York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S14

Local New Study Set Up: Capacity and Capability Assessment

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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SOP Reference:	R&D/S14
Version Number:	6.0
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Implementation date of current version:	21st August 2017

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	Date:	19th July 2017
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	Signature:	Signed copy held by R&D Unit
	Date:	19th July 2017

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

Contents

1 Introduction, Background and Purpose

This SOP sets out to provide clarity about the process to be followed before Confirmation of Capacity and Capability is given to deliver a research study in York Teaching Hospital NHS Foundation Trust (the Trust) for studies receiving HRA Approval. Obtaining Confirmation is an essential precondition to the conduct and delivery of any portfolio or non-portfolio study.

HRA Approval is the new process for the NHS in England that comprises a review by a 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 confirm their capacity and capability to deliver the study.

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. Further information about this can be found at http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/

2 Who Should Use This SOP

This SOP should be used by:

- Members of York NHS Foundation Trust R&D Unit (the R&D Unit);
- Any other NHS organisation that has a current contract with York Teaching Hospital NHS Foundation Trust for use of its SOPs

3 When this SOP Should be Used

This SOP should be used when anyone applies for Confirmation of Capacity and Capability to undertake a research study in the Trust. This includes studies sponsored or co-sponsored by the Trust as well as studies that are externally sponsored and hosted within the Trust. It includes applications for non-Portfolio studies made direct to the R&D Unit.

4 The stages of setting up a research study at site

The HRA has defined the different stages that sponsors and participating organisations (the Trust) go through on the way to mutually agreeing that the study can open at that organisation (the Trust). Please see below for an outline of these.

NB 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.

4.1 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.

NB Starts before or after HRA application by the Sponsor

4.2 Assess: Assessing Capacity and Capability

- The Local Research Team, supporting services and the Research Delivery Facilitators (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/ Third party working on behalf of the Sponsor assess whether there is the appropriate patient populations and the necessary staff and resources to deliver the study. Some Sponsors may choose to undertake a site selection visit as part of assessing capacity and capability.

NB 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.

4.3 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 Local Information Pack and confirm receipt of this with the Sponsor which will then trigger the 70 day clock and set the benchmark for recruiting the first participant into the research study. Please refer to Appendix 4 for details of the NIHR 70 day Benchmark Metric.
- The RDFs will share with the Local Research Team and supporting services, relevant documentation contained in the Local Information Pack and liaise with them to put any practical arrangements in place to enable the delivery of the study at site.

4.4 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 or the third party working on behalf of the Sponsor.
- The RDFs issue confirmation of capacity and capability at site using template email R&D/T04.

4.5 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 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.

5 Local New Study Set Up: Procedures and Actions

The HRA expects local research management staff (such as the RDFs) to work alongside the Local Research Teams and supporting services in setting up and delivering studies. Research management staff should proactively support Local Research Teams and these Teams should involve local research management staff in discussions with Sponsors, CIs, and Study Coordinators.

The below processes and actions refer to the different stages specified by the HRA as noted above. They are to be used as a guide by RDFs, Local Research Teams and supporting services when setting up a new research study at site but may not necessarily occur in the stated order.

It is essential that regular communication between relevant parties throughout the set up process occurs and that collaborative working between parties is at the forefront of decision making and action. Relevant template emails have been produced to aid with this and the local set up of new studies which can be identified in the right hand column of the below tables next to the applicable process/action.

NB The below processes and actions are to be used alongside SOP R&D/F12: Local Study Set Up Form and the Pharmacy Clinical Trials guidance noted in Appendix 3 and the Radiology guidance noted in Appendix 2 as well as the related SOPs including R&D/S94 that refers to laboratory medicine.

Identify and Assess: Site identification and assessing capacity and capability

Stage	Content	Template email
Start Point	Local Research Team/RDF is approached about the study via the Sponsor, CI, RDF or Clinical Research Network.	*R&D/T52*
Processes and Actions	An EOI is completed by the Local Research Team or RDF and sent back to the requesting Organisation/ Individual. RDF sends a copy of the completed EOI and associated initial study outline documents to supporting services *(Clinical Trials Pharmacy, Laboratory Medicine, Radiology)* for initial feasibility review. A Site Selection Visit may be collaboratively arranged between the Sponsor/ Co-ordinator and the Local Research Team with assistance from the RDF.	*R&D/T53*
End Point	Joint decision by the Sponsor/coordinator and the Local Research Team that the Trust has been selected to take part in the study. Confirmed by email.	

Arrange: Practical arranging

Stage	Content	Template email
Start Point	Sponsor/ Coordinator confirm site selection with Local Research Team, PI and RDF. If the Team is unable to proceed with the study after assessing capacity and capability then the sponsor/coordinator must be informed via email.	*R&D/T54*
Processes and Actions	The Local Information Package of documents *(see Appendix 1)* is received/requested and acknowledged with the Sponsor/Coordinator by the RDF. The RDF informs the Sponsor/Coordinator, Local Research Team and Supporting Services that the 70 day benchmark clock has begun *(see Appendix 4).* The RDF clarifies with the Local Research Team the sites recruitment target and the name of the PI. Where relevant, the RDF sends the relevant documents *(Protocol, Schedule of Events or Industry Costings Template)* by email to the study's Lead Research Nurse for review and	*R&D/T58* *R&D/T59*

	confirmation that they are happy with the noted activities and what is being asked of them throughout the studies lifetime. RDF reviews the Local Information Pack including the Protocol, Information Sheets and Consent Documents, the IRAS Form, Industry Costings Template/Schedule of Events. 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/Coordinator adding the site)* Where radiology modalities are required within the study the RDF is to refer to Appendix 2 and assess the need to complete an IRMER or request a copy of the trusts ARSAC certificate. Request for "Authorisation" sent by the RDF via email to the relevant supporting services with appropriate documents *(Protocol, Schedule of Events or Industry Costings Template, Manuals, IRAS Form, IRMER)* 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. RDF requests CVs and GCPs from the Local Research Team and details of any known training to be arranged/completed pre-opening the study. The Local Research Team arranges the Site Initiation Visit (SIV)/Teleconference and liaises with the RDF to inform of date. The RDF may attend the SIV if relevant or requested to do so by the Local Research Team. The RDF requests any amendments to the Industry Costing's Template to be made with the Sponsor/Coordinator and this document is then finalised and confirmed as correct with the Sponsor/coordinator via email. If the Schedule of Events is being used for non-commercial studies then any queries relating to the categorisation of costings should be made with the Sponsor/Coordinator and resolved. The RDF requests Directorate Management "Authorisation" to the appropriate Directorate Manager depending on the study field via email and awaits confirmation of this request. RDF liaises with the Laboratory Research Team as to whether they have received all necessary documents, packs 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/Coordinator is complete. RDF liaises with the Pharmacy contact for the study and enquires about the IMP arrangements *(if applicable)*	*R&D/T55* *R&D/T56* *R&D/T57*

	Identify (check the Schedule of Events and Statement of Activities) honorary employment contract / letter of access requirements and ensure that all relevant research passports/honorary contract (or letter of access) application forms and/or copies of NHS substantive contracts are available (or are obtained). The RDF enquires with the Local Research Team and supporting services the preferred recruitment start date. The template Agreement is reviewed and localised by the RDF or the Sponsor/Coordinator. Where the Statement of Activities is being used instead of the template Agreement the RDF will localise this appropriately. Organisational involvement is requested by the RDF on EDGE. Once granted the RDF will create the local template for the study and upload all Local Information Pack and Study Set up documentation into the R&D templated files. Relevant staff will be given appropriate access. The RDF will create a study specific file on the X-Drive including all Local Information Pack and Study Set up documentation. RDF enquires with the Sponsor/Study Coordinator as to who will be uploading the patient accruals onto CPMS and at what point a patient is considered recruited/ an accrual.	
End Point	HRA Approval is in place and the Sponsor/ Coordinator confirms site participation in writing (email) by finalising the study specific content of the unexecuted agreement ready for signature or final confirmation of content of the statement of activities.	

Confirm and Site Initiation: Exchange agreements and Sponsor initiates site

Stage	**Content**	**Template email**
Start Point	The Site Initiation Visit/Teleconference takes place at site and the Local Research Team and supporting services issue their readiness.	

Processes and Actions	The template Agreement or where used the Statement of Activities is signed and dated by the relevant person at site. Letters of Access and or Honorary Contracts are finalised by the Unit Administrator using guidance laid out in SOP R&D/S20. The RDF sends template email R&D/T04, Confirmation of Capacity and Capability to the Sponsor. The Sponsor will issue the Site with their "Green Light" to commence recruitment. Pharmacy will issue their "Green Light" Letter *(if they have been waiting on IMP delivery otherwise this will be provided at the point of issuing readiness)* The RDF sends template email R&D/T05 to the Local Research Team confirming recruitment can now commence at site. Any remaining documents are added to the study on EDGE by the RDF as well as adding the site attributes and changing "project in set up" to "Open". Any financial information noted in the template Agreement/ Statement of Activities is passed onto the Unit Administrator.	*R&D/T04* *R&D/T05*
End Point	Research activity may commence at site.	

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/S94	Laboratory Procedures for Research Studies
R&D/S25	Providing and Documenting Training for Researchers
Pharm/S45	Setting up a Clinical Trial
R&D/T04	Template email to confirm capacity and capability
R&D/T05	Template email to team copied to the Sponsor following confirmation of capacity and capability
R&D/T52	Template email to inform the research team of a new study opportunity
R&D/T53	Template email of notification to support departments of expression of interest (EOI)
R&D/T54	Template email; Site Selection
R&D/T58	Template email; Request and acknowledgement of receipt for the HRA Local Information Pack
R&D/T59	Template email; Review of the Industry Costing's Template by Research Team and Support Services
R&D/T55	Template email; Request for Authorisation from support services
R&D/T56	Template email; Request for CV's, GCPs and study training requirement's
R&D/T57	Template email; Request for Directorate Management Authorisation

7 Appendix 1: 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 – non-commercial studies
- Statement of Activities – 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

8 Appendix 2: 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 changed the way they assess and agree imaging 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 the R&D Unit's Research Studies Officer and therefore it is essential that the Research Studies Officer is informed of the set- up of all new studies involving radiology at the point of issuing confirmation of capacity and capability.

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.

9 Appendix 3: Local Study Set Up: Pharmacy

In line with the above key stages that Sponsors and the Trust go through on the way to mutually agreeing that a study can open in the Trust the Clinical Trials Pharmacy Team in collaboration with the RDFs have specified the below actions they will complete to facilitate study opening at site.

Please refer to Pharmacy SOP *Pharm/S45* for full details of the different stages of pharmacy new study set up.

Identify: Site Identification:

- RDFs send the initial documentation received and a copy of the EOI to the Pharmacy Team shortly after sending this to the Clinical Research Network/Sponsor/ Third Party working on behalf of the Sponsor.
- Pharmacy commence *Stage 1- Feasibility*

Assess: Assessing Capacity and Capability:

- Upon reviewing initial documentation and possibly attending a site evaluation visit/ pre site selection visit an email is provided to the RDFs confirming whether they have the facilities and resources to conduct the study at site.
- Pharmacy *Stage 1- Feasibility*

Arrange: Practical Arranging:

- RDFs will inform the Pharmacy Clinical Trials Team (via the shared inbox) that the site has been selected and will send all required documentation from the Local Information Pack.
- Pharmacy will acknowledge the above email and confirm receipt of the documentation with the RDFs.
- Upon reviewing the documentation an email confirming authorisation is sent to the RDFs.
- Pharmacy *Stage 2- Review and Authorisation*

Confirm: Exchange Agreements:

- All necessary documentation and practical arrangements are in place.
- IMP arrangements are known by the Pharmacy Clinical Trials Team and have been communicated to the RDFs.
- “Pharmacy Readiness” notification is received via email by the RDFs.
- Pharmacy *Stage 3- Pharmacy Readiness*

Site Initiation: Sponsor Initiates Site:

- IMPs are at site and Pharmacy issue their “Green Light” Letter to commence recruitment/the study at site.
- Pharmacy *Stage 4- Pharmacy Green light*

NB In the instances in which the IMP is delivered prior to the RDFs issuing the go ahead at site to commence recruitment “Pharmacy Readiness” and the Pharmacy “Green Light” Letter may be received at the same time.

10 Appendix 4: The NIHR 70 Day Benchmark Metric

The NIHR 70 Day Benchmark performance metric for initiating new studies (as outlined here: : http://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm) is triggered at the point at which the RDF acknowledges, by email receipt, the Full Local Information Pack from the Sponsor following a request by the RDF. Should the documents contained within the pack be sent in separate emails or should a document not be available until a later date, the RDF will not consider this pack complete or trigger the 70 day benchmark clock until the final document needed to complete the Local Information Pack has been received and acknowledged. Please see Appendix 1 for a list of those documents that make up the Local Information Pack.

For all studies, the RDF will confirm with the Research Team and the supporting services that they are in a position to run the study prior to requesting the complete Local Information Pack and triggering the 70 benchmark clock. Should the study Sponsor send the full Local Information Pack to the RDF before it has been requested, or if the RDF has no prior knowledge of the study in question, the RDF will not acknowledge receipt of this documentation until they have discussed with the Research Team, supporting services and PI that they are aware of the study and confirmed that they are in a position to commence study set up.

At the early stages before set up has been initiated the RDF may request that the Sponsor sends some documentation through to gather greater information on the study and complete pre-set up feasibility reviews, for example the study Protocol and Laboratory, Imaging or Pharmacy Manuals. This should not be considered by the sponsor as a request for the full Local Information Pack and if this Pack is sent receipt will not be acknowledged by the RDF aside from the named documents requested.