Document Title: Management of External Research Staff – Research Passport Scheme

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Summary of Amendments

Version Number	Modification:
Version 5.0	**Minor amendments throughout**
Version 6.0	**Checks and changes to external links; included the QMS system QPulse; updated R&D Clinical Director. Clarifying the timing needed for a DBS check.**

Key Points of this Document

- This Policy applies to all research conducted by individuals whose substantive employment is external to the Trust and who do not hold an existing clinical contract with the Trust.
- It provides guidance on the steps involved in issuing Honorary Research Contract and Letter of Access to external Research staff to ensure compliance with the Trust's policies.

1 Purpose and Content

a. This document defines the Trust's research SOP for issuing honorary research contracts and letters of access to researchers external to the Trust.

b. This document implements the Research Passport Scheme via the adoption of the Research in the NHS – NIHR HR Good Practice Resource Pack (HR Good Practice Resource Pack Information for researchers RP001_v3_0 (002) April 2019.pdf), accessed 08 November 2023.

2 Roles & Responsibilities

a. This Policy applies to all research conducted by individuals whose substantive employment is external to the Trust and who do not hold an existing clinical contract with the Trust.

b. Staff involved in arranging for non-Royal Papworth employees to come on site for the purposes of performing research must comply with the requirements set out within this SOP.

c. The Research and Development Directorate is responsible for:

1. ensuring the implementation and the requirements outlined within this procedure are observed, and

2. ensuring all directorates are made aware of the procedure

d. The R&D Department is responsible for:

1. providing a single point of contact for externally employed researchers seeking to conduct research in the Trust,

2. ensuring the appropriate application forms are completed based upon the applicant's employment status,

3. training R&D staff within the Trust to ensure compliance with the Research Passports Policy,

4. identification of an appropriate local manager/ supervisor for all individuals carrying out research within the Trust

5. ensuring that the applicant has read relevant departmental SOPs prior to starting the research.

e. The R&D Governance Team is responsible for:

1. assessing, in conjunction with Human Resources and the NIHR guidance, the need for pre-engagement checks based on the nature of the proposed research project or programme. Also, assessing the appropriateness of pre-engagement checks already conducted by the researcher's substantive employer, with respect to the research being undertaken.

2. requesting additional pre-engagement checks if required,

3. issuing Honorary Research Contracts and Letters of Access as appropriate,

4. maintaining an accurate record of applications received as well as Honorary Research Contract and Letters of Access granted

f. The Human Resources Directorate is responsible for:

1. conducting and arranging any additional pre-engagement checks (e.g. DBS disclosures) as requested by the Department and provide advice on changing NHS legislative requirements,

2. supporting Trust employees in providing evidence to other NHS organisations,

3. undertaking engagement checks and access arrangements for commercial employed staff who wish undertake research activities at the Trust.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

3.1 DEFINITIONS AND GLOSSARY

a. The Research Passport is the standard form which provides information about a non- NHS researcher - including evidence of the pre-engagement checks that have already been conducted – to enable the NHS Trust/s hosting the research to allow researchers access to their site/s for the purposes of research.

b. An Honorary Research Contract (HRC) permits access to patients and confirms responsibilities of a researcher who has no contractual relationship with the NHS. An HRC is only issued if the planned activities of the researcher involve interacting with individuals 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

c. The Letter of Access (LoA) is the standard letter permitting access to patients and confirming the responsibilities of a researcher. These letters will be issued based upon the substantive employment or the Higher Education Institution (HEI) as stipulated in Table 1 of the NIHR HR Good Practice Resource Pack (HR Good Practice Resource Pack Information for researchers RP001_v3_0 (002) April 2019.pdf

d. The NHS to NHS Confirmation of Pre-engagement check is the standard form which provides information about a NHS researcher - including confirmation pre-engagement checks that have already been conducted - to enable the NHS Trust hosting the research to issue a LoA. The form is completed by the researcher's employer.

3.2 Pre-engagement checks:

a. Pre-engagement checks are determined by the nature of the research project following the algorithm in the Good Practice Resource Pack ((The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf, accessed 08 November 2023)).

b. The R&D Department will accept Occupational Health clearance given by another NHS organisation, or other substantive employer provided that the clearance was at the level required by the research. The R&D Department will confirm that the NHS to NHS pre-engagement checks has been accurately completed (via the pre-engagement check algorithm listed above) and received. For Honorary Research Contract applicants, the R&D Department will confirm that the relevant section of the Research Passport has been completed and appropriate evidence has been supplied.

c. For criminal records checks the R&D Department will accept a current DBS check requested by either the R&D department or the employee's current substantive employer, provided that the clearance was at the level required by the research and provided that the applicant confirms that there have been no changes to their latest DBS/CRB or Occupational Health checks prior to the validation of the Research Passport. Individuals whose research activity is concerned with the provision of health services and is of such a kind as to enable the researcher to have access to persons in receipt of such services in the course of her/his normal duties are required to provide a standard criminal record disclosure. Individuals whose research involves regulated activity as defined by the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012), are required to provide an enhanced criminal record disclosure with checks against the relevant Independent Safeguarding Authority (ISA) barred list(s).

d. The Trust retains the right to request any additional pre-engagement checks or evidence it considers necessary in line with its legislative entitlements.

e. All applicants should comply with SOP049 GCP Training for Research Staff in providing an in-date Good Clinical Practice certificate and signed Research CV.

4 Procedure

a. The procedure for an external researcher to gain access to the Trust for research and the nature of the subsequent checks will vary depending on the researcher's employment status and the nature of the project. The processes involved are detailed in the Research in the NHS – HR Good Practice Resource Pack (HR Good Practice Resource Pack Information for researchers RP001_v3_0 (002) April 2019.pdf, accessed 08 November 2023)

b. What Research Passport is required is to be determined by the following: –

1. Are individuals NHS staff members?

2. Do they already have an honorary clinical contract with the NHS?

3. Are they a GP?

4. Student currently working for/on placement with the NHS - or a student who will be monitored by a NHS employee the whole time.

If any of the above apply, then the researcher is eligible for a Letter of Access, if none apply researcher will require an Honorary research Contract.

Documentation allowing access to the trust for research purposes is only submitted and processed once study feasibility and set up is complete, but before C&C for the named study is issued.

4.1 Letter of Access

a. If a researcher from another NHS trust requires a Letter of Access to conduct research activities at Royal Papworth, the NHS to NHS confirmation of pre-engagement check proforma should be completed. This is signed off by the researcher's HR department.

(S:\shared\R&D\Governance\Processes\Local\Research Passports\1. Template Folders\LoA - [enter name of applicant]\NHS-to-NHS-confirmation-of-pre-engagement-checks.doc)

If any other of the above researchers who do not work at an NHS trust require a Letter of Access to conduct research activities at Royal Papworth, the Research Passport application should be completed, signed off by the researchers HR & returned, along with any documentation the application states they require.

(S:\shared\R&D\Governance\Processes\Local\Research Passports\1. Template Folders\LoA - [enter name of applicant]\ResearchPassportApplicationForm_F001_v5_1.doc)

b. The completed form is sent to Royal Papworth R&D governance team who are able to confirm that the researcher is eligible to access the site and can complete and sign form if required (research passport application only). A LoA will be generated for the dates provided within the completed form and will then be sent for signature by the R&D Director or suitably delegated member of the senior staff. LoA will be either for the length of study or researchers contract, whichever comes first.

c. A copy will be emailed to the researcher, current employer & Royal Papworth Study team leader A copy will also be saved to EDGE.

4.2 Honorary Research Contract

a. A research passport application should be completed by the researcher. Guidance for completion and blank copies of the form can be requested from the R&D governance team or found online here: Research Passport_Instructions_V2_0_April_2019.pdf)

b. The researcher/R&D Governance Team will need to submit their application to their HR department along with the appropriate supporting documentation. More information on the supporting documentation can be found here: IRAS Help - Preparing & submitting applications - HR Good Practice Resource Pack (myresearchproject.org.uk) (accessed 08 Novemeber 2023) The researcher should then submit the application and copies of the supporting documentation to the Royal Papworth R&D Governance team. The final relevant sections of the form are then completed and appropriate HRC can be generated. This will be signed by the Director of R&D or appropriately delegated member of senior staff

c. Dependant on the project, additional checks may be required before a researcher's application can be accepted (e.g. proof of vaccination status). These would need to be reviewed by the HR of the lead NHS site before being submitted to R&D.

d. If the researcher's activities are different at Royal Papworth than the lead NHS Trust or other research sites, further checks may be required before access to Royal Papworth can be granted. These checks will be facilitated by the Royal Papworth HR department.

e. Once all checks are completed, the final section of the Research Passport application can then be filled in by the R&D office and the appropriate HRC will be generated ready for signature. HRC will be either for the length of study or researchers contract, whichever comes first.

f. Upon signature through DocuSign, a copy will be emailed to the researcher, current employer & Royal Papworth Study team leader. A copy will also be saved to EDGE and QPulse.

4.2.1 Extension/Modification of a Research Passport application

a. Once the LoA or HRC has been issued to the researcher they can apply to extend or modify their HRC by filling in an amendment form, which can be found at the back of the Research Passport application form, or for a LoA by completing the NHS-to-NHS Performa again and re submitting.

b. If the researcher requires an extension of the end date of their access without modification to their research activities, a new letter can be issued by Royal Papworth R&D with a new extension date. NOTE: Access can only be extended up until the end of their contract date.

Applications for after this period require a new application as new pre-engagement check would be required by the Researcher's HR department

c. Modifications may require further pre-engagement checks to be carried out prior to approval. Royal Papworth HR department will be required to assist with this

4.3 ID Badges and other access

a. Researchers will be issued with an ID badge from recruitment services which must be worn whilst on Trust property.

b. Researchers will be issued access cards from recruitment services on their start date.

c. If a researcher requires access to patient records as part of the research project, the researcher via their nominated manager should apply to the appropriate Trust department for access to records and systems.

4.4 Termination of contract

a. Researchers must notify the R&D Department when they complete a research project or when there are any changes in their circumstances (e.g. health, employment status).

b. On termination of the contractual or access arrangements, access to the Trust and its associated data systems must cease.

c. The Trust reserves the right to terminate access to the Trust.

4.5 Further provisions

a. Substantive employers will retain responsibility for other research activities that do not affect the Trusts duty of care to a participant, i.e. study management, data entry.

b. Honorary Research Contracts do not provide a mechanism for access to confidential patient information without consent from the participant. The necessary regulatory approvals must be in place to access data without consent.

c. Before issuing an Honorary Research Contract or Letter of Access, the R&D Department will verify that an identified Trust Manager, who is to provide managerial supervision for the research activity, is in place.

d. Honorary Research Contracts and Letters of Access will not be issued for a period that will exceed the remainder of the life of the researcher's substantive contract, the researcher's right to reside and work in the United Kingdom or 3 years after the CRB was issued.

e. All HRC and Letters of Access are copied to the substantive employer.

f. The R&D Department will maintain an electronic record of Letters of Access and HRC on an appropriate electronic document management system.

g. All LoA/HRC applications must be reviewed and confirmed that they are for a research study only. If non research related or involve research and non-research related work, documents must be forwarded onto HR for a general honorary contract.

h. The R&D Governance Team will regularly run Research Passport reports via EDGE and QPulse and make contact with applicants whose expiry date is approaching and review to ensure applicants' passports remain in date. The Governance Team will work with the HR department to reissue honorary clinical contracts for external staff members involved with research.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Managment/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	[Current active version approved date]
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2018)
Key related documents:	Trust Research Policy SOP034: Trust Approval and Research Governance

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	September 2023

I certify the contents of this SOP has been reviewed and ratified

Patrick Calvert 17-12-2023

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Signed by Dr Patrick Calvert, Clinical Director of R&D Date

SOP release date: .....