

Standard Operating Procedure

Honorary Research Contracts & Letters of Access

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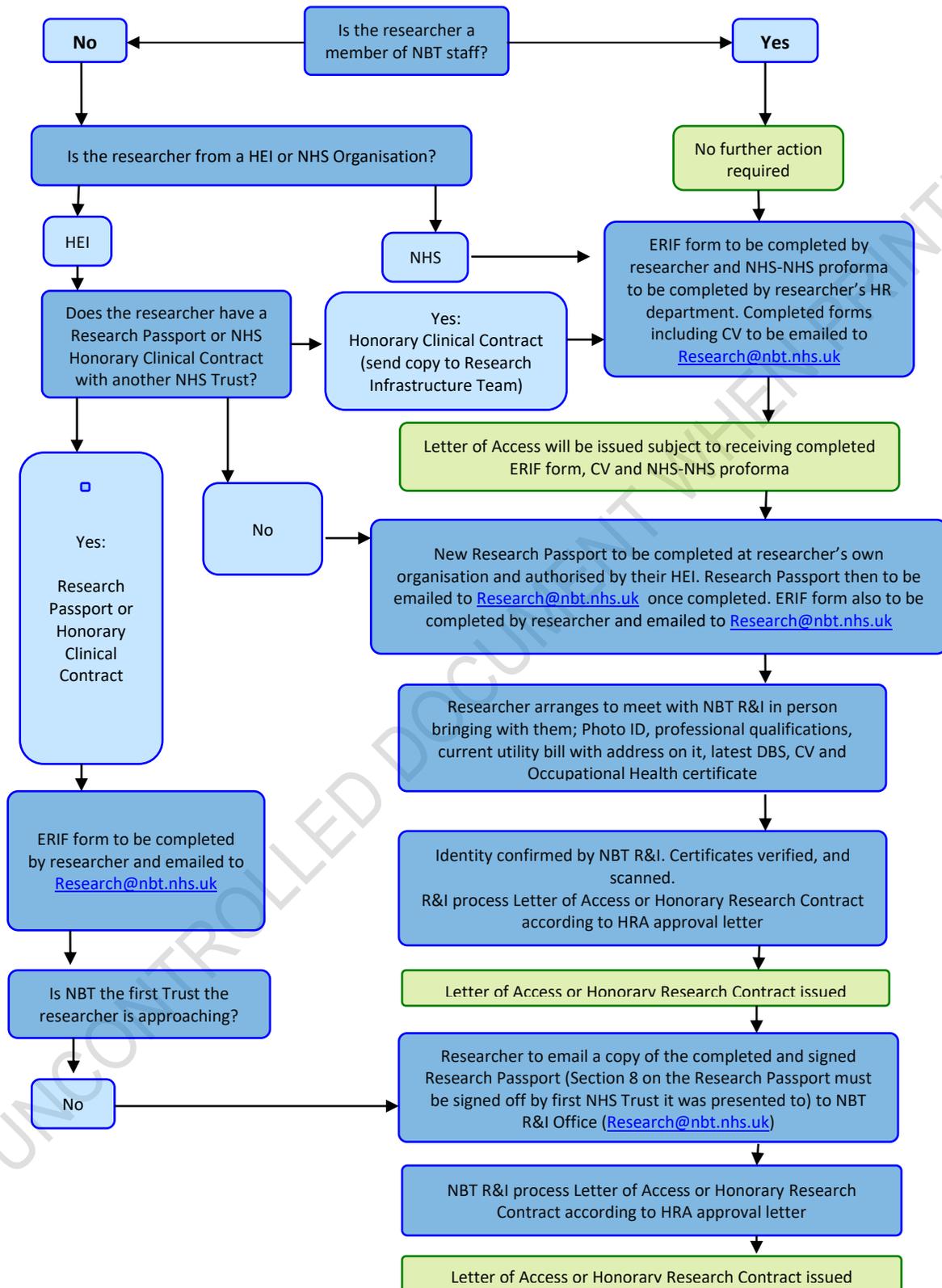
Document Version History

VERSION NUMBER	EFFECTIVE DATE	SUMMARY OF CHANGES SINCE THE PREVIOUS VERSION
1.0	27-08-10	N/A
2.0	01-04-11	Updated guidelines
3.0	08-02-16	SOP renamed, updated in line with new template and recoded from ISOP-C01
4.0	13-06-16	Updated in line with new HRA guidelines
4.1	01-07-20	Updated links and flow chart

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT CHECKING IT IS THE LATEST VERSION

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i. SOP Flowchart



1. PURPOSE AND SCOPE

The purpose of this SOP is to outline the procedure within NBT of the process to follow when setting up Honorary Research Contracts and Letters of Access in order to undertake research related activity in the NHS.

Research in the NHS often involves working in partnership with staff from other NHS organisations and Higher Education Institutions (HEIs). The Research Governance Framework for Health & Social Care (2nd Edition, April 2005) calls for a clear understanding about responsibility, accountability, patient safety, and duty of care in relation to research. One of the ways this can be achieved is through the use of Honorary Research Contracts (HRC) and Letters of Access (LoA).

The underlying principles for issuing an HRC or LoA are to ensure that:

- non-NHS researchers (who have no paid contract with an NHS organisation) are contractually bound to take proper account of the NHS duty of care and to follow the requirements of research governance and other research regulations at every stage of their research process;
- research participants, researchers, services users, care/host organisations are protected;
- there is clarity in a legal situation, should an adverse incident occur in respect to research activity.

2. DEFINITIONS/ABBREVIATIONS

CV	Curriculum Vitae
ERIF	NBT External Researcher Information Form
HEI	Higher Education Institution
HR	Human Resources department
HRA	Health Research Authority
HRC	Honorary Research Contract
LoA	Letter of Access
NBT	North Bristol NHS Trust
PI	Principal Investigator
R&I	NBT Research & Innovation Office
SOP	Standard Operating Procedure

3. WHO SHOULD USE THIS SOP

This SOP is aimed at researchers employed by a HEI or NHS organisation (other than NBT), who are applying to undertake research within NBT. This SOP applies where the external researcher does not already have an appropriate contractual relationship with NBT.

4. WHEN SHOULD THIS SOP BE USED

This SOP should be referred to when requesting access to NBT for research purposes. Researchers who do not already have an appropriate contractual relationship with NBT must follow this SOP in order to apply for an HRC or LoA, as appropriate.

5. PROCEDURE

5.1. Access Arrangements

All researchers without a contractual relationship with the NHS organisation in which they plan to undertake their research will require either a HRC or LoA in order to undertake research within that trust.

- (a) **Where researchers have either a substantive employment contract or an honorary clinical contract with one NHS organisation**, an HRC is not required in order to undertake research in another NHS organisation, but additional pre-engagement checks may occasionally be required.

NBT R&I will accept the 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.

Please refer to section 5.2 of this SOP for details.

- (b) **Where researchers are from a HEI and do not hold an NHS substantive employment contract or NHS honorary clinical contract**, a Research Passport will be required, which enables the NHS to decide whether or not the individual needs an HRC or LoA to enable them to undertake research within NHS facilities.

NBT R&I accept the Research Passport.

Please refer to section 5.3 of this SOP for details of how to apply for a Research Passport.

5.2. NHS to NHS Letter of Access

Where researchers have either a substantive employment contract or an honorary clinical contract with one NHS organisation

- (a) **Obtaining a NHS to NHS Letter of Access from NBT**

Substantive employees of NBT who require a LoA to carry out research in another NHS trust should liaise with R&I to confirm details of the research activity to be undertaken and complete the NHS to NHS confirmation of pre-engagement checks proforma which can be found on the NIHR website:

www.myresearchproject.org.uk/help/help%20documents/NHS-to-NHS-confirmation-of-pre-engagement-checks.doc

The applicant should then submit this completed form to all NHS trusts in which a LoA is required for that study.

(b) **Requiring Access to NBT**

Research staff that do not hold a substantive or honorary clinical contract with NBT may be identified by:

- HRA during initial assessment;
 - The PI for the research;
 - The individual concerned by contacting R&I directly.
- i. The staff member should complete an [External Researcher Information Form \(ERIF\)](#) available on the R&I website and request that the 'NHS to NHS proforma: confirmation of pre-engagement checks' is completed by the HR department of their NHS employer.
 - ii. The research office of the NHS employer will liaise with the HR department (or the HR department will undertake) to confirm that existing pre-engagement checks are sufficient for the research activity proposed to be carried out at NBT. If necessary, the staff member will need to undergo any additional clearances and complete any outstanding pre-engagement checks.
 - iii. The staff member will be issued with a signed copy of the 'NHS to NHS proforma' which must be submitted to research@nbt.nhs.uk along with the completed ERIF, a current CV.
 - iv. Upon receipt of a correctly completed NHS to NHS confirmation of pre-engagement checks proforma and the research study being approved by R&I, a LoA will be issued to the staff member and to their substantive NHS employer.
 - v. An NBT identification badge will be required where the staff member will need to come to an NBT site. A form requesting access will be enclosed with the LoA.

5.3 Research Passport

Where researchers are from a HEI and do not hold an NHS substantive employment contract or NHS honorary clinical contract

The Research Passport system provides:

- a single set of checks on a HEI researcher who intends to conduct research within the NHS;
- a standard form to be completed by the HEI researcher and their employer which is **validated** by an NHS organisation;

- a Research Passport which can be presented to all relevant NHS organisations, enabling faster start-up and an overall reduction in duplication and inconsistencies.

There are two types of Research Passport:

- **Project specific passport** for researchers who will be involved with only one project over the course of a three year period; or
- **Three year passport** for researchers who will be working on a number of projects over the course of a three year period and have an on-going research portfolio.

The effect of holding a substantive contract, HRC or LoA with NBT is that the staff member will be covered by the NHS Indemnity Scheme for the conduct of the research. However, the substantive employer remains accountable for the actions of the staff member.

(a) Research Passport Algorithm – HRC or LoA?

The [Research Passport Algorithm](#) will be assessed by the HRA during the initial assessment and the HRA approval letter will provide details regarding the need for either a LoA or HRC. It will also confirm what pre-engagement checks should or should not be requested, in line with the HRA Good Practice Resource Pack and the HRA assessment criteria and standards.

Please note that the HRA will not be validating Research Passports. An NHS organisation in England will validate the Research Passport and put in place the necessary local HR arrangements in line with the initial assessment letter, HRA assessment criteria and standards and the HRA Good Practice Resource Pack as part of supporting participating NHS organisations in arranging capacity and capability.

Neither an HRC or LoA will be required if the researcher:

- Is employed substantively by NBT (although additional pre-engagement checks may occasionally be required).
- Is an independent contractor (eg a General Practitioner) or employed by an independent contractor.
- Is a medical student who will be supervised within a clinical setting by an NHS employee or is covered by local agreements in place between an HEI and NHS trust (pan-Bristol agreements).

(b) PROCEDURE – RESEARCH STAFF FROM HIGHER EDUCATION INSTITUTIONS (HEIs)

- i. Staff which do not hold a substantive or honorary clinical contract with NBT may be identified by:
 - HRA during initial assessment;
 - The PI for the research;

- The individual concerned by contacting R&I directly.
- ii. The researcher should complete a Research Passport Application Form and obtain signed approval from their HEI for the relevant sections on the application form. This form is available to [download from the NIHR website](#). A support document for completing this form is available to [download from the NIHR website](#).
- iii. **EITHER:**
 - (A) If **NBT is the first NHS Trust** to be approached then the researcher should email research@nbt.nhs.uk to arrange a meeting in person. The applicant will need to bring with them the following:
 - Their completed and approved Research Passport Application Form;
 - Photographic ID i.e. Passport or Provisional or Full Driving Licence;
 - Evidence of Professional Qualifications & Professional Registrations claimed;
 - A utility bill dated within the last 3 months that includes the current address of the researcher;
 - Original documents of Disclosure and Barring Service (DBS) check;
 - Confirmation of Occupational Health (OH) check;

OR:

- (B) If your research passport has already been signed off (section 8) by another NHS Organisation, then the researcher should submit the signed Research Passport Form to R&I to apply for access.

In either case, a request will be submitted to the NBT HR department to process the HRC or LoA.

- iv. If necessary, the researcher will undergo any additional clearances and complete any outstanding pre-engagement checks. Subject to the research being approved by the R&I, an HRC or LoA will be issued to the researcher and to their HEI.
- v. An NBT identification badge will be required where the staff member will need to come to an NBT site. A form requesting access will be enclosed with the HRC or LoA.

6. DISSEMINATION AND TRAINING

SOPS will be distributed in accordance with SOP [RI/QMS/SOP/001 – Preparation of R&I Research SOPs](#).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the Trust intranet shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP. The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

7. RELATED SOPS AND DOCUMENTS

- Health Research Authority
UK Policy Framework for Health and Social Care Research
www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- National Institute for Health Research (NIHR)
Research in the NHS - Human Resources (HR) Good Practice Resource Pack
[www.myresearchproject.org.uk/help/help%20documents/HR%20Good%20Practice%20Resource%20Pack%20Information%20for%20researchers%20RP001_v3_0%20\(002\)%20April%202019.pdf](http://www.myresearchproject.org.uk/help/help%20documents/HR%20Good%20Practice%20Resource%20Pack%20Information%20for%20researchers%20RP001_v3_0%20(002)%20April%202019.pdf)
- The following NBT documents are available on the R&I website: www.nbt.nhs.uk/research

RI/QMS/SOP/006a	External Researcher Information Form
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Appendix A

NHS-to-NHS Proforma: Confirmation of Pre-engagement Checks

**NHS to NHS letter of access: 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 employer¹ 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:

Signed:

Date:

¹ For clinical academics, this would be a representative from their HEI employer