York Foundation Trust R&D Unit
Standard Operating Procedures
R&D/S63

Sub-contracting Services for Research Activities

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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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	Signature:	Signed copy held by R&D Unit
	Date:	15th November 2017
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	Signature:	Signed copy held by R&D Unit
	Date:	15th November 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	15th November 2010	
2.0	30th April 2012	Made applicable for CTIMP and non-CTIMP studies. Change of SOP Controller. Removal of North and East Yorkshire R&D Alliance references
3.0	21st October 2013	Change to ensure that decision as to whether lab is fit for purpose does not reside with investigator alone.
4.0	4th January 2016	Incorporation of requirements to specify how laboratory results are reported
5.0	13th December 2017	

Contents

1 Introduction, Background and Purpose

Various activities such as laboratory analysis of pathology samples and the performance of radiological exams often form key procedures in the visit schedule of research studies. These activities provide important data and it is therefore essential that they are performed to an acceptable standard that ensures patient safety is not compromised and that data are unbiased, accurate and complete.

This SOP outlines guidance and procedures for the sub-contracting of activities/services relating to all categories of Research Studies at York Teaching Hospital NHS Foundation Trust. It aims to provide 'due diligence' measures, ensuring that establishments that are selected to undertake research related activities are fit for purpose and adhere to Good Clinical Practice (GCP) guidelines. These requirements are clarified by means of a contract between the two parties that is reviewed and approved by the appropriate personnel in line with Trust procedure.

Note; The Medicines for Human Use (Clinical Trials) Regulations provide for the inspection of facilities by the Medicines and Healthcare products Regulatory Agency (MHRA) to ensure compliance with the legal standard. Facilities involved in Clinical Trial of an Investigational Medicinal Product (CTIMP) work must therefore meet the essential requirements of the UK Clinical Trial Regulations.

2 Who Should Use This SOP

This SOP is relevant to those members of the Research and Development (R&D) Team who, on behalf of the Sponsor, will review the due diligence activities undertaken prior to contracting with the selected establishment and those members of the Trust that are involved in the preparation and/or review of Contracts/ Clinical Trial Agreements.

It is also relevant to all Chief Investigators/Principle Investigators and Study Coordinators planning a clinical research study Sponsored or Co-Sponsored by York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

The guidance and procedures outlined below should be followed when setting up a research study that requires the sub-contracting of services for research activity.

4 Procedure(s)

4.1 Assessment and selection of establishments for the Sub-contracting of research activities

Firstly, relevant members of the R&D Team and Study Team (i.e. CI/PI, Study Co-ordinator) must meet to discuss and agree the requirements, expectations, deliverables and timelines of the named study prior to approaching any potential establishment that may be able to provide the research activities required. If the study is a Trust Sponsored/Co-Sponsored study or one that is being generated and designed by members of the Trust then this meeting should take place within the early stages of development.

Once this meeting has taken place the Head of R&D and relevant members of the R&D Team will identify possible establishments that could potentially be sub-contracted with to provide the required research activities for the named study.

Upon identifying potential establishments the Head of R&D will liaise with the appropriate personnel at each to commence the initial assessment activities. Such activities will include the following;

- Establish whether the facility has the necessary equipment to perform the research activity.
- Obtain CVs and note previous experience
- Obtain information relating to quality systems and procedures
- Obtaining an estimated quote

The Head of R&D and relevant members of the R&D Team will review the above and make an initial assessment of the suitability of each establishment and its ability to perform the required research activities in a safe and appropriate manner. A short list of establishments will be created based on some or all of the below criteria.

- Good evidence of quality systems and procedures in place
- The amount of previous experience in conducing similar research activities
- Reputation and/or previous experience of using the establishment as a sub-contractor
- Appropriate licences/accreditations in place and the qualification of the staff that would be involved.
- Having the correct equipment and facilities in place to perform the required research activities.
- The cost to the Trust for the establishment to perform the required research activities.
- Timelines for set up and contracting
- Location and implication *i.e. transporting samples, patient travel*

Once a shortlist of potential establishments has been made then arrangements will be put in place with the Head of R&D and relevant members of the R&D Team to meet with the relevant parties from the establishment. Prior to these meetings taking place a Confidentiality Disclosure Agreement (CDA) will be provided by the Head of R&D or a delegated member of the R&D Team to the establishments for them to sign and return. Upon receipt of the (CDA) the Head

of R&D will provide the establishments with further information relating to the study and processes.

Ideally the meeting will take place at the establishment's facilities where the required activities will take place and may include some or all of the following activities.

- A guided tour of the facilities if required and these have not been visited previously.
- Review of the location and use of SOP's as well as quality assurance records
- Introduction to team members who will be preforming the required activities
- Assessment of the establishments understanding of Good Clinical Practice and UK Clinical Trial Regulations if required.
- Communication requirements throughout the course of the studies lifetime.
- GCP and study specific training requirements for staff
- Review of the costings
- Review of the protocol and details of the work to be performed as well as timelines, deliverables and standards.

Each meeting with the potential sub-contracting establishment will be documented appropriately and copies of this and associated documentation will be retained in the Trial Master File (if applicable) and in the R&D Department so that these can be referred to for future sub-contracting activities.

Once all meetings have taken place with the potential sub-contracting establishments the Head of R&D and relevant members of the R&D Team will meet to discuss the findings and any concerns that have been identified. The checklist noted in R&D/F01 will be completed for each establishment and if required a request for further information may be made to an establishment before The Head of R&D makes the final decision.

The establishment that has been selected to perform the sub-contracted research related activities will be informed by the Head of R&D in writing and no work must be entered into until a finalised Service Level Agreement/Contract has been put in place.

4.2 Contracting with establishments to perform research activities

The Service Level Agreement/Contract must include but is not limited to the following.

- Location where the specified activities will take place
- Responsibilities and expected standards of working
- Record keeping and retention
- Expected deliverables and timelines
- Monitoring and/or Auditing requirements for Quality Assurance (Periodic quality checks should be agreed with the R&D QA staff and documented to ensure suitability and performance of the service during the study)
- Insurance and Indemnity
- Costs and payment details

- Communication requirements (Including clearly documented instructions for reporting of results, as well as format, timescale and recipient of results, particularly for blinded studies)

The Service Level Agreement/Contract must be between legal entities in respect of both parties and must not be made between individuals such as the CI/PI person performing the required research activity.

All Service Level Agreements/Contracts must be subject to English Law and not fall outside of this without prior consultation being made. The establishment will not be allowed to further sub-contract research activities that are being undertaken in accordance with the Service Level Agreement/ Contract without receiving full written permission from the Head of R&D to do so.

Copies of the draft Service Level Agreement/Contract must be reviewed by the appropriate members of the R&D Team and The Head of R&D prior to sending to the proposed establishment for review. Once the Service Level Agreement/ Contract has been agreed by both parties the signature process can commence. Either party may sign the Service Level Agreement/ Contract first and who is to initiate this will be agreed prior to commencing. The Head of R&D will sign the Service Level Agreement/ Contract on behalf of the Trust.

Two wet ink copies of the Service Level Agreement/ Contract will be retained by the Trust with one copy being held in the Trial Master File/Investigator Site File and the other in the R&D Study Folder. An electronic version of the Service Level Agreement/ Contract will be held in the appropriate place on the R&D Departments X-Drive and on EDGE. The establishment may choose how many wet ink copies of the Service Level Agreement/ Contract they require and this will be arranged.

5 Related SOPs and Documents

R&D/F01 Sub-contracting Services for Research Activities: Checklist for Assessing Potential Establishments

R&D/S28 Quality Assurance

R&D/F60 Laboratory Checklist

R&D/S23 Contracts for Clinical Trials of Investigational Medicinal Products