York Foundation Trust R&D Unit
SOP
R&D/S35

Laboratory Research Clinical Trial Set-up SOP

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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.northyorksresearch.nhs.uk/sops.html and/or Q-Pulse

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Author:	Laura Jeffery
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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	8th November 2017
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	8th November 2017

This SOP will normally be reviewed at least 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	9th November 2017	

Contents

1 Introduction, Background and Purpose

All clinical research studies which involve use of the Trusts' Laboratory for processing research specific samples must be reviewed by the Laboratory Research Team prior to the trial being approved for conduct in the organisation. This is to ensure that the Laboratory is able to support the trial, taking into account costs, workload, other resource implications and practical aspects of the processing, storing and shipping of study samples including any specific staff training that may be required. Laboratory readiness must also be confirmed prior to participant recruitment, to ensure that, where applicable, the appropriate lab kits and documentation have been received.

For all trials (sponsored or hosted), a Laboratory review and authorisation of the trial, and subsequent confirmation of readiness, are required prior to the issue of the 'Confirmation of Capacity and Capability' (CCaC) email, that allows to open the study for recruitment

2 Who Should Use This SOP

This SOP should be used by all members of the Laboratory Research Team and the R&D Department who are involved in the review and set up of research studies in the Laboratory.

3 When this SOP Should be Used

This SOP should be used when reviewing a research study involving the use of the Trusts' Laboratory and for the set-up of studies in the Research Laboratory.

4 Procedure(s)

Clinical research studies must be setup using a 4 stage process in conjunction with the Laboratory Research Clinical Trial Setup Form R&D/F73.

4.1 Stage 1 – Initial Feasibility Assessment

The information available at this stage is usually very limited and includes an expression of interest (EOI) and a copy of the study protocol (but not always). A copy of the laboratory manual is often not provided at this stage and may be completed prior to a site selection visit (SSV)/or site initiation visit (SIV). Generally the feasibility review will be limited to assessing whether the required equipment is available and if there is capacity within the Lab Research teams to set up and deliver another study.

Upon receipt of an email from a Research Delivery Facilitator (RDF) initiating Stage 1 - Initial Feasibility Assessment, the following tasks must be completed in a timely manner:

1. Record the new clinical trial on the '*SET UP*' sheet '*Clinical Trial Summary Spreadsheet*' (Appendix A) by completing columns A – D (if the information is available).

2. Create a new study specific folder on the X drive using the '*TEMPLATE Clinical Trial File'* (saved on the X drive) and save all relevant documents in the folder, finally create a new folder in the shared labresearch@york.nhs.uk inbox in the STUDIES IN SET UP folder.

3. The Stage 1 - Initial Feasibility Assessment section of the Laboratory Research Clinical Trial Setup Form R&D/F73 should be completed, electronically signed and sent back to the RDF who requested it. (Please see section 4.5 for guidance on completing the form.) This should also be documented in column F of the Clinical Trial Summary Spreadsheet.

Please note: If a new clinical trial is brought to the attention of the Laboratory Research Team by a CTA or Research Nurse it should be documented on the Clinical Trial Summary Spreadsheet and the corresponding electronic folders set up. The relevant RDF should be contacted, and they should make the decision on whether Stage 1 – Initial Feasibility Assessment should be initiated.

4.2 Stage 2 – Review & Authorisation

This Stage will usually be completed once a site has been selected by the sponsor but prior to the Site Initiation Visit (SIV). Stage 2 – Review & Authorisation must be done in far more detail. All aspects must be considered including; costs, workload, equipment, other resource implications and practically processing specimens, storing and shipping of study samples including any specific staff training that may be required.

Upon receipt of an email from an RDF initiating Stage 2 – Review & Authorisation, the following tasks must be completed in a timely manner;

1. Ensure all the study documents are saved in the folder in the X drive. By this stage the laboratory research team should have received all study documents from the RDF, the Research Team or the Sponsor. This must include a study Protocol and will usually be accompanied by a Laboratory Manual or Laboratory SOP(s). Any outstanding documents are to be requested as they must be reviewed as part of this stage.

2. The Stage 2 – Review & Authorisation section of the Laboratory Research Clinical Trial Setup Form R&D/F73 should be completed, electronically signed and sent back to the RDF who requested it. (Please see section 4.5 for guidance on completing the form.) This should also be documented in column G of the Clinical Trial Summary Spreadsheet. The Laboratory Research Clinical Trial Setup Form R&D/F73 includes the following;

a) The costing template review must be completed. Please see Laboratory Research Costing Template Review Guidance R&D/S37 for further information.

b) Authorisation of a new clinical trial, in all instances, must be obtained from the Head BMS at York Teaching Hospital NHS

Foundation Trust. The email confirming approval must be saved on the X drive.

c) If the study requires local laboratory involvement, permission must be obtained from the relevant department. All emails confirming approval or rejection from local pathology departments must be saved on the X drive. For the local laboratory to make their assessment, they must have access to a copy of protocol, laboratory manual and the costing template review.

4.3 Stage 3 – Readiness Checklist

This stage must be completed once at the soonest available opportunity after Stage 2 – Review & Authorisation has been sent to the RDF setting up the clinical trial. The Lab Research Team should ensure that all the documents and equipment/kits/consumables/packaging have been ordered, and will be received prior to CCaC being issued for the study.

The following tasks must be completed in a timely manner;

1. The Stage 3 – Readiness Checklist section of the Laboratory Research Clinical Trial Setup Form R&D/F73 should be completed, electronically signed and sent back to the corresponding RDF. (Please see section 4.5 for guidance on completing the form.) This should also be documented in column H of the Clinical Trial Summary Spreadsheet.

a) If laboratory specific instructions or other documentation are required, these should be created at this stage and reviewed by another member of the Laboratory Research Team.

4.4 Stage 4 – Green Light

This stage must be completed once at the soonest available opportunity after Stage 3 – Readiness Checklist has been sent to the RDF overseeing set-up of the clinical trial. It can also be completed at the same time as Stage 3 – Readiness checklist. The Laboratory Research Team is responsible for ensuring that all key aspects to perform the required Laboratory support for the trail are in place prior to CCaC being issued.

The following tasks must be completed in a timely manner;

1. The Stage 4 – Green Light section of the Laboratory Research Clinical Trial Setup Form R&D/F73 should be completed, electronically signed and sent back to the corresponding RDF. (Please see section 4.5 for guidance on completing the form.) This should also be documented in column I of the Clinical Trial Summary Spreadsheet. The Laboratory Research Clinical Trial Setup Form R&D/F73 includes the following ;

a) The Laboratory Site File for the study must be organised and ready prior to CCAC being issued (Prepare the following: A4 leaver-arch file, set of dividers (1-20), Spine Template R&D/T09, place all template documents in the relevant section and clearly write the page number and the name of the clinical trial on every page). The Laboratory Site File Contents (R&D/T07) and Laboratory Site File Audit Checklist (R&D/F13) can be used as a guide alongside Table 1.

If any documents that form part of the Laboratory Site File are stored elsewhere (for example, if a sponsor provides a bound copy of the laboratory manual), please use the Laboratory Site File Document Reference Log R&D/F76 to give details of their location and file the sheet in the relevant Laboratory Site File section.

b) Any study specific training should be completed and documented at this stage (if required), including appropriate technical competence and an adequate understanding of GCP requirements (including patients' safety, consent and confidentiality, scientific value of the study)

c) Delegation of duties must be formalised and signed off by the study PI.

Table 1

Section	Document(s) to File
Front Page	- Laboratory Site File Contents (R&D/T07); additional sections may be added by naming sections 18-20.
1. Key Information & Clinical Trial Setup	- Laboratory Research Clinical Trial Setup Form (R&D/F73); ensure it is fully completed and signed. - File copies of all permissions. - File a copy of the CCaC once it has been issued.
2. Staff Signature &Training Log	- Staff Signature & Training Log (R&D/F72); sign and complete one document per member of staff. - Record all future training in the log. - - File any evidence of training, for example, copies of training certificates obtained.
3. Protocol	- File a copy of the Protocol (ensure it is the correct version). - Superseded versions should be removed.
4. Amendment Log	- Laboratory Amendment Log (R&D/F23); all amendments are to be documented on this form.
5. Correspondence	- All key correspondence should be printed and filed in the relevant section; however, if it is general correspondence (not related to a specific section) it should be filed here.
6. Laboratory Manual & Clinical Trial SOP(s)	- File a copy of the laboratory manual and/or SOPs (ensure it is the correct version). - Superseded versions should be removed and placed in section 17.
7. Specimen Receipt Log	- Specimen Receipt Log (R&D/F51).
8. Requisition Form(s)	- File all requisition forms in this section. - If the original is to be sent with the samples/required to be filed in the main site file, ensure a photocopy is made.
9. Specimen Location Log	- Specimen Location Log (R&DF32); complete when moving a specimen, i.e. if it is no longer in the location stated in the Specimen Receipt Log (R&D/F51).
10. Specimen Shipping Log & Specimen Destruction Log	- Specimen Shipping Log R&D/F62 - Specimen Destruction Log (R&D/F28); complete if the sample is destroyed. - File the correspondence with the sponsor requesting sample destruction if applicable.
11. Shipping Document(s)	- File all receipts from couriers (signed and dated if applicable). - Multiple small tear-off slips can be stuck on an A4 sheet and

	filed.
12. Specimen Deviation Record	- Specimen Deviation Log (R&D/F31); record any sampling, storage, shipping or other deviation. Follow R&D/04 for reporting suspected serious breaches of GCP or the study Protocol.
13. Clinical Trial Specific Paperwork	- Ensure all clinical trial study specific paperwork, for example temperature recording charts or sample processing records, are filed in this section. - Master copies of these template documents should be clearly marked as such or saved electronically. - Specimen Incubation Log (R&D/F74); optional (do not file a copy unless applicable to the clinical trial).
14. Specimen Checklist	- Specimen Checklist (R&D/F24); ensure it is fully completed for every sample
15. File Note Log & File Note(s)	- File Note Log (R&D/59) - File Note Template (R&D/T20); complete file notes when appropriate and record in the File Note Log (R&D/59)
16. Audit Assessment(s)	- Laboratory Audit Checklist (R&D/F13); to be used when auditing the laboratory site file and filed in this section.
17. Superseded Laboratory Manual(s) & Clinical Trial SOP(s)	- File superseded versions of the laboratory manual and/or SOPs. - The current version(s) should be filed in section 6.
18.	- Optional
19.	- Optional
20.	- Optional

Once approvals have been received from relevant departments (including Laboratory Research Stage 4 – Green Light) and regulatory authorities the Research Delivery Facilitator will issue 'Confirmation of Capacity and Capability'. The following must be completed once CCaC has been issued:

1. CCaC email is to be saved on the X drive and a paper copy is to be filed in section 1 of the laboratory site file.

2. The clinical trial specific file on the X drive must be moved from '*Studies IN SET UP*' file to the relevant research speciality.

3. The information documented in the '*Clinical Trial Summary Spreadsheet*' on the '*SET UP*' sheet must be moved to the '*YORK OPEN*' or '*SGH OPEN*' sheet depending on which site the clinical trial is opening at.

4. Move the clinical trial specific folder in the labresearch@york.nhs.uk inbox to the relevant research speciality.

Please note: Receipt of any study specific research samples should not be accepted by the Laboratory Research staff until all set up stages can be confirmed as completed and CCaC email received. Laboratory must only perform work that is detailed in the study Protocol/Laboratory Manual. It's an equal

responsibility of the Research Team and Labs Research Team to ensure that only appropriate samples are taken to, and processed by the Trust's Laboratory.

4.5 Laboratory Research Clinical Trial Setup Form R&D/F73 Completion Guidance

Please fill in the short title of the clinical trial on every page.

Complete the 'Key Information' as and when the information becomes available during the setup process. Ensure it is fully completed as part of Stage 4 – Green Light.

Date actions where appropriate and complete all boxes and ensure no blank spaces are left. If the information is not available or not applicable this should be indicated with a '-', 'N/A' or other appropriate comment. The form can be adapted to meet the varying requirements of clinical trials. For example, if there is more than one central laboratory involved additional boxes can be added to include the second central laboratory details.

Key questions raised and their responses must be documented. This can be done in one of three ways:

1. Email correspondence

2. The 'Questions Raised and Outcomes' section of the Laboratory Research Clinical Trial Setup Form R&D/F73 can be used.

3. File notes

Related SOPs and Documents

R&D/F73	Laboratory Research Clinical Trial Setup Form
R&D/S37	Laboratory Research Costing Template Review Guidance
R&D/T07	Laboratory Site File Contents Page
R&D/F13	Laboratory Audit Checklist
R&D/F74	Specimen Incubation Log
R&D/F23	Laboratory Amendment Log
R&D/F24	Specimen Checklist
R&D/F28	Specimen Destruction Log
R&D/F31	Specimen Deviation Log
R&D/F32	Specimen Location Log
R&DF51	Specimen Receipt Log
R&D/F59	File Note Log
R&D/F62	Specimen Shipping Log
R&D/F72	Staff Signature & Training Log
R&D/T09	Spine Template
R&D/T20	File Note Template
R&D/F76	Laboratory Sile File Document Reference Log

5 Appendix A

R&D Ref	*Trial*	*Site*	*Department*	*AP R&D*	*Stage 1*	*Stage 2*	*Stage 3*	*Stage 4*