North Bristol NHS Trust

# Standard Operating Procedure

# Obtaining R&I Confirmation for Research to Start

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| **REFERENCE:** | RI/QMS/SOP/002 |
| **VERSION NUMBER:** | 4.1 |
| **EFFECTIVE DATE:** | 05-02-18 |
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| **AUTHOR:** | Clinical Trials Manager; Clinical Trials Officer |
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| **APPROVED BY:** | Deputy Director of Research |
| **CONTROLLER:** | Contracts & Quality Management Officer |

Document Version History

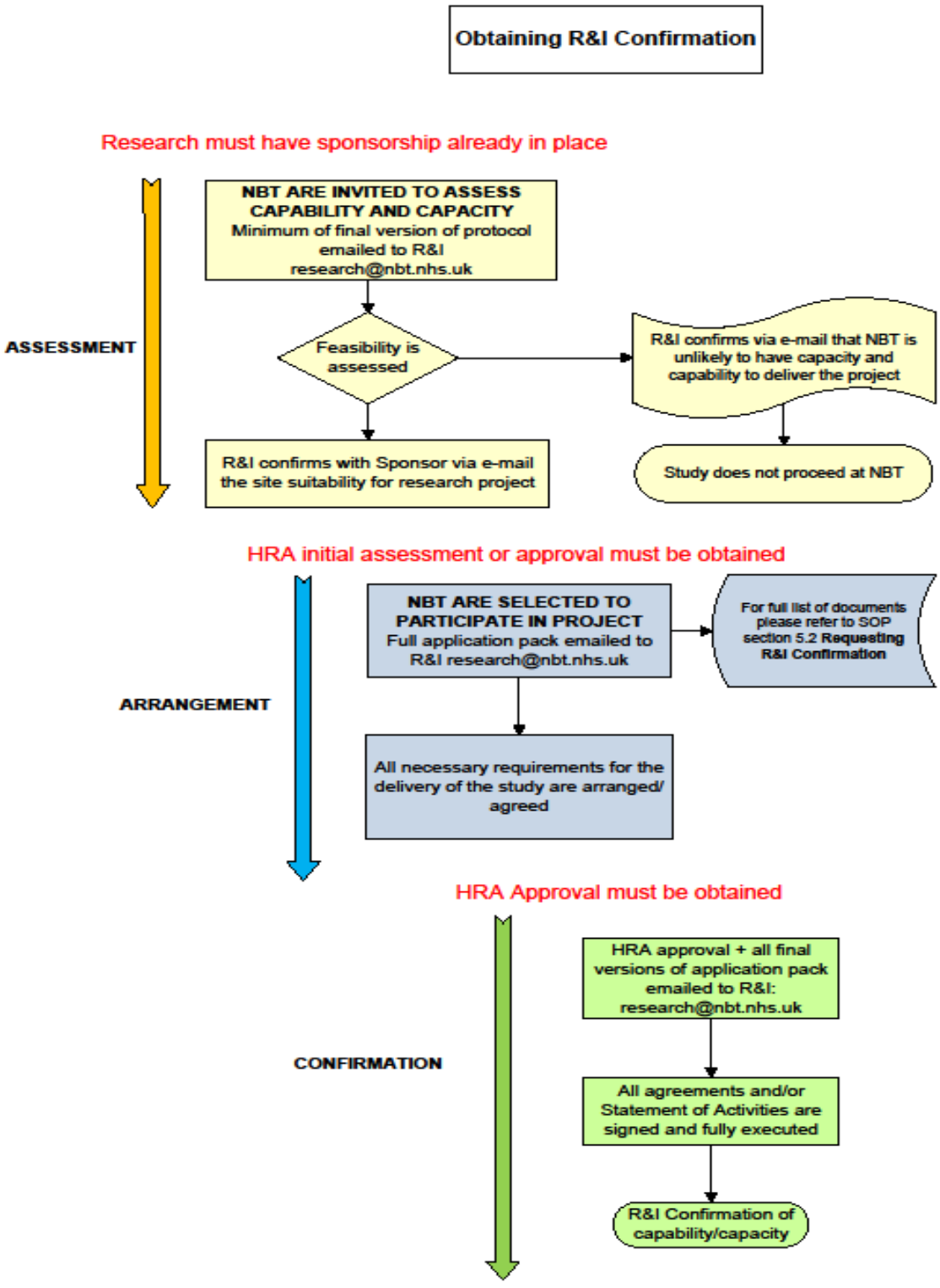
| VERSION NUMBER | EFFECTIVE DATE | REASON FOR CHANGE |
|---|---|---|
| 1.0 | 27-08-10 | Amended to ensure SOP clearly defines procedure for obtaining R&I approval |
| 2.0 | 09-07-12 | SOP renamed, updated in line with new template and recoded from ISOP-E05 |
| 3.0 | 08-02-16 | Updated in line with HRA requirements |
| 4.0 | 28-11-16 | Updated references to UK Policy Framework and HRA requirements |



**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



## 1. PURPOSE AND SCOPE

**The purpose of this SOP is to describe the process for obtaining confirmation from NBT Research and Innovation office (R&I) for research to take place within the trust.**

At NBT, R&I is the department with the authority from the Chief Executive to assess, arrange and confirm capability and capacity for research activity to be conducted at NBT. This process is referred to as 'R&I Confirmation' and all research projects must receive R&I Confirmation before commencing at the Trust (for exceptions, please see section 4 of this SOP).

This SOP is not for use if the proposed project is an *audit* or *service evaluation*. For further information about classification of your project please use the HRA, 'Is my study research?' link: www.hra-decisiontools.org.uk/research.

## 2. DEFINITIONS/ABBREVIATIONS

| | |
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| CI | Chief Investigator |
| CTIMP | Clinical Trial of an Investigational Medicinal Product |
| EDGE Database | The research database used by NBT for managing set up and delivery of studies |
| HRA | Health Research Authority |
| HRA Approval | The new single application process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by the HRA, with the independent REC opinion provided through the UK research ethics service |
| ICH GCP | International Conference on Harmonisation Guidelines for Good Clinical Practice |
| IRAS | Integrated Research Application System |
| MHRA | Medicines and Healthcare Products Regulatory Agency |
| NBT | North Bristol NHS Trust |
| PI | Principal Investigator |
| REC | Research Ethics Committee |
| R&D | Research & Development |
| R&I | NBT Research & Innovation Office |
| R&I Confirmation | The confirmation of capability and capacity for research activity to be conducted at NBT |
| SOP | Standard Operating Procedure |
| Sponsor | The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research |

## 3. WHO SHOULD USE THIS SOP

This SOP should be used by anybody wishing to conduct research activity at NBT.

## 4. WHEN SHOULD THIS SOP BE USED

This SOP should be used when applying for R&I Confirmation.

In most cases, R&I Confirmation will be required from NBT (and also from the R&D offices for any other health and social care organisation involved in the research). However, in limited exceptional cases, the HRA will be clear in the HRA Approval letter for a study that some or all participating English sites in that study will not need to provide formal confirmation of the capacity and capability (see section 5.1 of this SOP '*Before Requesting R&I Confirmation'* for more information about HRA approval). R&I can advise if a study falls into this category once they have received the HRA approval letter from the sponsor (see section 5.2 of this SOP '*Requesting R&I Confirmation*').

## 5. PROCEDURE

### 5.1. Before Requesting R&I Confirmation

NBT R&I may be contacted at any point for help and support. R&I can be reached via email on research@nbt.nhs.uk.

(a) Before requesting R&I Confirmation (and approval for any other regulatory bodies) a Sponsor for the research must be identified. If you require NBT to act as a Sponsor, please refer to the SOP on Applying for NBT Sponsorship (RI/QMS/SOP/007).

(b) The proposed project needs to be a research project. It should be assessed whether the proposed activity is 'research' as defined in the UK Policy Framework for Health and Social Care Research. Further information and guidance can be found on the HRA website: www.hra.nhs.uk. Your project Sponsor and local R&D office can help you determine this classification.

(c) All research studies will have to be submitted for HRA Approval[1] and HRA guidance must be followed, www.hra.nhs.uk. Application and submission will occur via IRAS. For further details, see www.myresearchproject.org.uk. HRA approval will not be issued until all other relevant regulatory approvals (e.g. REC/MHRA) are in place. To facilitate this process, please ensure that when you have received these other regulatory approvals, you forward these on to the HRA assessment team via email (hra.approval@nhs.net).

### 5.2. Requesting R&I Confirmation

Submission and review of requests occurs in three main stages**: *Assessment, Arrangement*** and ***Confirmation.*** The Sponsor (or their nominated delegate) is responsible for submitting the relevant paperwork to allow each stage to commence. If the study is sponsored by NBT, the CI

[1] HRA Approval is the new single application process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by the HRA, with the independent REC opinion provided through the UK Health Department's Research Ethics Service. All project-based research taking place in the NHS in England is required to obtain HRA Approval. Studies with sites in Northern Ireland, Scotland or Wales will be supported through existing UK-wide compatibility systems, by which each country accepts the centralised assurances, as far as they apply, from national coordinating functions without unnecessary duplication.

is responsible for submitting these documents. All documents should be submitted to research@nbt.nhs.uk. Each section is outlined below, including details of the relevant paperwork to be submitted at each stage, and what subsequently happens at each stage.

(a) **ASSESS:**

i. Initial *Assessment* involves R&I liaising with researchers and other key stakeholders to identify whether it is feasible that NBT will have the capability and capacity to deliver the research study.

ii. This assessment can occur when a protocol is submitted to R&I via email. This should be the final version that will be (or has already been) submitted for HRA Approval.

iii. Once the final protocol is received by R&I, the study will be given an R&I reference number and registered on the EDGE Database (if not already registered). It will be assigned to member of the R&I delivery team who will act as your first point of contact throughout the R&I process.

iv. Assessment will be based upon an assessment covering:

- Participant population.
- Staff requirements.
- The equipment/space/specialist services/emergency processes/safety reporting processes/IT etc. needed to deliver the study.

v. Once assessment outcome is positive and site selection is confirmed between Sponsor and R&I (via email), further documentation will be required to progress into the '*Arrangement*' stage (see below).

vi. If the assessment outcome is that NBT are not likely to have the capacity and capability to deliver the study, this will be communicated with the sponsor and NBT will not proceed to set up as a site.

(b) **ARRANGE:**

i. R&I must make arrangements to enable local capacity and capability to deliver the research study. To initiate this stage, all documents as indicated below must be submitted to R&I by email once the research study has received a HRA Initial Assessment Letter (or HRA Approval Letter where no Initial Assessment letter is issued):

- Copy of IRAS Form (combined REC and R&D form) as submitted for HRA Approval.
- Protocol.
- Any amendments.
- Participant information and consent documents.

- Statement of Activities relevant to the participating NHS organisation (non-commercially sponsored studies only).
- Relevant template contract/model agreement (if needed in addition to Statement of Activities).
- Costing template (commercially sponsored studies only) or Schedule of Events (non-commercially sponsored studies only).
- Any other documents that the Sponsor wishes to provide to the site to support the set up and delivery of the study.
- HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter and final document versions.

ii. R&I will put in place the arrangements to deliver the study. These arrangements may include, but are not limited to:

- Ensuring any HRA guidance (as indicated in Initial Assessment/Approval) is acted on;
- Putting in place any necessary contractual arrangements;
- Negotiation and agreement of financial arrangements;
- Ensuring that there are adequate resources are available at NBT from commencement to completion of the research - including finance, staff, and facilities (e.g. Pharmacy, Radiology, laboratories and other support departments);
- Ensuring that all research staff possess the necessary level of access and are trained by education and experience for their roles in research, see the SOP on Honorary Research Contracts & Letters of Access (RI/QMS/SOP/006);
- Ensuring ICH GCP compliance is met by local research team members.

iii. Where the following documents are not already held by R&I, local research personnel will be asked to submit the following to R&I during the assess stage:

- A Curriculum Vitae dated within the last **12 months**; and
- A valid Good Clinical Practice (GCP) certificate (if the study is a CTIMP) - NBT policy indicates these are valid for **3 years** from date of issue. See SOP on Research Staff Training (RI/QMS/SOP/005).

iv. It is likely that R&I will need to contact the research team and Sponsor with queries during the arrangement process. It is essential that the research team/Sponsor co-operate fully with any such queries, as this prevents delay during study set up. Research teams may be asked to provide information about study feasibility using the EDGE Database (NBT's research management system) and guidance will be offered on how this is done.

(c) **CONFIRM:**

i. In order for *Confirmation* of local capability and capacity to be obtained, final HRA approved versions of the documents and/or Statement of Activities will be required. This should be submitted to R&I by email.

ii. Confirmation can only occur once HRA Approval is obtained and NBT is ready to start the study. Confirmation will be provided via email to all relevant parties.

iii. Subject to all relevant actions being completed, R&I Confirmation will be issued alongside full execution of all agreements/ Statement of Activities. This is issued electronically via email to the PI, Sponsor, and research team.

iv. Once R&I Confirmation is given, the research can proceed at NBT, subject to relevant compliance as indicated on the confirmation email.

## 6. DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001).

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

- Health Research Authority
  *Decision Tool for Research*
  www.hra-decisiontools.org.uk/research

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

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| RI/QMS/SOP/005 | Research Staff Training |
| RI/QMS/SOP/006 | Honorary Contracts & Letters of Access |
| RI/QMS/SOP/007 | Applying for NBT Sponsorship |