



Standard Operating Procedure

Research Passport Process

Document Control Sheet

Title:	Research Passport Process
Document Status:	Final
Document Type:	Standard Operating Procedure
Version Number:	v03.2
Document location:	Governance / SOP Library / Current SOPs
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Date Effective From:	2 nd April 2025
Review Frequency:	2 years
Next Review Date:	2 nd April 2027

Revision History:

Version:	Date:	Summary of Changes:	Responsible Officer:
01.0	09/01/2012	This SOP was named Honorary Contracts which has been updated and revised to reflect current practice	Natalie McLuckie Libby Mullings
03.0	15/03/2022	Email templates added for when a Letter of Access is due to expire and when a Letter of Access has expired. Information on where to update SReDA once a Letter of Access has been issued.	Colin Irving
03.1	06/06/2024	Minor Updates	Colin Irving
03.2	26/02/2025	Minor updates to reflect change in local sign off process.	Colin Irving

Approvals: this document was formally approved by:

Name & Title / Group:	Date:	Version:
Carolina Borda, Head of Research, Development and Innovation	02/04/25	v03.2
RDI Team	02/04/25	v03.2

Dissemination Arrangements:

Intended audience:	Method:	Date:	Version:
RDI Team	Access on shared drive	02/04/25	v03.2

Linked Documentation:

Document Title:	Document File Path:
Letter of Access - Uni Researchers who DO NOT require HRC	..\..\..\..\Project Team\Proforma\Letters of Acces & Research Passport\Templates\Letter of Access\Letter of Access - Uni reserachers who DO NOT require HRC.doc
Letter of Access – Accepting HRC	..\..\..\..\Project Team\Proforma\Letters of Acces & Research Passport\Templates\Letter of Access\Letter of Access - accepting HRC.doc
NHS to NHS confirmation of pre-engagement checks	..\..\..\..\Project Team\Proforma\Letters of Acces & Research Passport\Templates\NHS Staff\NHS to NHS confirmation of pre-engagement checks v1.0.doc
Research Passport Form	..\..\..\..\Project Team\Proforma\Letters of Acces & Research Passport\Templates\Research Passport\Research Passport Form 2012-09-01 v3.0.doc
Research Passport Form Appendix	..\..\..\..\Project Team\Proforma\Letters of Acces & Research Passport\Templates\Research Passport\Research Passport Form Appendix v3.0.doc
Email Template for LoA Due To Expire	R:\Project Team\Proforma\Letters of Acces & Research Passport\Templates\Email Templates\EM V0.1 LoA Due to expire.docx
Email Template for LoA That Has Expired	R:\Project Team\Proforma\Letters of Acces & Research Passport\Templates\Email Templates\EM V0.1 LoA Expired.docx
Letter of Access – non-NHS staff	..\..\..\..\Project Team\Proforma\Letters of Acces & Research Passport\Templates\Letter of Access\Letter of Access - non-NHS Staff.doc
Letter of Agreement between NHS organisations	..\..\..\..\Project Team\Proforma\Letters of Acces & Research Passport\Templates\NHS Staff\Letter of Agreement between NHS organisations v2.doc

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BACKGROUND

All those involved in research have a duty to ensure that they, and those they manage, are appropriately qualified, both by education and experience for the role they play in relation to research. The Research Passport system, launched nationally in October 2007, facilitates NHS review of Higher Education Institution (HEI) employed researchers who require direct or indirect contact with patients, their data, tissues or NHS staff.

National Institute for Health Research [NIHR] NIHR website:
<http://www.nihr.ac.uk/policy-and-standards/research-passports.htm>

The Chief Scientist Office recommended the implementation of the Research Passport system to the NHS and to HEIs with the effective date from 10 September 2012 (CEL (24)2008).

R&D offices undertake review of new study submissions where the research project will be hosted by the NHS organisation. This assessment includes review of the Principal Investigator (PI) and research team to ensure that they are appropriately qualified, experienced and hold a contract with the NHS. For some studies, members of the research team will not be employees of NHS Ayrshire & Arran and will not already hold a honorary contract. For these research team members the Research Passport captures information that the researcher is appropriately qualified and trained to undertake the research as well evidence that the pre-engagement checks by the substantive HEI employer are appropriate. Pre-engagement checks consist of occupational health and Disclosure checks. There are three levels of Disclosure checks: Basic, Standard and Protecting Vulnerable Groups (PVG) scheme membership.

The Research Passport facilitates sharing of personal information for external research team members with NHS organisation(s) that are hosting the research. The NHS organisation will review the Research Passport and determine whether the researcher will be subsequently issued an Honorary Research Contract (HRC) or Letter of Access (LoA).

PURPOSE

The purpose of this SOP is to define the process of reviewing Research Passport Application Forms and issuing external HEI researchers with either an HRC or LoA.

SCOPE

This procedure applies to NHS Ayrshire & Arran RD&I Department and to:

- non-NHS, non-Commercial external researchers who require permission to work in support of research studies hosted within NHS Ayrshire & Arran

Notes relating to scope:

- In the majority of cases, the external researchers will be substantively employed by, or be a student at, a Higher Education Institution (HEI). There are some other cases where permission may be required, such as researchers employed by UK charities or by the Scottish Government. The process for such researchers is the same as for HEI staff and students.
- academic staff holding only Honorary **Research** Contracts are regarded as HEI staff
- academic staff holding Honorary **Clinical** Contracts are regarded as NHS staff and would therefore apply via the 'NHS to NHS' process for issuing Letters of Access
- The Research Passport process cannot be used for employees of Commercial companies. In such cases, NHS Ayrshire & Arran's existing arrangements for allowing access to commercial company staff will be followed. All such circumstances should be discussed with the Head of RDI who will liaise with senior colleagues as required.

RESPONSIBLE PERSONNEL

Head of Research, Development and Innovation
Senior Research Advisor
Lead R&D Facilitator
R&D Co-ordinator

ABBREVIATIONS

CI – Chief Investigator
CSO – Chief Scientist Office
HEI – Higher Education Institution
HR – Human Resources
HRC – Honorary Research Contract
ICH GCP – International Conference on Harmonisation Good Clinical Practice

LoA – Letter of Access
OH – Occupational Health
OID - Organisation Information Document
PI – Principal Investigator
RDI – Research, Development & Innovation

PROCEDURE

WHO?

The R&D Lead Facilitator/R&D Coordinator are responsible for identifying which members of a research team require access to NHS Ayrshire and Arran.

WHEN?

Ideally prior to approval of a study but sometimes not all members of the research team are known until the project is approved.

HOW?

When an OID form is submitted the appropriate R&D Lead Facilitator/R&D Co-ordinator will identify if there are external members of the research team who will require access to NHS Ayrshire and Arran premises / patients by reviewing the Local Information Appendix. If it is unclear on the Appendix then contact with the CI / PI will be required to determine who requires access.

Once these individuals have been identified the R&D Lead Facilitator/R&D Co-ordinator will email the researcher to request the relevant paperwork (see Work Instruction 1). See Appendix 1 for additional guidance.

The R&D Lead Facilitator/R&D Co-ordinator will review the Research Passport to make sure the sections have been completed accurately (see Work Instruction 2) before the Senior Research Advisor signs the Research Passport.

When the Research Passport has been signed or the NHS to NHS confirmation of pre-engagement checks has been received the Letter of Access can be prepared (see Work Instruction 3).

When the Letter of Access has been issued the notes section on SReDA should be updated. The Honorary Contract and Courses section within the Investigators Details should be updated to reflect the Letter of Access and also the Upcoming Projects section, under the Governance tab should be updated to include a check on the Letter of Access status a month prior to the LoA expiring. (see Work Instruction 4)

Copies of Occupational Health checks and Disclosure checks should be deleted from the electronic folder.

OTHER RELATED PROCEDURES;

N/A

REFERENCES

NIHR - 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

APPENDICES:

Appendix 1 – Research Passport Algorithm

Appendix 2 – Email template for LoA due to expire

Appendix 3 – Email template for LoA that has expired

Work Instruction 1

Paperwork Required

HEI Employee or Student

If the researcher requiring access to NHS Ayrshire and Arran premises / patients is *employed by a University or studying at a University*, the R&D Lead Facilitator/R&D Co-ordinator will ask them to complete a Research Passport, which should be signed off by their HR Department and the Lead R&D Site.

The R&D Lead Facilitator/R&D Co-ordinator will request copies of the Occupational Health Clearance, Disclosure Check and CV to accompany the signed Research Passport. This will be stored in the electronic project folder until the Research Passport can be signed by the Senior Research Advisor.

Employee of another NHS Board

If the researcher requiring access to NHS Ayrshire and Arran premises / patients is *employed by another NHS Board* the R&D Lead Facilitator/R&D Co-ordinator will request that a 'NHS to NHS confirmation of pre-engagement checks' form is completed.

This should be completed by the HR Department of the researchers NHS employer. This completed signed and dated form will be returned to the R&D Lead Facilitator/R&D Co-ordinator for saving in the electronic project file until the Letter of Access can be issued.

Work Instruction 2

Research Passport Checking

Section 2 Question 5

- NHS Ayrshire & Arran should be listed under NHS Organisation
- The department, proposed research activities and NHS Manager details should be completed
- If this is an amendment to a Research Passport, NHS Ayrshire & Arran details will be added to the Appendix at the end of the document.

Section 5 Question 8

- Details of the disclosure date and disclosure number must match Section 8 and the hardcopy disclosure check.

Section 5 Question 9

- This section must be completed in full.
- Make sure that if the contract end date is due that the end date has been added.
- If the contract end date has passed the new contract end date should be added to the amendments section at the end of the document.

Section 8

- The Lead R&D Office must complete this section
- Make sure that the disclosure date and disclosure number match Section 5 Question 8 and the hardcopy disclosure check.

Passport Appendix List of Projects and Amendments

- If NHS Ayrshire and Arran has been added as an additional site then this would be added on the Appendix section, detailing the research activities and Manager in NHS Ayrshire and Arran.
- If there is a change to the employment end date (originally stated at Section 5 Question 9) then this should be added to the Amendments box. The change could also relate to a change in research activities. The last box must be signed by the Lead R&D site to authorise the change.

Work Instruction 3

Completion of Letter of Access

There are four different letters of access that are used as listed below (the last type listed is rarely used):

NHS staff and HEI staff holding an Honorary **Clinical** Contract:
Letter of Agreement between NHS organisations

Non-NHS staff:
Letter of Access – non-NHS Staff

HEI staff/employees:
Letter of Access – University researchers who NO NOT require HRC

Those who hold an Honorary Research Contract:
Letter of Access – Accepting HRC

Right of Access

The right of access commences on the date the Research Passport has been signed by the Senior Research Advisor.

The right of access should end either on the contract end date of the researcher or the end-date of the study as detailed on the R&D Management Approval, whichever is earliest.

Details of Employer and NHS Contact

The researcher's employer and NHS Ayrshire and Arran Manager details should be added into the following paragraph:

While undertaking research through NHS Ayrshire & Arran you will remain accountable to your employer but you are required to follow the reasonable instructions of in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Letter should be sent to:

- HR department contact (as named in section 5 Question 9 of the Research Passport)
- Principal Investigator
- Chief Investigator (only if no local PI)
- Project manager (if appropriate)

Work Instruction 4

Updating SReDA with LoA information

On SReDA, select the Stakeholders tab under Study Details. Select the appropriate investigators name, once in the investigators details, then select Honorary Contract and Courses. Add new honorary contract details and enter the start date and end date of the letter of access, the employer of the researcher and update the notes to reflect Letter of Access.

Once you have updated the researcher's details, you will then need to update the Project Reminders under the Governance tab. The following details will be used to add an impending project report.

- Licence - NHS Ayrshire & Arran
- Attention Of - Leave Blank
- Project Notes Title - Check LoA for XXXX
- Due Date – a month prior to LoA expiring

Save Project, Project Notes.

Periodically someone would go into SReDA and run a report on LoA that are due to be renewed. Appendix 2 would be used for LoA expiring and appendix 3 for those that have already expired.

Appendix 1

Table 1 – RESEARCH PASSPORT ALGORITHM

Version 3.0, September, 2012

Activity	Criminal record check necessary? ³	Occupational Health Clearance Necessary?	LOA or HRC
Researcher is a health care professional ⁴ providing health care ⁵ 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 health care to an adult and/or child under the direction or supervision of a health care 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 or 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 unsupervised: teach, train, instruct, care for or supervise children, or provide advice/guidance on well-being, or drive a vehicle only for children; with likely direct bearing on the quality of care ⁶ .	Yes, if done regularly this is Regulated Activity. 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 (formerly 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 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).	Yes, standard	Yes, if there is direct contact	LoA

Algorithm continues on the next page

Table 1 – RESEARCH PASSPORT ALGORITHM

Version 3.0, September, 2012

Activity	Criminal record check necessary? ^d	Occupational Health Clearance Necessary?	LOA or HRC
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)

Appendix 2

Email template for LoA due to expire

Dear XXXX

INSERT R&D PROJECT NUMBER AND TITLE

According to our records your letter of access for the above study is due to expire on **(INSERT DATE)**.

Can you please advise us if you will have completed your involvement in the study by this date and if not an email along with your updated research passport is required to be submitted to R&D to request an extension to your letter of access.

Kind regards
XXXX

Appendix 3

Email template for LoA that has expired

Dear XXXX

INSERT R&D PROJECT NUMBER AND TITLE

According to our records your letter of access for the above study expired on **(INSERT DATE)**.

I would be grateful if you could please let us know the status of the study and your involvement with it?

If the study has finished can you please complete the attached Research & Development final report template and submit it to us.

If the study is on-going an email along with your updated research passport is required to be submitted to R&D to request an extension to your letter of access and please advise us of the new expected study end date.

Kind regards
XXXX