

Livewell Southwest

Research Passport Policy

Version No 1:5
Review: September 2017

Notice to staff using a paper copy of this guidance

The policies and procedures page of Intranet holds the most recent version of this guidance. Staff must ensure they are using the most recent guidance.

Author: Professional Lead

Asset Number: 764

Reader Information

Title	Research Passport Policy v1:5
Asset Number	764
Rights of Access	Public
Type of Formal Paper	Policy
Category	Corporate
Format	Word Document
Language	English
Subject	Research Passport Policy and Process Description
Document Purpose and Description	Guide for the appropriate use of Research Passports, Honorary Research Contracts and Letters of Access for researchers external to Livewell Southwest whose research will take place within Livewell Southwest
Author	Peninsula Comprehensive Local Research Network Assistant Research Manager.
Ratification Date and Group	17 th September 2014. Policy Ratification Group.
Publication Date	31 st August 2016
Review Date and Frequency of Review	17 th September 2017 Three years after publication, or earlier if there is a change in evidence.
Disposal Date	The Policy Ratification Group will retain an e-signed copy for the archive in accordance with the Retention and Disposal Schedule, all copies must be destroyed when replaced by a new version or withdrawn from circulation.
Job Title of Person Responsible for Review	Professional Lead
Target Audience	Livewell Southwest Human Resources staff, Research and Development Staff and Researchers whose activity will take place within Livewell Southwest.
Circulation List	Electronic: Plymouth Intranet and LSW website Written: Upon request to the Policy Ratification Secretary on ☎ 01752 435104. Please note if this document is needed in other formats or languages please ask the document author to arrange this.
Consultation Process	Consultation took place with the Human Resources Directorate, key Human Resources staff responsible for the processing of honorary research contracts and the Head of Clinical Effectiveness and Research.
Equality Analysis Checklist completed	Yes
References/Source	The Research Passport Scheme is a national scheme and documents used to inform this policy can be found on http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx
Associated Documentation	<ul style="list-style-type: none"> Equality and Diversity Policy

	<ul style="list-style-type: none"> • Protection of Freedoms Bill (as a result of the review of the Vetting and Barring Scheme) • Guidance Note: Clarification of Disclosure and Barring Service http://LSWnet.derriford.phnt.swest.nhs.uk/Portals/3/Documents/Guidance%20Notes/Guidance%20Note%20-%20DBS%20CHECKS%20v1.pdf • Honorary Contracts Policy • National Institute for Health Research: various guidelines to support research practice http://www.crn.nihr.ac.uk/learning-development/
Supersedes Document	V.1.4
Author Contact Details	By post: Local Care Centre Mount Gould Hospital 200 Mount Gould Road Plymouth Devon PL4 7PY Tel: 0845 155 8085 Fax: 01752 272522 (LCC Reception)

Document Review History

Version No.	Type of Change	Date	Originator of Change	Description of Change
0.1	New document	July 2009	Peninsula Comprehensive Local Research Network Assistant Research Manager	
1.		Sept 09	Approved at Policy Ratification Group.	
1.1	Updates	Sep 11	Peninsula Comprehensive Local Research Network Assistant Research Manager	Policy updated to reflect review of Vetting and Barring Scheme and to refer policy users to the most up to date information on the NIHR website
1.2	Extended	Nov 13	Professional Lead	Extended no other changes.
1.3	Extended	June 2014	Deputy Director of Professional Practice, Quality and Safety	Extended no other changes.
1.4	Minor amendments	September 2014	Professional Lead	Updating to Plymouth Community Healthcare ownership and branding. Streamlining of application processes – now held within

				partner organisation.
1.5	Minor amendment	August 2016	PRG Secretary	Extended and updated to LSW.

Contents		Page
1	Introduction	5
2	Purpose	6
3	Duties	6
4	Definitions	7
5	Process for delivering research passports/letters of access/ honorary contracts	7
6	Monitoring Compliance and Effectiveness	8

Research Passport Policy

1 Introduction

- 1.1 This policy implements the NHS Research Passport Scheme, introduced by the UK Clinical Research Collaboration (UKCRC) to streamline NHS approval for clinical access by non-NHS researchers. Procedures are included for its implementation in Livewell Southwest, and for new arrangements for governance of access to Livewell Southwest facilities, staff and service users for all health researchers.
- 1.2 Research is an integral part of healthcare activity.
- It identifies innovative ways of preventing, diagnosing and treating illness.
 - It provides information on the costs, effectiveness and broader impact of health technologies.
 - It provides the evidence base for the organisation, management and delivery of healthcare services to increase the quality of patient care, ensure better patient outcomes and contribute to improved population health.
- 1.3 The UK Clinical Research Collaboration (UKCRC) is a partnership of organisations working to establish the UK as a world leader in clinical research, by harnessing the power of the NHS. It is working to promote a streamlined regulatory and governance environment that facilitates high-quality clinical research while protecting the rights, dignity and safety of patients. As part of its activities, it has coordinated the development of a Good Practice Resource Pack to help the NHS and other research employers take a consistent approach to handling Human Resources arrangements for those undertaking research in the healthcare. The Pack forms the basis for this policy, and is available on the National Institute for Health Research Website (http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx).
- 1.4 Research within healthcare relies on working in partnership with the Higher Education sector and is often undertaken by non-clinical staff, including staff employed by Higher Education institutions. This relationship calls for a clear understanding about responsibility, accountability, patient safety and duty of care. The Research Governance Frameworks published by the UK health departments require all parties undertaking research within healthcare to be clear about responsibilities and liabilities. One of the ways this is achieved is through appropriate use of honorary research contracts.
- 1.5 Inconsistency and the lack of clear guidance about the requirement for honorary research contracts have meant that they have been issued inappropriately in parts of the NHS. Where they have been underused, this has resulted in lack of clarity about liability. Where they have been overused, this has not only wasted the resources and time of the Human Resources, Research and Development (R&D) departments and researchers themselves, but has also placed inappropriate liability on NHS organisations as well as putting potential strain on working relationships.
- 1.6 Livewell Southwest is a partner in the UK Clinical Research Network via its contract with the Peninsula Comprehensive Local Research Network (PenCLRN). Livewell Southwest has agreed in this contract to implement the Research Passports

Scheme. The CLRN's Lead Research Management and Governance Manager is supporting R&D Managers across NHS organisations in PenCLRN to adopt an approach to implementation that is as uniform as possible to reduce inconsistencies and ensure a smooth process for healthcare access for researchers.

2 Purpose

- 2.1 This policy and procedure applies to all R&D conducted by individuals whose substantive employment is external to Livewell Southwest.
- 2.2 The primary objective is the implementation of the Research Passports Scheme via the adoption of the Good Practice Resource Pack.

3 Duties

3.1 Livewell Southwest Board is responsible for:

- Ensuring the implementation and the requirements outlined within this Policy are observed and will receive regular Performance Reports from the Governance Directorate.
- Ensuring their individual Directorates and Localities are made aware of the policy and their responsibilities within it and that staff are appropriately trained.

3.2 The Governance Directorate is responsible for:

- Providing a single point of contact for externally employed individuals seeking to conduct research in Livewell Southwest.

3.3 The Human Resources Directorate is responsible for:

- Ensuring appropriate pre-engagement checks are completed for external researchers, in order to complete a research passport, when Livewell Southwest is the first healthcare organisation approached by the researcher.
- Ensuring that procedures for pre-engagement checks enable the research process.
- Ensuring that all Honorary Research Contracts (HRC) and Letters of Access are regularly reviewed to ensure that the period of cover has not expired for the respective researchers.
- Training Human Resources staff within Livewell Southwest to ensure compliance with the Research Passports Policy.
- Working with the Governance Directorate to ensure audit compliance with this policy.

4 Definitions

- 4.1 The **Research Passport** is a standard pack of forms for each researcher which

provides evidence of one set of checks on a researcher conducting research in healthcare. The form is completed by the researcher and her/his employer, and validated by the provider organisation. The completed Research Passport is presented to all the relevant healthcare organisations in order for an honorary research contract to be issued rapidly, with no duplication of checks.

- 4.2 The **Honorary Research Contract (HRC)** is between the healthcare organisation and the employer of the Researcher. It allows the Researcher access to Livewell Southwest premises, patients, clinical samples and clinical personal information.
- 4.3 A **Letter of Access** will be issued to those who do not require an Honorary Research contract. The standard letter concerns responsibilities of such Researchers and may be used for one project or a series of projects. PenCLRN (contact details below) will quality assure the letter of access for the researcher but the researcher will still need to seek permission from the healthcare provider (in this case, Livewell Southwest (CIC) for access).
- 4.4 **HEIs**- Higher Education Institutions

5 Process for delivering Research Passports/Letters of Access/ Honorary Contracts

- 5.1 Implementation of the Research Passports Policy must comply with anti-discrimination legislation and particular care should be taken not to include discriminatory conditions or requirements in relation to age, colour, disability or illness (including HIV/AIDs) ethnic origin, gender, marital status, nationality, race religion or belief, sexual orientation or social background.
- 5.2 **Please note that all documents referred to that are highlighted in bold are found on http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx. Copies of the forms and documentation have also been provided to the relevant Human Resources department.**
- 5.3 The procedure for an external researcher to gain access to Livewell Southwest for research will vary depending on the researcher's employment status, and the nature of the project. For all requests for access, the Governance Directorate will be the first point of contact.
- 5.4 The researcher will provide a full protocol for their research project together with details of their employment status. Research Management and Governance is provided by the Peninsula Comprehensive Local Research Network: contact details are provided here:
http://www.crncc.nihr.ac.uk/about_us/ccrn/peninsula/rmg/rmg_contacts

PenCLRN provides signposting to assist the local research community in improving communication and navigating around the many changes happening within Research Management & Governance (RM&G) including:

- Research approvals in the NHS using the National Institute for Health Research (NIHR) Co-ordinated System for Gaining NHS Permission (CSP).

- Using the Integrated Research Application System (IRAS) to submit your research application.
 - Requests for honorary research contracts using the Research Passport scheme.
- 5.5 Researchers with a substantive employment contract with one NHS organisation do not need an honorary research contract to conduct research in another NHS organisation. As a social enterprise, Livewell Southwest will normally accept an existing NHS contract of employment, but additional pre-engagement checks may occasionally be required. A **letter of access** should be issued, which details the researcher's responsibilities.
- 5.6 Researchers with no contractual relationship with Livewell Southwest or other NHS Providers require an honorary research contract only if the planned activities of the researcher involve interacting with individuals in a way that has a direct bearing on the quality of their care, i.e. the researcher could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to patients or service users to whom Livewell Southwest has a duty of care.
- 5.7 Substantive employers (usually HEI's) retain responsibility for other research activities that do not affect the healthcare organisation's duty of care.
- 5.8 Honorary research contracts do not provide a mechanism for access to confidential patient information without consent.
- 5.9 Researchers who do not require an honorary research contract may require additional pre-engagement checks to undertake permitted research activities in healthcare organisations.
- 5.10 All external researchers will have an identified Livewell Southwest Manager providing managerial supervision for their healthcare activities.
- 5.11 Disclosure and Barring Service (DBS) checks will be accepted as part of the Research Passport as a valid pre-engagement check up to a maximum of three years since the last check was completed. It is expected that where research involves Livewell Southwest's service users they will be considered a vulnerable group, so that enhanced DBS checks will be the normal requirement.

6 Monitoring Compliance and Effectiveness

- 6.1 **The Policy Author will be required to outline the process to monitor compliance with and the effectiveness of the document they have developed, including:**
- Details of audits, review, survey, etc.
 - Responsibilities for conducting the monitoring/audit.
 - Methodology to be used for monitoring/audit.
 - Frequency of monitoring/audit.
 - Process for reviewing results and ensuring improvements in performance occur.

All policies are required to be electronically signed by the Lead Director. Proof of the e-signature is stored in the policies database.

The Lead Director approves this document and any attached appendices. For operational policies this will be the Locality Manager.

Signed: Director of Professional Practice, Quality & Safety.

Date: 18 September 2014