

Setting up new studies with your Research Delivery Facilitator (RDF) (Research Teams)

To be used in conjunction with R&D/F103

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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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	15th April 2019		Creation of new document
2.0	18 th April 2023	Lisa Carr-Knott	Updated due to process changes and staff roles.
3.0	18 th September 2023	Monica Haritakis	Information on AI added

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1. Introduction, Background and Purpose

Health Research Authority (HRA) Approval is required for studies that take place in the NHS in England. It 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 the Local Governance Review.

This allows NHS organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver a study. The HRA and the Clinical Research Network (CRN) expects members of the local Research and Development team to collaboratively work with Investigators and Research Teams when they have been notified that they have been selected to participate in a new study they expressed an interest in.

This Standard Operating Procedure (SOP) provides guidance to Investigators and Research Teams about what points to consider when collaboratively working with their named Research Delivery Facilitator (RDF) to set up a new research study in their Specialty so that a study may open.

2. Who Should Use This SOP

This SOP should be used by Investigators and Research Teams when they are collaboratively working with their RDF to complete set up activities to open a new research study in the Trust.

3. When this SOP Should be Used

This SOP should be used when an Investigator or Research Team are completing set up activities in order to open a study in the Trust.

4. Completing Study Set up Activities

Note: Your allocated RDF will be your primary point of contact throughout the course of study set up unless otherwise noted by them. Your RDF may also delegate the full or partial set-up of a particular study if deemed appropriate.

If you have been notified by a Sponsor representative that the Hospital has been successfully selected as a research site it is important to inform all relevant parties involved of this in case they have not been directly notified. This includes your named RDF, Sub Investigators, and any relevant Support Departments.

The Local Information Pack (LIP) (*see Appendix 1 for content*) will be received by the RDF either via the Sponsor, the Investigator or Research Team. Once the study has been prioritised for set up the RDF and their support staff will commence the Capacity and Capability Assessment. They will collaboratively work with the Research Team, Investigator and relevant Support Departments in order to set the new study up in a timely manner so that it may open and if required Confirm Capacity and Capability.

Note: Often the LIP will not come through as a complete set of documents as not all may be available at that stage, but all required documents will be received and

reviewed by the RDF before Confirmation of Capacity and Capability can be issued.

5. Types of Site Activity

Recruiting Site

A recruiting site is one where an NHS organisation may host or sponsor a research study whereby participants are recruited, and activities conducted in accordance with an approved research protocol.

Participant Identification Centre (PIC)

A PIC can be an NHS organisation that identifies potential research participants for a particular study for which they are not the recruiting research site.

For an organisation to operate as a PIC it has to perform the following;

- Identify potential research participants by processing personal data through carrying out a search of patient records against a set of eligibility criteria for example.

and

- Is following the Sponsors instructions in identifying potential research participants;

and

- Directs these potential participants elsewhere without undertaking any further research activity for that study.

Continuing Care Site

A Continuing Care Site is one where a patient is transferred to an NHS organisation for ongoing care and study conduct, having been recruited and consented by another organisation who are the recruiting site. A variety of activities may occur at a continuing care site, and these will be clearly laid out as part of study set up. We often see our organisation participating as a continuing care site as part of neonatal and paediatric research studies.

6. Things to consider when setting up a new study;

Communicate regularly with your RDF and all relevant support departments to ensure the progression of set up. **Use R&D/F103 to help you work through and record your set up activity.**

6.1 Study Documents;

- Every study has an Investigator Site File (ISF) and this may be provided to you by the Sponsor representative fully made up or they may only provide you with electronic copies of the documents to go in an ISF that you will need to make up. If you receive one that has been provided by the Sponsor thoroughly check through the documents enclosed and ensure they are the

current versions. Your allocated RDF will be able to tell you the current versions in line with the approval documents they have received if you are in doubt.

Note; if you have to make your own ISF up from scratch please do refer to the R&D Unit SOPs, Forms and Templates available to help you with this

- Create an electronic site file on your Q-drive that is accessible to all of the study team (it is recommended to keep the electronic ISF in the same format as the paper ISF copy to ensure complete document control).
- You will be required to localise relevant study documents such as the Patient Information Sheet and Consent Form with information such as the Trust header.

Note; if you do not have access to the Trust header or you are unsure as to what to put in relation to reporting complaints or providing advice please do contact your allocated RDF who will be able to provide you with the requested information.

- Complete the Version Control Log supplied by the Sponsor or if not available use the Trust templated version R&D/F101.
- Depending on the type of study and the Sponsor, you may be asked to organise the completion and sign off of important documents such as protocol signature pages, financial disclosures and confidentiality agreements...etc.
- Ensure a fully completed Study Delegation Log (signed off by the site PI) is in place. Please note: the study Delegation Log it's not just a paper exercise. It's a document by which the PI authorises staff to work on studies. Staff can't work on a study until they are authorised & confirmed as competent and qualified by education, training and experience to perform their assigned duties.

6.2 Radiology;

- If a study involves Ionising Radiation or exposure to Radioactive Substances then an IRMER (Ionising Radiation) or ARSAC (Radioactive Substances) will be required. The RDF will work with Leeds Radiation Protection Unit and the radiology leads at sites to complete these for the study where required. The RDF may request your assistance in obtaining signatures on these from the PI.
- If the study involves RECIST reporting then approach appropriate colleagues in the radiology department who may be able to perform this activity for you. Inform your RDF if you have identified a suitable person to complete this activity. Provide the identified member of staff with a good overview to the study and any necessary documents or protocol specific training required by the Sponsor. If you are unsure of who to ask to perform this activity, please liaise with the core clinical team who may be able to offer suggestion.
- Check whether any central reading of results is required for the study. Some Sponsors require Radiology images or ECG results to be read off site by a member of the central study team or their associates. This will be specified in

the protocol if this is a requirement. If this is the case then ensure you are aware of the method for sending these off and who in the research team or radiology department will be responsible for completing this activity. Your RDF will liaise with the PACS team to seek assistance with imaging send off if required. Liaise with them closely ensuring they have completed any specific training required and answer any questions they may have.

6.3 Electronic Data Capture (EDC), EDGE, Safety and Randomisation;

- If EDC online training is required try and arrange completion of this by all parties at the earliest opportunity to avoid delays.
- If the study involves electronic data capture and/or IVRS/IWRS randomisation systems request logins to these and ensure that all relevant parties have access ready for study opening. For blinded trials please ensure that an emergency unblinding procedure is in place/or it is specified in the study protocol. Always perform an unblinding test prior to the study commencing, and on regular basis for studies with long term recruitment & follow-ups (test if the provided details/logins/telephone numbers work and document the test in the study ISF).
- Check that all members of the Research Team have access to the project on EDGE so that patient recruits can be uploaded in a timely manner.
- If the PI is to receive Safety Reports from the Sponsor via an electronic system, please ensure they have a login, and that the system works for them. These are of prime importance for patient safety, and reporting and assessment of AEs/SAE.

6.4 Training;

- Check all CV's and GCP's are up to date at the earliest opportunity and are sent through to the RDF and their support staff when requested. In line with Trust policy GCP should be updated every 3 years and CVs should be updated, signed and dated as required.

Note; if you have a new member of staff in the team or a new investigator who is yet to complete a research CV and you do not have a template available, please do contact you allocated RDF as they will be able to send you one.

- Check with the Sponsor representative whether there is any study specific protocol training involved, particularly online training, and if there is request access to this for relevant individuals at the earliest opportunity to prevent delays.

Note; For example, if the study involves ward staff completing study activities you need to ensure that they have received the recommended level of training to comfortably complete their activity.

6.5 Equipment & Study Supplies

- Receive any supplies being provided to the site for the study e.g., lab kits, shipping boxes...etc and check through these. Please ensure that your team

arranges adequate storage & stock check controls (particularly for expiry dates and any amendments/changes to protocol requirements).

- If you are being provided with any electronic equipment for a study e.g., ECG machine, scales, Site Pad...etc please ensure calibration certificates are in place. Check if regular servicing and calibration are required, make sure that any maintenance checks are performed as per the manufacturers recommendations, and contact Medical Engineering Department (EME) in relation to testing these once they arrive.

Note: liaise with the Laboratory Research Team once lab kits have arrived so that they can go through them if they wish.

6.6 Other:

- RDFs will ask Research Nurses and the relevant support departments to review the Schedule of Events (SoE)/ Schedule of Events Cost Attribution Tool (SoECaT) (non- commercial studies only) against the current protocol to check whether they are happy with the activities noted, the timings provided for these and that they relate to the protocol accurately. The Commercial Research Manager will contact Teams and Support Departments as needed in relation to the review of the Industry Costings Template (ICT) (commercial studies only)
- Commercial Sponsors will ask for their own type of source data location checklist to be completed which may include IT related questions. If you would like assistance in completing this, please do contact your RDF who will be able to help you.
- You may be asked to provide the Sponsor representative with laboratory equipment calibration certificates and reference ranges. The Laboratory Research Team will be able to provide you with these upon request. They will also liaise with you throughout set up if they have any questions in relation to sampling and processing.
- Check whether samples will be processed in the local laboratory or whether these will be couriered/ shipped to a central laboratory. If local laboratory results are required, please make sure these tests are available as per standard care/or whether any additional set up is required.
- If a central laboratory is going to be involved ensure you are aware of the process for booking the courier, including ordering dry ice, sample pick up times for the Trust, and the courier service cover for weekends/bank holidays. Please check and agree with the Laboratory Research Team all details regarding clinic times and times for sample delivery to Labs, also check if there is a specific time frame for sample prep/processing/storage and/or shipping.
- If the study is a CTIMP the Pharmacy Clinical Trials Team will liaise with you throughout the set-up period in relation to things such as prescription format, drug dosing and dispensing.
- If the study requires blinded and un-blinded staff, please discuss this you're your Senior Research Nurse in terms of who may perform these roles.

Evidence of staff training in the emergency unblinding & the unblinding test should be documented in the study ISF.

- If the study requires home visits review the “Lone Working” SOP (R&D/S98) and complete the associated Forms (R&D F113 & R&D F114).
- Organise any practical arrangements such as ensuring there is adequate room space to see patients, any ordering has taken place for specific materials, and clinic files or study aids have been created.
- If the study is one that requires safety reporting, ensure you know what information to place on a patients CPD alert/flag including out of hours contact information. Please refer to R&D/S24.
- If the study involves the use of Artificial Intelligence (AI) the RDFs will ensure that relevant confidentiality agreements and contracts are in place. If there are any IT requirements they will ensure the arrangements to implement them are in place.
- Liaise with all parties in relation to booking a suitable date and time to have the Site Initiation Visit (SIV) (*if applicable*).
- Ensure you have received the Confirmation of Capacity and Capability email sent by the RDF.
- Ensure the Sponsor has issued their “Green Light” or “Site Activation” (*where applicable*).
- Ensure you have received the second email from the RDF and/or their support staff addressed to the PI noting that recruitment can commence.
- Place a copy of the completed “Set up Checklist for New Studies (Research Teams)” (R&D/F103) in your Investigator Site File.

7. Things to consider when the study opens.

- Ensure all relevant parties are aware of the study opening particularly those members of the clinical team that may not be included in Confirmation of Capacity and Capability email and the Sponsors Activation of the site.
- Put into practice any recruitment strategies including pre-screening activity.

Note: IT can assist with pre-screening activities by providing a list of potentially eligible patients from CPD records if suitable criteria are provided to them to complete their search. However, this is not something IT are required to do as part of their jobs, and they will be doing this to help so please consider carefully which studies would require their assistance. Please see Appendix 2 for further details.

- Notify the RDF once you have successfully recruited your first patient into the study and upload onto EDGE.

8. Related SOPs

R&D/S31 Claiming Research Participant Travel Costs

R&D/S24 Identifying Research Participants in the Medical Records and on CPD

R&D/S98 Lone Working

R&D/S25 Providing and Documenting Training for Researchers

R&D/S77 Identification of Potential Research Participants

R&D/S14 Issuing Confirmation of Capacity and Capability

R&D/F103 Set up Checklist for New Studies (Research Teams)

R&D/F101 Document Version Control Log

R&D/F113 Lone Working Visit Log

R&D/F114 Lone Worker Profile

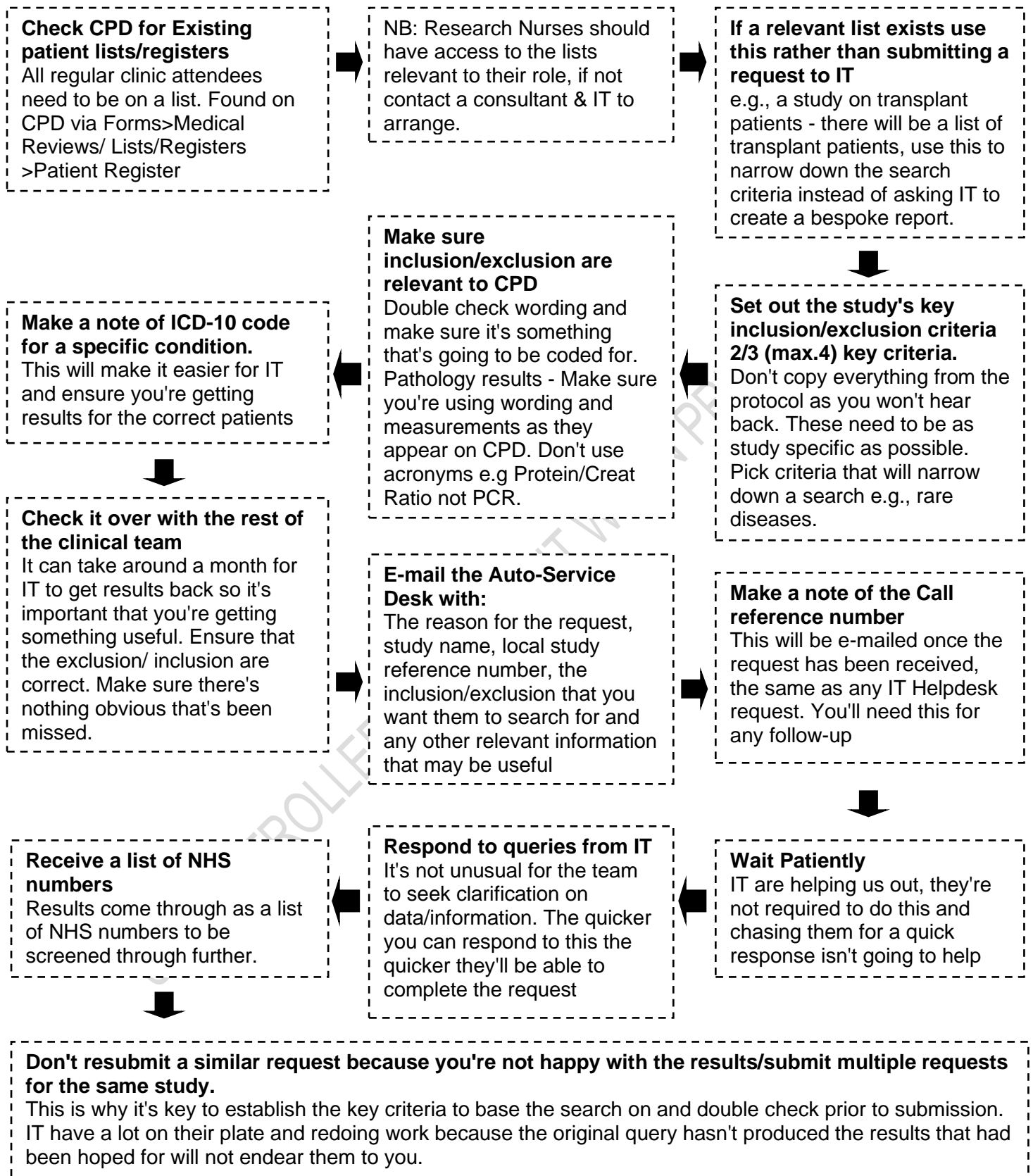
UNCONTROLLED DOCUMENT WHEN PRINTED

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/ Schedule of Events Cost Attribution Tool – 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

Appendix 2: CPD search request flow chart



Taken with permission from the original CPD search request flowchart, 01/Mar/2017, Renal Research