

Initiating Research 02 – Application Process for an Honorary Contract, Letter of Access or Research Passport

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research & Development Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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<http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/>

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Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	13/05/2015
2.0	Update to terminology used in EDGE, clarification of process for HR role in Honorary contracts	18/05/2017
3.0	Rebranding to GHNHSFT, updating of contact details and reference documents	31/03/2018

This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

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1. Introduction, Background and Purpose

The Department of Health's UK Policy Framework for Health and Social Care Research v3, 2017 requires that all NHS Trusts ensure that individuals undertaking research that involves NHS staff or patients, their organs, tissue or data must have either a Substantive Contract or Honorary Contract or a Letter of Access with the NHS organisation that specifically stipulates compliance with the Framework.

2. Who should use this SOP?

This SOP is aimed at all researchers applying for NHS Permission to undertake research within the Trust where the researcher does not already have an appropriate contractual relationship with the organisation. This SOP is also applicable to R&D staff involved in the assessment and issuing of Research Passports / Honorary Contracts or Letters of Access.

3. When this SOP should be used

Researchers who do not have an appropriate contractual arrangement with the Trust must follow this SOP in order to apply for a Research Passport, Honorary Contract or Letter of Access as appropriate. This is relevant to studies sponsored or co-sponsored by the Trust as well as studies that are externally sponsored and 'hosted' within the Trust.

4. Procedure

All researchers without a contractual relationship with the NHS organisation in which they plan to undertake their research will require either a Letter of Access or an Honorary Contract in order to undertake research within that Trust. All researchers should contact the Trust R&D Department for both NIHR portfolio studies and non NIHR portfolio studies to determine what documentation is required (See appendices 1-3 and Table 1).

4.1 Researchers in the NHS

Those involved in conducting and supporting research in the NHS fall into a number of categories:

- staff with substantive NHS employment contracts;
- researchers with a substantive university employment and an honorary NHS clinical contract, e.g. clinical academics;
- researchers with substantive university employment contracts and no honorary NHS clinical contract;
- researchers who are contracted to provide NHS services, e.g. GPs, who may or may not have a substantive university employment contract;

- researchers with substantive employment contracts with other employers, e.g. social workers;
- university undergraduate or postgraduate students (some of whom may also have substantive NHS employment contracts);
- researchers in any of the above categories conducting research where the participants are NHS staff. Different arrangements are needed for each of these categories, and these are outlined in HR Good Practice: Information for researchers, R&D and HR staff in Higher Education Institutions and the NHS Research in the NHS: HR Good Practice Resource Pack

4.2 Access Arrangements and NHS Permission

For all research studies an application for NHS Permission should be made to the Trust R&D Department following the procedure outlined in Section 5, see also (R&D SOP RDVL 02), and should include an application for an Honorary Contract / Research Passport / Letter of Access where appropriate.

In order to determine whether an application is required applicants must refer to: *The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks* (Research in the NHS: HR Good Practice Resource Pack) found at: <http://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm>

Applicants should use the document (Table 1) to ensure that they currently hold or apply for the correct access arrangements.

During the NHS Permission Application Process, a Senior Research Manager is responsible for checking that honorary contract / letter of access arrangements are in place or have been initiated. In order to avoid delay to processing of applications, applicants are requested to ensure that an appropriate application is made along with the application for NHS Permission.

- For applicants with a substantive employment contract or an honorary clinical contract with one NHS organisation it is not necessary to apply for an honorary contract to conduct research in another NHS organisation, but additional pre-engagement checks may occasionally be required. The Trust will accept a dated NHS to NHS proforma confirmation of pre-engagement checks from the researcher's substantive employer as evidence that the appropriate clearances are in place and inform the researcher's substantive employer of her/his activities in their organisations by issuing the NHS to NHS Letter of Access. Refer to section 4.3 for details.

- For applicants without an NHS substantial employment contract or honorary clinical contract undertaking research in more than one NHS organisation, investigators are strongly advised to apply for a Research Passport. The Trust accepts the Research Passport and details of how to apply for a Research Passport are detailed in section 4.4. Please note that the R&D Department cannot issue Research Passports on behalf of other lead NHS organisations.

- For applicants without an NHS substantial employment contract or honorary clinical contract who are unable to apply for a Research Passport from their lead NHS organisation an application for an Honorary Contract or Letter of Access from the Trust may be made directly to the Trust R&D Department.

4.3 NHS to NHS Letter of Access

Where researchers have either a substantive employment contract or an honorary clinical contract with one NHS organisation an honorary contract is not required in order to undertake research in another NHS organisation. The Trust R&D Department, will accept the NHS to NHS proforma confirmation of pre-engagement checks (see section 4.3.1) from the researcher's substantive employer as evidence that the appropriate clearances are in place and inform the researcher's substantive employer of her/his activities in their organisations by issuing the NHS to NHS Letter of Access.

4.3.1 Obtaining a NHS to NHS Letter of Access from the Trust

Substantive employees of the Trust who require a NHS to NHS Letter of Access to carry out research in another NHS Trust should download and complete the NHS to NHS confirmation of pre-engagement checks proforma which can be found at: <http://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm> and send it, dated, along with a current CV, to their Head of Department or Line Manager who should sign the form as the 'employer's representative' and return it to the applicant. The applicant should then submit this completed form to all NHS Trusts in which a NHS to NHS Letter of Access is required for that study.

4.3.2 Trust R&D Department actions upon receipt of an NHS to NHS Letter of Access Application form

Upon receipt of a completed NHS to NHS confirmation of pre-engagement checks proforma:

- A Senior Research Manager will confirm that the proforma has been completed correctly and has been dated.
- If the application is complete Senior Research Manager will then issue an NHS to NHS Letter of Access which will be signed by the Head of R&D (or Senior Research Manager in the absence of the Head of R&D).
- A copy of the Letter of Access and NHS Proforma will be sent to the signee of the NHS Proforma.
- A copy of the complete proforma together with the NHS to NHS Letter of Access will be placed in the Honorary Contract / Letter of Access File which is held in the Trust R&D Department and saved onto the RDSU drive.

- An EDGE entry against the relevant research study will confirm that an NHS to NHS Letter of Access has been issued.

4.4 The Research Passport – Information for Applicants

If a researcher has no contractual relationship with the NHS, a Research Passport may be required, which enables the NHS to decide whether or not the individual needs an Honorary Contract (HC) or Letter of Access (LoA) to enable them to undertake research within NHS facilities (see Appendix 1, 2 and 3 and Table 1).

The Research Passport system 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. The Research Passport therefore means just one set of checks is needed on a researcher and the completed Research Passport can be presented to all relevant NHS organisations, as such they are strongly recommended when undertaking multi-centre research studies although they may be used for both single-site and multi-site studies. A Research Passport is valid for a maximum period of three years and may be project-specific or may cover a number of projects.

Please note: The Research Passport does not guarantee access to an NHS organisation but is the mechanism by which investigators apply for access.

In England, the Clinical Research Networks (CRNs) of the National Institute for Health Research (NIHR) have adopted the Research Passport system as standard practice and the Trust accepts Research Passports.

4.4.1 Applying for a Research Passport

A Research Passport can be issued for the duration of a single research project. Alternatively, researchers can apply for a three year Research Passport - designed for multiple studies. These studies must be defined in the three year passport. Additions or amendments to the studies approved in a three year Research Passport must be agreed with the substantive employer (who will decide if any new checks are needed) and the amended Research Passport counter signed by each R&D Office.

Investigators should:

1. Read the guidance for completing the Research Passport form found at <http://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm>

2. Complete sections 1-3 and 6 of the downloadable Research Passport Form.

3. Ask their line manager or other authorised person to complete section 4.
4. Take the form to their HR department to complete sections 5 and 7.
5. Complete occupational health assessments, and /or a barring and disclosure service application, and/or provide additional documents as determined by the HR department. The HR department will sign off the form once all of the checks have been completed and return it to the investigator.
6. Take the completed Research Passport form with attachments to the lead NHS organisation.

Note: Where the Trust is the Lead NHS organisation the completed Form should be sent to the Trust R&D Department for authorisation. A Senior Research Manger will complete the first part of section 8 (excluding the final section: Date Honorary Contract/Letter of Access issued, which will be completed once an application for NHS Permission has been approved).

A letter or email to confirm that the Research Passport has been authorised will be issued and a copy of the letter or email together with an initialled copy of the passport will be put on file and scanned and retained on the RDSU drive.

Investigators should note that this letter does not itself constitute an honorary contract or Letter of Access, these will be issued to the investigator once an application for NHS Permission is approved. See section 4.4.2 for more details.

7. Provide the Form to other NHS organisations as required. Once the form has been authorised by one NHS organisation it becomes a valid Research Passport.
8. Provide evidence of access arrangements (Research Passport/Letter of Access/Honorary Contract) to an NHS Trust when making an application for NHS Permission.
9. Ensure that they notify their substantive employer should a change to the study affect the validity of the research passport in a timely manner.

4.4.2 R&D responsibilities (if the Trust is the Lead NHS Organisation)

On receipt of an application for a Research Passport to be issued by the Trust:

- A Senior Research Manager will, on behalf of the lead NHS organisation, assess the research passport form and supporting documents. It is the responsibility of the substantive employer to undertake additional checks as may be required.
- A Senior Research Manager will validate the research passport by completing the first part of section 8 of the form and will issue a letter, signed by the Head

of R&D (or in their absence the Senior Research Manager), confirming that the research Passport has been authorised by the NHS organisation. This will be saved on the RDSU drive.

- A copy of the dated and initialled Form will be held by the Trust R&D Department until an application for NHS Permission is considered.
- Upon NHS Permission, a Senior Research Manager will work with Trust HR to issue an Honorary Contract or with the Head of R&D (or delegate) to issue a Letter of Access.

Note: Three copies of the Honorary Contract will be issued for signature by the applicant with two to be returned to the Trust R&D Department once signed. The Trust R&D Department will forward one of the returned signed copies to the applicant's substantive employment organisation. A photocopy of any Letter of Access issued will be retained by Trust R&D Department.

- A copy of the completed research passport form and issue letter is retained in the Research Passport Folder held in the Trust R&D Department. A copy of the Honorary Contract/Letter of Access is kept on the RDSU drive.
- An EDGE workflow against the relevant research study will confirm that an Honorary Contract/Letter of Access has been issued.

4.4.3 R&D Responsibilities (if lead NHS Organisation is not the Trust)

On presentation of a Research Passport authorised by another Trust:

1. A Senior Research Manager will check that the first part of section 8 has been correctly completed.
2. A Senior Research Manager will then complete the second part of section 8 on behalf of the Trust.
3. A copy of the completed initialled and dated Form is filed in the Honorary Contract Folder held in the Trust R&D Department.
4. Upon NHS Permission, a Senior Research Manager working with HR will issue an Honorary Contract/Letter of Access.

Note: Three copies of the Honorary Contract will be issued for signature by the applicant with two to be returned to the Trust R&D Department once signed. The Trust R&D Department will forward one of the returned signed copies to the applicant's substantive employment organisation. A photocopy of any Letter of Access issued will be retained by the Trust R&D Department .

5. A copy of the completed Research Passport Form and issue letter is retained in the Research Passport Folder held in the Trust R&D Department. A copy of the Honorary Contract/Letter of Access is kept on the RDSU drive.
6. An EDGE workflow against the relevant research study will confirm that an Honorary Contract/Letter of Access has been issued.

4.5 Applying for an Honorary Contract / LoA (non-Research Passport) for small low-risk studies

For research studies taking place at the Trust and where applicants without a substantial employment contract or honorary clinical contract are unable to apply for a Research Passport from their lead NHS organisation an application for an Honorary Contract or Letter of Access from the Trust may be made directly to the Trust R&D Department. In this case, the investigator should contact Trust R&D Department with a copy of a recent CV for further paperwork.

4.5.1 R&D Responsibilities (non-Research passport HC or LoA)

Upon application for an Honorary Contract/ Letter of Access Application :

- A Senior Research Manager will check that the form is complete and signed and that a CV has been submitted. A copy of the completed Form will be retained in the Honorary Contract Folder held in the Trust R&D Department.
- The Senior Research Manager will refer to: The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks (Research in the NHS: HR Good Practice Resource Pack) found at: <http://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm> to determine the necessary required pre-engagement checks.
- The Trust R&D Department team will send the necessary Disclosure and Baring Service (DBS) and/or Occupational Health Forms to the applicant in the post.
- The applicant must make an appointment with the Trust R&D Department team to return the completed DBS Forms in person. Appropriate identification documentation must be presented at this appointment. The applicant will return occupational health forms in the confidential envelope provided.
- The R&D Department will send the completed DBS application form to the relevant HR department.
- On confirmation of
 - (i) DBS and OH clearance from the HR department and

(ii) NHS Permission, the R&D Department will issue an Honorary Contract/Letter of Access. Note: Two copies of an Honorary Contract will be issued to the applicant (one to be countersigned and returned to the Trust R&D Department). A photocopy of any Letter of Access issued will be retained.

- An EDGE workflow against the relevant research study will confirm that an Honorary Contract/Letter of Access has been issued.

5 Related SOPs and Documents

R&D SOP RDVL 02 Application to the Trust for Sponsorship of a CTIMP

The Research Passport: Algorithm of Research Activity and Pre-Engagement Checks (Research in the NHS: HR Good Practice Resource Pack) found at: <http://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm>

Trust R&D Department contact details are:

Address: R&D Office,
Leadon House,
Gloucestershire Royals Hospitals
Great Western Road
Gloucester
GL1 3NN

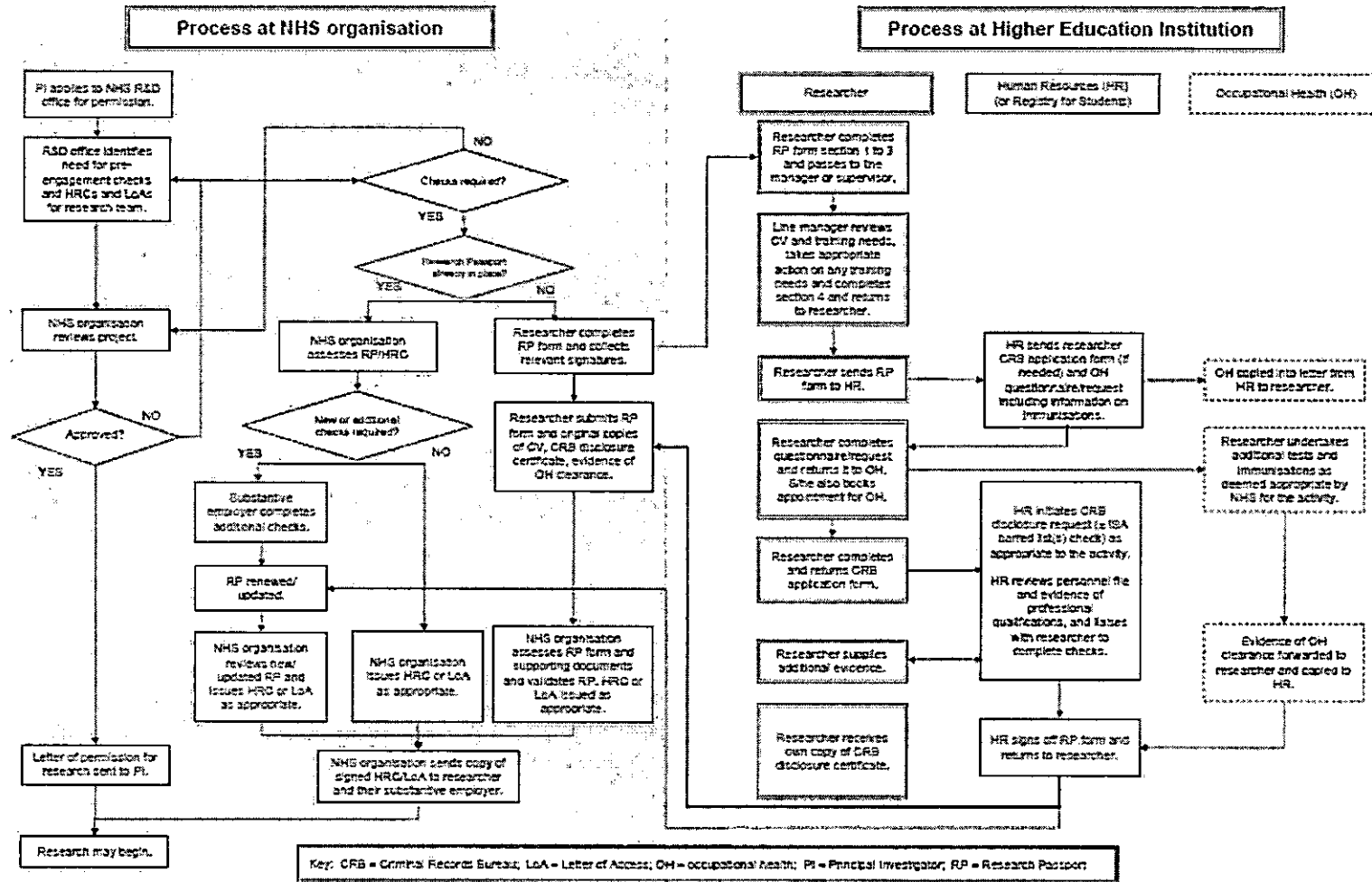
Email: ghn-tr.glos.rdsu@nhs.net

Telephone: 0300 422 5467

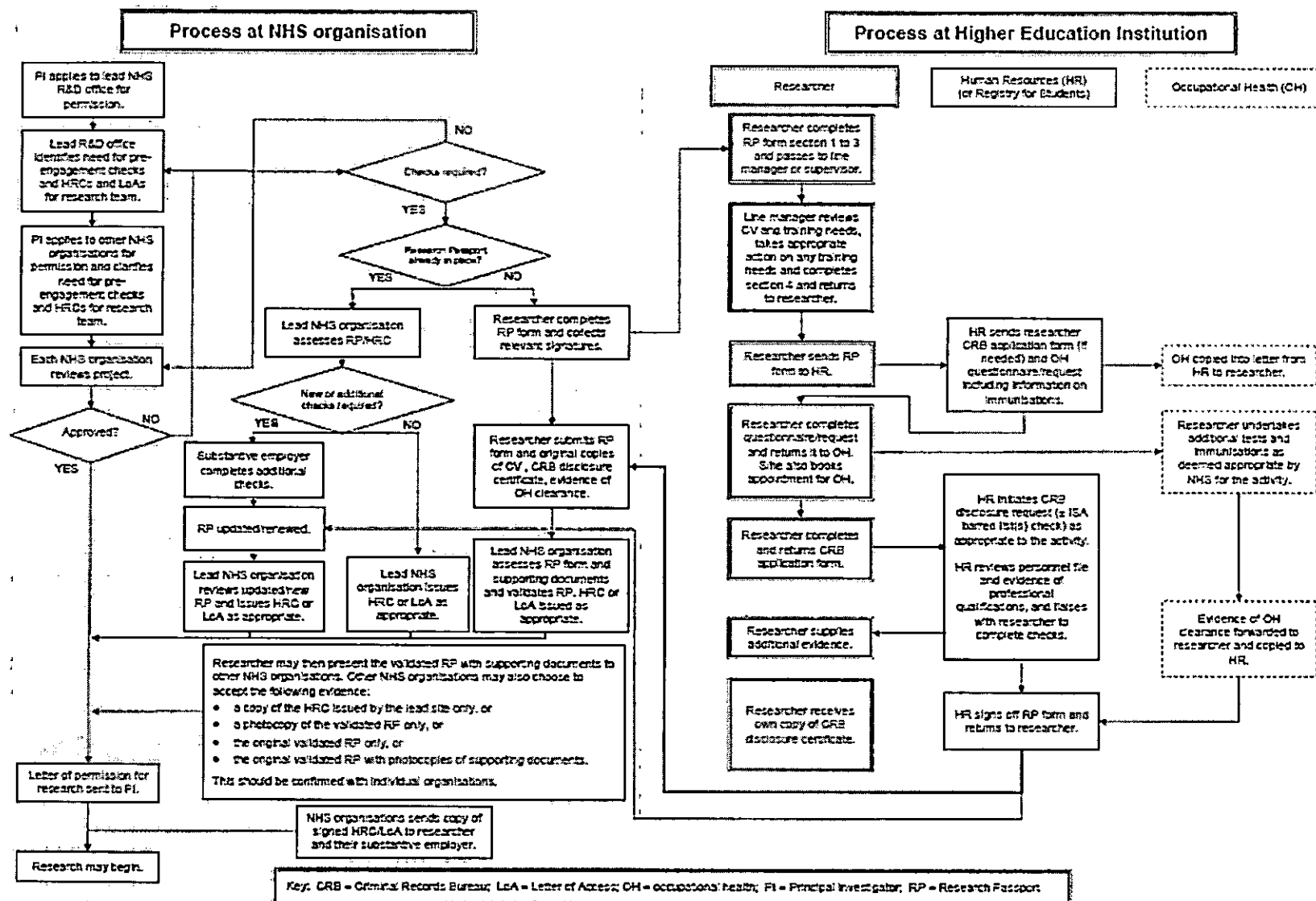


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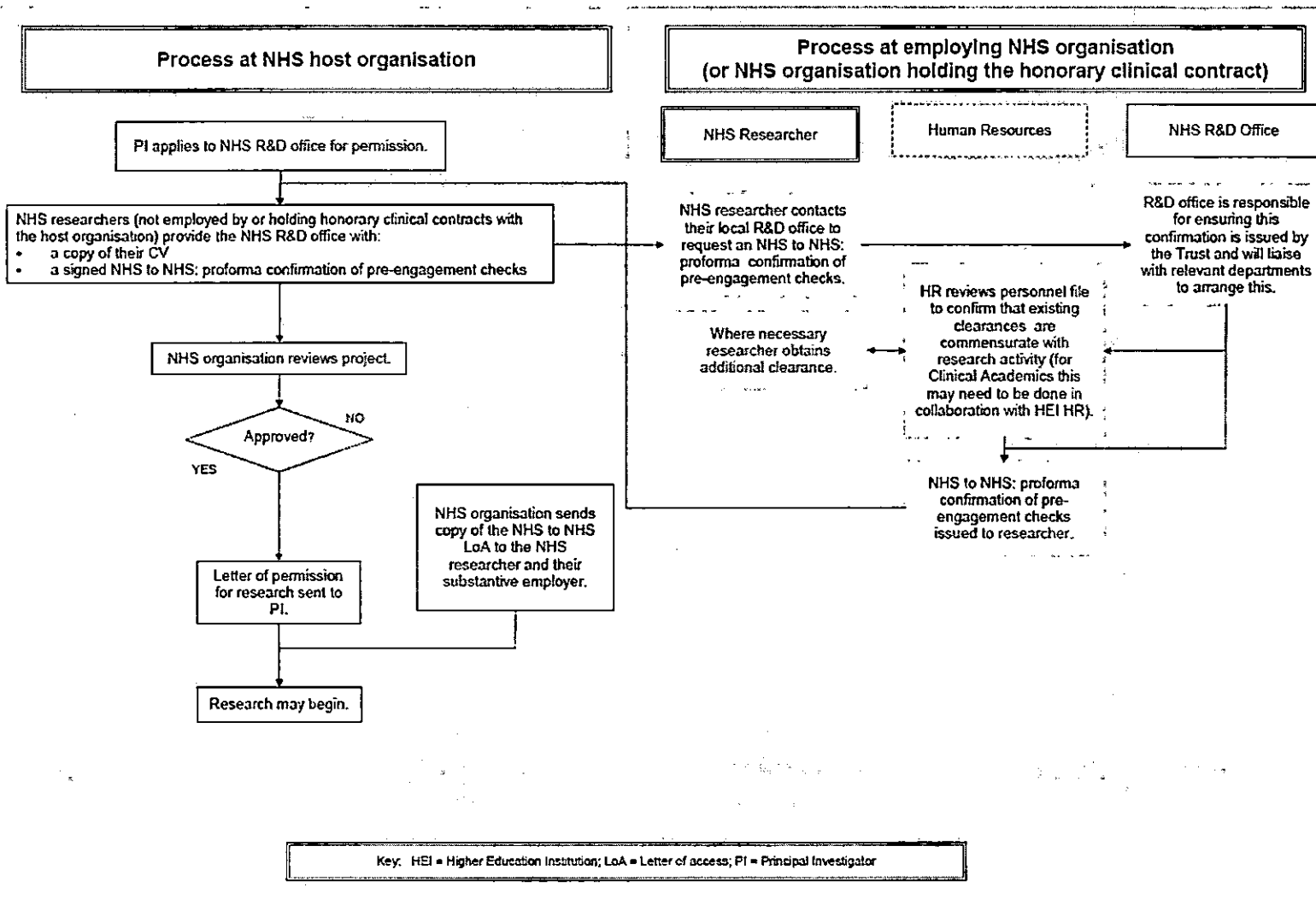
Research Passport system: research at one site



Research Passport system: research at more than one site



NHS to NHS arrangements: all types of research



Appendix 3

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.cr.b.homeoffice.gov.uk/guidance/crb_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.

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.