Research Passport Procedure

SOP05

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Version number:	**3**

See Document Summary Sheet for full details

CONTENTS

DOCUMENT SUMMARY SHEET

Document title*:	Research Passport Procedure
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Member of the Executive Team Responsible *:	Medical Director
Document author*:	Senior Clinical Studies Officer/Research Nurse
Members of procedural document development group:	Head of Research HR Manager
People (please use titles) / committees or groups consulted:	Medical Director Research Director HR Manager
Approved by (group/committee):	Research Forum
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Responsible for the review:	Research Management

Target audience: (List, by title, the people for whom this procedural document is essential)	All researchers and Staff participating in research
Responsible for dissemination:	R&D Dept: Research Staff
Copies available from:	R&D Dept and Connect Site
Where are essential paper copies held (include unit addresses):	R&D Dept : R&D office

DOCUMENT AMENDMENT SHEET

Please record what changes you have made to the procedural document since the last version.

This is a detailed tracked change document and is designed to show people exactly what has changed. The version number recorded below should correspond to the ratified version number shown on the Document Summary Sheet.

Version	Amendment	Reason	
1		New Procedure	
2	2.1 Re written procedure to conform with new guidance and WYCLRN requirements.	New document drafted in response to updated guidance from NIHR, and model documentation. Current document based on existing WYCLRN model in an attempt to create commonality of documentation across R&D organisations.	New document drafted in response to updated guidance from NIHR, and model documentation. Current document based on existing CLRN model in an attempt to create commonality of documentation across R&D organisations.
	• Clarification of terminology to reflect application to all Partnership Trust management structures • Addition of procedural flow chart to Appendices.	Comments received from HR Procedure Review Group	
2.3	Clarification of terminology Clarification of dissemination	Comments received in response to consultation	
2.3	Revision of 7.2 – Training and	Increased guidance	

	Support section	for researchers following suggestion from JRGC
2.4	Amendment to section 5.3 to align wording with that in appendix C	Mismatch identified and judged to be liable to create misunderstanding.
2.5	Amendment to document for new partnership governance arrangements	Revisions to allow for new arrangements between SWYPFT and LPFT following withdrawal of BDCFT form Partnership.
2.6	Amendments to section 5, and replacement of NHS to NHS checks Inclusion of details for Students and independent Contractors/Commercial researchers	Revision to reflect new NIHR Guidance, February 2010.
2.7	Rewording of 5.4 to fit intended review of Vetting and Barring regulations	Feedback from consultation with Trusts' HR Departments/Trust R&D Committee/TAG membership
3	Changes to Logos and organisations. Removed references to partnership Trusts of West Yorkshire MH consortium. Changes to wording to include the new NIHR and HRA processes and networks and change to GDPR New version of documents and updated web links. Amendments to the checks and algorithm: Appendix E. Changes to the Criminal barring and vetting checks. Modified the Schematic process in line with passport processes devolved to R&D Dept : Included Appendix K for localised checks and Appendix L for monitoring processes:	BDCFT no longer with the West Yorkshire Mental Health Research and development consortium : To amend logos and to modify according to the latest NIHR revisions, changes in HR legislation and to align to Trust procedures

1 INTRODUCTION

Research is an integral part of NHS activity but relies on working in partnership with staff from other NHS Trusts and also researchers from external organisations. This calls for a clear understanding about responsibility, accountability, patient safety and duty of care. The Research Passport Scheme has been introduced to aid this understanding and provide a standard approach to issuing NHS Honorary Research Contracts, or Letters of Access (as appropriate) , to those, with no contractual relationship with the NHS Trust that is the research site, wishing to conduct studies within that site.

The Research Passport system also provides a streamlined, standard application system for honorary research contracts therefore saving valuable time and resources of Human Resources, R&D departments and researchers. Importantly, it minimises the demand for repeated checks for every honorary research contract, by providing guidance on the circumstances when it is reasonable to rely on assurances offered by those who have already conducted these checks.

2 PURPOSE OF DOCUMENT

2.1 Procedure Statement

With regard to this procedural document the overarching strategies are the Trust R&D Strategy and the Human Resources Strategy.

2.2 Purpose of Document

The purpose of this document is to inform researchers and Trust employees about the process for the use of Research Passports and to ensure a consistent approach is taken to the issuing of appropriate documents to non-BDCFT researchers coming onto BDCFT premises to undertake their projects, or interact with BDCFT patients, service users or carers, or their data.

3 DEFINITIONS

3.1 Definitions of types of procedural documents

This document is a procedure and defines how the Trust will manage applications to conduct research within the Trusts.

3.2 Glossary of definitions

In the context of this document the following definitions are of relevance:-

- **HEI:-** Higher Educational Institutions including organisations such as Universities

- **Honorary Research Contract (HRC): -** The document issued to researchers from outside NHS organisations, binding them to abide by the rules and regulations applicable within that organisation, whilst offering protection and indemnity cover offered to those holding substantive posts within that organisation.
  HRC are also to be issued to staff undertaking tasks that are outside their usual job role/duties.

- **HRA: - Health Research Authority.** An organisation established in December 2011 to promote and protect the interests of patients in health research and to streamline the regulation and governance of research.

- **Letter of Access**: - A document issued to researchers offering access to research data, within certain restrictions. The recipient researcher is also bound by a number of codes of conduct, but the liability for their activity remains with the external organisation employing the researcher. See Appendix J.

- **NHS authorisation** A process of checks and reviews by an NHS organisation to have :

- adequate arrangements and resources to meet the standards set out in the UK Framework for Health & Social Care Research;
- an identified sponsor has taken on responsibility for the study;
- the study has received ethical approval (where required)
- there is a clinical trial authorisation in place for a clinical trial of a medicinal product (CTIMP);
- the allocation of responsibilities is agreed and documented;
- appropriate contractual arrangements are in place;
- legislation relating to the research is followed within the organisation;
- the Trust is able to deliver all aspects of the project in line with the requirements of the protocol and relevant regulation
- A person authorised to do so has given written permission on behalf of the NHS organisation.

4 DUTIES

Duties within the organisation

4.1 Chief Executive
Overall accountability for all R&D activities in the Trust lies with the Chief Executive. Responsibility for specific processes is delegated by the Chief Executive as set out below.

4.2 Medical Director & Caldicott Guardian
The Medical Director has overall delegated responsibility for R&D in the Trust. It is the responsibility of the Medical Director to ensure and give assurance to the Board of compliance with the systems and processes described in this procedure.

4.3 Research & Development Director
It is the responsibility of the R&D Director, supported by the Head of Research & Coordinator, BDCFT to ensure all relevant staff are aware of the Procedure, and to facilitate compliance with its contents.

It is the responsibility of directors to ensure they receive assurance from senior managers that those procedures within their area of responsibility have been reviewed, developed, consulted on, approved, ratified and implemented in line with the 'Procedure for the Development and Management of Procedural Documents'.

4.4 Head of Research, Bradford District Care NHS Foundation Trust (BDCFT)
The Head of Research, BDCFT is responsible for the effective implementation and operation of the procedure. The Head of Research also has responsibility to ensure all researchers working at any Trust site are aware and compliant with the R&D policy and procedures.

4.5 Project Lead Clinical Studies Officers/Research Nurses–The effective implementation and operation of this procedure. Co-ordinating the approval processes for projects across the Trust.

4.6 Line Managers – It is the responsibility of all line managers to ensure that staff participating in research within their areas of responsibility are aware of this procedure and that they follow the procedure.

4.7 Human Resources Department - The HR Department are able to advise and support employees and managers in the application of the procedure. The Occupational Health Department and Staff Support Services are also available for advice and support**.**

4.8 **All staff** – Any member of staff who becomes aware of any practice that is not in accordance with this procedure, or where there are difficulties with implementing this procedure, has a responsibility to report this to their line manager who will assess the problem. If there is a problem specifically with this procedure this should be reported to the Document Author, who will note this for consideration at the next review of the procedure.

4.9 **Procedural Document Authors** – It is the responsibility of procedural document authors to action the 'Procedure for the Development and Management of Procedural Documents' and ensure all procedural documents for which they have responsibility are developed, reviewed, authorised, ratified and implemented in accordance with the requirements of the procedure, and that they have been put onto R&D Department Website.

5 PROCEDURE

A diagrammatic summary of the procedure can be found in Appendix M

5.1 Background

The Research Passport is the standard approach to issuing NHS Honorary Research Contracts (HRC) or Letters of Access (LoA) to those, with no contractual relationship with the NHS, wishing to conduct studies in the NHS.

The research passport procedure allows researchers to obtain either:

- an Hhonorary rResearch Ccontract (HRC) with the NHS organisation(s) at each of the study sites

- a Lletter of Aaccess (LoA) into the Trust, (Appendix H - Standard letter or annexe to letter giving NHS permission for research) to confirm responsibilities of NHS employees or staff with an honorary clinical contract with an NHS organisation. It may be used for one project or a series of projects.

The `passport' element simply refers to the procedure of checks which are conducted in order to issue an individual with an HRC/LoA. Where the research study is multi-centre (or site), the researcher will then not have to repeat each of these checks in order to obtain an HRC or LoA at each site. Trusts will accept the checks from a validated Research Passport and issue either an Honorary Research Contract or Letter of Access.

The NIHR 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 (HR) arrangements for those undertaking research in the NHS. The 'Research in the NHS - Human Resource (HR) Good Practice Resource Pack' describes the Research Passport system and consists of:

- A Research Passport system, which provides a mechanism for assuring NHS organisations of the pre-engagement checks conducted on a researcher.

- Other standardised procedures for handling the HR arrangements for researchers. The Research Passport system and associated procedures have been developed in parallel with the development of the Integrated Research Application System (IRAS) and other arrangements across the UK to streamline the arrangements for obtaining authorisation for research from NHS organisations.

The Resource Pack sets out guidance and good practice standards so that individual NHS bodies can be confident of the process used to carry out criminal record and occupational health checks on honorary researchers. If an NHS body is

in any doubt about these checks it should take the action it considers necessary to confirm them. The Department of Health (DH) recommends the Research Passport Scheme to the NHS, to Higher Education Institutions (HEIs) and to other research employers working in partnership with the National Institute for Health Research (NIHR)[1].

NOTE: The Chief/Principal Investigator must also apply for authorisation to conduct the research in the NHS organisation/s.
The Research Passport does not remove the need to apply to the NHS organisation/s for authorisation, nor does it replace an Honorary Research Contract/Letter of Access.

5.2 Types of Research Passport

There are two types of Research Passport: a project specific and a three-year Research Passport.

- The project specific Research Passport is for researchers who will be involved with only one project for a maximum of **three** years.

- The three-year Research Passport is for researchers who will be working on a number of studies over the course of three years and have an on-going research portfolio.

For researchers who require a three-year Research Passport, details of the initial projects should be entered in the Research Passport Appendix. Subsequent projects that begin or take place during the period of validity of the Research Passport need to be added to the Appendix. The complete, validated, Research Passport and Appendix is then presented to the Research & Development (R&D) Departments at the relevant NHS organisations where these additional projects are to be undertaken. R&D will then facilitate the issue of appropriate contractual documents for that new project.

As long as there is no substantial difference in the requirements for pre-engagement checks for the research activities for the subsequent projects, **the original checks may be relied upon and no additional checks need be undertaken**. Additional checks would need to be carried out if the research activity differs greatly from the first application (e.g. subsequent studies involve children).

[1] National Institute for Health Research, *Research in the NHS - HR Good Practice Resource Pack*

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

Additional appendix pages should be added as required with each appendix being numbered sequentially.
The appendices reviewed in the initial application should be noted in Section 8 of the Research Passport Application Form.
Review of further appendices should be noted in the amendments section at the end of the Research Passport.

The researcher will be required to re-submit the application form if a research project is planned to last for longer than three years, and the relevant checks should be re-assessed.

For future projects submitted the HRA will identify whether an Honorary Research Contract or Letter of Access is needed using the criteria above. If there is any uncertainty researcher should contact the Trust R&D Department who will identify requirements in accordance with this Procedure.

The maximum duration of a Research Passport is three years. If a researcher requires a Research Passport for longer than this, a repeat application should be completed and the relevant checks should be re-assessed. This is in line with the advice on arrangements for highly mobile NHS staff groups, where criminal record and other appropriate checks should be undertaken at three-yearly intervals. A researcher cannot start any research activity at the NHS organisation until the correct documentation has been received, the appropriate correspondence sent out and Trust R&D permission has been granted.

5.3 Procedure for issue

The requirement for an HRC/LoA depends on the type of research taking place, and the employment status of the researcher.
Generally, researchers with no contractual relationship with the NHS, wishing to conduct studies in the NHS that affect patient care will need an Honorary Research Contract. Before any research activity takes place within an NHS Trust, the HRA/R&D Office will ascertain whether the researcher requires an Honorary Research Contract Or Letter Of Access (and any associated additional checks) by using the information provided in the relevant Statement of Activities/Schedule of Events.

Researchers will need an Honorary Research Contract if the research/researcher:

- will have a direct impact on the quality of patient care, for example, providing prevention, diagnosis or treatment of illness.
- Will have access to identifiable patient data, tissues or organs with likely impact on prevention, diagnosis or treatment.
- will have indirect contact with patients/service users whose research has a direct bearing on the quality of their care, for example, some types of telephone interviews.

- wish to access "with consent" identifiable patient data, tissues or organs with likely direct bearing on the quality of their care (with likely impact on prevention, diagnosis or treatment).
- Wishes to be granted a Trust Logon and Email Address

Researchers **will not** need an Honorary Research Contract if they fall in to any of the following categories, they will need to obtain a Letter of Access into other NHS sites if:

- They are employed by another NHS organisation.
- They are an Independent Contractor (e.g.GP) or employed by an Independent Contractor.
- They have an honorary clinical contract with the NHS (e.g. clinical academics).
- They are a student who will be supervised within clinical settings by an NHS employee or HEI staff member with an honorary clinical or research contract.
- They wish to undertake research that has no direct impact on patient care
- They wish to undertake research using anonymised data only

(For further types of research, please see **Appendix B** **'**What type of pre-engagement check is needed?')

5.4 HEI/Other Organisational Responsibilities

Researchers coming from Higher Educational Institutions (HEIs) or other organisations e.g. charities, commercial etc. are required to present staff to the NHS who are appropriate to undertake the role within the project.

They therefore incur responsibilities as a result, as detailed below:

In order for a researcher to acquire a Research Passport, the form in Appendix D must be completed by the researcher and relevant departments in the University/organisation. The completed form, when signed and validated, acts as the Research Passport. A number of screening checks must be conducted by the HEI before a research passport can be issued.

(i) Criminal Record Checks - Disclosures and Barring Service (DBS)

Criminal record disclosures may only be requested in line with the relevant legislation. When a researcher plans to conduct research activities that will require a criminal record disclosure please refer to the Disclosure, Vetting and Barring regulation and checks which came into effect on **10th September 2012.** **http://connect.bdct.local/hr/Documents/Policies%20and%20Procedures/Employment%20Policy/3.%20Guidance%20Disclosure%20+%20Barring%20Service%20Checks.pdf**

The university/organisation will arrange for the relevant DBS Check to be obtained if a previous application has not been made within the past **six months**. The

university will confirm that the appropriate level of check has been undertaken and the date. (For the latest guidance please check the NIHR website: https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

(ii) Employment Screening

On commencement at the University/organisation, pre-employment checks should have been carried out in line with the NHS Employment Check Standards, including obtaining two references and verification of permission to work/study in the UK. These checks may be confirmed as having been conducted on an applicant, and do not need to be repeated.

It is recognised, however, that exploration of gaps in employment and confirmation of identity may not routinely be carried out by the University/organisation in the same way as expected of NHS organisations. Therefore, the University/organisation is expected to check for gaps in employment/study of more than six months in the past three years. Where this has not been done previously, the University/organisation should arrange for the applicant's Curriculum Vitae (CV) to be checked.

(iii) Occupational Health Assessment

The occupational health service for the University/organisation should confirm, so far as is possible, that the individual is fit for the research activities she/he will be undertaking, in order to protect the health and safety of the researcher and others.

The Department of Health recommends checks for tuberculosis disease/immunity and the offer of hepatitis B immunisation, with post-immunisation testing of response, and the offer of tests for hepatitis C and HIV as standard health clearance checks for new healthcare workers.

For those who will perform exposure-prone procedures (EPPs[2]) for the first time, additional health clearance should also be undertaken. Additional health clearance means being non-infectious for HIV, hepatitis B and hepatitis C. The purpose of this guidance is to restrict those with blood-borne viruses from working in those clinical areas where their infection might pose a risk to patients in their care.

New healthcare workers include: healthcare workers new to the NHS; healthcare workers moving into training or posts involving exposure-prone procedures for the first time; and healthcare workers returning to the NHS, depending on the activities they have been engaged in while away.

Laboratory test results required for clearance for performing EPPs must be derived from an identified, validated sample. If additional vaccinations are required, these should be identity validated.

[2] EPPs are those invasive procedures where there is a risk that injury to the worker may result in exposure of the patient's open tissues to the blood of the worker. These include procedures where the worker's gloved hands may be in contact with sharp instruments, needle tips or sharp tissues inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times.

The Research Passport system, in line with existing systems, places an on-going obligation on researchers to seek professional advice about the need to be tested if they have been exposed to a serious communicable disease.

University/organisations should familiarise themselves with the guidance on occupational health screening for the NHS, in order to develop systems that are compliant with NHS requirements. University/organisation staff should liaise with the Principal Investigator to ensure that the check is sufficient for the type of research being carried out. University/organisations may be able to use their local NHS Trust or NHS Plus occupational health services to undertake health checks and clearance on their behalf.

5.5 Trust Responsibilities

5.5.1 Where NHS staff wish to conduct research in another NHS organisation the R&D department will:

- Check the individual's employment status in the CV supplied by the applicant as part of the application for permission to conduct the research at that site.
- Liaise with the employing NHS organisation to ensure that appropriate pre engagement checks are in place.
- Arrange for any additional pre-engagement checks required by the research activity to be undertaken.
- Check whether any previous Honorary Research Contracts and pre-employment checks are still sufficient for the research activity.
- Check whether an appropriate agreement is in place between the organisations, or confirm arrangements by letter to the NHS organisation providing the employment contract (**Appendix E** - Example confirmation of pre-engagement checks).
- make arrangements for appropriate management and supervision of the research activity.
- Inform the employing NHS organisation about its employee's proposed research (**Appendix H** - Example letter of access for NHS researchers); give permission for the research, which should include confirmation of indemnity for clinical negligence through NHS schemes.
- Issue a letter of access where applicable.

The NHS employer should agree arrangements with the NHS organisation hosting the research and maintain records of the research activity of its employees and retain quarterly reports detailing the number of Honorary Research Contracts and/or Letters of Access issued.

5.5.2 Where a researcher is not an NHS employee and the research does not have a direct bearing on patient care, the R&D department will:

- Ensure through the Research Passport system that appropriate pre-engagement checks have been completed.

- Ensure through the Research Passport system that arrangements are in place for handling access to identifiable patient data.
- arrange for any additional pre-engagement checks required by the research activity to be undertaken.
- make arrangements for appropriate management and supervision of the research activity.
- issue a letter to the researcher outlining her/his responsibilities to the NHS organisation, copying it to the researcher's employer (**Appendix G** - Letter of Access for Non-NHS Researchers)
- Give permission for the research.

5.5.3 Where a researcher is not an NHS employee but the research involves a direct bearing on patient care, the R&D department will:

- Ensure through the Research Passport system that appropriate pre-engagement checks have been completed.
- Ensure through the Research Passport system that arrangements are in place for handling access to identifiable patient data.
- Arrange for any additional pre-engagement checks required by the research activity to be undertaken by the appropriate Trust HR Department
- Make arrangements for appropriate management and supervision of the research activity.
- Facilitate the issue an Honorary Research Contract using the local template, copied to the researcher's employer or, accept an existing honorary contract subject to the issuing organisation complying with the Research Passport System
- Give permission for the research, which should include confirmation of NHS Indemnity for clinical negligence through NHS schemes.

The Letter of Access also allows current NHS employees to begin their research studies without the need for the host Trust to repeat DBS Checks (criminal records check) and other checks on the researchers.

5.6 Student Researchers

5.6.1 Students on Healthcare Placements

Students on healthcare placements as part of professional training are subject to a memorandum of understanding between their training provider and the Trusts in which they undertake their placements. As such, they will be supervised by NHS employees, or HE staff with appropriate honorary contracts.
Students undertaking research as part of these placements do not require HRC or LOA, and therefore do not need to complete a research passport application.

5.6.2 Students with substantive NHS Contracts or existing honorary NHS Contracts

These students should be treated in the same way as similar staff groups (see above).

5.6.3 HEI students with no contractual relationship to the NHS

These students must complete the Research Passport form, in conjunction with their HEI, and their application will be processed by the Trust R&D Department with reference to the NIHR Algorithm of Research Activity and Pre Engagement Checks, and the terms of this procedure as above.

5.7 Independent Contactors/Commercial Researchers

Independent contractors providing services to the NHS, including GPs, approaching the Trust as researchers are not covered by NHS Indemnity schemes. They should ensure they have proof of sufficient indemnity to meet the requirements of the project before application to R&D.

5.8 Granting of LOA

Once It has been agreed that a Letter of Access is required the document checks are undertaken by the Research Governance Lead and the Template in Appendix K is used to create the letter this is sent in PDF form to the applicant and the Trust representative for the project (Lead CSO).

5.9 Granting of Honorary Contract

If it has been agreed that a Honorary contract is required the Research Governance Lead will apply to HR for this using the Honorary Contract Confirmation/Declaration for to confirm that all relevant checks have been completed. This form should be requested from HR Service desk

If the researcher requires system, access e.g. Trust Logon and Email the Research Governance Lead will need to request this via **New User** Request Form - Non substantive staff

The researcher's substantive employer is responsible for the researchers conduct whilst on the NHS organisations premises. The NHS organisation issuing the LOA or Honorary Contract: can terminate the researchers right to attend at any time either by giving seven days' written notice or immediately without any notice if the researcher is in breach of any of the terms or conditions described in the letter or if the researcher commits any act reasonably consider to amount to serious misconduct or if convicted of any criminal offence. The organisation will not indemnify the researcher against any liability incurred as a result of any breach of confidentiality or breach of the General Data Protection Regulation 2018.

6 THE DEVELOPMENT OF PROCEDURAL DOCUMENTS

6.1 Prioritisation of work

It is the responsibility of the Trust to develop this Procedure in conjunction with the HR departments.

6.2 Identification of stakeholders

There were two stages of involvement and consultation:

a) Involvement of Experts, relevant managers during the procedure's development.
b) Wider consultation with stakeholders once initial development work has been completed.

This process included the following as stakeholders in line with Trust policy:

- R&D Staff
- Trust staff
    i. HR managers
    ii. R&D Directors

6.3 Equality Impact Assessment

The completed Equality Impact Assessment in is Appendix B.

7 DISSEMINATION AND IMPLEMENTATION

The plan for dissemination and implementation is attached as Appendix B.

7.1 Dissemination

The Procedure will be disseminated in accordance with the plan detailed in Appendix B.

7.2 Training and support for the implementation of the procedural document

This procedure provides guidance which someone not familiar with the process can follow.

Specific training for guidance enquiries will be provided to all new Research and Development Team members.

Specific guidance for researchers, HR departments and others, will be made available from the R&D Department.

8 MONITORING COMPLIANCE WITH AND THE EFFECTIVENESS OF PROCEDURAL DOCUMENTS

8.1 Process for Monitoring Compliance

- Confirmation of receipt of appropriate documentation in a randomly selected sample of researchers as part of the annual R&D audit.

8.2 Process for Monitoring Effectiveness

- Confirmation of compliance in the randomly selected sample of researchers in the R&D audit

8.3 Standards/Key Performance Indicators

The standard and key performance indicators for the Research Passport Procedure are as follows:-

- All researchers external to the Trust are appropriately issued with HRC/LOA as appropriate.

9 REFERENCES

This procedure was informed by the following:

National Institute for Health Research, *Research in the NHS - HR Good Practice Resource Pack HR Good Practice: Information for researchers, R&D and HR staff in Higher Education Institutions and the NHS, version 2.1 September 2012*
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

The Research Passport: Algorithm of Research Activity and Pre- engagement Checks Version 3.0, September, 2012
https://www.nihr.ac.uk/02-documents/policy-and-standards/Faster-easier-clinical-research/Research-passports/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf

10 ASSOCIATED DOCUMENTATION

R&D Strategy Version 2; BDCFT date
RD SOP01 Approval Procedure v3_june 2017; BDCFT 2017

Appendix A–Plan for Dissemination and implementation of Procedural Documents

SECTION 1 – DETAILS OF DOCUMENT TO BE DISSEMINATED

Title of Document	Research Passport Procedure		
Date Ratified			
Dissemination lead name		**Contact details**	

SECTION 2 – DETAILS OF PREVIOUS DOCUMENT TO BE RETRIEVED

Previous document already in use (Y/N)	Y	**Version No & Date**	3
Name of document if different from Section 1	As above		
In what format (paper/electronic)	Paper & electronic	**Where is this filed locally**	Various: Connect site and R&D dept folders
Proposed action to retrieve out-of date copies of the document	E-mail to all individuals identified in Section 3 below to remove previous versions and use link to ratified document		

SECTION 3 – DETAILS OF DISSEMINATION

Date put on Web-site				
Who is the document to be disseminated to				
Disseminated to (either directly or via meetings, etc.)	**Format**	**Date disseminated**	**No of copies sent**	**Contact details/comments**
HR Directors and Departments	Electronic			Via HR Advisors
R&D Directors and R&D Committees	Electronic			Via R&D Distribution lists
All researchers	Electronic			Posting on website and notification via R&D Bulletin. Use by Project Lead CSOs

Appendix B: Completed Equality Impact Assessment Screening

Area	Response
Service Area	Research and Development
Function or Policy	Research Management and Governance
Manager / Author	Head of Research
Directorate	Medical
Date	December 2014
Review date	[INSERT 3 YEAR FROM DATE EFFECTIVE] 26 June 2017
Purpose of Policy	The purpose of this document is to inform researchers and Trust employees about the process of applying for, and using Research Passports, and to ensure a consistent approach is taken.
Associated frameworks e.g. national targets NSF's	
Who does it affect	
Consultation process Start Date: End Date:	This is an amended version: So has only been sent to HR services
Clearly state who has been involved and where there is service user, carer and community sector involvement	The consultation was undertaken in the original version – this is an updated version to align with current legislation

Equality Group	Positive Impact	Negative Impact	Rational for response
Age	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol
Disability	x		Contact R&D on 1 to 1 basis as appropriate

Gender Re-Assignment	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol
Pregnancy & Maternity	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol
Race	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol
Religion or Belief	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol.
Sex	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol
Sexual Orientation	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol

Equality Impact Assessment Screening Sign Off		Yes
Are you satisfied that the conclusions of the EqIA Screening are accurate?		Y
Completed by Head of Dept John Hiley		
Head of Dept / Senior Manager approved John Hiley		
Quality Approved by:	Policy Group	
	Equality & Diversity	
EqIA Action Plan completed		Y
EqIA Report completed		

APPENDIX C: COMPLIANCE CHECKLIST

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	Title	Y	
	Is the title clear and unambiguous?		
	Is it clear whether the document is a guideline, policy, protocol or standard?	Y	
2.	Rationale	Y	
	Are reasons for development of the document stated?	Y	In the amendments
3.	Development Process		
	Is the method described in brief?		
	Are people involved in the development identified?	Y	Mainly as part of the original version this is an amendment
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Y	
	Is there evidence of consultation with stakeholders and users?	Y	With the initial version and is based upon a wider consultation and implementation by the DH
	Have the requirements of the following been taken into account where applicable: Mental Health Act Mental Capacity Act Care Programme Approach (CPA) Guidance	Y	This is directed at researchers wishing to come on site
4.	Content	Y	
	Is the objective of the document clear?	Y	
	Is the target population clear and unambiguous?	Y	
	Are the intended outcomes described?	Y	
	Are the statements clear and unambiguous?		
5.	Evidence Base	Y/N/A	
	Is the type of evidence to support the document identified explicitly?		
	Are key references cited?	Y	
	Are the references cited in full?	Y	
	Are supporting documents referenced?	Y	
6.	Approval		
	Does the document identify which committee/group will approve it?	Y	

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	Y	Version 1 and 2
7.	Dissemination and Implementation		
	Is there an outline/plan to identify how this will be done?	Y	
	Does the plan include the necessary training/support to ensure compliance?	Y	Only dept training required
	Is the Training Needs Analysis completed	N/A	
8.	Document Control		
	Does the document identify where it will be held?	Y	Within R&D Dept and accessible on Trust Intranet
	Have archiving arrangements for superseded documents been addressed?	Y	Will be saved within R&D folders
9.	Process to Monitor Compliance and Effectiveness		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Y	To ensure swift and safe process to enable timely set up of studies within the trust in accordance with the NIHR
	Is there a plan to review or audit compliance with the document?	Y	annually
	Does the above plan include the minimum NHSLA monitoring requirements (if applicable)	Y	
10.	Review Date		
	Is the review date identified?	N	Review will be a year from the approval date.
	Is the frequency of review identified? If so is it acceptable?	Y	
11.	Overall Responsibility for the Document		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Y	

Individual Approval			
If you are happy to approve this document, please sign and date it and forward to the chair of the committee/group where it will receive final approval.			
Name	John Hiley	Date	26 June 2017
Signature			
Committee Approval			
If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			

Name		Date	
Signature			

APPENDIX D: TRAINING NEEDS ANALYSIS

1.1 Training Profile & Training Plan

This is document is not intended to be part of the final approved version of the policy or procedure, but in order for the document to be ratified a copy must be included for approval purposes. After approval it will be removed from the published version and forwarded to the Training and Development Manager for inclusion in the Trust Training Needs Analysis Policy.

	Total No of Trust Staff	**Training Course**		**Training Course**		**Training Course**		**Training Course**	
		Essential	Achievable	Essential	Achievable	Essential	Achievable	Essential	Achievable
Refresher Period									
Staff Group									
Medical & Dental – Consultants									
Medical & Dental - Other									

	Total No of Trust Staff	Training Course		Training Course		Training Course		Training Course	
Nursing, Midwifery & Health Visiting (NM&HV)									
NM&HV support staff									
Allied Health Professionals (AHP)									
AHP support staff									
Senior managers									
Managers									
Administrative Staff	2								
Estates									
Facilities									

	Total No of Trust Staff	Training Course		Training Course		Training Course		Training Course	
Total	2								

- *Essential: the minimum level of training that should be in place to meet standards / assessment and legislative requirements, where it is a requirement for the role irrespective of current resources.*
- *Achievable: the level of training that can be delivered within the resources available.*

It is recognised that in some cases you may identify a 3rd category – Ideal: the number of staff it would be good to have training (which exceeds minimum / baseline requirements and might include "nice to do" aspirations). This category is not something to be reflected in your Training Profile but may form part of your decision making process and debate with your director / head of service.

Notes:

Medical & Dental – Consultants	
Medical & Dental – Other	
Nursing, Midwifery & Health Visiting (NM&HV)	Qualified HCHS nursing, midwifery and health visiting staff
NM&HV support staff	HCA's and support workers including Nursing assistants / auxiliaries who support Nursing/Health Visiting etc. staff
Allied Health Professionals (AHP)	e.g. Occupational therapists, Physiotherapists, Clinical Psychologists, etc.
AHP support staff	Scientific, Therapeutic and Technical support staff including student trainees and helper assistants, assistant practitioners, HCA's and support workers who support AHP's
Senior managers	Band 8a and above
Managers	
Administrative Staff	
Estates	NHS works & estates staff
Facilities	NHS ancillary staff. Hotel staff etc.
Pre-registration Learner	e.g. Pre-registration Diploma Nurse Training, Post 1st level Registration Learner - Health Visiting, etc.

1.2 Training Action Plan

Responsible Director: Andy McElligott Plan Updated:

Responsible Officer to Monitor Training: John Hiley

Name of Training	Delivery Frequency (per month/year)	Length of sessions	Numbers to be trained per session	Job titles of Trainer's identified to deliver	Current training & delivery method	Refresher frequency (e.g. 1, 2 or 3 years)	Agreed Timescale	Training attendance records held by:	Action rqd	Residual Risks and Action (Identify any Gaps in provision / resource implications etc.)	Date of Review/ Completion	Risk to Trust
In –house/Dept training		2 hours		Head of Research or delegated staff member		As required		R&D Dept				

Costs

Essential: the cost of delivering training to the number of staff who actually need be trained as part of their role irrespective of currently available resources.

Cost Of Training days x 7.5 hours @ £18 ph (cost of staff time diverted from paid duties to be trained)	Sub Total	NA

Cost of Backfill days x 7.5 hours @£10 ph	Sub Total	NA
Cost of Admin	Sub total	
Additional Costs: materials etc.	Sub Total	NA
	Total	

Achievable: the cost of delivering training to the number of staff who can be trained in line with the currently available resources

Cost Of Training days x 7.5 hours @ £18 ph (cost of staff time diverted from paid duties to be trained)	Sub Total	NA
Cost of Backfill days x 7.5 hours @£10 ph	Sub Total	NA
Cost of Admin	Sub total	NA
Additional Costs: materials etc.	Sub Total	NA
	Total	

Appendix E: Algorithm of Research Activity and Pre-engagement Checks

Please note: You are advised to regular check the NIHR site for updates on documents https://www.nihr.ac.uk/02-documents/policy-and-standards/Faster-easier-clinical-research/Research-passports/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf

Table 1 – RESEARCH PASSPORT ALGORITHM Version 3.0, September, 2012

Activity	Criminal record check necessary?[3]	Occupational Health Clearance Necessary?	LOA or HRC
Researcher is a health care professional[4] providing health care[5] to an adult and/or child	Yes, if done once this is Regulated Activity (new definition). Requires enhanced CRB + appropriate barred list check	Yes, if there is direct contact	HRC
Researcher provides health care to an adult and/or child under the direction or supervision of a health care professional	Yes, if done once this is Regulated Activity (new definition). Requires enhanced CRB + appropriate barred list check	Yes, if there is direct contact	HRC
Researcher provides personal care to an adult or child Or Researcher is a social care worker providing social work which is required in connection with any health care or social services to an adults who is a client or potential client	Yes, if done once this is Regulated Activity (new definition). Requires enhanced CRB + appropriate barred list check	Yes, if there is direct contact	HRC
Researcher undertakes the following activities unsupervised: teach, train, instruct, care for or supervise children, or provide advice/guidance on well-being, or drive a vehicle only for children; with likely direct bearing on the quality of care[6].	Yes, if done regularly this is Regulated Activity. Requires enhanced CRB + barred list check	Yes, if there is direct contact	HRC
Researcher has opportunity for any form of contact with children in the same Children's Hospital (formerly a specified place) but is not providing healthcare or other types of regulated activity and has no direct bearing on the quality of care.	Yes, if done regularly enhanced CRB (pre-Sept 2012 definition). No barred list check.	Yes, if there is direct contact	LoA
Researcher has access to persons in receipt of healthcare services in the course of their normal duties but is not providing health care or other types of regulated activity and has no direct bearing on the quality of care ('Access' relates to where individuals will have physical, direct contact with patients e.g. observation, qualitative interviews, focus groups).	Yes, standard	Yes, if there is direct contact	LoA

Algorithm continues on the next page

[3] *Please refer to http://www.crb.homeoffice.gov.uk/guidance/rb_guidance/eligible_posts.aspx for guidance on specific activities which are eligible for CRB checks.*
[4] *"health care professional" means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002.*
[5] *"Health care" includes all forms of health care provided for individuals, whether relating to physical or mental health and also includes palliative care and procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition.*
[6] *A "direct bearing on the quality of care" suggests that the actions of researchers 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.*

Table 1 – RESEARCH PASSPORT ALGORITHM Version 3.0, September, 2012

Activity	Criminal record check necessary?[3]	Occupational Health Clearance Necessary?	LOA or HRC
Researcher has indirect contact with patients or service users but is not providing healthcare or other types of regulated activity and has no direct bearing on the quality of care (e.g some types of telephone interview).	No	No	LoA
Researcher requires access to **identifiable** patient data derived from health records, tissues or organs with a likely direct bearing on the quality of care	No	Yes, only if working with tissues or organs in NHS facilities	HRC
Researcher requires access to **identifiable** patient data derived from health records, tissues or organs with no direct bearing on the quality of care	No	Yes, only if working with tissues or organs in NHS facilities	LoA
Researcher requires access to **anonymised** patient data derived from health records, tissues or organs only (including by research staff analysing data)	No	Yes, only if working with tissues or organs in NHS facilities	LoA (only if reviewed in NHS facilities)
Researcher is working on NHS premises (e.g. laboratory) only (no access to identifiable data)	No	Yes, only if working with tissues or organs in NHS facilities	LoA
Researcher requires direct contact with staff only but no access to patients (e.g. staff interviews)	No	No	LoA (if in NHS facilities)
Researcher requires access to **identifiable** staff data only	No	No	LoA (if in NHS facilities)
Researcher requires access to **anonymised** staff data only	No	No	LoA (if in NHS facilities)

The NIHR Comprehensive Local Research Networks (CLRNs) are supporting the implementation of this guidance across HEIs and the NHS in England. If you have any questions, in the first instance, please contact the Lead RM&G Manager of your local CLRN. Further information is also available from Jacqueline Mathews, NIHR Clinical Research Network Coordinating Centre at jacqueline.n.mathews@nihr.ac.uk.

Appendix F
The latest version of the Research Passport Application can be obtained on the the link below:

https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

Appendix G NHS to NHS Proforma confirmation of pre-engagement checks Version 1

For NHS researchers who have a substantive NHS contract of employment or clinical academics with an honorary clinical contract with an NHS organisation, and who need an NHS to NHS letter of access from an NHS organisation hosting their research

CONFIRMATION OF PRE-ENGAGEMENT CHECKS

To: R&D Office

Address of NHS site hosting the research

Re: Researcher's name:

Job title:

Contract end-date:

Workplace and postal address:

Electronic Staff Record number:

As the representative of the NHS employer[3] of the above-named person, I can confirm that s/he is employed by this organisation. I understand that the responsibility for ensuring that the appropriate pre-engagement checks have been undertaken rests with us as the individual's substantive employer. I can confirm that the appropriate pre-engagement checks have been completed, commensurate with her/his job description and proposed research role in your NHS organisation, and in line with NHS employment checks standards

Name of employer's representative:

Job Title:

Workplace address:

Tel:

Email:

[3] For clinical academics, this would be a representative from their HEI employer

Appendix H Example evidence of occupational health clearance

Name of researcher:	
Employer or place of study:	

The occupational health department should complete the information below about the applicant. This document will be made available to HR and research support staff in the employing organisation and in those NHS organisations where the applicant will be undertaking research. It should not contain confidential information without the consent of the applicant. In signing this form, the researcher consents to the sharing of relevant health information between occupational health staff of her/his employer and occupational health staff of those NHS organisations where she/he wishes to undertake research to inform the assessment of her/his suitability to conduct research within the NHS.

Any questionnaire, checklist or other document used in conducting an occupational health assessment must not be attached to this document or passed to any NHS organisation.

Please confirm which occupational health assessments have been carried out in respect of the applicant.	
▪ Occupational health self-assessment questionnaire including physical conditions, psychological conditions, current workplace adjustments	Yes ☐ No ☐
▪ Interview with occupational health staff	Yes ☐ No ☐
▪ Medical examination by occupational health staff	Yes ☐ No ☐

Clearance details	
▪ Has an occupational health assessment confirmed that there are no health-related matters that could affect the health and safety of the applicant or others within the NHS?	Yes ☐ No ☐
▪ Is the applicant cleared for exposure-prone procedures?	Yes ☐ No ☐ N/A ☐
If no to either of the above, it may be necessary for occupational health staff in those NHS organisations where the applicant wishes to undertake research to discuss health-related information with the occupational health staff of the substantive employer.	

Contact details of occupational health staff:

Name:	Job Title:
Organisation:	Department:
Email:	
Signed:	Date:

VACCINATION HISTORY

Please enter dates of vaccinations.

Immunisation History		
1a	MMR vaccination	Dates: 1st 2nd
1b	Measles, mumps and rubella blood test	Date:
		Result:
2a	Hepatitis B vaccinations	Date: (1)
		Date: (2)
		Date: (3)
2b	Hepatitis B booster	Date:
2c	Hepatitis B antibody screening	Date:
		Result:
3a	Heaf, Mantoux or Tine test (TB test)	Date:
3b	BCG (TB vaccination)	Date:
4	Polio booster	Date:
5	Tetanus booster	Date:
6	Have you had chicken pox?	Yes ☐ No ☐ Unsure ☐
6a	Varicella (chickenpox) blood test	Date:
		Result:
	Varicella immunisations	Dates: 1st 2nd
7	Other (specify)	Date:

To be completed by the researcher before including this document in the Research Passport:

I consent to the information in this document being shared with relevant staff in the NHS for the purposes of ensuring my suitability to conduct research within the NHS. In addition, I consent to the sharing of relevant health information between my employer and those NHS organisations where I wish to undertake research to inform the assessment of my suitability to conduct research within the NHS.

Name:	
Signed:	Date:

Appendix I – Letter of Access Template

Research Governance Office
Osprey House,
Lynfield Mount Hospital
Heights Lane
Bradford
BD9 6DP

Tel: 01274 363208
research@bdct.nhs.uk

www.bdct.nhs.uk

PRIVATE & CONFIDENTIAL

«First_Name» «Surname»
«Address»

«Date_Application_Received»

Letter of access for research at Bradford District Care Foundation Trust

RE: «Research_Title»

BDCFT R&D Ref: «BDCFT_RD_Ref»

Dear «First_Name»,

This letter confirms your right of access to conduct research through Bradford District Care Foundation Trust (BDCFT) for the purpose and on the terms and conditions set out below. This right of access commences on «Start_Date» and ends «End_Date» unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at BDCFT has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to BDCFT premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through BDCFT, you will remain accountable to your employer, «Employer», but you are required to follow the reasonable instructions of «Location_at_our_Trust» in this NHS organisation or those given on their behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any

investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with BDCFT policies and procedures, which are available to you upon request, and the Research Governance Framework. You are required to co-operate with BDCFT in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on BDCFT premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and the Trust research governance office, prior to commencing your research role at the Trust.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

BDCFT will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

If your circumstances change in relation to your health, criminal record, professional registration or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

On your first day on site, please bring originals of your photographic ID and other documents for clearance with the research governance office.

Yours sincerely

John Vertannes

Chair: Michael Smith
Chief Executive: Nicola Lees

cc:

Appendix J Example letter of agreement between NHS organisations Version 1

Please note: this letter is not required where organisations can demonstrate that they are effectively managing and implementing the recommendations of the HR Good Practice Resource Pack within the UK Clinical Research Network.

To confirm arrangements underpinning NHS to NHS Letters of Access, which enable NHS employees or staff with an honorary clinical contract (e.g. clinical academics) with one NHS organisation to conduct research in another NHS organisation. This letter need only be used <u>where there is doubt with regard to the substantive employer's compliance with the recommendations of the HR Good Practice Resource Pack.</u>

Standard letter from an NHS organisation hosting research to the NHS employer or provider of an honorary clinical contract. It may be used for one project or a series of projects.

Human Resources Directorate
X NHS organisation

Date:

To Human Resources Directorate, Y NHS organisation

This letter is to confirm the arrangement between this NHS organisation and **[insert Y NHS organisation]** whereby your employees are permitted to conduct research in this NHS organisation. Such staff do not require an honorary research contract with this NHS organisation.

We offer a right of access to your staff to conduct research in this organisation in accordance with the clauses below.

Your staff have a right of access to conduct such research as is confirmed in writing in the letter of permission for research from this NHS organisation.

You are responsible for ensuring that such checks as you consider necessary for the clinical activities of your staff have been carried out, and we require you to undertake the necessary checks commensurate with the activities your staff will be conducting in this NHS organisation. We will require you to conduct additional checks if the research activities of your staff in this NHS organisation differ substantially from the current clinical activities of your staff. We agree to accept the checks undertaken by you, in order to enable your employee(s) to undertake research activities in this NHS organisation.

Your staff are considered to be legal visitors to the premises of this NHS organisation. They are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between them and this NHS organisation, in particular that of employees.

While undertaking research through this NHS organisation, your staff will be accountable to you as their employer but they will be required to follow the reasonable instructions of an

appropriate head of department or supervisor or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with the right of access, your staff are required to co-operate fully with any investigation by us in connection with any such claim and to give all such assistance as may reasonably be required by us regarding the conduct of any legal proceedings.

Your staff must act in accordance with our policies and procedures, which are available to them upon request, and the UK Framework for Health & Social Care Research.

Your staff are required to co-operate with us in discharging our duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of themselves and others while on our premises. Your staff must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and they must act appropriately, responsibly and professionally at all times.

Your staff are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. They must ensure that they understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the General Data Protection Regulation 2018. Furthermore they should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

We will not indemnify your staff against any liability incurred as a result of any breach of confidentiality or breach of the General Data Protection Regulation 2018. Any breach of the General Data Protection Regulation 2018 may result in legal action against your staff and/or you as the substantive employer.

We accept no responsibility for damage to or loss of the personal property of your staff.

We may terminate the right of your staff to attend at any time either by giving seven days' written notice to them or immediately without any notice if they are in breach of any of the terms or conditions described to them or if they commit any act which we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to our interests and/or business or if they are convicted of any criminal offence.

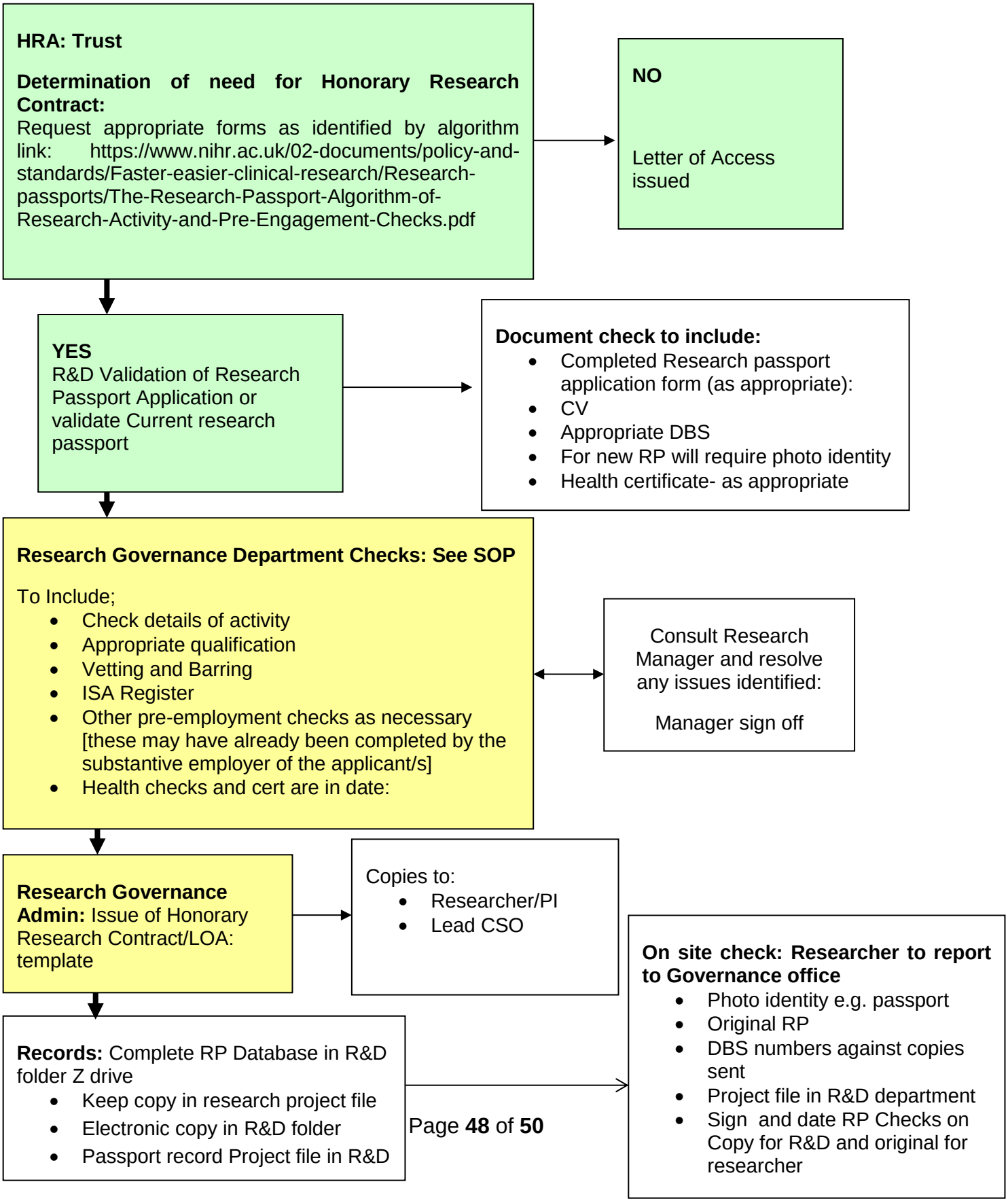
We will inform you when any of your employees wishes to conduct research in this NHS organisation. Your staff must inform us of any changes to their circumstances in relation to their health, criminal record, professional registration or any other aspect that may impact on their suitability to conduct research. Your staff must also inform us of any change to their role in research in this NHS organisation.

Yours sincerely

2 X
Director of Human Resources, X NHS ORGANISATION
3
cc: R&D offices, NHS organisations X and Y

Appendix K Schematic flow diagram of Process

Schematic Process for Issuing Honorary Research Contracts and Letters of Access



Appendix L: R&D Governance Checks and Monitoring

Prior to issuing contracts and letters of access to BDCFT site.

1. **Providing letter of access for external Staff with Honorary Research Contracts or research passports:**

Ensure Receipt of CV, research passport: with details of study and activity, and (if appropriate) Honorary Research Contract from issuing site.

Research passport (RP) checks:

- Check that it is in date. Signed by the appropriate departments and research manager from issuing organisation.
- Obtain email confirmation from employer HR (address on RP form) that person is a member of staff with end date of contract (if not received Honorary Research Contract):
- Check activities of researcher against the passport form (may need to contact researcher to clarify if not clear on SSI form):
- identify any amendments that need to be made- may need to refer to researcher back to the issuing organisation to inform changes
- Appropriate DBS barring disclosure as identified on the algorithm and is in date.
- Signed by occupational health if required: Occupational health cert/vaccinations are in date.
- Other pre-employment checks: these may have been completed by substantial employer and check they are in date
- Identify any enhanced checks required for activity – check with Manager
- Confirm local manager or responsible Local PI: contact service manager or CSO to ensure that head of service is aware of the project

CV checks

- Appropriate research experience and training
- GCP if applicable is in date (renewal every 3 years)

All checks satisfied: Contact R&D manager for final check

Issue Letter of Access: as directed by NIHR algorithm and guidance.

2. **Issuing Research Passport and contracts.**

All of the above checks but must provide the original documents (depending on activity- see manager) prior to issue of passport and contract.

- Educational certificates
- DBS/barring disclosure
- GCP- if appropriate
- Occupational health certificate : if required

3. **Issue of letter of Access for NHS staff**
    - Obtain email confirmation from employer HR that person is a member of staff with end date of contract (if not received Honorary Research Contract)
    - Confirm activity on site
    - Confirm local responsible of applicant manager or Principle investigator

4. **Identity checks on arrival to Trust: Research Governance**
    - DBS numbers and dates matches RP form received: sign and date on copy of RP form
    - Passport ID. Photo ID (preferably passport) in date
    - Sign and date that have seen identity on RP form : Ensure the checks have been signed on copies for the R&D files and the original returned to Researcher

5. **Record information on research passport database in RGM Folder.**

Monitoring of passport database

Database records to include:

- Contact Details of applicant
- Location and supervisor
- Date of issue of and expiry
- Accompany pre-engagement and health checks and dates
- New activities assigned to passports

Monthly check of the database:

- expiry dates of research projects
- Duration of Check Letters of Access and research passports
- New activities are assigned to passport
- Check original checks apply to new projects
- Closed projects are identified and closed on the RP data base
- Expired letters of access against open projects – inform researchers that RP needs to be updated if wish to return to the Trust
- Send monthly print out of database to HR dept.