York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S14

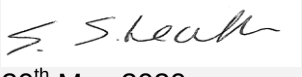
Issuing Confirmation of Capacity and Capability

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 R&D Unit's website and/or Q-Pulse 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit 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 Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

SOP Reference:	R&D/S14
Version Number:	8.0
Author:	Lisa Carr- Knott
Implementation date of current version:	30th June 2020

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	
	Date:	20th May 2020
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	
	Date:	20th May 2020

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	24th August 2009	
2.0	23rd August 2010	Clarification re Site Initiation for CTIMPs not sponsored by Alliance Trusts – Sections 5.3 and 6. Other minor revisions. Addition of trial to eSUSAR database added. Clarification of CLRN and R&D Unit roles.
3.0	16th January 2012	Merging previous SOPs into one: Portfolio, Non-Portfolio, CTIMP & Non-CTIMP. Change of SOP Controller.
4.0	9th February 2015	Change of author. Removal of references to the North and East Yorkshire Alliance. Updating of process to reflect embedded CLRN RM&G function.
5.0	12th September 2016	Complete re-write to incorporate the new HRA process
6.0	21st August 2017	Complete re-write to incorporate the new HRA process in more detail
7.0	30th November 2018	Re-write to incorporate recent process changes
8.0	30th June 2020	Change of link to R&D website. Minor changes to accommodate change of process in line with HRA guidance and local agreement.

Contents

1. Purpose

This Standard Operating Procedure (SOP) sets out to provide clarity on the process to be followed before Confirmation of Capacity and Capability is given to deliver a research study in York and Scarborough Teaching Hospitals NHS Foundation Trust (the Trust). The issuing of Confirmation of Capacity and Capability by Research Sites is required for all studies where it is noted on the Health Research Authority (HRA) Approval letter.

2. Background

HRA Approval is the process for the NHS in England that comprises a review by an NHS Research Ethics Committee (REC) (where required) as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA Staff. In England, it replaces the need for local checks of legal compliance and related matters previously known as local governance review. This allows NHS organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

Note; HRA Approval applies only to the NHS in England. The HRA has compatibility arrangements in place with the national NHS Permission coordinating function in Northern Ireland, Scotland and Wales that mean that the HRA will share information with those national coordinating functions to benefit study set up in participating NHS/HSC organisation across the UK where applicable.

3. Who Should Use This SOP

This SOP should be used by members of the Trusts Research and Development (R&D) Unit to aid in the completion of the local Capacity and Capability Assessment for research studies that require Confirmation of Capacity and Capability to be issued before recruitment activity can commence.

4. When This SOP Should Be Used

This SOP should be used when anyone requests Confirmation of Capacity and Capability to undertake a research study in the Trust in line with the requirement for this as noted on the HRA Approval letter.

5. Issuing Confirmation of Capacity and Capability

The HRA expects local R&D staff such as the Research Delivery Facilitators (RDFs) to work alongside the local Research Teams and supporting services in setting up and delivering studies. R&D staff should proactively support local Research Teams and these Teams should involve R&D staff in discussions with Sponsors, Chief Investigators, and Study Coordinators.

The HRA has defined the different stages that Sponsors and participating NHS Organisations such as the Trust should go through on the way to mutually agreeing that the study can open locally in the Organisation. These stages are

defined in Appendix 1 for reference. The below local processes and actions align to these stages and facilitate the completion of the Capacity and Capability Assessment and the issuing of Confirmation of Capacity and Capability by R&D staff when required as outlined by the HRA. The Capacity and Capability Assessment may be completed by an RDF or those members of R&D Unit staff who are delegated to perform this duty by the RDF on a study by study basis.

Note; the below processes and actions are to be used alongside SOP R&D/F12: Capacity and Capability Checklist, the Radiology guidance noted in Appendix 3 and related SOPs. Template emails have been developed to assist with Capacity and Capability assessments and these can be used for ease if required.

A new study opportunity is received by the RDF and/or local research team. An Expression of Interest/ feasibility form is completed and submitted by the local research team and RDF to the Sponsor/ Clinical Research Organisation (CRO) or the NIHR CRN.
(Template Email; R&DT52)

The completed form is then sent by the RDF to the relevant support departments with a request to complete a feasibility assessment. Known external providers may also be approached about capacity at the feasibility stage and relevant information passed to them if agreed with the Sponsor.
Note: For Laboratory Research and Pharmacy this will be specifically stated as a Request for Stage 1; Feasibility.
(Template Email; R&DT64 & R&DT65)

A Site Selection Visit may be arranged with the Sponsor/CRO, the relevant local research team and support team members.

The Sponsor/CRO confirms site selection with the local Research Team, Principle Investigator and RDF. If it is felt that the Trust is unable to proceed with the study after feasibility assessment then the Sponsor/CRO will be informed via email.
(Template Email; R&DT54)

The Local Information Package (LIP) of documents (see Appendix 2) is requested, received and acknowledged with the Sponsor/CRO by the RDF.

The RDF reviews the LIP ensuring all documents are present and correct in order to complete the Capacity and Capability Assessment. The RDF identifies whether the site is noted on the IRAS Form (if not an amendment will need to be submitted to the HRA by the Sponsor/CRO adding the site)

Organisational Involvement is requested by the RDF on EDGE. Once granted the RDF will create the local template for the study and continue to upload all LIP and study set up documentation into the R&D templated files. Relevant staff will be given appropriate access.

EDGE attributes; C&C Assessment and Audit Assessment will be completed by the RDF.

The RDF will create a study specific file on the X-Drive including all LIP and study set up documentation.

The RDF will complete a costings review of the Industry Costings Template (ICT)/ Schedule of Events (SoE)/ Schedule of Events Cost Attribution Tool (SoECAT) and Contract (agreement)/Statement of Activities (SoA)/ Organisational Information Document (OID). If Excess Treatment Costs (ETCs) are identified the RDF will discuss these with the Head of R&D and determine whether these costs can be met through local means e.g. Care Group and R&D funding.

The RDF sends the relevant documents (Protocol, SoE/SoECAT or ICT) by email to the teams Research Nurse for review and confirmation that they are happy with the noted activities and what is being asked of them throughout the studies lifetime. Confirmation of PI and study target will be sought.
(Template Email; R&DT68)
Alternatively the SoE/SoECAT or ICT may be reviewed during the studies Intensity Tool meeting.

A request for Stage 2; Review and Authorisation (Pharmacy) and Stage 2; Funding with Stage 3; Review and Authorisation (Lab Research) is sent by the RDF via email to the Laboratory Research Team and Pharmacy Clinical Trials Team (where applicable) with appropriate documents (Protocol, SoE/SoECAT or ICT, Manuals, IRAS Form) attached for review and confirmation that they are happy with the noted activities and what is being asked of them throughout the studies lifetime as well as assessing the noted costs and their correctness.
(Template Email; R&DT55 & R&DT66)

An email Request for Authorisation may be sent to other support services such as Radiology or Physiotherapy. In this instance these services will also be provided with the relevant documents and an outline of any funding or cost incurred so that they can review and confirm that they are happy with the noted activities and what is being asked of them throughout the studies lifetime

If the study is a commercial research project then the RDF will send the ICT to the Head of R&D to review before returning to the Sponsor/CRO with suggested amendments

The RDF requests any amendments to the ICT to be made with the Sponsor/CRO and this document is then finalised and confirmed as correct by the Sponsor/CRO via email. If the SoE/SoECAT is being used for non-commercial studies then any queries relating to the categorisation of costings should be made with the Sponsor/CRO and resolved.

The RDF receives by email completed Stage 2; Review and Authorisation from Pharmacy and completed Stage 2; Funding with Stage 3; Review and Authorisation from Laboratory Research where applicable along with Authorisations from any other support departments involved.

The RDF sends an email request for Care Group Management Authorisation to the appropriate Care Group Manager and Deputy Finance Manager via email and awaits confirmation of this request.
(Template Email; R&DT57)

The RDF will review the contract/agreement (where the SoA/OID is not being used for non-commercial research) and the Sponsor/CRO will populate the document with the funding as outlined in the ICT/SoE/SoECAT if not already done so and send it back to the RDF for final review.

A request for Stage 3; Readiness (Pharmacy) and Stage 4; Green Light (Lab Research) is sent by the RDF via email to the Laboratory Research Team and Pharmacy Clinical Trials Team.
(Template Email; R&DT69 & R&DT70)

Whilst the above authorisations and communications are taking place the RDF will complete other set up activities as noted below.
Note; these activities will take place in no particular order but in a manner that suits the set-up of the particular study in which capacity and capability is being assessed.

Where radiology modalities are required within the study the RDF is to refer to Appendix 3 and assess the need to complete an IRMER or make any ARSAC enquires in order to ensure the appropriate certificates are in place.

RDF requests CVs and GCPs from the local Research Team and details of any known training to be arranged/completed pre- opening the study wherever possible.

The local Research Team arranges the Site Initiation Visit (SIV)/Teleconference and liaises with the RDF to inform them of the date. The RDF may attend the SIV.

RDF liaises with the Laboratory Research Team (where required) as to whether they have received all necessary documents, kits and packaging required to run the study at site.

RDF liaises with the local Research Team as to whether they have received all necessary equipment and Investigator Site Files, and that all documentation requested by the Sponsor/CRO is complete.

RDF liaises with the Pharmacy contact for the study and enquires about the IMP arrangements (if applicable)

Identify (check the SoE/SoECAT and SoA/OID) Honorary Employment Contract / Letter of Access requirements and liaise with the Unit Administrator to arrange completion of relevant documentation where required. Unit Administrator to copy RDF into email to external researcher issuing the Letter of Access/ Honorary Contract.

The RDF enquires with the local Research Team and supporting services the preferred recruitment start date.

The rdf will complete the intensity tool template (it) and meet with a local research team member to complete this in line with the study requirements.

Where a Service Level Agreement is required for an external organisation to provide certain research support services for the project, the RDF and Head of R&D will liaise with the external organisation to implement this agreement.

The RDF will localise the contract/agreement and return it to the Sponsor/CRO to commence signatures.
Note; on occasion the Sponsor/CRO may wish for the Trust to sign first.
Note; unless specified otherwise the Head of R&D can sign all agreements that are within their finance sign off threshold.

The RDF receives by email completed Stage 3; Readiness from Pharmacy and Stage 4; Green Light from the Laboratory Research Team if they are in a position to provide these. The RDF will request Stage 4; Green Light* from the Pharmacy Clinical Trials Team.

*Note; Stage 3; Readiness and Stage 4; Green Light may be provided together depending on IMP and supply arrangements.
(Template Email; R&DT70)

The SIV will take place and all members of staff participating in the study at site will be invited to attend.

The Contract/Agreement is signed at site once returned from the Sponsor. Alternatively if the SoA/OID is being used as the agreement then the RDF will complete the necessary fields and sign.
Note; the OID must be completed and returned for all commercial studies where it is provided. The OIDs only needs returning to the sponsor for non commercial research studies if it is being used as the agreement.

The RDF checks with the local Research Team that they are ready to begin.

Letters of Access and/or Honorary Contracts are finalised by the Unit Administrator and the RDF is notified of this.

Note; Letters of Access and/ Honorary Contracts may take some time and may not be complete before issuing Confirmation of Capacity and Capability. When this is the case a note is to be placed on the Confirmation email notifying the Sponsor/CRO that they cannot complete the research activity related to requiring these until they are in place.

The RDF sends template email R&D/T04, Confirmation of Capacity and Capability to the Sponsor/CRO and attaches a copy of the Contract or SoA/OID. If the study is commercially sponsored then the OID will be returned with the Contract.

The Sponsor/CRO will issue the Site with their “Green Light” or “Site Activation” to commence recruitment (if required).

Pharmacy Clinical Trials and Laboratory Research will issue their Stage 4; Green Light if they have not done so already.

The RDF sends template email R&D/T05 to the PI and local Research Team confirming recruitment can now commence at site.

Any financial information noted in the Contract or SoA/OID is passed onto the Unit Administrator and Deputy Finance Manager.

The project is changed to “Open” on EDGE.

6. Related SOPs

R&D/F12	Confirmation of Capacity and Capability Checklist
R&D/S15	EDGE Database Management
R&D/S64	Setting-up Research Studies Involving Imaging (including studies using Ionising Radiation)
R&D/S35	Laboratory Research Clinical Trial Set up
R&D/S36	Expressing and Interest and setting up new studies: Guidance for Researchers and Research Teams
R&D/S25	Providing and Documenting Training for Researchers
Pharm/S45	Pharmacy Study Set Up
R&D/T04	Template Email; Confirmation of Capacity and Capability
R&DT05;	Template Email; Open to Recruitment; Email to the PI following Confirmation of Capacity and Capability
R&DT52;	Template Email; New Study sent to Local Research Teams; Review and EOI completion
R&DT52;	Template Email; New Study sent to Local Research Teams; Review and EOI completion
R&DT54;	Template Email; New Study; Site Selection
R&DT55;	Template Email; Request for Stage 2; Review and Authorisation (Pharmacy)
R&DT57;	Template Email; Request for Directorate Management Authorisation
R&DT64;	Template Email; Request for Stage 1; Feasibility (Pharmacy and Laboratory)
R&DT65;	Template Email; Request for Feasibility Review (additional support departments)
R&DT66;	Template Email; Request for Stage 2; Funding with Stage 3; Review and Authorisation (Laboratory)
R&DT67;	Template Email; Request for Authorisation (other support departments)
R&DT68;	Template Email; Review of Industry Costings Template & Schedule of Events by Research Nurse
R&DT69;	Template Email; Request for Stage 3; Readiness (Pharmacy) and request for confirmation of Readiness from all other support departments
R&DT70;	Template Email; Request for Stage 4; Green Light (Laboratory and Pharmacy)

Appendix 1: The stages of setting up a research study at site as defined by the HRA

Note; These stages are acknowledged as being correct as defined by the HRA however; some of the activities within these stages may not happen in the order noted but the key principles of these stages will be adhered to.

1. Identify: Site Identification

- The local Research Team may be approached by the Sponsor, CI or Clinical Research Network about a new research study.
- They indicate their interest in the study by completing an Expression of Interest (EOI) Form.

Note; Starts before or after HRA application by the Sponsor

2. Assess: Assessing Capacity and Capability

- The local Research Team, supporting services and the RDFs will receive the final protocol.
- The purpose of this stage is site selection. The RDFs in collaboration with the local Research Team, supporting services and the Sponsor/CRO assess whether there is the appropriate patient populations and the necessary staff and resources to deliver the study. Some Sponsors/CROs may choose to undertake a site selection visit as part of assessing capacity and capability.

Note; this stage will not be required, or will be minimal, for some types of studies where it is automatically expected that the Trust will participate unless there is a significant reason why not. These study types include emergency public health research, studies involving minimal local activity such as distributing questionnaires, on line surveys or supplying previously collected clinical data where consent is already in place, and studies where the clinical pathway has meant that a patient has been transferred for on-going clinical care but the responsibility for the research remains with the original Principal Investigator.

3. Arrange: Practical Arranging

- The RDFs and/or the local Research Team and supporting services are informed by the sponsor or the third party on behalf of the Sponsor that they have been selected as a site.
- The RDFs will process the new study using Local Study Set up Checklist R&D/F12.
- The RDFs will receive the LIP and confirm receipt of this with the Sponsor.
- The RDFs will share with the local Research Team and supporting services, relevant documentation contained in the LIP and liaise with them to put any practical arrangements in place to enable the delivery of the study at site.

4. Confirm: Exchange Agreements

- All preparations to efficiently run the study at site should now be in place and the Local Research Team and supporting services should be ready to start.
- RDFs should now be at a point of exchanging the contract/agreement with the Sponsor/CRO.
- The RDFs issue confirmation of capacity and capability at site using template email R&D/T04.

5. Site Initiation: Sponsor Initiates Site

- The local Research Team, supporting services and the RDF will participate in the Site Initiation Visit/ Teleconference if required.
- The local Research Team and supporting services will receive necessary supplies and IMPs.
- The Sponsor/CRO will issue their “Green Light” to begin.
- The RDFs issue the local Research Team and supporting services with the go ahead to commence recruitment at site using template email R&D/T05.

Appendix 2: Local Information Pack

The Sponsor/third party working on behalf of the Sponsor should provide the following information to the site:

- Copy of the HRA Initial Assessment letter
- HRA Approval Letter for the study (to be provided once available)
- Copy of IRAS application form (R&D form if pre HRA Approval study (April 2016))
- Regulatory Approvals (MHRA-where applicable, Ethics)
- Protocol
- Any amendments (including the amendment adding the Trust as a site if not done so with the original application)
- Participant Information and Consent documents
- Relevant Model Agreement (where applicable)
- NIHR Industry Costing Template (validated by the Clinical Research Networks – check front page) – commercial studies
- Schedule of Events (only for older studies, pre 6th June 2019 where the HRA have provided confirmation that this document can still be used by sites for a particular study)/ Schedule of Events Cost Attribution tool – non-commercial studies
- Statement of Activities (only for older studies, pre 6th June 2019 where the HRA have provided confirmation that this document can still be used by sites for a particular study) – non-commercial studies
- Organisational Information Document- commercial and non commercial studies
- Pharmacy, Laboratory, and Radiology Manuals (where applicable)
- Any other documentation deemed required by the site in order to complete the capacity and capability assessment
- Confirmation of NIHR portfolio adoption

Appendix 3: Local Study Set Up: Radiology

In collaboration with the Radiology Department the R&D Unit have agreed the below procedures for gaining involvement and authorisation for studies involving Radiology modalities.

To ensure that all research scans are appropriately set-up and delivered within the required timelines the Radiology Department and the R&D Unit have agreed a way for radiology requirements to be assessed and arranged for research purposes.

Modality Leads (listed below) have been appointed within the Radiology Department as the first points of contact in relation to new research studies and radiology authorisation.

- Ken Kay – Scarborough
- Gwen Haley – CT York
- Julie Caddick – MRI York
- Steve Baker – Plain Imaging York
- Lynn Boyes/Kirsty Cutt – Ultrasound York
- Debbie Brian – Breast Imaging Unit
- Faye Barnet – VIU York

The Modality Leads will provide the RDFs with a final decision on capacity and capability to accommodate any required imaging.

A Radiology Research spread-sheet has been set up to ensure all clinical studies that require Radiology support are clearly documented. This spread-sheet will be maintained and kept up to date by a named member of the R&D Unit.

Please refer to SOP R&D/S64 (Setting-up Research Studies Involving Imaging (including studies using Ionising Radiation)) for further guidance on Research involving Radiology.