University Hospitals of Leicester NHS
NHS Trust

Policy for Research Passports

Approved By:	**Policy & Guideline Committee**
Date Approved:	**18 January 2010**
Trust Reference:	**B1/2010**
Version:	V5
Supersedes:	V4 November 2019
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Latest Review Date	27 October 2023 – Policy and Guideline Committee
Next Review Date:	January 2027

CONTENTS

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

January 2010 – V1 of this policy was written.

June 2013 – V2 of this policy was updated and re-formatted.

March 2016 V3 of this policy was updated and re-formatted. All changes are the renaming of the R&D office to R&I and the hyper-links updated.

September 2019 - V4 of this policy was updated in line with the NIHR August 2019 national guidance and re-formatted.

August 2023 V5 revised and updated.

KEY WORDS

Research Passport

Letter of Access (LoA)

National Institute of Health Research (NIHR)

UK Clinical Research Collaboration (UKCRC)

Honorary Research Contract (HRC)

1 INTRODUCTION & OVERVIEW

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for the implementation of the NHS Research Passport Scheme, introduced by the UK Clinical Research Collaboration (UKCRC) to streamline NHS approval for clinical access by non-NHS researchers. Research is an integral part of NHS activity but relies on working in partnership with staff from other NHS Trusts and also researchers from external organisations. This requires a clear understanding about responsibility, accountability, patient safety and duty of care. Holding a Research Passport does not in any way confirm NHS continuous service.

1.2 The UK Clinical Research Collaboration (UKCRC) has coordinated the development of a Good Practice Resource pack to help the NHS and other research employers take a consistent approach to handling Human Resources (HR) arrangements for those undertaking research in the NHS. The pack describes the process for handling HR arrangements for researchers and provides a streamlined approach for confirming details of the pre-engagement checks they have undergone with the NHS, saving valuable time and resources. The pack forms the basis for this policy, and is available on the National Institute for Health Research website. The pack includes a number of useful documents including a guide to completing the research passport form, an algorithm of research activity and pre-engagement checks, information for researchers, Research & Development (R&D) and HR staff in Higher Education Institutions (HEIs) and the NHS, background information on principles and legal requirements for honorary research contracts, and a frequently asked questions supplement.

https://www.hra.nhs.uk/planning-and-improving-research/best-practice/research-passport/

2 POLICY SCOPE

2.1 This policy and procedure applies to all research conducted by individuals whose substantive employment is external to the Trust and they are substantively employed or a student of an educational provider.

2.2 All other (non-research) requests for Honorary Contracts with the Trust must be applied for through the Trust's Recruitment Services Department in line with the UHL NHS Trust Unpaid Placement Policy.

2.3 Hospice Care for Leicester, Leicestershire and Rutland (LOROS) have had an agreement with UHL to utilise the research passport scheme for their substantively employed staff. UHL R&I will issue a letter of access on receipt of a fully completed Research Passport application and all supporting documentation

3 DEFINITIONS & ABBREVIATIONS

3.1 The **Research Passport** is one standard form for each researcher which provides evidence of one set of checks on a researcher conducting research in the NHS. The form is completed by the researcher and her/his employer, and validated by an NHS organisation. The completed Research Passport is presented to all the relevant NHS organisations in order for an honorary research contract to be issued rapidly, with no duplication of checks.

3.2 The **Honorary Research Contract** is between the NHS organisation and the employer of the Researcher. It allows the Researcher access to the Trust premises, patients, clinical samples and clinical personal information.

3.3 A **Letter of Access** will be issued to those who do not require an Honorary Research contract. The standard letter concerns responsibilities of such Researchers and may be used for one project or a series of projects.

3.4 **HEIs** - Higher Educational Institutions including organisations such as Universities

4 ROLES

4.1 **The Medical Director:**

- The Medical Director has overall delegated responsibility for R&D in the Trust. It is the responsibility of the Medical Director to ensure and give assurance to the Board of compliance with the systems and processes described in this procedure.

4.2 **Director of Research and Innovation**

- It is the responsibility of the Director of Research and Innovation, supported by the Research & Innovation Director of Operations to ensure all relevant managers and staff are aware of the Procedure, and to facilitate compliance with its contents.

4.3 **The R&I Department are responsible for:**

- Providing a single point of contact for externally employed individuals seeking to conduct research in the Trust.

- Assessing the need for an honorary research contract from the individual's employment status and the nature of the proposed research project or programme.

- Ensuring that appropriate pre-engagement checks are completed for external researchers, in order to complete a research passport, when the Trust is the first NHS organisation approached by the researcher.

- Ensuring that an honorary research contract or letter of access is issued in response to a request received by the R&I Department for an external researcher, where a research passport already exists.

- Ensuring that procedures for pre-engagement checks and the issuing of honorary research contracts enable the research process.

- Issuing a standard Letter of Access where an honorary research contract or further pre-engagement checks are not needed.

- Training R&I staff within the Trust to ensure compliance with the Research Passports Policy.

4.4 **The HR Department are responsible for:**

- Advising and supporting the Research & Innovation Director of Operations in the application of the procedure.

4.5 **Line Managers are responsible for:**

- Ensuring that staff participating in research within their areas of responsibility are aware of this procedure and that they follow the procedure.

4.6 **All Staff:**

- It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

5 POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS

This policy mandates the use of the following processes and procedures found in the associated documents as detailed below, which must be used in conjunction with this policy:

5.1 The procedure for an external researcher to gain access to the Trust for research will vary depending on the researcher's employment status, and the nature of the project. For all requests for access, the R&I Department will be the first point of contact.

5.2 The researcher will provide a full protocol for their research project together with details of their employment status. The R&I Department will then assess the need for the issuing of a research passport (if the Trust is the first NHS organisation an external researcher has approached), or more commonly an honorary research contract or letter of access. The Research Passport template document is accepted as the standard form either for application for a new Research Passport, or when complete, as the basis for issuing an honorary research contract. The Pre-Engagement Checks Grid and Section 5 of the Information for NHS HR detailing the requirements for different categories of staff should be used in making the judgement as to whether an honorary research contract is needed. The expectation is that the substantive employer of the researcher has undertaken all necessary right to work checks and that the R&I office is informed at once if the right to work is revoked.

5.3 If a letter of access with no further pre-engagement checks is all that is required, the R&I Department will issue the letter of access using the standard template letter.

5.4 The procedure for processing requests for access is indicated in the flowcharts shown on the link below, depending on whether a single or multiple sites are involved in the research.

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

5.5 Researchers with a substantive employment contract with one NHS organisation do not need an honorary research contract to conduct research in another NHS organisation. The Trust will normally accept an existing NHS contract of employment, but additional pre-engagement checks may occasionally be required. A letter of access should be issued detailing the researcher's responsibilities.

NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations via a copy of the letter of access. An agreement should be put in place between the Trust and the employing organisation to cover this.

5.6 Researchers with an honorary clinical contract with one NHS organisation do not need additional honorary research contracts to conduct research in other NHS organisations. Additional pre-engagement checks may occasionally be required dependent on the researchers proposed activities whilst at UHL. NHS organisations should inform the researcher's substantive employer of her/his activities in their organisations.

5.7 Researchers with no contractual relationship with the NHS require an honorary research contract only 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 Trust has a duty of care. The IRAS website will indicate how this influences the need for pre-engagement checks and the decision to seek an honorary research contract. There are template honorary research contracts and covering letters for use by the Trust. https://www.myresearchproject.org.uk/

5.8 Substantive employers (usually HEIs) retain responsibility for other research activities that do not affect the NHS organisation's duty of care.

5.9 Honorary research contracts do not provide a mechanism for access to confidential patient information without consent. Access to confidential patient information, either with patient consent or statutory support, does not require an honorary research contract.

5.10 Researchers who do not require an honorary research contract may require additional pre-engagement checks to undertake permitted research activities in NHS organisations.

5.11 All external researchers will have an identified Trust Manager providing managerial supervision for their NHS activities which will include a local induction. This person will be a named manager within the department at UHL of where the research activities are proposed to take place.

5.12 Disclosure and Barring Scheme (DBS) checks will be accepted from other organisations as part of the Research Passport as a valid pre-engagement check up to a maximum of two years since the last check was completed. This valid DBS check must be from the current researcher's substantive employer. Guidance on when a DBS check is required is given in the research passport guidance. It is expected that where research involves the Trust's service users they will be considered a vulnerable group, so that enhanced DBS checks will be the normal requirement.

5.13 If a new Research passport is required after the original one has expired a new DBS check will not be required if the proposed role and activities remain the same.

5.14 Occupational Health screening performed by another NHS organisation will be accepted as part of the Research Passport's pre-engagement checks without the need to routinely repeat this, unless the specific research project requires this. The Good Practice Resource Pack includes examples of occupational health screening documents recommended for use in processing research access requests.

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

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 The training of R&I staff within the Trust to ensure compliance with the Research Passports Policy will follow the guidance that is current on the NHIR website. https://www.hra.nhs.uk/planning-and-improving-research/best-practice/research-passport/

7 PROCESS FOR MONITORING COMPLIANCE

7.1 The procedure for monitoring compliance is to ensure that the NHIR Research Passport information and guidance is followed at all times.

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

9.1 The National Institute for Health Research document, "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" is available via the following link:

https://www.myresearchproject.org.uk/help/help%20documents/HR%20Good%20Practice%20Resource%20Pack%20Information%20for%20researchers%20RP001_v3_0%20(02)%20April%202019.pdf

Procedure / Process
Research Passport (NIHR) https://www.hra.nhs.uk/planning-and-improving-research/best-practice/research-passport/
Algorithm of Research activity https://www.myresearchproject.org.uk/help/help%20documents/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 This Policy will be reviewed every three years.

10.2 The updated version of the Policy will then be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system.

POLICY MONITORING TABLE

The top row of the table provides information and descriptors and is to be removed in the final version of the document

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements	Lead(s) for acting on recommendations	Change in practice and lessons to be shared
The whole policy	Lisa Wann	The Research Passport Good Practice Resource pack	Every 3 years (& as and when the UKCRC national guidance is updated).	Research and Development Management meeting	Lisa Wann	Through regular updates and latest links to the websites.
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