1. PURPOSE

This document provides guidance on the use of Research Passports, Honorary Research Contracts (HRC) and Letters of Access (LoA) in NHS Fife. It provides a clear process and route for any researcher requiring either type of contract/letter from NHS Fife.

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 the Research & Development pages on the NHS Fife Intranet (www.nhsfife.org/research) or for guidance, contact the R&D Office (fife-uhb.randd@nhs.net).

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. Refer to Section 4 (Procedure) to identify which categories of researcher need an HRC and which categories need a LoA.

The primary contact for researchers wishing to apply for a Research Passport, an HRC or LoA is the Research Coordinator in the Research & Development Department in NHS Fife. The R&D Research Coordinator will liaise with the NHS Fife Human Resources (HR) Department to facilitate the issue of HRCs, whereas LoAs can be processed immediately in the Research & Development Department and signed off by the Assistant R&D Director.

3. POLICY

3.1 All staff involved in health and social care research using NHS patients, their tissues, samples or data, must be employed by or have an honorary contract with the NHS organisation. This is for three main reasons:

1. The organisation must be aware of and have knowledge of all individuals who may have contact (direct or indirect) with their patients.
2. The organisation must ensure that the appropriate security checks have been carried out before an individual can have direct or indirect contact with patients.
3. The organisation must ensure that any individual who may have direct or indirect contact with patients is qualified to do so.

An investigator who is not employed by or holding an honorary clinical contract with the NHS, who wishes to undertake research involving patients, their tissue, samples or data, can be given an HRC to cover these activities. An HRC permits an individual to conduct work in an organisation other than their employing organisation - the HRC does not constitute an employment contract.

In certain cases an investigator may require a LoA rather than a full HRC. Many of the requirements and procedures are the same, and the two are treated similarly throughout this SOP.

The Research Passport scheme streamlines procedures for university researchers and for R&D Offices when working with HRCs or LoAs. Use of the Research Passport means that if a researcher is working across multiple NHS sites, or on multiple studies, the pre-engagement checks are done once by the university and the lead NHS site and all other sites accept the evidence of this provided in the Research Passport.

4. PROCEDURE

4.1 The R&D Research Coordinator must establish the employment status of any researcher carrying out study activities within Fife and determine whether they need an HRC or LoA. If the study is multi-centre and being co-ordinated by National Research Scotland Permissions Coordinating Centre (NRSPCC), the Generic Reviewer may make these identifications on behalf of the other sites.

The requirement for an HRC or LoA is determined by the researcher’s current contractual status and the type of contact/activity they will be undertaking within NHS Fife. This is illustrated in Appendix 1.
4.2 The applicant may also need a criminal record disclosure application or to provide additional documents, including Protection of Vulnerable Groups (PVG) Scheme Record information. The applicant will have to obtain the disclosure documents from their employer’s HR Department. The documents required are dependent upon the proposed research and the research population:

- 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 NIHR website):
- 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](http://www.disclosurescotland.co.uk/basicdisclosureonline/index.htm)
- Disclosure and Barring Service (DBS):

4.3 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.

4.4 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.

5. ASSOCIATED DOCUMENTS

Appendix 1 - External Researchers Flowchart

Appendix 2 - Research Passport Algorithm
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. REFERENCES

National Institute for Health Research (NIHR)
http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

Research Governance Framework for Health and Community Care (version 2, 2006)

Protection of Vulnerable Groups (Scotland) Act 2007.

NIHR Research Passports:

Research Passport Algorithm
Appendix 1

DOCUMENTATION REQUIRED FOR EXTERNAL RESEARCHERS

- Honorary Clinical Contract with another NHS organisation
  - NHS to NHS' pre-engagement checks form, CV, GCP certificate (if judged necessary) and R&D reference number(s)

- Substantive Contract with another NHS organisation

**NO** contractual relationship with the NHS:

**Research Passport and *HRC or *LOA - REQUIRED**

*HRC or *LOA dependent upon impact on patient care

**YES**

Does the applicant already have a Research Passport?

**REQUuired:**

- Copy of Research Passport, CV, GCP certificate (if required) and R&D reference number(s)

**NO**

Research Passport Application Form, CV, and R&D reference number. PVG, GCP certificate and Occupational Health Clearance Certificate if required.
## Appendix 2

**Research Passport Algorithm**

<table>
<thead>
<tr>
<th>Activity</th>
<th>LGA or HRC</th>
<th>HRC</th>
<th>LA</th>
<th>OCC</th>
<th>Direct Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher provides health care to an adult and/or child</td>
<td>Yes, if there is direct contact</td>
<td>Yes, if there is direct contact</td>
<td>Yes, if there is direct contact</td>
<td>Yes, if there is direct contact</td>
<td>No</td>
</tr>
<tr>
<td>Researcher provides health care to an adult or child under the direction or supervision of a healthcare professional</td>
<td>Yes, if done once in a Routine Activity</td>
<td>Yes, if done once in a Routine Activity</td>
<td>Yes, if done once in a Routine Activity</td>
<td>Yes, if done once in a Routine Activity</td>
<td>No</td>
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<td>Yes, if done once in a Routine Activity</td>
<td>No</td>
</tr>
<tr>
<td>Researcher has access to personal health information in the course of their normal duties</td>
<td>Yes, if done once in a Routine Activity</td>
<td>Yes, if done once in a Routine Activity</td>
<td>Yes, if done once in a Routine Activity</td>
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<td>No</td>
</tr>
</tbody>
</table>

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*Please refer to [Web link] for more information on specific activities which are eligible for CRB checks.*

*The Research Passport Algorithm and the Engagement Checks in the NHS are Good Practice Resource Pack.*
### Table 1 – RESEARCH PASSPORT ALGORITHM

<table>
<thead>
<tr>
<th>Activity</th>
<th>Occupational Health Clearance Necessary?</th>
<th>LOA or HRC</th>
<th>Criminal record check necessary?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher has direct 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 research in health records, tissues or organs with a likely direct bearing on the quality of care)</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Researcher requires access to identifiable patient data derived from health records, tissues or organs with a likely direct bearing on the quality of care</td>
<td>Yes</td>
<td>Only reviewed in NHS facilities</td>
<td>No</td>
</tr>
<tr>
<td>Researcher requires access to identifiable patient data derived from health records, tissues or organs only (including by research staff working on NHS premises or a laboratory)</td>
<td>Yes</td>
<td>Only reviewed in NHS facilities</td>
<td>No</td>
</tr>
<tr>
<td>Researcher requires access to identifiable data on staff only</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Researcher requires access to identifiable staff data only</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Appendix 2 (cont)