GIG CYMRU NHS WALES Bwrdd Iechyd Prifysgol Caerdydd a'r Fro Cardiff and Vale University Health Board	**Reference Number: UHB 146** **Version Number: 3.0** **Date of Next Review: 30 Apr 2022** **Previous Trust/LHB Reference Number: N/A**

RESEARCH AND DEVELOPMENT
HUMAN RESOURCES ARRANGEMENTS FOR RESEARCHERS WORKING IN THE NHS (GUIDELINES)

Introduction and Aim

The Research Passport (RP) System has been developed to provide a mechanism for assuring NHS organisations of the pre-engagement checks conducted on a researcher, thus reducing duplication of checks for researchers working across a number of NHS institutions. This provides a common approach towards issuing NHS honorary research contracts and letters of access for researchers who are not NHS employees.

Objectives

- To ensure that all staff undertaking research activities in the UHB have appropriate pre employment checks and are issued with the appropriate documentation to allow access to NHS resources.
- To reduce duplication of checks for researchers working across a number of NHS institutions

Scope

These HR arrangements apply to all researchers wishing to conduct research in Cardiff & Vale UHB who do not hold a substantive contract with this organisation, and all researchers employed by Cardiff & Vale UHB who wish to undertake research activities in another NHS organisation.

Equality Impact Assessment	An Equality Impact Assessment has not been completed for this procedure. 'This is because this procedure has been written to support the implementation the Research Governance Policy (UHB 099). The Equality Impact Assessment completed for the policy found there to be no impact.
Documents to read alongside this Procedure	Research Governance Policy (UHB 099)
Approved by	Research Governance Group
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Governance Officer Human Tissue Act – Research

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	03/07/2012	15/11/2012	New Guideline
2.0	14/04/15	27/05/15	SOP reviewed at review date and put into new UHB format References to CBS updated to DBS References to Research in the NHS – HR Good Practice Resource Pack updated to (Version 2.1, September, 2012) Section 5.1 updated in light of researcher feedback and delays in issue of LoA/HRC.
1.1	17/07/18	25/07/18	Changed 'Research Governance Framework' references to 'UK Policy Framework for Health and Social Care
3.0	30/04/2019	11/06/2019	Confusion over version numbers occurred during routine document updating. V1.1 accidentally omitted section 4.6. V3.0 simply merges the content of v1.1 and v2.0. No new or amended content has been included.

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1. Introduction

Research in NHS settings often relies on working in partnership with the Higher Education sector and other organisations. This raises a number of Human Resources (HR) management issues for NHS organisations, as research is often undertaken by NHS staff not directly employed by the host NHS organisation, or by non-NHS staff from Universities and other external organisations. Both NHS and non-NHS staff may also be required to work across a number of NHS organisations.

The UK Policy Framework for Health and Social Care Research requires all parties undertaking research within the NHS to be clear about responsibilities and liabilities. One of the ways that this is achieved is through using HR procedures consistently and appropriately.

2. Scope

These HR arrangements apply to all researchers wishing to conduct research in Cardiff & Vale UHB who do not hold a substantive contract with this organisation, and all researchers employed by Cardiff & Vale UHB who wish to undertake research activities in another NHS organisation.

3. Background

3.1 Research in the NHS – HR Good Practice Resource Pack

The UK Health Departments are working together to promote a streamlined regulatory and governance environment that facilitates high-quality clinical research while protecting the rights, dignity and safety of patients. The National Institute for Health Research (NIHR) provides detailed advice in *Research in the NHS – HR Good Practice Resource Pack* (version 2.1, September 2012) to help the NHS and other research employers take a consistent approach to managing HR arrangements for individuals undertaking research in the NHS. This includes a number of useful documents including a guide to completing the research passport form, an algorithm of research activity and pre-engagement checks, information for researchers, Research & Development (R&D) and HR staff in Higher Education Institutions (HEIs) and the NHS, background information on principles and legal requirements for honorary research contracts, and a frequently asked questions supplement.

3.2 The Research Passport System

The Research Passport (RP) System has been developed to provide a mechanism for assuring NHS organisations of the pre-engagement checks conducted on a researcher, thus reducing duplication of checks for researchers working across a number of NHS institutions. This provides a common approach towards issuing NHS honorary research contracts and letters of access for researchers who are not NHS employees.

Researchers who are not employed in the NHS should complete a RP form to provide information about themselves, the activities they plan to undertake, and the pre-engagement checks which have been carried out by their substantive employer. This

form then provides a mechanism for obtaining an Honorary Research Contract (HRC) or Letter of Access (LoA) as appropriate depending on the nature of the proposed research activities, and can be taken to each NHS organisation where the research will be undertaken.

Researchers may request a project-specific or multi-project RP, and amendments may be added using appendices to add new projects and/or new research sites to an existing project.

The fully completed RP will provide information about

i) The researcher
ii) The nature of the research work they seek to undertake within the NHS
iii) The suitability of the researcher, as assessed by their line manager in their employing organisation
iv) Pre-engagement checks carried out by the researcher's employer
v) Evidence of these checks provided to the lead (first) NHS organisation
vi) The type of RP issued (project-specific or multi-project)
vii) Subsequent NHS organisations receiving and relying on the completed RP in order to issue HRC/LoA

The application form, once completed and signed by all parties (researcher, line manager, employer, lead NHS R&D office) is the valid passport document. This document should be returned to the researcher by the lead R&D office for use at other NHS organisations.

4. Principles

4.1 Researchers employed by HEIs

Researchers with substantive HEI employment contracts wishing to undertake research activities in Cardiff & Vale UHB should be processed through the RP system.

Where a researcher is conducting activities that will have a direct bearing on the quality of care (see appendix 1), the individual will be accountable to the NHS organisation that gave permission for this activity. An HRC should be issued to clarify and confirm this accountability.

Where a researcher is conducting activities with no direct bearing on the quality of care, the vicarious liability for the actions of the individual remains with the substantive employer. An HRC should not be issued. Researchers should be issued with a LoA.

If a researcher has already obtained a validated RP and HRC from another (lead) NHS organisation, and now needs to undertake the same research activity in Cardiff & Vale UHB, it is not necessary to issue an HRC for this organisation. Instead a LoA accepting the existing HRC should be issued.

4.2 Researchers employed as Clinical Academics

Individuals with a substantive university contract and honorary clinical NHS contract are commonly referred to as 'clinical academics'. If a clinical academic wishes to undertake research in the organisation where they undertake their clinical duties this will be covered by their honorary clinical contract. No HRC or LoA is required. When clinical academics wish to undertake research in other NHS organisations (where they do not hold an honorary clinical contract) they should be treated as a substantive NHS employee (see below).

4.3 Researchers employed by the NHS

Researchers with a substantive employment contract with one NHS organisation (including clinical academics, see above) do not need an HRC to conduct research activities in another NHS organisation. HR arrangements for such researchers are not managed through the RP scheme.

The researcher should provide confirmation of their NHS employment and pre-engagement checks using the proforma confirmation of pre-engagement checks and an NHS-to-NHS LoA should be issued.

4.4 Research involving Cardiff and Vale UHB employees as participants

All employers have a common law duty of care for the health, safety and welfare at work of all their employees. Where research involves Cardiff & Vale UHB employees as participants, the duty of care of the NHS organisation to its employees is non-delegable – Cardiff and Vale UHB will always be liable, regardless of who employs the researcher. An HRC will not affect accountability or liability and is therefore inappropriate and should not be issued.

If Cardiff & Vale UHB employees participate in research outside work, this participation is outside the employer's duty of care, even if their participation makes use of knowledge or experience gained as a result of their employment.

Research involving NHS staff as participants is not exempt from requirements for R&D approval and consideration of ethical review, and usual procedures should be followed to obtain all necessary permissions. If the research involves access to NHS facilities/premises then a LoA should be obtained by the researcher.

4.5 Research involving staff such as research nurses provided to Cardiff and Vale UHB by Contract Research Organisations (CROs), to undertake research activities in the UHB which, form part of a commercial study

In commercially sponsored trials, commercial research staff should not be given a Research Passport, or issued with an HRC or LoA or any other document that could be construed as indicating that the NHS organisation is accepting liability for their actions. With the exception of clinical study data monitors, the UKCRC model agreements do not cover issues relating to commercial organisations providing staff to undertake commercial research activities in the host NHS site (e.g. commercial research nurses). Therefore, the UHB needs to ensure that a contract for the provision of these services is put in place with the commercial organisation. This contract should address all issues relating to the activities and suitability of the commercial staff (e.g. pre-engagement check requirements, (Disclosure and Barring Service (DBS),

occupational health, professional registration, right to work, qualification etc.), training, accountability and management arrangements, insurance for negligent actions etc.).

4.6 General principles

When an HRC or LoA is issued, the researcher's substantive employer (NHS or HEI) should be informed and supplied with a copy of the HRC / LoA. Substantive employers should also be informed when a new research project is added to an existing research passport.

Researchers may sometimes require additional pre-engagement checks to undertake research activity in the NHS – this decision rests with the NHS organisation but should be commensurate with the role of the researcher and nature of the activities to be undertaken.

Inappropriate use of honorary contracts could potentially transfer to the NHS organisation liability that should be retained by the substantive employer.

Substantive employers retain responsibility for all research activities that do not affect an NHS organisation's duty of care.

The Criminal Records Bureau (CRB) and the Independent Safeguarding Authority (ISA) have merged to become the Disclosure and Barring Service (DBS). Changes to the system were included in the Protection of Freedoms Act 2012. The first changes came into effect on 10 September 2012, and include:

- a new definition of regulated activity
- repeal of controlled activity
- repeal of registration and continuous monitoring.

The HR Good Practice Resource Pack has been updated to reflect the changes. Researchers and their employers should ensure that where applicable new Research Passport applications are supported by an appropriate disclosure.

5. Procedures for researchers who do not hold a substantive NHS contract

5.1 Completing a new RP application

- Researchers should complete and sign sections 1-3 of the RP. Where a project-specific RP is required, details of the research project should be entered into section 2, including the responsible manager in each host NHS organisation. Applications for a multi-project (three-year) RP should contain details of each research project in the RP appendices. The full title of each project should be entered as it appears on the protocol and applications for R&D and REC approval.
- Section 4 of the RP should be completed and signed by the researcher's line manager / academic supervisor in their HEI / employing organisation. In relation to the NHS Manager this section is completed by the applicant. Usually it will be a substantive employee of Cardiff and Vale UHB but in the absence of this

Clinical Academics with an Honorary Clinical Contract with the UHB will be accepted.

- Section 5 of the RP should be completed by the HR Department of the employing organisation. HEI students should contact their Registry for completion of section 5. The employing organisation will request any additional checks required at this stage, for example, a DBS check. Where Disclosure information reveals that the research passport applicant has a current or spent conviction, caution, reprimand or final warning on their criminal record, the line manager/supervisor in conjunction with their Human Resources Department, must consider the following factors before a decision is made regarding supporting the research passport application:
  - Whether the conviction(s) or other matter(s) revealed is relevant to the post they have been appointed to;
  - The seriousness of the offence(s) or the other matter(s) revealed;
  - The length of time since the offence(s) or other matter(s) occurred;
  - Whether the individual has a pattern of offending behaviour or other relevant matter(s);
  - Whether the individual's circumstances have changed since the offence(s) or other relevant matter(s) occurred;
  - The circumstances surrounding the offence(s) and the explanation(s) offered by the individual;
  - Whether the individual has been disqualified from working with children.

A record of the decision made must be kept using the form at Appendix 2.

- Section 6 of the RP should be completed by the researcher.
- The RP form should then be forwarded to the R&D Office of the lead NHS organisation – this is simply the first NHS organisation to process the RP. Appropriate supporting documents should be included, for example, DBS disclosure, curriculum vitae, occupational health clearance. Where Appendix 2 is forwarded with the RP form, then the R&D Senior Management Team will consider the application in conjunction with Cardiff and Vale UHB Human Resources Manager and make a decision as to whether an HRC/LoA may be processed.
- The R&D Office of the lead NHS organisation will complete section 7 (if additional pre-engagement checks are required) and section 8, and will arrange for an HRC/LoA (as appropriate) to be issued. The date of issue for the HRC/LoA will be entered into section 8.
- The fully validated RP form, supporting documents, and HRC/LoA will be returned to the researcher, with a copy of the HRC/LoA to the substantive employer/HEI as well as a copy to the NHS Manager indicated on the passport. The HRC/LoA will refer to the activities and timeframes outlined in the Research Passport application

5.2 Using an existing RP to work in a new NHS organisation

- The researcher should ensure that details of the new NHS organisation are entered into section 2 (for project-specific RP) or the appendices (for multi-project RP) of the RP, and an appropriate manager in that organisation is identified.

- The RP form should then be forwarded to the R&D Office of the new NHS organisation, accompanied by a copy of the HRC/LoA issued by the lead NHS organisation.
- The new NHS organisation will complete the white part of section 8, and issue an HRC/LoA as appropriate.
- The fully validated RP form, supporting documents, and HRC/LoA will be returned to the researcher, with a copy of the HRC/LoA to the substantive employer/HEI.

5.3 Amendments to a RP after an HRC/LoA has been issued

- Additional projects should be notified to the R&D Office using the RP appendices. Likewise, any new research activities to be undertaken on an existing project should be recorded here.
- The host NHS organisation may issue a new HRC if necessary, for example, if new research activities will have a direct bearing on patient care, where previous activities did not.

6. Procedures for researchers employed by the NHS (including clinical academics)

6.1 Applying for a LoA in a new NHS organisation

- The RP system should not be used for researchers holding a substantive NHS or clinical academic contract.
- Researchers should request that the HR Department of their employing NHS organisation complete a proforma confirmation of pre-engagement checks.
- The proforma confirmation of checks and a curriculum vitae should be forwarded to the R&D Office of the NHS organisation hosting the research. A covering letter should be included, identifying full details of the research project/s the researcher will be working on.
- The R&D Office will arrange for issue of an NHS-to-NHS LoA, with a copy sent to the researcher's employing NHS organisation.

6.2 Adding or amending project information on an existing LoA

- Information on new projects (or new research activities to be undertaken on existing projects) should be notified to the R&D Office of the NHS organisation hosting the research.

7. References

UK Policy Framework for Health and Social Care Research. V3.3, 07/11/17. Available from: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

National Institute for Health Research (2010). *Research in the NHS – Human Resources (HR) Good Practice Resource Pack*. [online] February 2010. Available from: http://www.nihr.ac.uk/systems/pages/systems_research_passports.aspx. [Accessed 20th June 2011]

Criminal Records Bureau CRB (2009) Code of Practice for Registered Persons and other recipients of Disclosure Information [online] April 2009. Available from: http://www.crb.homeoffice.gov.uk/PDF/code%20of%20practice.pdf [Accessed 20th June 2011

National Institute for Health Research (2010) Research in the NHS: HR Good Practice Resource Pack Frequently Asked Questions Full Supplement [online]. February 2010. Available from: http://www.nihr.ac.uk/files/research%20passport%20current/FAQs_complete_version.pdf. [Accessed 20th June 2011]

Appendix 1

Defining activities which have a direct bearing on patient care

(National Institute for Health Research. 2010) Excerpt taken from the *Research in the NHS: HR Good Practice Resource Pack Frequently Asked Questions Full Supplement* (2010)

"A researcher's activity may be deemed to have a direct bearing on the quality of patient care if:

- the researcher's activity could directly influence decisions made on:
    - a patient's access to care
    - the care pathway which the patient followed
    - the type, quality or extent of prevention, diagnosis or treatment of illness
- the researcher's action could foreseeably cause injury or loss to patients or service users to whom the NHS organisation has a duty of care, leading to a possible case of clinical negligence being made against the NHS organisation.

Examples of activities that could have a direct impact on care include:

- taking consent for an interventional study (as this will determine an individual's access to a specific treatment)
- delivering a treatment that forms part of the research study
- performing phlebotomy on trial patients (as this is an invasive procedure which could lead to injury or infection).

Activities that would not have a direct impact on care include:

- some types of interview study, where information from the study will NOT feed into the patient's care plan or decision-making in relation to the care of the patient
- undertaking the randomisation procedure to allocate trial patients to a specific treatment, as this is preceded by the consent process. Randomisation is considered a research procedure."

Appendix 2

Disclosure Record
(to be completed on receipt of Disclosure Outcome)

DBS Ref Number	
Research Passport Applicant Full Name	
Type of disclosure Undertaken	Enhanced /Standard (delete as appropriate)
Date disclosure received by employer/University registry	
Title of project(s)on passport application	
Record of decision taken, whether to support the passport application or not	
Signatures & Date	
Line Manager	
Departmental/School Manager or student supervisor	
Employing HR Department Manager	

If the decision is to support the research passport application, please forward to Research and Development Department,
2nd Floor TB2,
University Hospital of Wales,
Heath Park
Cardiff CF14 4XW