passport Activity Algorithm

Activity	Criminal record check necessary?[3]	Occupational Health Clearance Necessary?	LOA or HRC
Researcher is a health care professional[4] providing health care[5] to an adult and/or child	Yes, if done once this is Regulated Activity (new definition). Requires enhanced CRB + appropriate barred list check	Yes, if there is direct contact	HRC
Researcher provides health care to an adult and/or child under the direction or supervision of a health care professional	Yes, if done once this is Regulated Activity (new definition). Requires enhanced CRB + appropriate barred list check	Yes, if there is direct contact	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 health care or social services to an adults who is a client or potential client	Yes, if done once this is Regulated Activity (new definition). Requires enhanced CRB + appropriate barred list check	Yes, if there is direct contact	HRC
Researcher undertakes the following activities unsupervised: teach, train, instruct, care for or supervise children, or provide advice/guidance on well-being, or drive a vehicle only for children; with likely direct bearing on the quality of care[6].	Yes, if done regularly this is Regulated Activity. Requires enhanced CRB + barred list check	Yes, if there is direct contact	HRC
Researcher has opportunity for any form of contact with children in the same Children's Hospital (formerly a specified place) 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 CRB (pre-Sept 2012 definition). No barred list check.	Yes, if there is direct contact	LoA
Researcher has access to persons in receipt of healthcare services in the course of their normal duties but is not providing health care or other types of regulated activity and has no direct bearing on the quality of care ('Access' relates to where individuals will have physical, direct contact with patients e.g. observation, qualitative interviews, focus groups).	Yes, standard	Yes, if there is direct contact	LoA

Algorthim continues on the next page

[3] *Please refer to http://www.crb.homeoffice.gov.uk/guidance/rb_guidance/eligible_posts.aspx for guidance on specific activities which are eligible for CRB checks.*
[4] *"health care professional" means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002.*
[5] *"Health care" includes all forms of health care provided for individuals, whether relating to physical or mental health and also includes palliative care and procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition.*
[6] *A "direct bearing on the quality of care" suggests that the actions of researchers could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to an individual to whom the organisation has a duty of care.*

Activity	Criminal record check necessary?[3]	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 **identifiable** 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 **identifiable** 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)