York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S20

Application Process for an Honorary Contract, Letter of Access or Research Passport

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.northyorksresearch.nhs.uk/sops.html and/or Q-Pulse

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Author:	Deborah Phillips
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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	18th July 2017
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	18th July 2017

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	19th March 2012	
2.0	22nd October 2012	Removal of references for the North and East Yorkshire R&D Alliance
3.0	9th March 2015	Change of job title from R&D Manager to Head of R&D. Update to some web links
4.0	21st August 2017	

Contents

1 Introduction, Background and Purpose

The Department of Health's Research Governance Framework 2005 requires that all NHS Trusts ensure that individuals undertaking research that involves NHS staff or patients, their organs, tissue or data must have either a substantive or Honorary Contract or a Letter of Access with the NHS organisation that specifically stipulates compliance with the Research Governance Framework.

2 Who Should Use This SOP

This SOP is aimed at all Researchers who do not already have an appropriate contractual relationship in place that would like to undertake a research study in the Trust and are requesting Confirmation of Capacity and Capability.

This SOP is also applicable to R&D Unit staff involved in the assessment and issuing of Research Passports / Honorary Contracts or Letters of Access as well as those members of staff responsible for the assessment of Capacity and Capability in the Trust.

3 When this SOP Should be Used

This SOP should be followed by Researchers who do not have an appropriate contractual arrangement with the Trust in order for them to apply for a Research Passport (RP), Honorary Contract (HC) or Letter of Access (LoA) as appropriate. This is relevant to studies sponsored or co-sponsored by the Trust as well as studies that are externally sponsored and 'hosted' within the Trust.

4 Procedure(s)

4.1 NHS Organisation Access Arrangements and Confirmation of Capacity and Capability

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

During the assessment of Capacity and Capability, the Research Delivery Facilitator is responsible for checking that HC/RP/LoA arrangements are in place or have been initiated. Please refer to Appendix A (Table 1) for a summary of the contractual arrangements required for individuals wishing to undertake research in the Trust. An overview of applying for a RP/HC/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, R&D and HR staff in Higher Education Institutions and the NHS*".

4.2 NHS to NHS Letter of Access

Where researchers have either a substantive employment contract or an honorary clinical contract with one NHS organisation an HC is not required in order to undertake research in another NHS organisation. The R&D Unit, on

behalf of the Trust, will accept the NHS to NHS Proforma as 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 her/his activities in their organisations by issuing the NHS to NHS LoA.

4.2.1 Obtaining an NHS to NHS Letter of Access from the Trust

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.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm . This should then be dated and sent along with a current CV, to their Head of Department or Line Manager who should 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 NHS LoA is required for that study.

4.2.2 R&D Unit actions upon receipt of a NHS to NHS Letter of Access Application form

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

1. The R&D Unit Administrator will confirm that the Proforma has been completed correctly and has been dated.
2. If the application is complete the R&D Unit Administrator will then issue an NHS to NHS LoA which will be signed by the Head of R&D (or Research Adviser).
3. A copy of the LoA and NHS Proforma will be sent to the signee of the NHS Proforma.
4. A copy of the complete Proforma together with the NHS to NHS LoA will be provided to the Research Delivery Facilitator as part of their Capacity and Capability Assessment and a copy will also be placed in the Honorary Contract / Letter of Access File which is held in the R&D Admin Office and saved onto the x drive.
5. The R&D Unit Administrator will arrange for the applicant to have access to the Q-PULSE system so that they can receive SOP update alerts.

4.3 The Research Passport

If a researcher has no contractual relationship with the NHS, a RP may be required, which allows the NHS Organisation to decide whether or not the individual needs an HC or LoA to enable them to undertake research within NHS facilities.

The RP system provides a streamlined, standard application system for HCs and LoA therefore saving valuable time of Human Resources (HR), R&D departments and researchers. Importantly, it minimises the demand for repeated checks for every HC or LoA, by providing guidance on the circumstances when it is reasonable to rely on assurances offered by those who have already conducted these checks. The RP therefore means just one set of checks is needed on a researcher and the completed RP can be presented to all relevant NHS organisations.

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

In England, the Clinical Research Networks (CRNs) of the National Institute for Health Research (NIHR) have adopted the RP system as standard practice and the Trust accept RPs.

4.3.1 Applying for a Research Passport

A RP can be issued for the duration of a single research project. Alternatively, researchers can apply for a three year RP - designed for multiple studies. These studies must be defined in the three year 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.

Investigators should:

1. Read the guidance for completing the Research Passport Form found at

   https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

2. Complete sections 1-3 of the downloadable Research Passport Form found at the above web address.
3. Ask their line manager or other authorised person to complete section 4.
4. Take the form to their HR department to complete section 5.
5. 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 investigator.
6. Take the completed Research Passport 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.
7. Provide the validated RP to the NHS Trust when making a Valid Research Application (VRA).
8. Ensure that they notify their substantive employer should a change to the study affect the validity of the RP in a timely manner.

4.3.2 R&D Unit responsibilities (when the Trust is the Lead NHS Organisation)

On receipt of an application for a RP to be issued by the Trust:

1. The R&D Unit Administrator 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 R&D Unit Administrator will validate the Research Passport by completing the first part of section 8 of the form and will issue a validation letter, signed by the Head of R&D (or Research Adviser), confirming that the Research Passport has been authorised by the Trust. This will be saved on the x drive.
3. A copy of the dated and initialled Research Passport Form will be held by the R&D Unit until a full VRA is received and an assessment of Capacity and Capability is undertaken.

4. Once the Trust is in a position to issue Confirmation of Capacity and Capability, the R&D Unit Administrator will complete the final part of section 8 (Date HC/LoA issued) and issue an HC/LoA signed by the Head of R&D (or Research Advisor). *Note: Three copies of the HC will be issued for signature by the applicant with two to be returned to the R&D Unit once signed. The R&D Unit will forward one of the returned signed copies to the applicant's substantive employment organisation. A photocopy of any LoA issued will be retained by the R&D Unit.*
5. A copy of the completed Research Passport Form and validation letter is retained in the Research Passport Folder held in the R&D Admin Office. A copy of the HC/LoA is kept on the R&D Unit's x drive and provided to the Research Delivery Facilitator as part of their Capacity and Capability Assessment.
6. The R&D Unit Administrator will arrange for the applicant to have access to the Q-PULSE system so that they can receive SOP update alerts.

4.3.3 R&D Unit Responsibilities (when the lead NHS Organisation is not the Trust)

On presentation of a RP authorised by another Trust:

1. The R&D Unit Administrator will check that the first part of section 8 has been correctly completed.
2. The Unit Administrator will then complete the second part of section 8 (not the Date HC/LoA issued) on behalf of the Trust.
3. A copy of the RP is filed by the R&D Unit Administrator in the HC Folder held in the R&D Admin Office until a full VRA is received and an assessment of Capacity and Capability is undertaken.
4. Once the Trust is in a position to issue Confirmation of Capacity and Capability, the R&D Unit Administrator will complete the final part of section 8 (Date HC/LoA issued) and issue an HC/LoA. *Note: Three copies of the HC will be issued for signature by the applicant with two to be returned to the R&D Unit once signed. The R&D Unit will forward one of the returned signed copies to the applicant's substantive employment organisation. A photocopy of any LoA issued will be retained by the R&D Unit.*
5. A copy of the completed RP and validation letter is retained in the RP Folder held in the R&D Admin Office. A copy of the HC/LoA is kept on the R&D Unit's x drive and provided to the Research Delivery Facilitator as part of their Capacity and Capability Assessment.
6. The R&D Unit Administrator will arrange for the applicant to have access to the Q-PULSE system so that they can receive SOP update alerts.

4.4 4. 4 Applying for an Honorary Contract / LoA (non-Research Passport)

For research studies taking place at the Trust and where applicants without a substantial employment contract or honorary clinical contract are unable to apply for a RP an application for an HC or LoA from the Trust may be made directly to the R&D Unit.

In this case, the investigator should complete the Trust's Honorary Contract/Researcher Access Application Form, found on the York Teaching Hospital NHS Foundation Trust R&D Unit website, and send it to the R&D Unit Administrator with a copy of a recent CV.

4.4.1 R&D Unit Responsibilities (non-Research Passport HC or LoA)

Upon receipt of a completed HC/Researcher Access Application Form:

1. The R&D Unit Administrator will check that the form (Part 1 and 2) is complete and signed and that a CV has been submitted.
2. A copy of the completed Form is filed by the R&D unit Administrator in the HC Folder held in the R&D Admin Office.
3. The R&D Unit Administrator will send the necessary Barring and Disclosure and/or Occupational Health Forms to the applicant in the post.
4. The applicant must make an appointment with the R&D Unit Administrator to return the completed Barring and Disclosure Forms *in person*. Appropriate identification documentation must be presented at this appointment. The applicant will return Occupational Health Forms in the confidential envelope provided.
5. The R&D Unit Administrator will send the completed Barring and Disclosure Application Form to the relevant HR department.
6. On confirmation of (i) Barring and Disclosure and Occupational Health clearance from the HR department and (ii) the Trust is in a position to issue Confirmation of Capacity and Capability, the R&D Unit Administrator will issue an HC/LoA. *Note: Two copies of an HC will be issued to the applicant (one to be countersigned and returned to the R&D unit). A photocopy of any LoA issued will be taken.*
7. A copy of the completed HC/Researcher Access Application Form is retained in the RP Folder held in the R&D Admin Office. A copy of the HC/LoA is kept on the R&D Unit's x drive and provided to the Research Delivery Facilitator as part of their Capacity and Capability Assessment.
8. The R&D Unit Administrator will arrange for the applicant to have access to the Q-PULSE system so that they can receive SOP update alerts.

5 Related SOPs and Documents

Research in the NHS: HR Good Practice Resource Pack, HR Good Practice: Information for researchers, R&D and HR staff in Higher Education Institutions and the NHS version 2.1, September 2012, https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

Research in the NHS- HR Good Practice Resource Pack, The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks, Version 3.0, September 2012, https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

R&D/S14 Local New Study Set Up: Capacity and Capability Assessment

R&D/T13 Letter of Access

R&D/T19 Research Passport Validation Letter

R&D/T32 Research Passport Honorary Contract

R&D/T33 Non-Research Passport Honorary Contract

R&D/T34 NHS to NHS Proforma

R&D/F75 Honorary Contract/Researcher Access Application Form

6 Appendix A: 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**							
	HE Substantive Employer	Substantive HE with Honorary Clinical NHS Contract (Clinical Academic)	HE Student not on a formal healthcare placement	HE Student on a formal healthcare placement	NHS Substantive Employee	Independent Contractor e.g. GP	Commercial Researcher	Commercial Researcher under contract to HE (non-commercial research)
HC	YES	NO	YES	NO	NO	NO	NO	YES
LoA accepting an HC	YES	NO	YES	NO	NO	NO	NO	YES
LoA (no HC required)	YES	NO	YES	NO	NO	NO	NO	YES
NHS to NHS LoA	NO	YES	NO	NO	YES	NO	NO	NO
Service Level Agreement	NO	NO	NO	NO	NO	NO	YES	NO
Healthcare Placement Agreement	NO	NO	NO	YES	NO	NO	NO	NO
Is a Research Passport needed?	YES	NO	YES	NO	NO	NO	NO	YES

Table 1 taken from "Research in the NHS: HR Good Practice Resource Pack, HR Good Practice: Information for researchers, R&D and HR staff in Higher Education Institutions and the NHS" version 2.1, September 2012

7 Appendix B: Table 2: Research Passport Algorithm

Activity	Criminal Record Check necessary?	Occupational Health Clearance necessary?	LoA or HRC
Researcher is a healthcare professional providing health care 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 healthcare to an adult and/or child under the direction or supervision of a healthcare 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 of 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 un supervised: teach, train, instruct, care for or supervise children, or provide advice/guidance on wellbeing, or drive a vehicle only for children; with likely direct bearing on the quality of care	Yes, if done once this is regulated activity (new definition). 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(formally 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	Yes, standard	Yes, if there is direct contact	LoA

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…)			
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)

Table 2 taken from "Research in the NHS- HR Good Practice Resource Pack, The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks", Version 3.0, September 2012