APPENDIX 5

Research Passports, Honorary Research Contracts and Letters of Access Policy Version 3.0

Category:	Policy
Summary:	Research Passports, Honorary Research Contracts and Letters of Access Policy
Equality Impact Assessed:	July 2024
Valid From:	July 2024
Date of Next Review:	July 2027
Approval Date/ Via:	01 August 2024 Trust Management Executive
Distribution:	Via Research and Development to: • Researchers within OUH Foundation Trust • Trust website
Related Documents:	Capacity and Capability Approval of Clinical Research Policy Monitoring and Audit of Research Studies Integrity in Research Policy Safety Reporting in Clinical Research Policy Incident Reporting, Investigation and Learning Procedure
Author(s):	Senior Research Support Manager
Further Information:	shahista.hussain@ouh.nhs.uk
This Document replaces:	Version 2.0

Lead Director: Chief Medical Officer

Issue Date: 01 August 2024

Document History (This is a mandatory heading)

Use this table to record the revisions made to the approved policy and record document history.

Date of revision	Version number	Author	Reason for review or update
23/07/2009	1.0	Research Development Lead	New policy
15/04/2014	2.0	Research Development Lead	Review and minor updates
09/07/2024	3.0	Jo Franklin, Senior Research Support Manager	General update

Consultation Schedule

Use this table to evidence your involvement of staff and key stakeholders, where appropriate, in the development and review of documents.

Who? Individuals or Committees	Rationale and/or Method of Involvement
Shahista Hussain, Head of R&D Governance	Review of the document and changes
Katie Flight, Deputy Head of R&D Governance	Review of the document and changes
Louise Willis, Research Support Manager	Review of the document and changes

Endorsement

Use this table to list relevant Divisional and/Directorate leads who have endorsed the policy/procedural document.

Endorsee Job Title
Head of R&D Operations
Director of R&D

Contents

Who should read this document?

1. This policy should be read by anyone wishing to undertake clinical research activities within the Trust, who are employed by other organisations, and who need to make an application to the Trust for a Research Passport (RP), Honorary Research Contract (HRC) or for a Letter of Access.

Key Standards/Messages

2. Protect the safety, dignity, rights, and well-being of all patients involved in clinical research.

3. Ensure that arrangements are in place to ensure that anyone engaged in clinical research has the appropriate permissions for access to Trust patients and their data.

Background/Scope

4. Research in the NHS relies on working in partnership with the Higher Education Sector and is often undertaken by non-NHS staff, including staff employed by higher education institutions. This relationship calls for clear understanding about responsibility, accountability, patient safety, and duty of care. The UK Policy for Health and Social Care 2017 requires that all parties undertaking research in the NHS to be clear about responsibilities and liabilities. One way in which this can be achieved is the use of honorary research contracts.

5. This section should detail who the policy or procedural document does or does not apply to. The National Institute for Health Research (NIHR), in its implementation of the government White Paper 'Best Research for Best Health', identified the need for a streamlined approach for issuing and recognising honorary research contracts within the NHS. The response has been the development of the 'Research Passport' process. A common approach to the process is documented in detail in 'Research in the NHS – HR good Practice Resource Pack. 'Version 3, April 2019, produced by the NIHR.

6. This policy applies to all applications to the Trust for a Research Passport (RP), Honorary Research Contract (HRC) or for a Letter of Access (LoA).

Key Updates

7. The Equality Impact Assessment has been updated to the new template version.

Aim

8. This policy sets out a consistent procedure for the processing of all applications to the Oxford University Hospitals NHS Foundation Trust ('the Trust') for a Research Passport (RP), Honorary Research Contract (HRC) or for a Letter of Access (LoA).

9. It is the aim of this policy to ensure that these procedures are consistent with NIHR processes for implementation of the Research Passport process.

Content of the Policy

10. All NHS organisations work to a code of conduct for handling identifiable information in order to comply with the GDPR/Data Protection Act.

11. The Research Passport process involves access to identifiable and potentially sensitive information about researchers.

12. All information gathered will be treated and stored to enable privacy and confidentiality to be maintained.

Who needs a Research Passport?

13. A Research passport is not needed if the researcher is/has:

- Substantive employment with an NHS Organisation
- An independent contractor (e.g. GP) or employed by an independent contractor.
- An Honorary Clinical Contract with the NHS (e.g. Clinical Academics)
- A student who will be supervised within clinical settings by an NHS employee or Higher Education staff member with an NHS clinical contract.
- Undertaking research that does not require any of the checks outlined in the Research Passport form, or an Honorary Research Contract.
- These researchers will instead submit a Pre-engagement checks letter in support of their application for access to the trust available from the website: https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

14. Researchers not in any of the above categories and who have no contractual relationship with the NHS will need to complete the research passport process. Whether an HRC or a LA is required will also depend on the nature of the research.

15. A Research Passport may be project specific or cover multiple projects and last for a period of three years.

Approach to R&D for Research Passport/Honorary Research Contract/ Letter of Access for Non-NHS Researchers (Lead NHS Organisation)

16. The researcher approaches R&D in the lead NHS organisation for a Research Passport.

17. R&D staff check the nature of the research proposed and identify whether a research passport is required, and the type of pre-engagement checks required.

Form Completion

- The Research Passport Form available from: https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx should be completed as follows:
    - The Researcher (sections 1-3)
    - Substantive Employer - Line Manager/Academic Supervisor (section 4)
    - Substantive Employer - Human Resources Department (section 5)
    - The Researcher (Section 6)

Document Review

18. The Researcher emails the following original documents to the R&D Department:
    - Completed Research Passport Form -sections 1-6 and appropriate passport appendix
    - An occupational health screening/clearance (where appropriate)
    - Current signed and dated curriculum vitae (CV)
    - Original evidence of professional registration (as appropriate)
    - Original evidence of research related qualifications and training
    - Evidence of DBS (where appropriate)

19. The documents are reviewed, copied, and filed by R&D staff in a secure location, emails them back to the researcher.

20. An Honorary Research Contract or Letter of Access issued as appropriate, along with a copy of the NHS Confidentiality Code of Conduct.

21. A copy of the HRC or LoA, along with a link to the NHS Confidentiality Code of Conduct, is sent to the substantive employer and the Medical Revalidation team (where appropriate).

Approach to Host NHS Organisations

22. Where access is required to more than one NHS organisation, the Researcher can then take the HRC or completed and signed Research Passport to another host NHS organisation for Letters of Access.

23. (NB. Documents related to the research will also be submitted as part of the Capacity and Capability Approval Process to R&D).

Amendments to a Research Passport

24. A three-year Research Passport may be amended to add new studies, or to change the details of the researcher.

25. A study specific Research Passport may be amended to a three-year passport covering multiple studies.

26. In some circumstances a new research passport will be required.

27. The researcher approaches the R&D Department (where the Trust is the Lead NHS Organisation) to discuss amending the Research Passport.

28. To add a new study to an existing three-year passport the researcher completes a new Passport Appendix page with details of the new study. Pages should be sequentially numbered.

29. R&D reviews the project to determine whether any additional pre-engagement checks are required. If so, the researcher is referred to their substantive employer.

30. If no further checks are required R&D will issue a Letter of Access to cover the new study. (A full review of documents is undertaken as part of the Capacity and Capability Approval Process).

31. If the researcher's employment status has changed an assessment is made about whether a new passport is needed. In such circumstances, the procedure outlined in above is repeated.

32. Where a study specific passport is to be amended to a three-year passport, to include a second study an appendix page is added.

33. R&D reviews the study and determines whether any additional checks are required. The process is then followed as above.

Letter of Access (where another NHS organisation is Lead)

34. A letter of Access issued by a host NHS organisation is project specific.

35. The Researcher approaches the R&D Department for access to the Trust for the conduct of research.

36. The nature of the proposed research is reviewed.

37. The researcher presents their Honorary Research Contract and completed authorised Research Passport.

Letter of Access (where a Substantive or Honorary Contract is held with another NHS Organisation)

38. The Researcher approaches the R&D Department for access to the Trust for the conduct of research.

39. The nature of the proposed research is reviewed.

40. The researcher presents their Substantive or Honorary Contract or NHS to NHS letter of access: Confirmation of pre-engagement checks available from the NIHR website.

41. The documents are reviewed, copied, and filed by R&D staff in a secure location, the originals being returned to the researcher.

42. A Letter of Access is issued.

43. A copy of the Letter of Access is sent to the substantive employer and the Medical Revalidation team (where appropriate)

44. (NB. Documents related to the research will also be submitted as part of the Capacity and Capability Approval Process, to R&D)

Review

45. This policy will be reviewed every 3 years, as set out in the Developing and Managing Policies and Procedural Documents Policy.

46. The Trust Management Executive has delegated authority to the Head of R&D Governance for the approval of any further supporting or associated documents.

References

47. The UK Policy Framework for Health and Social Care 2017
https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

Appendix 1: Responsibilities

Researcher

1. Collation of all the relevant documentation.

2. Communicate with all relevant departments in employing organisation, Lead NHS Trust, and other trusts as appropriate.

Principal Investigator

3. Assuring the suitability and experience of the researcher to undertake duties associated with the proposed research activities.

4. Ensure that members of the research team have the appropriate documentation in place for access to research site.

Research and Development Staff (R&D)

5. Provide advice and information on the Research Passport process.

6. Identify the level of checks required for issues of an HRC.

7. Review and retain copies of relevant documents provided by researcher.

8. Issue Research Passport, HRC, LoA.

9. Maintain a record of those researchers to whom a Research Passport, HRC or LoA have been issued.

Employing Organisation

10. Provide confirmation of pre-engagement checks.

11. Where required to do so, undertake applications for Disclosure and Barring Service (DBS).

12. Undertake additional checks, where those specified as required in the Research Passport form exceed those already undertaken.

Human Resources Department

13. Completes pre-engagement checks for Trust employees.

14. Where required to do so, countersign applications for DBS checks.

Appendix 2: Definitions

Research Passport

1.   The Research Passport consists of a single 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 their employer, and validated by an NHS   organisation. The completed Research Passport is presented to all the relevant NHS organisations for an HRC or LoA to be issued rapidly, with no duplication of checks.

Honorary Research Contract (HRC)

2.   Honorary employment can be described as performing work for the benefit of an organisation without remuneration.

3.   An HRC may be issued to an individual who has no contractual relationship with the NHS, and who is conducting research activities within an NHS organisation that may have an impact on patient care.

Letter of Access (LoA)

4.   A letter issued to the researcher, to enable them to carry out research within a host NHS organisation. The terms of the letter will depend on whether it is an NHS-to-NHS letter of access or a non-NHS to NHS letter of access. N.B. Trust Management Approval/capacity and capability (C&C) approval is still required for the study itself.

Confirmation of Pre-Engagement Checks

5.   A document issued by an employing NHS institution for NHS researchers who have a substantive NHS contract of employment or clinical academics with an honorary clinical contract with an NHS organisation, and who need an NHS-to-NHS letter of access from an NHS organisation hosting their research.

Lead NHS Organisation

6.   The NHS organisation approached by the researcher for a Research Passport; the organisation that co-ordinates the process necessary to issue an HRC or LoA.

Host NHS Organisation

7.   An NHS organisation hosting the research, which, where appropriate, issues an LoA or an HRC.

Appendix 3: Education and Training

1. Training required to fulfil this policy will be provided in accordance with the Trust's Training Needs Analysis. Management and monitoring of training will be in accordance with the Trust's Core Skills Policy. This information can be accessed via the Practice Development and Education pages on the Trust intranet

2. Staff involved in the conduct of clinical trials will undertake the appropriate training in clinical research prior to beginning their involvement in a trial.

3. Where mandatory training is identified, the author must ensure that this is updated in the Trust's training needs analysis.

4.

Appendix 4: Monitoring Compliance

5. Compliance with the document will be monitored in the following ways.

What is being monitored:	How is it monitored:	By who, and when:	Minimum standard	Reporting to:
Issue of Honorary Research Contracts and Letters of Access	Report numbers, issues	Head of R&D Governance	Reviewed on an ongoing basis	Joint R&D Committee

Appendix 5: Equality Impact Assessment (This is a mandatory heading)

Equality Impact Assessment Template
1.   Information about the policy, service, or function

What is being assessed	Existing Policy / Procedure
Job title of staff member completing assessment	Head of R&D Governance
Name of policy / service / function:	Research Passports, Honorary Contracts and Letters of Access Policy
Details about the policy / service / function	This policy sets out a consistent procedure for the processing of all applications to the Oxford University Hospitals NHS Foundation Trust for a Research Passport (RP), Honorary Research Contract (HRC) or for a Letter of Access (LoA). It is the aim of this policy to ensure that these procedures are consistent with NIHR processes for implementation of the Research Passport process.
Is this document compliant with the [Web Content Accessibility Guidelines](#)?	Yes
Review Date	July 2024
Date assessment completed	July 2024
Signature of staff member completing assessment	Jo Franklin
Signature of staff member approving assessment	Shahista Hussain

2.   Screening Stage

Who benefits from this policy, service or function? Who is the target audience?

- Staff
- Others – external researchers

Does the policy, service or function involve direct engagement with the target audience?
Yes - *continue with full equality impact assessment*

3. Research Stage

Notes:
- If there is a neutral impact for a particular group or characteristic, mention this in the 'Reasoning' column and refer to evidence where applicable.

- Where there may be more than one impact for a characteristic (e.g. both positive and negative impact), identify this in the relevant columns and explain why in the 'Reasoning' column.

- The Characteristics include a wide range of groupings and the breakdown within characteristics is not exhaustive, but is used to give an indication of groups that should be considered. Where applicable please detail in the 'Reasoning' column where specific groups within categories are affected, for example, under Race the impact may only be upon certain ethnic groups.

Impact Assessment

Characteristic	Positive Impact	Negative Impact	Neutral Impact	Not enough information	Reasoning
Sex and Gender Re-assignment – men (including trans men), women (including trans women) and non-binary people.			X		**This policy applies to honorary research contracts and letters of access issued to staff within the trust, regardless of race, religion, disability, age, gender or sexuality**
Race - Asian or Asian British; Black or Black British; Mixed Race; White British; White Other; and Other			X		**This policy applies to honorary research contracts and letters of access issued to staff within the trust, regardless of race, religion, disability, age, gender or sexuality**
Disability - disabled people and carers			X		**This policy applies to honorary research contracts and letters of access issued to staff within the trust, regardless of race, religion, disability, age, gender or sexuality**
Age			X		**This policy applies to honorary research contracts and letters of access issued to staff within the trust, regardless of race, religion, disability, age, gender or sexuality**
Sexual Orientation			X		**This policy applies to honorary research contracts and letters of access issued to staff within the trust, regardless of race, religion, disability, age, gender or sexuality**
Religion or Belief			X		**This policy applies to honorary research contracts and letters of access issued to staff**

Template
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Characteristic	Positive Impact	Negative Impact	Neutral Impact	Not enough information	Reasoning
					within the trust, regardless of race, religion, disability, age, gender or sexuality
Pregnancy and Maternity			X		**This policy applies to honorary research contracts and letters of access issued to staff within the trust, regardless of race, religion, disability, age, gender or sexuality**
Marriage or Civil Partnership			X		**This policy applies to honorary research contracts and letters of access issued to staff within the trust, regardless of race, religion, disability, age, gender or sexuality**
Other Groups / Characteristics - for example, homeless people, sex workers, rural isolation.			X		**This policy applies to honorary research contracts and letters of access issued to staff within the trust, regardless of race, religion, disability, age, gender or sexuality**

Sources of information
- No protected groups were targeted during the consultation process.

Consultation with protected groups

Group	Summary of consultation
N/A	

Consultation with others

The update has been based on feedback from the R&D Governance team and National guidance in the HR Good Practice Resource Pack*.*

4.   Summary stage

<u>Outcome Measures</u>

List the key benefits that are intended to be achieved through implementation of this policy, service or function and state whether or not you are assured that these will be equitably and fairly achieved for all protected groups. If not, state actions that will be taken to ensure this.

No specific positive impacts on protected groups have been identified.

This policy applies to research passport applications and letters of access which are purely factual in nature.

All applications are assessed in a fair and open manner.

<u>Positive Impact</u>

List any positive impacts that this policy, service or function may have on protected groups as well as any actions to be taken that would increase positive impact.

No specific positive impact on protected groups have been identified.

<u>Unjustifiable Adverse Effects</u>

List any identified unjustifiable adverse effects on protected groups along with actions that will be taken to rectify or mitigate them.

No specific adverse effects on protected groups have been identified.

<u>Justifiable Adverse Effects</u>

List any identified unjustifiable adverse effects on protected groups along with justifications and any actions that will be taken to mitigate them.

No specific adverse effects on protected groups have been identified.

Equality Impact Assessment Action Plan

Complete this action plan template with actions identified during the Research and Summary Stages

Identified risk	Recommended actions	Lead	Resource implications	Review date	Completion date
None identified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable