Standard Operating Procedure

Honorary Research Contracts & Letters of Access

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Document Version History

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

Current versions of all Research & Innovation SOPs and accompanying documents are available online. If you are reading this document in printed form, please check that the version number and date match the most recent version on the Research & Innovation website: www.nbt.nhs.uk/research
i. SOP Flowchart

Is the researcher a member of NBT staff?

Yes

No further action required

No

Is the researcher from a HEI or NHS Organisation?

HEI

NHS

Yes: Honorary Clinical Contract (send copy to Research)

ERIF form to be completed by researcher and NHS-NHS proforma to be completed by researcher’s HR department. Completed forms including CV to be returned to R&I.

Yes

New Research Passport to be completed at researcher’s own organisation and authorised by their HEI. Research Passport then to be sent to NBT R&I once completed. ERIF form also to be completed by researcher and returned to R&I.

No

Does the researcher have a Research Passport or NHS Honorary Clinical Contract with another NHS Trust?

Yes: Research Passport or Honorary Clinical Contract

ERIF form to be completed by researcher and returned with Research Passport to Research & Innovation Office

Is NBT the first Trust the researcher is approaching?

Yes

Identity confirmed by NBT R&I. Certificates verified, photocopied and scanned and request submitted by NBT R&I to HR to process Letter of Access or Honorary Research Contract according to algorithm

No

Researcher sends copy of previously completed and signed Research Passport (signed off by first NHS Trust) to NBT R&I Office.

Request submitted by NBT R&I to HR to process Letter of Access or Honorary Research Contract according to algorithm

Letter of Access or Honorary Research Contract issued

Letter of Access will be issued subject to receiving completed ERIF form, CV and NHS-NHS proforma

Letter of Access or Honorary Research Contract issued
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

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CV</td>
<td>Curriculum Vitae</td>
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<tr>
<td>ERIF</td>
<td>NBT External Researcher Information Form</td>
</tr>
<tr>
<td>HEI</td>
<td>Higher Education Institution</td>
</tr>
<tr>
<td>HR</td>
<td>Human Resources department</td>
</tr>
<tr>
<td>HRA</td>
<td>Health Research Authority</td>
</tr>
<tr>
<td>HRC</td>
<td>Honorary Research Contract</td>
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<tr>
<td>LoA</td>
<td>Letter of Access</td>
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<tr>
<td>NBT</td>
<td>North Bristol NHS Trust</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
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<tr>
<td>R&amp;I</td>
<td>NBT Research &amp; Innovation Office</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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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.

Version 4.0/13-06-16/ Page 3 of 9
RI/QMS/SOP/006
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:

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 (e.g., 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
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 bill including 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 NBT website (www.nbt.nhs.uk/research) 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

- Department of Health
  www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4108962

- National Institute for Health Research (NIHR)
  Research in the NHS - Human Resources (HR) Good Practice Resource Pack

- The following NBT documents are available on the R&I website: www.nbt.nhs.uk/research

| RI/QMS/SOP/006a | External Researcher Information Form |
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 employer 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:

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

Version 4.0/13-06-16/ Page 9 of 9
RI/QMS/SOP/006