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

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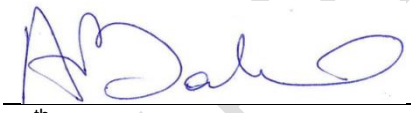
Signature	
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DOCUMENT HISTORY

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1.0	Allyson Bailey	30/03/2015	New
2.0	Julie Aitken R&D Trials Facilitator	08/06/2018	Revised for clarity and to reflect current practice.

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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 about 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.

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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): http://www.nihr.ac.uk/documents/policy-and-standards/Faster-easier-clinical-research/Research-passports/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf (Appendix 2).
- 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

4.3 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

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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)
http://www.cso.scot.nhs.uk/wp-content/uploads/2013/02/RGF-Second-Edition-February-06.pdf.

Protection of Vulnerable Groups (Scotland) Act 2007.

NIHR Research Passports:
http://www.nihr.ac.uk/policy-and-standards/research-passports.htm.

Research Passport Algorithm
http://www.nihr.ac.uk/documents/policy-and-standards/Faster-easier-clinical-research/Research-passports/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf.

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Appendix 1

DOCUMENTATION REQUIRED FOR EXTERNAL RESEARCHERS

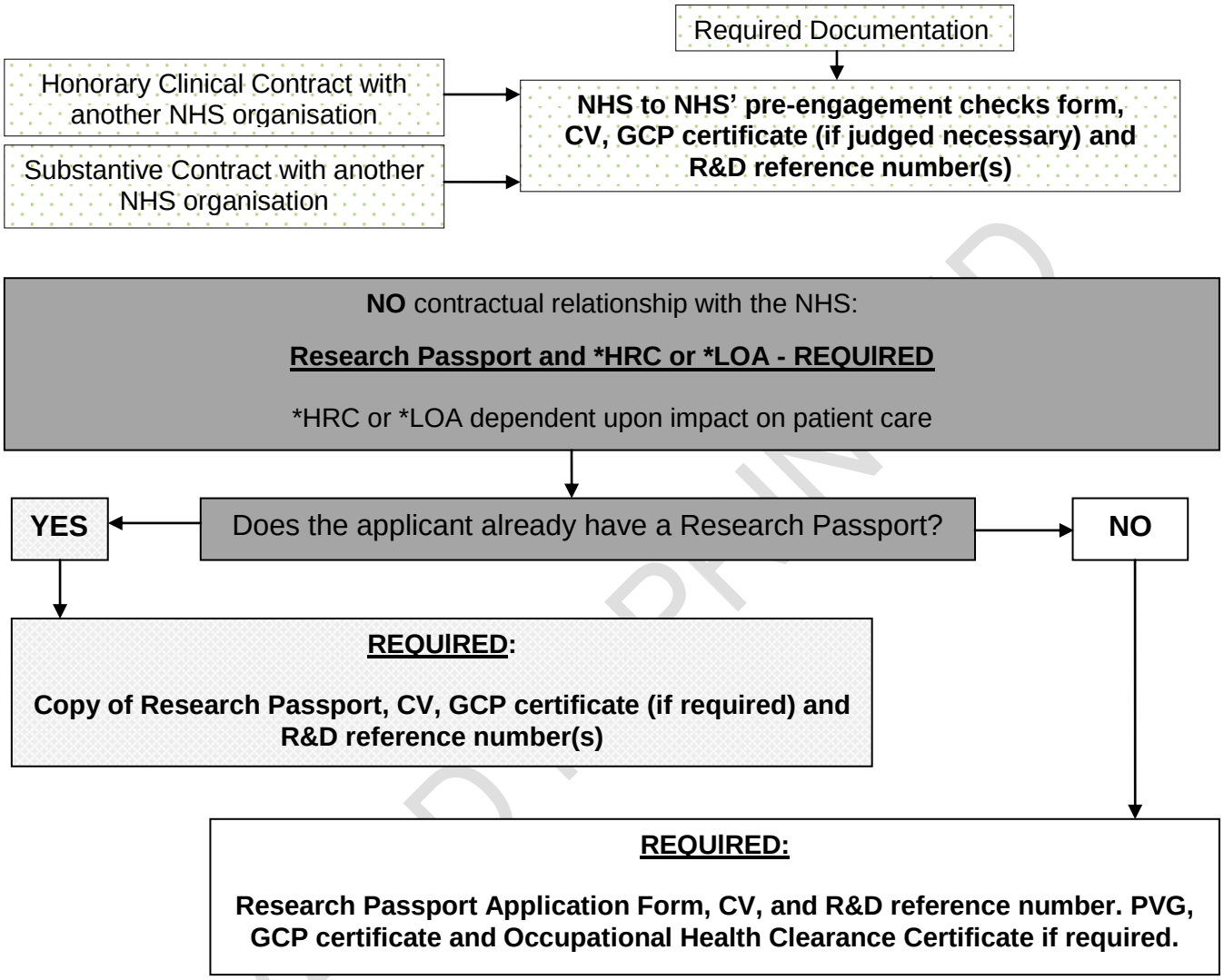

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Table 1 – RESEARCH PASSPORT ALGORITHM Version 3.0, September, 2012

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

Algorthim continues on the next page

[3] Please refer to http://www.crb.homeoffice.gov.uk/guidance/rb_guidance/eligible_posts.aspx for guidance on specific activities which are eligible for CRB checks.
[4] "health care professional" means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002.
[5] "Health care" includes all forms of health care provided for individuals, whether relating to physical or mental health and also includes palliative care and procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition.
[6] A "direct bearing on the quality of care" suggests that the actions of researchers could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to an individual to whom the organisation has a duty of care.

Appendix 2 (cont)

Version 3.0, September, 2012

Table 1 – RESEARCH PASSPORT ALGORITHM

Activity	Criminal record check necessary?[3]	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)

The NIHR Comprehensive Local Research Networks (CLRNs) are supporting the implementation of this guidance across HEIs and the NHS in England. If you have any questions, in the first instance, please contact the Lead RM&G Manager of your local CLRN. Further information is also available from Jacqueline Mathews, NIHR Clinical Research Network Coordinating Centre at jacqueline.n.mathews@nihr.ac.uk.