Lincolnshire Community Health Services
NHS Trust

Research Passport
and
Honorary Research Contracts Policy

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Name of originator/author:	Judy Smith
Name of responsible committee/individual:	JCNC / EPG
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Target audience:	Non NHS Researchers and all staff involved in research
Distributed via:	Website

Research Passport and Honorary Research Contracts Policy

Version Control Sheet

Version	Section/Para/ Appendix	Version/Description of Amendments	Date	Author/Amended by
1		New Policy	August 2009	Judy Smith
1.1	Whole document	Policy re-aligned following implementation of Transforming Community Services agenda (TCS) and new entity.	March 2011	Rachael Ellis-Ingamells
2	Whole document	Policy updated in line with the updated National Institute for Health Research HR Good Practice Resource Pack / Formatted and E&D statement added	August 2014	Katy Ward / Lenore Couchman
2.1	Whole document	Extension Agreed	August 2016	EPG
2.2		Extension Agreed	Feb 2017	Corporate Assurance Team
3	Whole document	Policy updated in line with the updated National Institute for Health Research HR Good Practice Resource Pack / Formatted and E&D statement added	January 2017	Katy Ward
4				
5				
6				
7				
8				
9				
10				

Research Passport and Honorary Research Contracts Policy

Contents

Research Passport and Honorary Research Contracts Policy

Policy Statement

Background	The Research Passport is a document which is the mechanism for non NHS staff to obtain an Honorary Research Contract (HRC) or Letter of Access (LoA) or a Letter of Human Resources Assurance (LoHRA). This policy has been devised by the former Trent Collaborative Local Research Network, now known as the Clinical Research Network: East Midlands (CRN:East Midlands), on behalf of its member organisations to ensure that all organisations are working to the National Guidelines. Lincolnshire Community Health Services NHS Trust wishes to adopt the aforementioned policy. Consultation has been undertaken with HR and R&D leads from all member organisations of the CRN:East Midlands.
Statement	The Research Governance Framework for Health and Social Care Version 2 2005(RGF) requires that all research conducted is safe, of high quality and undertaken by appropriately qualified individuals and that a researcher not employed by any NHS Organisation who interacts with individuals in a way that has direct bearing on the quality of their care should hold an NHS honorary contract.
Responsibilities	**The organisation providing care** is responsible for - ensuring that researchers with no contractual relationship with any NHS body hold honorary NHS contracts or Letters of Agreement (as appropriate to the activity to be undertaken), and that there is clear accountability and understanding of responsibilities. (RGF2005). **The Researcher's substantive employer (usually HEI)** is responsible for **e**nsuring that all pre-engagement checks required due to the nature of the research have been undertaken and for signing-off the Research Passport form, when all checks and disclosures are completed. **The Researcher** is responsible for liaising with their substantive employer regarding the completion of their research passport, liaising with the Organisation regarding any additional checks that may be required depending on the nature of their research, keeping up to date and disclosing any new information that may impact on their status (professional registration, DBS and Occupational Health) during the course of the research, returning all property at the end of their research and notifying security and IT so that access to buildings and IT facilities can be stopped. **NHS Board/ Management Team** is responsible for ensuring the implementation and requirements outlined in this policy are disseminated and observed. **The R&D Department** is responsible for **p**roviding a single point of contact for all individuals seeking to undertake research in the organisation, assessing the need for an HRC, LoA or LoHRA from the individual's employment status and the nature of the proposed research project or programme, using the Research Passport scheme and processes described in "Research in the NHS-HR Good Practice Resource Pack" to issue an HRC, LOA or LoHRA, liaising with HR where new scenarios arise that have not yet been addressed in the guidance. **The Human Resources Department** is responsible for working with R&D to audit, review and ensure compliance with this policy.
Training and Resource Implications	**The Principal Investigator** is responsible for ensuring that all members of the research team are appropriately trained, qualified and supported to undertake their delegated tasks.
Dissemination	**Website**

Research Passport and Honorary Research Contracts Policy

1. Introduction

The Research Governance Framework for Health and Social Care Version 2 2005(RGF) requires that:

- all research conducted is safe, of high quality and undertaken by appropriately qualified individuals.
- a researcher not employed by any NHS Organisation who interacts with individuals in a way that has direct bearing on the quality of their care should hold an NHS honorary contract.

Best Research for Best Health (2006) identified the need to harmonise and simplify HR processes being undertaken in NHS Trusts and Higher Educational Institutes (HEIs), in order to speed study set-up. The Research Passport scheme provides the mechanism for this.

Inherent within all of its practices the organisation is committed to the principles of diversity, equality of treatment and equality of opportunity and believes that direct or indirect discrimination against any person is unacceptable.

This policy aims to ensure that all employees are treated favourably on the grounds of gender, sexual orientation, civil partnership/marital status, colour, race, nationality, ethnic or national origins, creed, religion/belief, disability, age or trade union membership, and are not disadvantaged by conditions or requirements which are not justified by the job.

The Research Passport (RP) is a document which:

- Is the mechanism for non NHS staff to obtain an Honorary Research Contract (HRC), when the research they intend to undertake is likely to have a direct impact on the quality of care, or a Letter of Access (LOA) when the research requires access to and use of NHS facilities only or a Letter of HR Assurance (LoHRA) when the researcher requires access to GP practices within the 4 Lincolnshire CCGs.
- Is completed by the researcher and their substantive employer (usually a HEI).
- Lists the pre-engagement checks that have been undertaken by a researcher's substantive employer,
- Provides evidence of the pre-engagement checks the substantive employer has carried out.
- Where the research is to take place in more than one NHS Trust, can be submitted to each one to provide evidence of appropriate pre-engagement checks, therefore no duplication of checks.

To implement this scheme a resource pack "Research in the NHS-HR Good Practice Resource Pack" has been developed. This resource pack recommended by the Department of Health and endorsed by NHS Employers, contains example documents to be used by Trusts and sets out clear guidance together with good practice standards for the NHS and Universities regarding the use of the HRC, LOA, LoHRA and the RP.

2. Purpose

The purpose of this policy is to adopt and implement the current version of the "Research in the NHS-HR Good Practice Resource Pack" as the guidance that will be followed to ensure

a common approach among Member Trusts and HEIs of the Clinical Research Network: East Midlands, when issuing HRCs, LoAs or LoHRAs.

3. Policy Statement

Each organisation will issue HRCs, LoAs or LoHRAs to those non-NHS Researchers who present a completed Research Passport form, when it is satisfied;

- that the study for which the application is being made complies with all elements of research governance and has R&D approval;

- all the required passport documentation has been checked, is in order and the level of checks are commensurate with the activity to be undertaken within the research.

Each organisation will issue a Letter of Access to NHS researchers who hold a substantive NHS contract of employment but needs to undertake their research in a different NHS Organisation.

4. Associated Policies and Procedures

- Research Misconduct and Fraud
- Disciplinary Policy & Investigation Process
- Disclosure Barring Service (formerly criminal records)
- Professional Registration Policy
- Induction Policy
- Data Protection and Confidentiality Policy

5. Scope of Policy

This policy applies to researchers who are planning to undertake research in any member organisation, and who do not hold either a substantive or honorary contract with that organisation in which their research activity will take place.

Chief/Principal Investigator	Person responsible, individually or as leader of the researchers at a site, for the conduct of a study at that site. For clinical trials involving medicines, an investigator must be an authorised health professional.
Direct Impact on the Quality of Care	Suggests that the actions of researchers could foreseeable directly affect the type, quality or extent of prevention, diagnosis or treatment or foreseeable cause injury or loss to an individual to whom the organisation has a duty of care (Resource Pack Version 1.1 January 2009)
HEI	Higher Educational Institute
Honorary Research Contract	Is a contract to undertake research without remuneration and applies in circumstances where there is no contract of employment with any NHS organisation and the researcher's activity has a

	direct impact on patient care. An HRC clarifies the holders accountability to the NHS organisation in which the research is being undertaken
Letter of Access	A letter clarifying the holder's accountability to the NHS organisation in which the research is taking place and issued to non-NHS researchers who do not require an HRC, and to NHS researchers working in a different organisation from their employing organisation
Letter of Human Resources Assurance	A letter clarifying the holder's accountability to the GP practice in which the research is taking place and issued to non-NHS researchers who do not require an HRC, and to NHS researcher working in a difference organisation from their employing organisation. The researcher provides this Letter of HR Assurance to the GP practice that the researcher proposes to carry out their study in. This letter is an assurance from LCHS that the research study has received the necessary regulatory approvals and has received NHS approval.
Organisation providing care	Organisation responsible for providing health or social care to patients and/or service users and carers participating in a study. Health and social care organisations remain liable for the quality of care, and for their duty towards anyone who might be harmed by a study.
Research Passport	Is the mechanism for the substantive employer of non-nhs staff to demonstrate the pre-engagement checks which have been undertaken, in order to enable researchers to obtain an HRC, LOA or LoHRA.
Researcher	Person conducting the study.

6. Responsibilities

The organisation providing care is responsible for:

- Ensuring that researchers with no contractual relationship with any NHS body hold honorary NHS contracts or Letters of Access or Letters of HR Assurance (as appropriate to the activity to be undertaken), and that there is clear accountability and understanding of responsibilities. (RGF2005).

- Ensuring that the Research Passport scheme is used to process HRCs / LOAs/LoHRAs, in accordance with “Research in the NHS-HR Good Practice Resource Pack”

- Ensuring that appropriate local supervision arrangements for the HRC/LoA/LoHRA holder are put in place prior to the start of the research

- Issuing ID badges to researchers who hold HRCs, LoAs or LoHRAs where appropriate.

The Researcher's substantive employer (usually HEI) is responsible for:

- Ensuring that all pre-engagement checks required due to the nature of the research have been undertaken.
- Signing-off the Research Passport form, when all checks and disclosures are completed.

The Principal Investigator is responsible for:

- Ensuring that all members of the research team are appropriately trained, qualified and supported to undertake their delegated tasks.

The Researcher is responsible for:

- Liaising with their substantive employer regarding the completion of their research passport.
- Liaising with the organisation regarding any additional checks that may be required depending on the nature of their research.
- Keeping up to date and disclosing any new information that may impact on their status (professional registration, DBS and Occupational Health) during the course of the research.
- Returning all property at the end of their research and notifying security and IT so that access to buildings and IT facilities can be stopped.

NHS Board/Management Team is responsible for:

- Ensuring the implementation and requirements outlined in this policy are disseminated and observed.

The R&D Department is responsible for:

- Providing a single point of contact for all individuals seeking to undertake research in the organisation.
- Assessing the need for an HRC, LoA or LoHRA from the individual’s employment status and the nature of the proposed research project or programme.
- Using the Research Passport scheme and processes described in “Research in the NHS-HR Good Practice Resource Pack” to issue an HRC, LoA or LoHRA.
- Liaising with HR where new scenarios arise that have not yet been addressed in the guidance
- Where a RP already exists issuing an HRC, LoA or LoHRA as required for the research study.
- Where research is identified as being undertaken in high/medium secure units (e.g. forensic research), current best practice of that establishment and its associated NHS organisation will take precedence over the Research in the NHS-HR Good Practice Resource Pack.

- Ensuring staff processing the scheme are trained in the agreed procedure
- Setting up and maintaining a database of all LoAs, LoHRAs and HRCs issued in consultation with HR, which will be accessible to nominated staff from HR and R&D at each individual organisation.

Workforce Services is responsible for:

- Working with R&D to audit, review and ensure compliance with this policy.

7. Making an application for a HRC, LoA or LoHRA

All applications will follow the instructions of the current version of "Research in the NHS-HR Good Practice Resource Pack". Specific organisation contact details will be published on the East Midlands CRN website and each organisations website

8. Acknowledgement

Lincolnshire Community Health Services NHS Trust acknowledges the support of The East Midlands CRN and its member organisations in the development of this policy.

9. Equality & Diversity Statement

This policy aims to meet the requirements of the Equality Act 2010 and ensure that no employee or patient receives less favourable treatment on the grounds of gender, sexual orientation, transgender, civil partnership/marital status, appearance, race, nationality, ethnic or national origins, religion/belief or no religion/belief, disability, age, carer, pregnancy or maternity, social status or trade union membership.

Appendices

https://www.nihr.ac.uk/02-documents/policy-and-standards/Faster-easier-clinical-research/Research-passports/Hr%20Good%20Practice%20Resource%20Pack/HR-Good-Practice-Info-for-researchers-RD-and-HR-staff-in-the-NHS-and-HEIs.pdf

References

Research Governance Framework:-
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139566/dh_088288.pdf

Best Research for Best Health:-
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/568772/dh_4127152_v2.pdf

Equality Analysis

Name of Policy:	Research Passport and Honorary Research Contracts Policy
Equality Analysis Carried out by:	Katy Ward
Date:	11.01.2017
Equality & Human rights Lead:	Rachel Higgins
Director\General Manager:	Susan Ombler

***In this template the term policy\service is used as shorthand for what needs to be analysed. Policy\Service needs to be understood broadly to embrace the full range of policies, practices, activities and decisions: essentially everything we do, whether it is formally written down or whether it is informal custom and practice. This includes existing policies and any new policies under development.**

Section 1 – to be completed for all policies

A.	Briefly give an outline of the key objectives of the policy; what it's intended outcome is and who the intended beneficiaries are expected to be	The overriding objective of the policy is to provide a streamlined regulatory and governance approach for confirming details of pre-engagement checks to the NHS that researchers (both NHS-employed and non-NHS employed) have undergone.		
B.	Does the policy have an impact on patients, carers or staff, or the wider community that we have links with? **Please give details**	No		
C.	Is there is any evidence that the policy\service relates to an area with known inequalities? **Please give details**	No		
D.	Will/Does the implementation of the policy\service result in different impacts for protected characteristics?	No		
		Yes	No	
	Disability		√	
	Sexual Orientation		√	
	Sex		√	
	Gender Reassignment		√	
	Race		√	
	Marriage/Civil Partnership		√	
	Maternity/Pregnancy		√	
	Age		√	
	Religion or Belief		√	
	Carers		√	
	If you have answered 'Yes' to any of the questions then you are required to carry out a full Equality Analysis which should be approved by the Equality and Human Rights Lead – please go to section 2			
The above named policy has been considered and does not require a full equality analysis				
Equality Analysis Carried out by:		Katy Ward		
Date:		11.01.2017		

Monitoring Template

Minimum requirement to be monitored	**Process for monitoring e.g. audit**	**Responsible individuals/ group/ committee**	**Frequency of monitoring/audit**	**Responsible individuals/ group/ committee (multidisciplinary) for review of results**	**Responsible individuals/ group/ committee for development of action plan**	**Responsible individuals/ group/ committee for monitoring of action plan**
Annual review of the Research Passport and Honorary Research Contract policy. Frequent review of the National Institute for Health Research guidance on The Research Passport and Streamlined Human Resources Arrangements	Board reports 6th monthly monitoring exercises and yearly audits on active research studies.	LCHS Board Audit Committee Research Governance Committee Trust Executive Group Other formal Committees as appropriate	6th monthly monitoring exercises on all active research studies and yearly auditing of 10% high risk studies. Monthly monitoring of all Letters of Access/Honorary Research Contracts already issued by LCHS to ensure that they are all valid and that those requiring an extension to their Contracts or Letters of Access are contacted and appropriate arrangements made. Assessment of completed Research Passports/ NHS to NHS pre-engagement checks proformas (routinely carried out as part of the Research Governance review for each study)	Trust Board Trust Executive Group Research Governance Committee Other formal Committees as appropriate	Trust Executive Group Research Governance Committee Other formal Committees as appropriate	Research Governance Committee Other formal Committees as appropriate.