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

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1.0	24/07/23	Initial Document		

1. Introduction, Purpose

This Standard Operating Procedure defines the process, roles and responsibilities of researchers completing the Research Passport application for obtaining an Honorary Research Contract (HC), or Letter of Access (LOA), for the Swansea Bay University Local Health Board (SBU HB).

2. Background

The Department of Health's UK Policy for Health and Social Care Research and the General Data Protection Regulations (GDPR) require all NHS Health Boards ensure individuals undertaking research that involves NHS staff or patients, their organs, tissue or data, must have either a substantive or Honorary Contract (HC) or a Letter of Access (LOA) with the NHS organisation that specifically stipulates compliance with the UK Policy for Health and Social Care Research and GDPR.

3. Roles and Responsibilities

This SOP is aimed at persons wishing to undertake research within the SBU HB that do not already possess a substantive contract of employment/agreement with the HB prior to commencing research activities.

This SOP is also applicable to Research and Development (R&D) staff working with researchers to ensure the correct agreement, HC or LOA, is in place, in-line with confirmation of Capacity and Capability (C&C) for research activities to commence.

The requirement for establishing the proper contract/agreement is inclusive of research sponsored/co-sponsored by the HB, or research sponsored by a third party and 'hosted' by SBU HB.

It is the role of the Research Facilitator assigned to review your valid research submission pack, as part of the confirmation of capacity and capability process locally, to also liaise with the named researchers seeking to obtain an HC or LOA via the Research Passport application.

It is the role of the researcher to complete the research passport application form and provide any evidence required to validate a request to conduct research within SBU HB.

4. When this SOP should be used

When a researcher does not already hold the appropriate contractual agreement in place with SBU HB, prior to commencing research activities.

5. Procedures

5.1 NHS Organisation Access Arrangements in-line with Confirmation of Capacity and Capability

Confirmation of Capacity and Capability (C&C) must be requested from the Health Board, unless specified otherwise in the Health Research Authority (HRA) application approval letter. Assessment of C&C is led by the Research Facilitator and commences upon confirmation of receipt of a valid research application pack, otherwise known as a Local Information Pack (LIP). The LIP should include an application for an HC or LOA where one is required.

During the C&C review, the Research Facilitator is responsible for checking that valid HC/LOA arrangements are in place, or have been initiated.

5.2 The Research Passport Application Scheme

If a researcher has no prior contractual relationship with SBU HB a Research Passport application will be required. This enables the HB to decide whether or not the individual needs an HC or LOA to enable them to undertake research within SBU HB.

The Research Passport scheme provides a streamlined standardised application system for obtaining HCs and LOAs. This saves time for researchers and reduces the pressure on Human Resources (HR). Importantly, it reduces the demand for repeated checks by providing guidance on the circumstances when it is reasonable to rely on assurances offered by those who have already conducted these checks.

***Please note the completion of a Research Passport Application does not guarantee a researcher access to this NHS Organisation. They are assessed alongside capacity and capability to conduct/host the research project to which they are related*.**

The following link will take you to the RP algorithm, which will help you, and the Research Facilitator assigned to your study, decide if an HC or LOA is most appropriate for your access needs;
https://www.myresearchproject.org.uk/help/help%20documents/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf

The Health Research Authority (HRA) will advise the need for completing the RP application form during their initial assessment of your study submission and the HRA approval letter will provide details regarding the need for either an LOA or HC. It will also confirm what pre-engagement checks should or should not be requested, in line with the HRA Good Practice Resource Pack and the HRA assessment criteria and standards.

5.2.1 Applying for a Letter of Access or Honorary Contract using the Research Passport Application

An LOA or HC will ordinarily be issued for the duration of a single research project. However, researchers can apply for a three year access period via the RP application form - designed for multiple studies. **These studies must be individually defined in the three year passport application.** Additions or amendments to the studies approved in a three year LOA/HC must be agreed with the substantive employer (who will decide if any new checks are needed) and the amended RP application form counter signed by the Research Facilitator assigned to you.

If additional studies are to be added to an existing RP application, an Appendix (last page of RP form) needs to be completed for each new study, providing all information required; Study Title, Start and End Dates, Researchers Planned Activities

Researchers should:
1. Read the guidance for completing the RP Application Form found at;
https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

2. Complete sections 1-3 of the downloadable RP Application 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 substantive HR department to complete section 5.

5. Complete Occupational Health (OH) assessments, and/or a barring and disclosure service application (formally DBS), 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.

Please note; your OH assessments and paperwork are considered confidential and therefore should not be shared with the R&D Dept.

6. Provide the completed RP application form, and relevant supporting documents to the Lead NHS R&D Office to be validated.

7. Send your validated RP application to SBU HB R&D Office, as part of the LIP. A Research Facilitator will complete the first part of section 8. Once satisfied, an HC or LOA, depending on requirements, will be issued in-line with confirmation of capacity and capability for the research project/s included in the RP application.

8. Ensure that they notify their substantive employer should a change to the study affect the validity of the RP in a timely manner.

5.3 NHS to NHS Letter of Access

Where researchers have either a substantive employment contract or a valid honorary clinical contract with one NHS organisation, an HC is not required in order to undertake research in another NHS organisation. The R&D Dept, on behalf of the HB, will accept the NHS to NHS Proforma from the researcher's substantive employer, as confirmation of pre-engagement checks, as evidence that the appropriate clearances are in place, and inform the researcher's substantive employer of the activities taking place in this HB by issuing the NHS to NHS LOA.

5.3.1 Obtaining an NHS to NHS Letter of Access from the Health Board

Substantive employees of the SBU HB who require an NHS to NHS LOA to carry out research in another NHS Organisation 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 be dated and sent along with a current professional 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 Organisations in which an NHS to NHS LOA is required.

5.3.2 Research Facilitator actions upon receipt of an NHS to NHS Letter of Access Application form

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

1. The Research Facilitator will confirm that the Proforma has been completed correctly and has been dated.

2. The Research Facilitator will include review of the Proforma, and issuing of the NHS to NHS LOA, as part of their Capacity and Capability Assessment.

3. If the application is complete the Research Facilitator will go on to issue an NHS to NHS LOA alongside confirmation of Capacity and Capability for your research study. A copy of the LOA will be placed in the Honorary Contract / Letter of Access File which is securely held in the R&D Dept Office. A digital back-up will also be stored on the HB z/Drive. These are retained for auditing and monitoring purposes. The end date of you NHS to NHS LOA will be entered into a database, alongside your contact details. This enables the R&D Dept to maintain its responsibilities in-line with GDPR, as well as ensuring access rights are maintained, or with-held where needed.

4. A copy of the LOA and NHS Proforma will be sent to the substantive employer signee of the original NHS Proforma for their records.

5.3.3 R&D Facilitator responsibilities (when SBU HB is the Lead NHS Organisation)

On receipt of a RP application form to be issued by the Health Board:

1. The Research Facilitator will, on behalf of SBU HB, assess the Research Passport application form and supporting documents. It is the responsibility of the substantive employer to undertake additional checks as may be required.

2. The Research Facilitator will validate the Research Passport application form by completing the first part of section 8 and will issue a validation letter, signed by the Head of R&D, confirming that the Research Passport application has been authorised by the HB. This will be saved electronically to the HB secure zDrive.

3. A copy of the dated and initialled Research Passport application form will be held by the R&D Dept until confirmation of Capacity and Capability is undertaken by the 'host' NHS Organisation.

4. Once the 'host' organisation is in a position to issue Confirmation of Capacity and Capability, the Research Facilitator at the host site will complete the final part of section 8 (Date HC/LOA issued) and issue an HC or LOA signed by, or on behalf of the Head of R&D.

5. A scanned copy of the completed Research Passport application form and validation letter will be retained in the HC/LOA folder held on the HB secure zDrive for monitoring and audit purposes. All other original documentation included in the RP application will be returned to the researcher.

5.3.4 Research Facilitator Responsibilities (when the lead NHS Organisation is not SBU HB)

On receipt of a RP application authorised by another NHS Organisation:

1. The Research Facilitator will check the application form is completed correctly. Any errors will be highlighted to the researcher and corrections will be requested where needed.

2. Once satisfied the Research Facilitator will complete the final part of section 8 (Date HC/LOA issued), compile the draft response from the R&D Dept and a draft HC or LOA on behalf of the HB.

3. If an HC is deemed the appropriate agreement for access to SBU HB, the Research Facilitator will send an 'Honorary Research Contract Letter' to the researcher, which acts as a formal acceptance of the HC being made available to them. The researcher should sign and date the letter and return to the Research Facilitator for final sign off, returning a PDF version when complete. This then acts as the formal agreed HC.

5. A scanned copy of the completed Research Passport application form and validation letter will be retained in the HC/LOA folder held on the HB secure zDrive for monitoring and audit purposes. All other original documentation included in the RP application will be returned to the researcher.

Swansea Bay University Health Board offers thanks to both North Bristol NHS Trust and York Foundation Trust for making their Standard Operating Procedures for

obtaining Letters of Access and Honorary Contracts available during the development of this SOP for use in our Health Board.

Appendix 1

Helpful links;

https://www.myresearchproject.org.uk/help/help%20documents/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf

https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

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

https://www.myresearchproject.org.uk/help/help%20documents/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf

Appendix 2

HONORARY CONTRACT CHECKLIST (from NHS R&D Forum Guidance, August 2006 – minor layout adaptations)

Category		Honorary research Contract (HRC) necessary?	Made specifically aware of confidentiality?	CRB Check necessary?□	Occupational Health clearance necessary?
1	Direct contact with patients/service users and direct bearing on the quality of their care (not children or vulnerable adults)	Yes	Yes, in HRC	Yes, standard or enhanced*	Yes
2	Direct contact with children or vulnerable adults and direct bearing on the quality of their care	Yes	Yes, in HRC	Yes, standard or enhanced*	Yes
3	Direct contact with patients/service users but no direct bearing on the quality of their care (e.g. observer)	No	Yes, in letter	Yes, standard or enhanced*	Yes
4	Indirect contact with patients/service users and direct bearing on the quality of their care (e.g. some types of telephone interviews)	Yes	Yes, in HRC	Yes, standard or enhanced*	No
5	Indirect contact with patients/service users but no direct bearing on the quality of their care (e.g. telephone interviews, postal questionnaires)	No	Yes, in letter	No	No
6	Access with consent to identifiable patient data, tissues or organs with likely direct bearing on the quality of their care	Yes	Yes, in HRC	No	No
7	Access with consent to identifiable patient data, tissues or organs but no direct bearing on the quality of their care	No	Yes, in letter	No	No
8	Access without consent□□ to identifiable patient data, tissues or organs but no direct bearing on the quality of their care	No	Yes, in letter	No	No
9	Access to anonymised patient data, tissues or organs only (including by research staff analysing data)	No	No	No	No
10	Working on NHS premises (e.g. laboratory) only	No	Yes, in letter	No	No
11	Direct contact with staff (e.g. interviews	No	Yes, in letter	No	No
12	Access to identifiable staff data	No	Yes, in letter	No	No
13	Access to anonymised staff data only	No	No	No	No

Notes:

a. 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.
b. For students, the level of supervision should be taken into account in the decision whether to conduct a CRB check.
c. A standard or enhanced disclosure may be required depending on the type of contact. A check under the Protection of Children Act list (PoCA check) may also be required.
d. Regulations under Section 60 of the Health and Social Care Act 2001 specify the very limited circumstances when identifiable patient information may be used for research without consent. The Patient Information Advisory Group considers such cases.

Appendix 3

Honorary Research Contract Letter (examples/templates for Research Facilitators)

1. Example honorary research contract and letter for university researchers_v2_4 March 2019

Example honorary research contract an

2. Example letter of access for uni researchers not requiring honorary research contract_v2_4 March 2019

Example letter of access for uni resear

3. Example letter uni researchers: NHS site accepts existing honorary research contract

Example letter uni researchers_NHS site