STANDARD OPERATING PROCEDURE FOR RESEARCH PASSPORTS, HONORARY RESEARCH CONTRACTS AND LETTERS OF ACCESS

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1. PURPOSE

This document describes the processes relating to the use of Research Passports and the issuing of Honorary Research Contracts (HRC) and Letters of Access (LoA) to be used by researchers in NHS Fife and the NHS Fife R&D Approvals Team.

It is the responsibility of all staff and researchers using this SOP to ensure they are using the latest version of it. The latest version is available via StaffLink, the R&D section of the NHS Fife website (www.nhsfife.org/research) and EDGE (https://www.edge.nhs.uk). For guidance, contact the R&D Department via fife.randd@nhs.scot

2. APPLICABILITY

This SOP applies to all staff who need to apply for a Research Passport, an HRC or LoA to gain permission to undertake research in NHS Fife and to those staff who will prepare these documents.

3. POLICY

3.1 Research within NHS Fife is often undertaken by NHS staff not directly employed by NHS Fife, or by non-NHS staff, particularly researchers employed by universities. This raises issues about responsibility, accountability, patient safety and duty of care. Research is also frequently undertaken across a number of NHS organisations and requires arrangements for both NHS and non-NHS staff to work across those organisations.

3.2 The Research Governance Frameworks require all parties undertaking research within the NHS to be clear about responsibilities and liabilities. One of the ways this is achieved is through using HR procedures appropriately and the 'Research in the NHS – HR Good Practice Resource Pack' (https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx) has been developed by the UK Health Departments to help the NHS and other research employers take a consistent approach to handling HR arrangements for those undertaking research in the NHS.

3.3 The 'Research in the NHS – HR Good Practice Resource Pack' consists of:

- a Research Passport system for Higher Education Institution (HEIs) researchers who need to undertake their research within NHS organisations
- standardised procedures for issuing Honorary Research Contracts (HRCs) or Letters of Access (LoAs), in line with the nature of the researchers' activity, and the NHS and / or employer's responsibility for that activity

- standardised procedures for handling HR arrangements for NHS and HEIs researchers who need to work across one or more NHS organisations

3.3 In the event that it is discovered that an investigator requiring an HRC or LoA is carrying out work within NHS Fife without the appropriate document, their activity must be suspended until it can be issued. The R&D Office, responsible HR officer and Medical Director may also need to determine whether the person in question has been acting fraudulently, if they should in fact be allowed to continue with the study, and if there is any further action to be taken.

4. PROCEDURE

4.1 The primary contact for researchers who wish to carry out study activities within Fife is the R&D Approvals Team in the Research & Development Department (fife.fiferesearchapprovals@nhs.scot).

4.2 The R&D Approvals Team must establish the employment status of any researcher wishing to carry out study activities within Fife and assess whether they need an HRC or LoA. This assessment will be completed following the guidance available from the 'Research Passport: Algorithm of Research Activity and Pre-Engagement Checks within the 'NIHR HR-Good-Practice-Resource-Pack' available via the IRAS website: https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#Documents-HR-Good-Practice-Resource-Pack

If the study is multi-centre and being co-ordinated by National Research Scotland Permissions Coordinating Centre (NRSPCC), the Generic Reviewer may make these assessments on behalf of the other sites.

https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#Documents-HR-Good-Practice-Resource-Pack

4.3 If a researcher has either an Honorary Clinical Contract or a Substantive Contract with another NHS organisation then an HRC or LoA may not be required. In these circumstances the researcher must provide the R&D Approvals Team with the following documentation so that their requirements can be assessed:

- R&D reference number(s) for the projects they are involved in
- 'NHS to NHS Confirmation of Pre-engagement Checks' form available from the IRAS website: https://www.myresearchproject.org.uk/help/help%20documents/NHS-to-NHS-confirmation-of-pre-engagement-checks.doc.
- CV (signed and dated within the last 2 years)
- GCP certificate (where appropriate and completed within the last 2 years)

4.4 For researchers without an Honorary Clinical Contract or a Substantive Contract with another NHS organisation either an HRC or LoA is required. The process for obtaining this is via the Research Passport (https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx) which should be prepared and signed off by the Lead R&D Office. This can then be submitted to any other relevant R&D for processing. Processing involves brief

review of the Research Passport, ensuring that Fife details are included where necessary within the Passport Appendix. Section 8 should also be completed for each NHS R&D Office receiving the valid Research Passport Form and added to the original Research Passport. This page plus the HRC letter or Letter of Access is then sent to the Assistant R&D Director for signing.

4.4.1 Where an HRC or LoA is required and the researcher already has a Research Passport then the researcher must provide the R&D Approvals Team with the following documentation:

- R&D reference number(s) for the projects they wish to be involved in
- Copy of Research Passport
- CV (signed and dated within the last 2 years)
- GCP certificate (where appropriate and completed within the last 2 years)

4.4.2 Where an HRC is required and the researcher does not already have a Research Passport then the R&D Approvals team must liaise with the NHS Fife Human Resources (HR) Department to facilitate the issue of the HRC.

The researcher must provide the R&D Approvals Team with the following documentation:

- R&D reference number(s) for the projects they wish to be involved in
- Completed Research Passport Application Form
- CV
- GCP certificate (where appropriate)
- PVG*
- Occupational Health Clearance Certificate*

**The R&D Approvals Team will seek advice from HR if required and advise the applicant if they need to provide a criminal record disclosure application or any other additional documents e.g. Protection of Vulnerable Groups (PVG) Scheme Record information. The documents required will be dependent upon the proposed research and the research population being investigated (see 4.4.4 below)*

4.4.3 If a LoA is required then this can be processed immediately (as detailed above) by the R&D Approvals Team and signed off by the Assistant R&D Director.

4.4.4 Protection of Vulnerable Groups (PVG) Scheme

If a researcher is undertaking 'regulated work' with children or adults or both, they will need to become a PVG Scheme member in respect of the appropriate group. If a researcher has patient contact, but this falls outside the scope of regulated work, then a Standard Disclosure would be required.

Not all researchers will require PVG Scheme Membership/Standard Disclosure (see published algorithm on IRAS website):

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

Where a research study is multi-centre, the researcher's lead Health Board/other Health Boards does not have to request a PVG Scheme record update when preparing the research passport, as the substantive employer will be in receipt of any changes from Disclosure Scotland.

Relevant Scottish and UK Government Departments dealing with disclosure are:

- Disclosure Scotland: http://www.disclosurescotland.co.uk/basicdisclosureonline/index.htm
- Disclosure and Barring Service (DBS): https://www.gov.uk/government/organisations/disclosure-and-barring-service

4.5 It is the Sponsor's responsibility to inform the R&D office if a researcher leaves the project and therefore should have their HRC/LoA cancelled, or if a new member joins the team and requires an HRC/LoA. Should a study be extended beyond the original end date, an HRC/LoA can also be extended, or a new one issued if required.

5. REFERENCES

UK Policy Framework for Health and Social Care Research (2017)
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Protection of Vulnerable Groups (Scotland) Act 2007

HR Good Practice Resource Pack and Research Passport Algorithm
https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#Documents-HR-Good-Practice-Resource-Pack

6. ABBREVIATIONS

CV	Curriculum vitae
DBS	Disclosure and Barring Service
GCP	Good Clinical Practice
HR	Human Resources
HRC	Honorary Research Contract
LoA	Letter of Access
NRSPCC	National Research Scotland Permissions Coordinating Centre
PVG	Protection of Vulnerable Groups
R&D	Research and Development
SOP	Standard Operating Procedure

7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Allyson Bailey R&D Commercial Manager	30/03/2015	New
2	Julie Aitken R&D Trials Facilitator	08/06/2018	Revised for clarity and to reflect current practice.
3	Aileen Yell R&D Research Coordinator	15/04/2021	Format updated in line with current SOP template and text updated to clarify the process. Reference to Research Governance Framework updated to UK Policy Framework for Health and Social Care Research.

8. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research, Development & Innovation Director, NHS Fife Signature: 	15 April 2021