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

Issuing Confirmation of Capacity and Capability and Opening Studies in York and Scarborough Teaching Hospitals NHS Foundation Trust

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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:	9.0
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Implementation date of current version:	1st March 2023

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	Date:	31st January 2023
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	Date:	30th January 2023

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	Reviewers	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.
9.0	1st March 2023	Lisa Carr-Knott Deborah Phillips Richard Furnival Jordan Toohie	SOP name change, updates due to HRA changes as well as local process changes.

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 (Confirmation of C&C) is given to deliver a research study in York and Scarborough Teaching Hospitals NHS Foundation Trust (the Trust). The issuing of Confirmation of C&C by Research Sites is required for all studies where it is noted on the Health Research Authority (HRA) Approval letter. When the issuing of Confirmation of C&C is not required then the Trusts R&D Unit will take appropriate steps to ensure local processes are followed that will enable the study to open.

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), the Medicines and Healthcare Products Regulatory Agency (MHRA) (where required), as well as an assessment of governance 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 the 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 means 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 C&C Assessment for research studies that require Confirmation of C&C to be issued before recruitment activity can commence. It is also to be used by R&D Unit members for those studies that do not require a C&C Assessment.

4. When This SOP Should Be Used

This SOP should be used when anyone requests Confirmation of C&C to undertake a research study in the Trust in line with the requirement for this as noted on the HRA Approval letter. Please utilise the following R&D Forms (Checklists) and related R&D Templates as appropriate;

R&D/F12 Confirmation of Capacity and Capability Checklist for Hosted Portfolio and Non-Portfolio Adopted Studies
R&D/F83 Confirmation of Capacity and Capability Checklist for Hosted Portfolio and Non-Portfolio Adopted Studies- PIC Sites
R&D/F80 Confirmation of Capacity and Capability Checklist for Trust Sponsored Portfolio and Non-Portfolio Adopted Studies

Where Confirmation of C&C is not requested by the HRA and/or study Sponsor, members of the Trusts R&D Unit will take appropriate steps to ensure local processes are followed that will enable the study to open in a timely manner. Please utilise the following R&D Form (Checklist) and related R&D Templates as appropriate;

R&D/F93 R&D Checklist for Hosted Portfolio and Non-Portfolio Adopted Studies that do not require Capacity and Capability Assessment

5. Study Set Up, Issuing Confirmation of Capacity and Capability, and Opening to Recruitment

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, Principle 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 their way to mutually agreeing that a 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 study set up, which 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.

The below processes and actions are to be used alongside R&D associated SOPs. **Each action may take place in the order noted below or may differ as events arise and progress. Some actions may not be applicable depending on the study type and whether the issuing of Confirmation of C&C is required. Please refer to Appendix 4, your applicable Checklist, and EDGE Attribute Guidance document for direction.**

Once the study has been discussed at the R&D New Study Prioritisation Meeting or, if deemed urgent and cannot wait, at the R&D Management Meeting and it has been agreed as a "High Priority" for set up the RDF will then commence their C&C Assessment if one is required. If a C&C Assessment is not required the RDF will take appropriate steps to ensure the local processes are followed to enable the opening of the study at site.

To commence study set up the RDF will access the local template for the study on EDGE and assign the relevant Attributes in line with the "New Study" Workflow, including the "Research QA Audit Assessment Tool" Attribute.

Please refer to Appendix 4 which depicts the different study set up Checklists and EDGE Attribute guidance documents to be used to support this activity.

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 study set up. If the Trust is to be a PIC site (Patient Identification Centre) or a Continuing Care site ensure there is clear reference noted as to the responsibilities of the site i.e. whether this be advertising only, consenting patients, or any follow up patient activity...etc

The RDF will create a study specific file on the X-Drive including all LIP and study set up documentation. All documentation will also be uploaded onto the local study page on EDGE utilising the "R&D File" template.

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 key documents (Protocol, SoE/SoECAT or ICT, Manuals, IRAS Form) attached. (Template Email; R&D/T55 & R&D/T66)

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 costs 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. (Template Email; R&D/T67)

Non Commercial Studies

The RDF will complete a costings review of the Schedule of Events (SoE)/ Schedule of Events Cost Attribution Tool (SoECAT) and Contract /Agreement/ Organisational Information Document (OID).

If Excess Treatment Costs (ETCs) are identified the RDF will discuss these with the Head of R&D for them to be agreed in line with the Trust ETC Policy.

The RDF sends the relevant documents (Protocol and SoE/SoECAT) by email to the teams Research Nurse/Research Practitioner for review and confirmation that they are happy with the noted activities and what is being asked of them throughout the studies lifetime. RDF will refer any significant issues with SoE/SoECaT to the Sponsor. Confirmation of PI and study target will also be sought.
(Template Email; R&D/T68)

The OID/Contract/Agreement will be localised with necessary information in readiness for commencing execution/signatures.

Commercial Studies

The RDF will request from the Sponsor access to the Industry Costings Template (ICT) on CPMS (Central Portfolio Management System) for themselves and the Commercial Research Manager (CRM). The RDF will complete a review of the ICT and the draft Contract/Agreement.

The CRM will arrange to meet with Delivery Team members to complete a review of the ICT and agree any amendments to be made. Confirmation of PI and study target will also be sought. Any requested changes to the ICT and target will then be sent to the Sponsor by the RDF for approval.

Once negotiations have taken place with the Sponsor and the final ICT is agreed the RDF will review the financial appendix of the Contract/Agreement and check this accurately reflects the final ICT. The Contract/Agreement will then be localised in readiness for commencing execution/signatures.

The CRM will ensure the agreed ICT is then uploaded onto EDGE to aid invoicing.

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). HRA Approval for the site is not required if the site is only required to display leaflets or posters as part of PIC site activity.

Whilst the above authorisations and communications are taking place the RDF will complete further 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.

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.

RDF confirms the ABF (Accrual Based Funding) and accrual allocation to site (if applicable)

RDF and Delivery Team must consider any potential Data Opt Out issues that may be relevant for the project.

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 as well as having any discussions around challenges encountered.

RDF liaises with the local Research Team as to whether they have received all necessary equipment and Investigator Site Files (if provided), 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 and any associated set up challenges (if applicable)

Identify (check the SoE/SoECAT and 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.

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 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.

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&D/T69 & R&D/T70)

The RDF sends an email request for Care Group Management Approval to the appropriate Care Group Manager and Deputy Finance Manager via email and awaits confirmation of this request.
(Template Email; R&D/T57)

Once the PI has been confirmed the RDF will send out to them R&D/T58 to confirm their PI responsibilities (CTIMPs, Medical Devices and Interventional Studies only). If there is no response to this via email then R&D/F76 will be provided to the Delivery Team to obtain PI signature. Once executed this is then to be filed on EDGE, in the project folder on the X-Drive, and in the ISF by the Delivery Team.

Once in receipt of Care Group Management Approval the RDF will send the localised Contract/Agreement (if used) to the Sponsor/CRO to commence signatures. On occasion the Sponsor/CRO may wish for the Trust to sign first.
Note; Unless otherwise specified the Head of R&D can sign all agreements that are within the finance threshold. If the agreement specifies a finance sum that is above the threshold then the Chief Executive is to be approached to sign the Contract/Agreement.

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&D/T70)

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 OID is being used as the agreement then the RDF will complete the necessary fields and sign.

The RDF checks with the local Research Team that they have everything in place.

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 C&C. 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.

Where applicable the RDF sends template email R&D/T04 or R&D/T28 (PIC site/Continuing Care site), Confirmation of C&C to the Sponsor/CRO and attaches a copy of the Contract or OID. If a C&C Assessment was not required then R&D/T59 will be sent to the Sponsor when the RDF is in a position to do so.

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.

For those studies that required a C&C Assessment the RDF sends template email R&D/T05 or R&D/T51 (PIC site/Continuing Care site) to the PI and local Research Team confirming the project may commence at site.

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

The project is changed to “Open” on EDGE.

6. Related SOPs

R&D/F12	Confirmation of Capacity and Capability Checklist for Hosted Portfolio and Non-Portfolio Adopted Studies
R&D/F90	Confirmation of Capacity and Capability Checklist for Trust Sponsored Portfolio and Non-Portfolio Adopted Studies
R&D/F93	R&D Checklist for Hosted Portfolio and Non-Portfolio Adopted Studies that do not require Capacity and Capability Assessment
R&D/F80	Confirmation of Capacity and Capability Checklist for Hosted Portfolio and Non-Portfolio Adopted Studies- PIC Sites
R&D/T58	PI Declaration of Responsibilities (Email)
R&D/F76	PI Declaration of Responsibilities (Form)
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/S37	Setting up New Studies with your Research Delivery Facilitator (RDF)
R&D/S25	Providing and Documenting Training for Researchers
Pharm/S45	Pharmacy Study Set Up
R&D/T04	Confirmation of Capacity and Capability (Email)
R&D/T05	Open to recruitment; Email to the PI following Confirmation of Capacity and Capability (Email)
R&D/T28	C&C PIC and Cont.Care (Email)
R&D/T51	Study Commencing-PI Notification- PIC and Cont. Care (Email)
R&D/T55	Request for Stage 2; Review and Authorisation (Pharmacy)(Email)
R&D/T57	Request for Care Group Management Authorisation (Email)
R&D/T58	PI Declaration of Responsibilities (Email)
R&D/T59	Opening New Research Study- no C&C (Email)
R&D/T66	Request for Stage 2; Funding and Local Approval with Stage 3; Review and Final Authorisation (Laboratory Research) (Email)
R&D/T67	Request for Authorisation (other support departments) (Email)
R&D/T68	Review of Schedule of Events by Research Nurse (Email)
R&D/T69	Request for Stage 3; Readiness (Pharmacy) (Email)
R&D/T70	Request for Stage 4; Green Light (Pharmacy) (Email)

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 the appropriate set up Checklist.
- 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 where applicable.

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 where applicable.

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
- 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 via CPMS (validated by the Clinical Research Networks – check front page) – commercial studies
- Schedule of Events/ Schedule of Events Cost Attribution tool – non-commercial studies
- Organisational Information Document- 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.

Appendix 4: R&D Study Set Up Checklists and EDGE Attribute Guidance Documents