Obtaining R&D Confirmation for Research to Start

Division: Strategy & Transformation

Specific staff groups to whom this policy directly applies	Likely frequency of use	Other staff who may need to be familiar with policy
Staff employed by NBT who directly or indirectly work on Clinical Research and when confirmation of CCC from R&D is required	Weekly	Staff not employed by North Bristol NHS Trust who are working on Research studies sponsored or hosted by NBT and when CCC from R&D is required

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KEYWORDS:	Capacity and Capability, R&D Confirmation, Local Information Pack, HRA Approval
Summary of changes since the previous version	SOP naming convention changed from RI/QMS/SOP002 to RD/QMS/SOP/002 Name change throughout document from R&I to R&D. Other minor changes include references to updates in HRA documentation

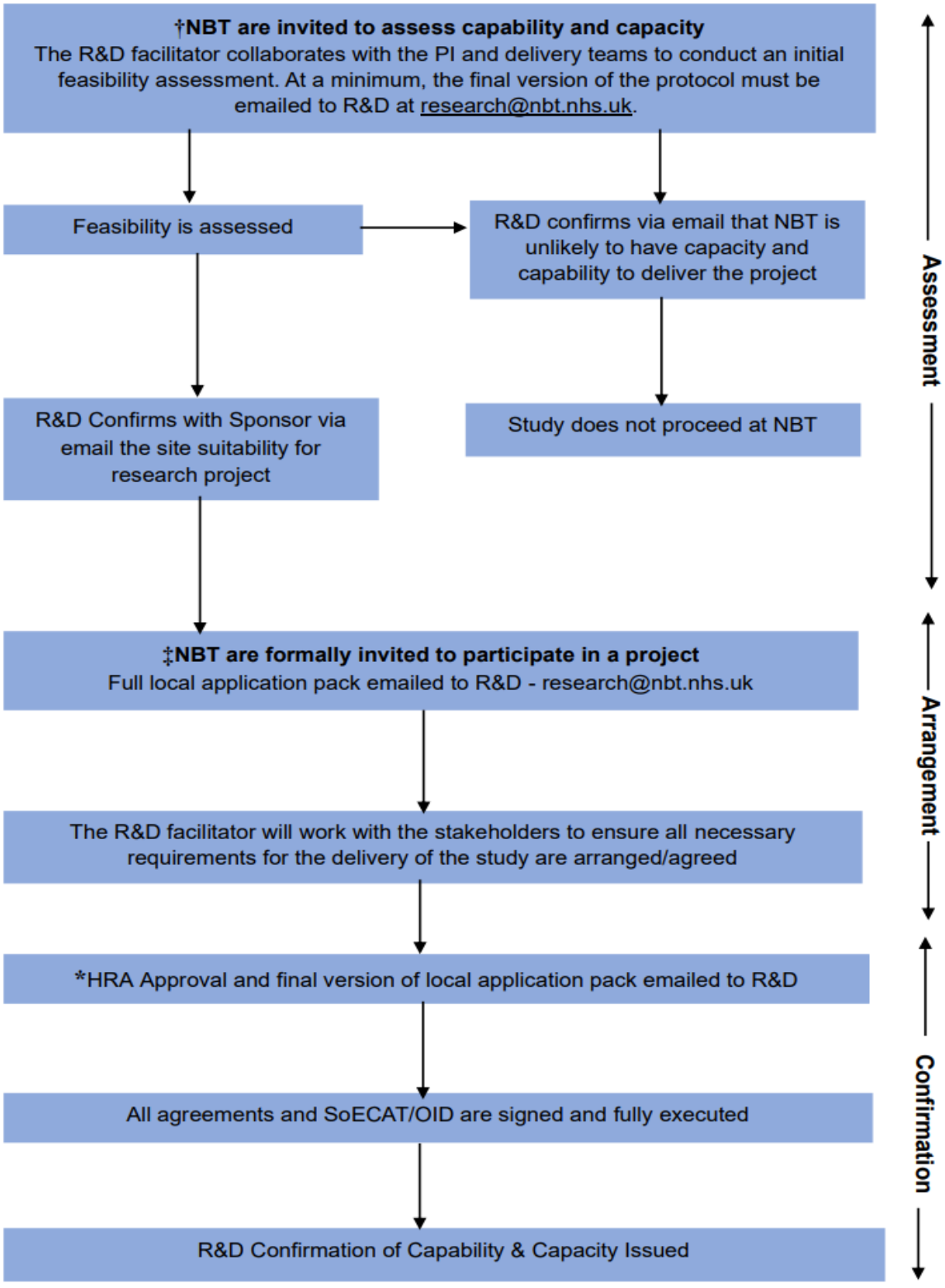
1. Purpose	The purpose of this SOP is to describe the process for obtaining confirmation from NBT Research and Development office (R&D) for research to take place within the trust when NBT are acting as a SITE, this also includes confirmation where NBT is the sponsor.
2. Key Messages	At NBT, R&D is the 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&D Confirmation' and all research projects must receive R&D Confirmation before commencing at the Trust (for exceptions, please see section 4 of this SOP). Under the UK Policy Framework for Health and Social Care Research, research is defined as 'the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods.' This SOP is not for use if the proposed project is an audit, service evaluation or Quality Improvement. For further information about classification of your project please use the HRA, 'Is my study research?' link: www.hra-decisiontools.org.uk/research. **ABBREVIATIONS/DEFINITIONS** **CI** Chief Investigator **CTIMP** Clinical Trial of an Investigational Medicinal Product **EDGE Database** It is a Clinical Research Management System used by NHS trusts to manage and monitor clinical research activities **HRA** Health Research Authority **HRA Approval** The research 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 **OID** Organisational information document **PI** Principal Investigator **REC** Research Ethics Committee **R&D** Research & Development **R&D Confirmation** The confirmation of capability and capacity (C&C) for research activity to be conducted at NBT **SoECAT** Schedule of Events Cost Attribution Tool **SOP** Standard Operating Procedure **Sponsor** The individual, company, institution, organisation which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research
3. Relevant Policies & Guidance	• 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&D documents are available on the NBT Website, LEARN or by submitting an email request to research@nbt.nhs.uk.: www.nbt.nhs.uk/research ○ RD/QMS/SOP/005 - Research Staff Training ○ RD/QMS/SOP/006 - Honorary Contracts & Letters of Access ○ RD/QMS/SOP/007 - Applying for NBT Sponsorship

4. Operational Areas Included	Research undergoing HRA approval involving NBT premises, staff, or patients.
5. Operational Areas Excluded	Research that does not involve NBT premises, staff or patients and does not require HRA approval. This includes research tissue banks, research databases and any other non-research projects e.g., audit, service evaluation, service improvement.
6. Who should read this	This SOP should be used by anybody wishing to conduct research activity at NBT.
7. Roles responsible for carrying out this procedure	**The Sponsor** is responsible for identifying the research project and ensuring that it meets the definition of 'research' as per the UK Policy Framework.The sponsor must ensure all necessary regulatory approvals (such as HRA, REC, MHRA) are obtained **The Sponsor or Chief Investigator (CI) or their Delegated Representative**, is responsible for submitting the study protocol and all required documentation necessary for obtaining R&D approval. The sponsor or the delegated representative or the CI (on some occasions) supports the review process through the Assess, Arrange, and Confirm stages in collaboration with the R&D Facilitator, ensuring that all queries are addressed in a timely and accurate manner. **R&D Facilitation Team** acts as the first point of contact throughout the review process. Their responsibility includes liaising with stakeholders to evaluate the feasibility of delivering the study. Register the study on the EDGE Database and create an electronic governance folder. The role of the facilitator is to help facilitate the setup of the study, ensuring that all required documentation is submitted and that the study is compliant with the necessary policies and appropriate resources are available. The facilitation team coordinates with the research team to ensure all preparations for the study are in place. **The Principal Investigator (PI)** is responsible for supporting the local Capacity and Capability assessment working with the facilitator and, if required the research delivery team. It is a requirement that they are aware of their responsibilities as PI when conducting research at NBT and they acknowledge this through signing this PI declaration.

8. Procedure:

Flowchart illustrating the process involved in obtaining R&D Confirmation



† Research must have sponsorship already in place; ‡ HRA initial assessment or approval must be obtained; * Final HRA approval must be in place

1.1. Before Requesting R&D Confirmation

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

(a) Before requesting R&D Confirmation (and approvals from 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 (RD/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. For further information about classification of your project please use the HRA, 'Is my study research?' link https://hra-decisiontools.org.uk/research/ 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]. HRA approval assesses the governance and legal compliance with an independent ethical opinion by a Research Ethics Committee (REC), where required HRA guidance must be followed, www.hra.nhs.uk. Application and submission will occur via IRAS. HRA approval will not be issued until all other relevant regulatory approvals are in place, such as MHRA. For further details, see www.myresearchproject.org.uk.

1.2. Requesting R&D Confirmation

Submission and review of requests to set studies up at NBT occurs in three main stages**:** ***Assess, Arrange*** and ***Confirm.*** The Sponsor (or their nominated delegate) is responsible for submitting the relevant paperwork to support each stage of the process. If the study is sponsored by NBT, the responsibility for submitting these documents lies with either the allotted sponsor representative for the study or with the representative delegated by the CI. All documents should be submitted to research@nbt.nhs.uk. Each stage is outlined below, including details of the relevant paperwork to be submitted at each stage, and what subsequently happens.

(a) **ASSESS:**

i. The assess stage begins when a protocol is submitted to R&D via email. This should be the final version that will be (or has already been) submitted for HRA Approval.

[1] HRA Approval is the 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.

ii. Initial *Assessment* involves R&D liaising with researchers and other key stakeholders, such as research delivery teams and support departments, to identify whether it is feasible that NBT will have the capacity and capability to deliver the research study.

iii. Once the final protocol is received by R&D, the study will be given an R&D reference number and registered on the EDGE Database (if not already registered). The reference number will be used to identify the study at all points during the life cycle of the research. During the initial assessment, the facilitation team is responsible for requesting the following documentation: the submitted IRAS form, the protocol, and the HRA initial assessment letter or approval. Following this, the team will issue the initial setup questions to the relevant delivery team or PI. The facilitation team will then add the required data fields to EDGE and an electronic governance folder will be created on TEAMS; all correspondence and documentation will be saved here. It will be assigned to a member of the R&D facilitation team who will act as the first point of contact throughout the R&D process.

iv. Initial Assessment will be based upon an assessment covering:

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

Once the initial assessment has been completed and both NBT and the sponsor are satisfied that the study is feasible at NBT, the study will move into the 'Arrange' stage and be assigned to a member of the R&D facilitation team, who will act as the first point of contact throughout the R&D process.

v. 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&D will make arrangements to enable local capacity and capability to deliver the research study. To initiate this stage, the sponsor or the CI (if NBT sponsored study) are responsible for submitting the relevant paperwork, in the form of a Local Information Pack (LIP). All documents that form a part of the LIP are indicated below. The LIP must be submitted to R&D 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.

  Organisation Information Document relevant to the participating NHS organisation (non-commercially sponsored studies only).
- Relevant template contract/model agreement (if needed in addition to the OID(OID)).
- Costing template (commercially sponsored studies only) or SoECAT/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.

Research teams will 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. If the delivery team is not involved, the PI is responsible for providing the required information.

The workflows consist of a list of numbered tasks that the R&D facilitator needs to work through, like a checklist. Each question has a 'show procedure' button that gives more details on what needs to be reviewed. Any comments made during the review will be written in the comments box, along with the date the comment was added. Once a question is complete, the R&D facilitator will mark it has done and add the completion date. These workflows will be available to research staff assigned to the study record on EDGE, so everyone can easily access them whenever needed. This helps keep the C&C review process transparent. Once the feasibility workflows have been completed our facilitation team will work with stakeholders to agree a date by which all parties aim to achieve C&C.

ii. R&D 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 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 (RD/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&D, local research personnel will be asked to submit the following to R&D during the assess stage:

- A Curriculum Vitae (CV) dated within the last **3 years or sooner if any changes** 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 (RD/QMS/SOP/005).
- To support oversight and compliance, all research staff are required to upload their evidence of ICH GCP training and a current research CV to their EDGE profiles.

iv. The local PI will be asked to review and acknowledge the Principal Investigator Declaration form, this ensures that the PI is fully aware of their responsibilities when undertaking research at NBT.

It is likely that R&D will need to contact the research team, PI and Sponsor with queries during the arrangement process. It is essential that the research team/PI/Sponsor co-operate fully with any such queries, as this prevents delay during study set up.

(c) **CONFIRM:**

i. In order to proceed with issuing *Confirmation* of local - capacity and capability (C&C), the final HRA approved versions of the documents must be provided. - Additionally, the OID or mNCA, as applicable, should be completed and authorised by the designated signing authority.

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, including completion of all workflows on EGDE. R&D Confirmation will be issued alongside full execution of all agreements/ OID.

iv. R&D confirmation is issued by the Deputy Director, Research Operations Manager or permitted member of R&D senior team via email to the PI, Sponsor, and research team and any applicable support departments. Prior to providing confirmation the authoriser will review EDGE workflows, check the contracts are in place and support departments approvals have been confirmed.

v. Once R&D confirms C&C, the Sponsor issues a Green Light letter or email, indicating that recruitment can begin at the site. In some cases, depending on the sponsor's policy, if both the sponsor and site have agreed on a study start date and the site has issued C&C, no additional greenlight is required to begin recruitment.

1.3 **After Study Set up**

The R&D facilitator will serve as the primary point of contact within the R&D department. Upon confirmation of C&C for the study, the research delivery team or the R&D facilitator (where a delivery team is not in place) will contact the researcher periodically to obtain recruitment information for upload, if applicable. For amendments submitted by the Sponsor, the R&D facilitator will collaborate with the research teams to review the amendment documents and engage relevant support departments to ensure that required changes can be implemented. If all necessary departments can accommodate the amendment, the R&D Facilitator will process the acknowledgement to the study amendment and issue a 'North Bristol NHS Trust Acknowledgment of Amendment' email to the Sponsor.

1.4 **Studies notified to R&D as not requiring a C&C review**

Within the HRA letter, it will detail whether a 35-day review for no objection is required. The study will be reviewed within the 35-day timescale provided to ascertain whether there is any objection to the research taking place at NBT. The R&D facilitators will liaise with the sponsor (or nominated delegate) PI and research team as required for this process. The review will involve assessing the documentation provided by the Sponsor in the email to establish whether any resource needs or funding are identified. Where applicable the R&D facilitators will liaise with the local team/service where the research will take place and discuss whether there are any objections. Relevant EDGE workflows will be completed by the R&D facilitator
Where a review of 'no objection' takes place, the R&D facilitator will request acknowledgment is issued by the Deputy Director, Research Operations Manager or permitted member of R&D senior team via email to the PI, Sponsor, and research team and any applicable support departments.

2. DISSEMINATION AND TRAINING

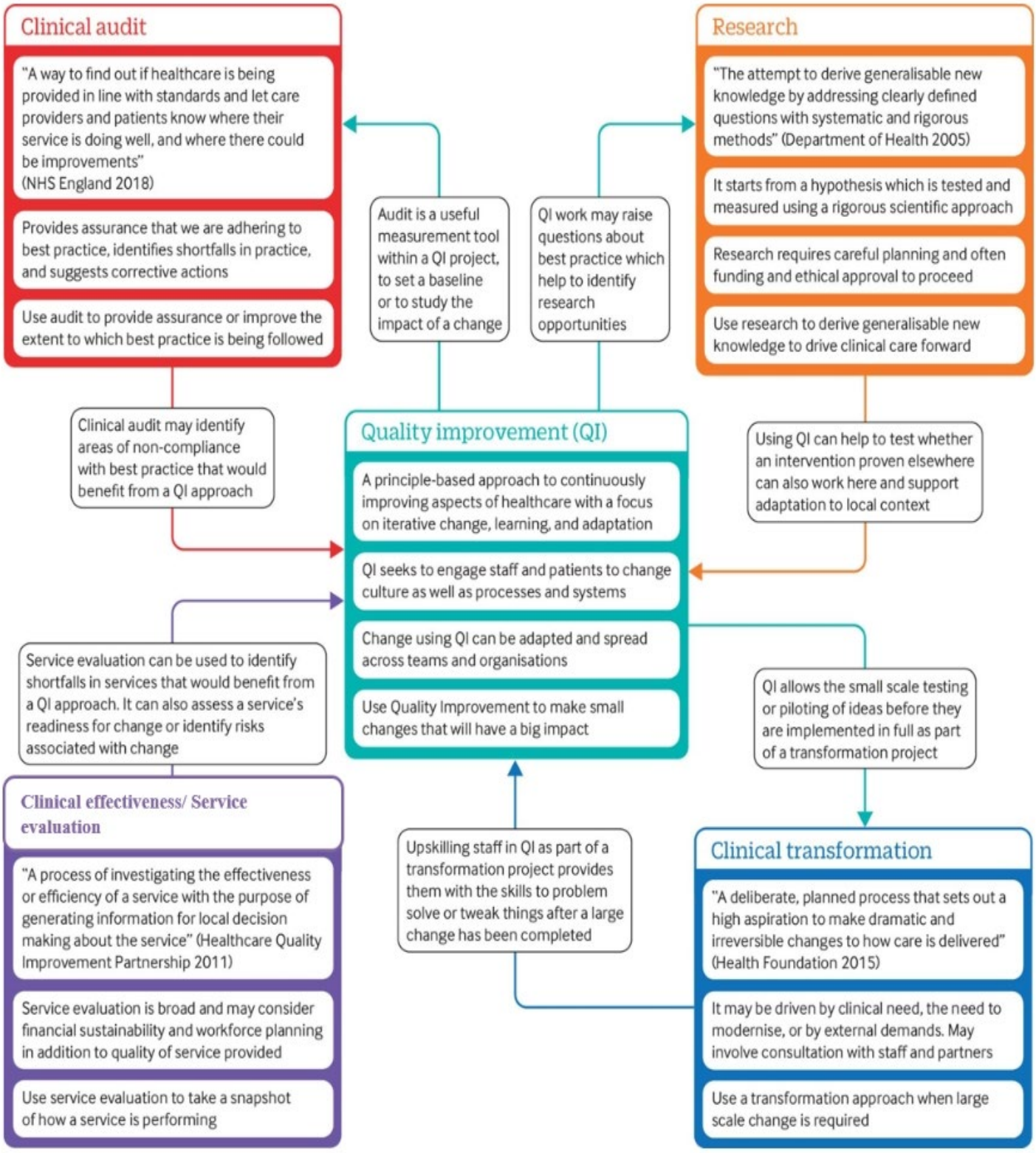
SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RD/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Managed Learning Environment "LEARN" system on the Trust intranet shortly after having been released, The trust website (www.nbt.nhs.uk/research) will be updated to capture the list of current SOP's in place

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP, this is monitored and audited via LEARN.

Appendix

Is my project research?



Backhouse., A (2020) *Quality Improvement into Practice*. BMJ 368.