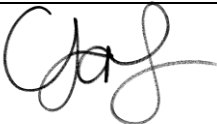



SOP 18 - Application Process for an Honorary Contract, Letter of Access or Research Passport

SOP reference:	SOP 18		
Version:	4.0		
Author:	Chris Ford		
Approved by Commercial Director:	Claire Richardson		
	22/09/2023		
Implementation date of current version:	30/10/2023		
Date of Review:	30/10/2025		

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the R&D website:

<https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals/>

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

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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
3.1	Updated links, amended typographical errors	Not implemented
4.0	Updated job roles, typographical errors, updating link to webpage, removed appendix with algorithm, updated information regarding Honorary Contracts SOP categories removed, references and reference codes updated Updated contact details	30/10/2023

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

Related Documents:

SOPs
SOP 28 - Application to the Trust for Sponsorship of a CTIMP

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1. Introduction, Background and Purpose

The Department of Health's UK Policy Framework for Health and Social Care Research and GDPR 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 UK policy for Health and Social Care Research and GDPR.

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 Resource Pack: see references

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 (SOP 28), 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* found in HR Good Practice Resource Pack

Applicants should use this algorithm to ensure that they currently hold or apply for the correct access arrangements.

During the NHS Permission Application Process, Research Portfolio Managers and Research Portfolio Support Officers are 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 within the HR Good Practice Resource Pack.

This should be send 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 Research Portfolio Manager or Research Portfolio Support Officer will confirm that the proforma has been completed correctly and has been dated.
- If the application is complete Research Portfolio Manager or Research Portfolio Support Officer will then issue an NHS-to-NHS Letter of Access which will be signed by 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.
- The EDGE workflow Letter of Access v2 August 2021 will be completed to confirm that an NHS-to-NHS Letter of Access has been issued for a specific research study.

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).

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 after this date will need renewing. The Passport 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 within the HR Good Practice Resource Pack
- 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 Research Portfolio Manager or Research Portfolio Support Officer 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 Research Portfolio Manager or Research Portfolio Support Officer 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 Research Portfolio Manager or Research Portfolio Support Officer 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 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 Research Portfolio Manager or Research Portfolio Support Officer will work with Trust HR to issue an Honorary Contract for non-medics and Medical Staffing for medics, or with the Head of R&D 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 (e signature is accepted). The Trust R&D Department will forward one of the returned signed copies to the applicant's substantive employment organisation. A copy of any Letter of Access issued will be retained by Trust R&D Department, saved to the relevant R&D study folder on the RDSU drive and uploaded to EDGE. A copy of the completed research passport form and issue letter is also retained in the relevant R&D study folder.

- The EDGE workflow Letter of Access and Honorary Contracts v2 will be completed against the specific research study to 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 Research Portfolio Manager or Research Portfolio Support Officer will check that the first part of section 8 has been correctly completed.
2. A Research Portfolio Manager or Research Portfolio Support Officer 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 Research Portfolio Manager or Research Portfolio Support Officer working with HR Recruitment 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 along with a copy of the Honorary Contract/Letter of Access is kept on the RDSU drive, in the specific study file.
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 Research Portfolio Manager or Research Portfolio Support Officer 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 specific study folder held in the Trust R&D Department.

The Research Portfolio Manager or research Portfolio Support Officer will refer to Algorithm of Research Activity and Pre-Engagement Checks found within the HR Good Practice Resource Pack. to determine the necessary required pre-engagement checks.

- The Research Portfolio Manager and Research Portfolio Support Officer will liaise with HR Recruitment for non-medics or Medical Staffing for medics who are responsible for issuing Honorary Contracts.
- 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 copy of any Letter of Access issued and countersigned Honorary Contract will be retained in the study specific R&D folder and uploaded to EDGE.
- An EDGE workflow against the relevant research study will confirm that an Honorary Contract/Letter of Access has been issued.

5. References

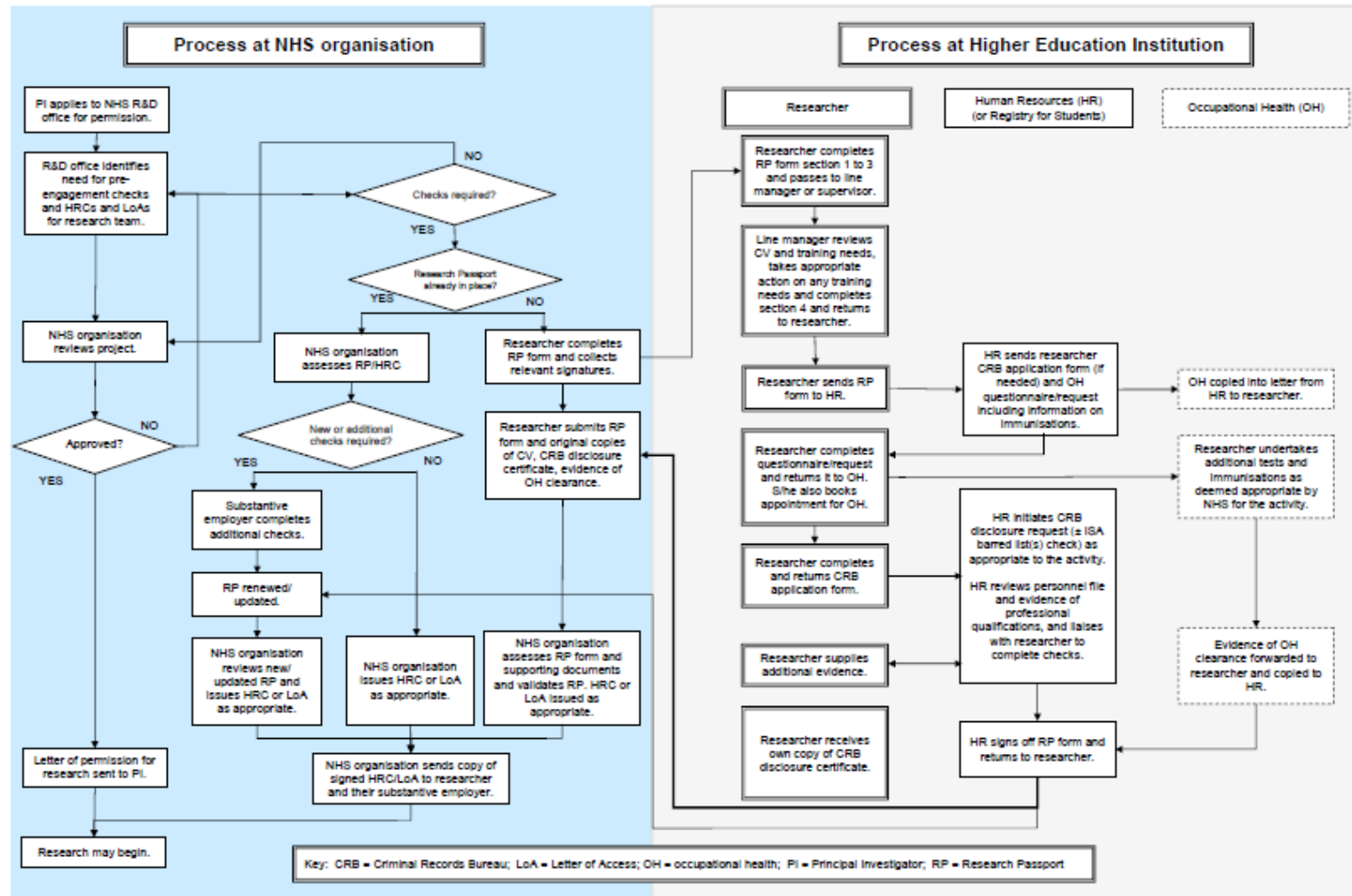
HR Good Practice Resource Pack

Trust R&D Department contact details are:

Email: ghn-tr.glos.rdsu@nhs.net
Telephone: 0300 422 5467

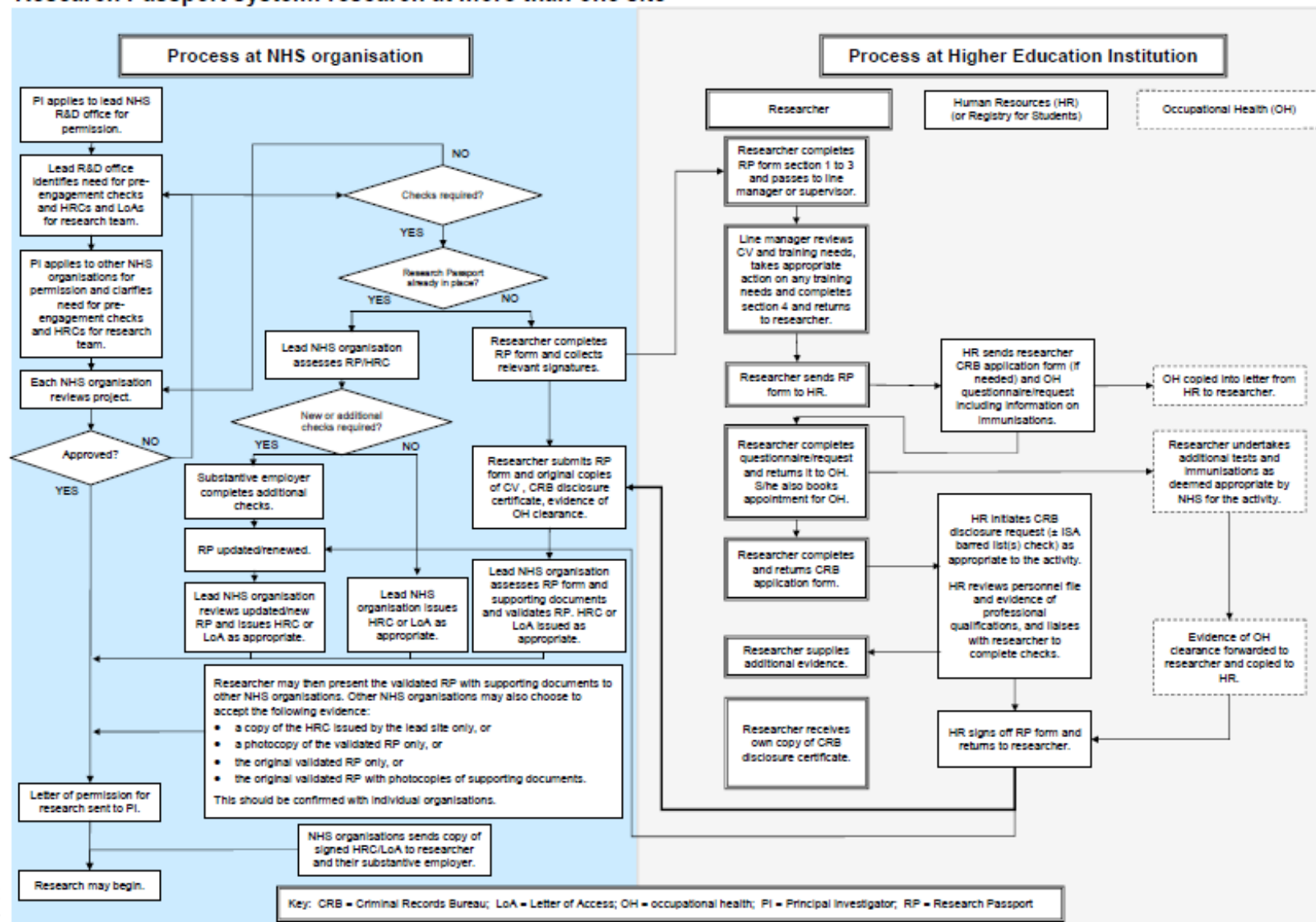
Appendix 1 Research Passport System: research at one site

Research Passport system: research at one site



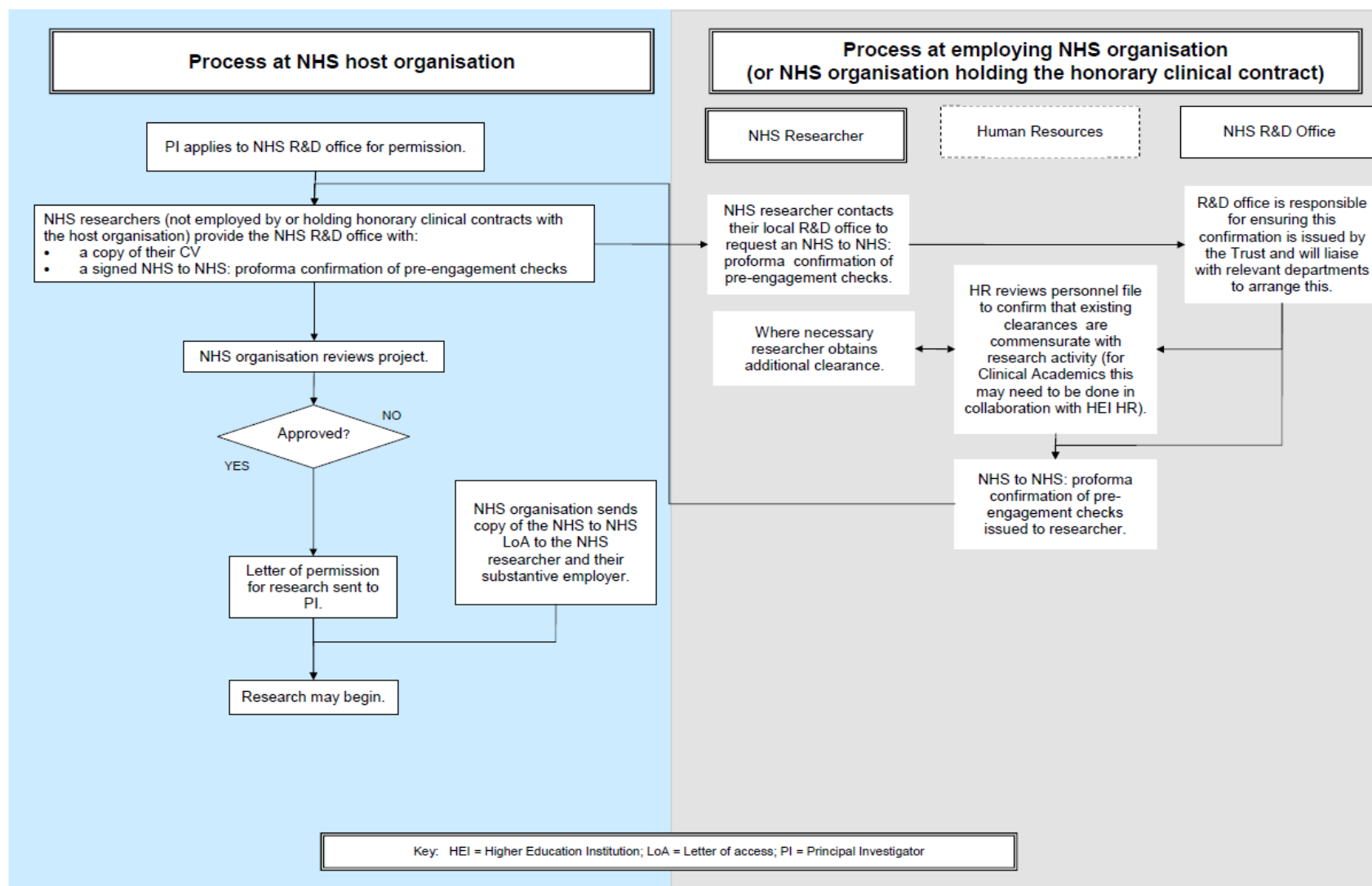
Appendix 2 Research Passport System: research at more than one site

Research Passport system: research at more than one site



Appendix 3 Research Passport System- NHS to NHS arrangements: All types of research

NHS to NHS arrangements: all types of research



SOP 18 - Application Process for an Honorary Contract, Letter of Access or Research Passport

Version: 4.0 Implementation date: 30/10/2023 Review date: 30/10/2025