

Research in the NHS: HR Good Practice Resource Pack

Frequently Asked Questions:
Managing and Monitoring the
Research Passport System

MANAGING AND MONITORING THE RESEARCH PASSPORT SYSTEM

1. Who should process and validate Research Passports, and then issue HRCs or LoAs for NHS organisations: R&D office staff or HR staff?

The Research Passport system relies on a combination of HR and R&D skills, where effective systems can support timely and efficient processing, and good communication. It is for local agreement within an NHS organisation how responsibility for tasks should be allocated, depending upon the resource and expertise available, to achieve the level of streamlining that the Research Passport system can provide.

In England, the Comprehensive Local Research Networks (CLRNs) of the National Institute for Health Research (NIHR) have adopted the Research Passport system as standard practice, and working procedures among local partners are being developed.

The expectation within the CLRN is that effective operating procedures to support implementation of the Research Passport system are agreed between HR and R&D departments, but that implementation is delegated to R&D departments.

2. A research nurse employed by a university needs to conduct research in a number of NHS Trusts. S/he is already undertaking this activity in one NHS Trust, who have reviewed and validated her/his Research Passport, and issued an HRC. What can the second and subsequent NHS Trusts do?

The Research Passport system is intended to streamline HR processes for researchers working across the NHS. Where NHS and HEI organisations can demonstrate that they are effectively managing and implementing the system within the UK research networks, then, following a proportionate risk assessment, an organisation can choose to accept checks carried out by others without needing to see all the original documents.

The Lead NHS organisation is responsible for reviewing the Research Passport when it is first submitted to the NHS and if it is accurately completed, for validating it by completing Section 8. Once the Research Passport is validated, subsequent Trusts can accept the checks and validation undertaken by the Lead NHS organisation. Where there is no difference in the activity that will be undertaken at each Trust, the options are as follows:-

- Requesting to see the existing HRC only
- Requesting a copy of the passport only
- Requesting the original passport only
- Requesting the original passport and photocopies of the supporting documents
- Requesting the original passport with the researcher's original copies of any supporting documentation

The second and subsequent Trusts can then either issue their own **HRC** or they can issue a **letter accepting the terms of the HRC** issued by the Trust that validated the Research Passport.

In any case, the organisation responsible for care will always retain the right to request additional information where there is uncertainty about the information received or where risk assessment indicates that this is necessary.

3. Is an HRC or LoA necessary where a university research team is undertaking university research in NHS office space? For example, when a GP practice acts as a participant identification centre (PIC) to refer patients to a university based study.

The university researchers will take consent and perform all research activities, however, the location of the research is based on the participant's preference and may include university premises, the participant's home, the town hall or sometimes the GP practice.

As outlined in paragraph 3.10.3 of the Research Governance Framework for Health and Social Care¹, HRCs are required where a researcher who is not employed by any NHS organisation interacts with individuals (to whom the NHS organisation owes a duty of care) in a way that has direct bearing on the quality of their care. Therefore, if the NHS organisation does not have a duty of care to the participants in respect of the research activity an HRC should not be issued. In this example, if the NHS organisation is simply renting or providing space to the university research team to undertake research that is the explicit responsibility of the university then it would not be appropriate to issue HRCs to the university researchers.

In addition, to the governance requirements relating to its role as a PIC, the NHS organisation will need to consider the appropriateness of and the arrangements for use of NHS premises for the research activities. In authorising the use of its facilities the NHS organisation would need to clarify issues such as the period of access, any fees and liability in relation to the use of facilities. A standard contract to cover the hire of facilities/rooms would address these issues. It would not be appropriate to issue a LoA.

From a wider governance perspective, what is really important in these situations is for the application to the Research Ethics Committee (REC) to set out clearly which organisation is the research site and what the role of the NHS is, and for the information on indemnity/insurance to be consistent with that. The REC and R&D applications should make clear:

- that NHS PICs are involved
- that the research site is non-NHS and therefore NHS indemnity does not apply
- that the university has appropriate insurance to cover the conduct of the study including any clinical interventions
- that if NHS or other premises are locations where research activities are conducted that this research remains the responsibility of the university and that appropriate contracts are in place
- that the patient information is explicitly clear about who is responsible for the research (including making sure that NHS headed paper is NOT used) and arrangements for compensation.

Where this has not been made clear in an application and incorrect information on indemnity and insurance has been provided which is uncovered by an R&D office, then a substantial amendment needs to be submitted to the REC.

4. Sometimes researchers employed by a university will conduct research with NHS organisations a long way from their university and their only contact with participants is one visit. Where the activity will require pre-engagement checks to be completed, how do we handle viewing the original criminal record disclosure or conducting occupational health checks that cannot be completed by the employer?

Where it would be difficult for a researcher to present her/his Research Passport to the NHS organisation in person, there are three options:

¹ Research Governance Framework for Health and Social Care
Department of Health, Second edition, 2005

www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf

- working through their local CLRN, the researcher can ask a Lead NHS organisation within their local network to validate their Research Passport, having viewed the original documentation and then subsequent NHS organisations can proceed as described in question 2.
- the Research Passport can be processed based on photocopies as long as the issuing of the HRC or LoA is conditional upon the NHS organisation viewing the original documents prior to the researcher conducting the research activity.
- the researcher may post the documents and request that they be posted back when they have been processed (using appropriate secure postage).

5. What monitoring systems should I put in place to support the implementation of the Research Passport system?

In relation to ensuring the Research Passport system is operated to a high standard, the systems should be developed to measure and monitor:

- Time from submission of complete application to issue of HRC or LoA
- Whether additional pre-engagement checks are being requested.

The NIHR Clinical Research Network Coordinating Centre will support CLRNs to develop appropriate information systems to monitor and report on performance management of the Research Passport system.

For management purposes, the following systems should be in place to monitor:

- the duration of the Research Passport
- the duration of the accompanying pre-engagement checks
- the duration of the HRC or LoA which have been issued following the validation of the Research Passport
- the researcher's activity as new projects are added to a Research Passport, to ensure that the original pre-engagement checks apply also to new projects, and to ensure enhanced checks are carried out if required.

The following monitoring mechanisms therefore need to be in place:

Substantive employer

- Monitoring employment contract start and end-dates
- Monitoring CRB disclosure certificate dates and triggering periodic re-checks (prior to the introduction of Independent Safeguarding Authority (ISA) registration)
- Monitoring occupational health test dates and triggering periodic re-checks/updates
- Monitoring changes in activity and triggering additional checks
- Monitoring changes in personal/professional circumstances and assessing impact on Research Passport.

Host site

- Monitoring HRC/LoA start and end-dates
- Monitoring CRB disclosure certificate dates and triggering periodic re-checks (prior to the introduction of ISA registration)
- Monitoring occupational health test dates and triggering requests for periodic re-checks/updates
- Assessing impact of changes in activity and triggering requests to substantive employer for additional checks

6. Where a researcher is recruiting through the prison healthcare service is it necessary for the healthcare provider to issue an HRC or LoA to the researcher or will the researcher's suitability be considered solely by the prison service and an equivalent document issued?

For prison research that is health related, the permission of the healthcare provider is required. This is usually the PCT and their permission is required where the research is related to the provision of care by the care organisation (i.e. where the research activity comes under the vicarious liability of the PCT). The PCT should follow its standard governance processes, which would include an assessment of the researcher's suitability. The Research Passport system or the NHS to NHS arrangements described in the HR Good Practice Resource Pack should be applied as appropriate. The PCT should issue an HRC or LoA appropriate to the nature of the research activity, which clarifies the location of the research and the accountability arrangements.

Researchers should note that it is the Prison Governor's responsibility to give final approval for the research and to allow the researcher access to the prison. The researcher can ask the prison to accept the Research Passport arrangements, whereby the researcher can provide a copy of their Research Passport and HRC or LoA to the Prison Governor. However, researchers should be aware that the decision to accept evidence of existing pre-engagement checks rests with the prison. Researchers should liaise with both the PCT and the prison at an early stage to clarify their requirements and minimise unnecessary delays. For further information about permissions for prison research, please refer to the Offender Health Research Network tool kit².

² Offender Health Research Network Toolkit, January 2010
www.ohrn.nhs.uk/toolkit/Toolkit4thEdition.pdf

List of Abbreviations

CLRN	Comprehensive Local Research Network
GP	General Practitioner
HEI	Higher Education Institution
HRC	Honorary Research Contract
HR	Human Resources
ISA	Independent Safeguarding Authority
LoA	Letter of Access
NIHR	National Institute of Health Research
NHS	National Health Service
PCT	Primary Care Trust
PIC	Participant Identification Centre
R&D	Research and Development
REC	Research Ethics Committee

References

1. Offender Health Research Network Toolkit, January 2010
www.ohrn.nhs.uk/toolkit/Toolkit4thEdition.pdf
2. Research Governance Framework for Health and Social Care
Department of Health, Second edition, 2005
www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf