

STANDARD OPERATING PROCEDURE

RESEARCH PASSPORT S29

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Date:	8 April 2014
Date due for revision:	8 April 2017

Controlled document

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<http://ian.exe.nhs.uk/welcome/directorates/research-and-development/rd-administration/policies-procedures-guidance/>

DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless;

- A study specific SOP exists
- A departmental SOP dictates a different working practice

Once printed this is an uncontrolled document.

UNDER REVIEW

VERSION HISTORY LOG

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

VERSION	Date Implemented	Details of significant changes
V2.0	8 April 2014	Significant changes made through-out SOP in-line with changes in NIHR policy. Changed Author of SOP.

UNDER REVIEW

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1 BACKGROUND

The 'Research in the NHS: Human Resource (HR) Good Practice Resource Pack' describes the process for handling HR arrangements for researchers and provides a streamlined approach for confirming details of the pre-engagement checks they have undergone with the NHS http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx. The 'Research in the NHS: Human Resource (HR) Good Practice Resource Pack' describes the process for handling HR arrangements for researchers and provides a streamlined approach for confirming details of the pre-engagement checks they have undergone with the NHS.

The Royal Devon & Exeter NHS Foundation Trust has adopted procedures that conform to the above guidance to enable researchers to gain access to the trust for the purpose of undertaking research related activity.

2 PURPOSE

This SOP describes the process for completing the forms necessary in order to undertake research related activity in the NHS. This SOP is relevant for Higher Education Institution (HEI) staff wishing to undertake research at the RD&E and for staff members employed by another NHS Trust to undertake research related activity in the RD&E.

3 SCOPE

The Research Governance Framework for Health and Social Care published by the Department of Health requires all parties undertaking research within the NHS to be clear about their responsibilities and liabilities in relation to research. The underlying principles for issuing an honorary research contract or a letter of access are to ensure that:

- Non-NHS researchers (who have no paid contract with an NHS organisation) are contractually bound to take proper account of the NHS duty of care and to follow the requirements of research governance and other research regulations at every stage of their research process
- Research participants, researchers, services users, care/host organisations are protected
- There is a clarity in legal situation should adverse incidents occur with respect to research activity.

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

- a Research Passport system for HEI researchers who need to undertake their research within NHS organisations; and
- 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

4 RESPONSIBILITIES

Relevant documents will need to be completed by the researcher and their substantive employer in order for them to be able to use the Research Passport System. It is the responsibility of the RD&E to ensure that the relevant pre-employment checks have been completed and to determine whether a HRC or a LoA should be issued depending on the nature of the research activity

5 PROCEDURES

5.1 Researcher's Employment Status

5.1.1 Researchers with substantive NHS employment contracts

Staff with a substantive NHS employment contract with another NHS organisation wishing to conduct research in the RD&E FT as part of their NHS standard duties, or where the research will not have a direct bearing on clinical care **do not require an Honorary Research Contract**. The vicarious liability for the actions of the individual rests with the substantive NHS employer.

Activities that could have a direct bearing on the quality of care are those that 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. (The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks) details when a HRC is required:

http://www.nihr.ac.uk/files/Research%20Passport%20Current/algorithm_v3.0.pdf

Actions:

Researcher's substantive employer to complete 'NHS to NHS proforma confirmation of preengagement checks'

R&D Department:

Ensure that appropriate pre-engagement checks are in place as follows:

- Disclosure and Barring Service **check** – As per current NIHR guidelines (see Algorithm of Research Activity and Pre-Engagement Checks link above)
- Check individual's employment status from CV supplied as part of R&D approval process and 'confirmation of preengagement checks'.
- OH clearance - Research does not involve direct contact with patients (i.e working with tissues or organs) - Researcher to complete *OH Form 1*. Research involves direct contact with patients - Researcher to complete *OH Form 1* and their OH Department to complete *OH Form*.
(NB additional vaccines required by RD&E must be administered by employing organisation).
- Ensure appropriate arrangements are in place for management and supervision of research
- Issue a letter of access to the researcher (copying in employing NHS organisation). Letter to be filed in R&D Office file with copy in study file.
- ie CRB and OH checks as required.

5.1.2 **Researchers with honorary clinical contract eg clinical academics**

Researchers with an honorary clinical contract with one NHS organisation do not need additional honorary research contracts to conduct research in other NHS organisations.

Actions:

As for researchers with substantive NHS contracts

5.1.3 **Researchers with substantive university employment contracts and no honorary NHS clinical contract**

Arrangements for University employees with no NHS honorary clinical contracts differ depending on whether or not the research activities have a direct bearing on the quality of care.

The 'Research Passport Algorithm' indicates what type of pre-engagement check is needed and when it is appropriate to issue an honorary research contract. *In summary a HRC is required when research activity involves direct contact with patients/service users, children or vulnerable adults and/or has a direct bearing on the quality of care and if access to patient data is required, but only if in NHS facilities.*

Where a researcher is conducting activities that will have a direct bearing on the quality of care, the individual will be accountable to the NHS organisation that gave permission for this activity. **An honorary research contract should be issued to clarify and confirm this accountability.**

When researchers conduct activities with no direct bearing on the quality of care, the vicarious liability for the actions of the individual rests with the university substantive employer, and **an honorary research contract is not required.** **In both cases this type of researcher will be processed through the Research Passport System.**

Research Passport System

The Research Passport is a form which enables HEI employers to share pre-engagement information about their researcher with NHS organisations hosting the researcher's activity. The Research Passport scheme provides:

- clear guidance on the relevant checks required;
- a robust process for HE employers to document and evidence the checks which have been undertaken; and
- clear principles that enable NHS organisations to record and rely on those checks for the duration of the Research Passport.

For the RD&E procedures when hosting research refer to the 'Guide to Completing the Research Passport Form', and the 'Process Flowcharts on the Research Passport System' on

http://www.nihr.ac.uk/systems/pages/systems_research_passports.aspx

Once the Research Passport Form is validated, HRC or LoA will be issued depending on the nature of the research activity

- 5.1.4 Procedures for other categories of researchers, eg researchers who are contracted to provide NHS services, undergraduate or postgraduate students, researchers conducting research where the participants are NHS staff are as detailed in 'HR Good Practice: Information for researchers, R&D and HR staff in Higher Education Institutions and the NHS' on the NIHR Research Passport website.

6. FURTHER READING

NIHR Research Passport website:

http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

RD&E OH Forms 1 and 2

[R&D Policy](#)