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

Contracting with Laboratories to undertake Research

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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	Signature:	Signed copy held by R&D Unit
	Date:	3rd December 2015
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	Signature:	Signed copy held by R&D Unit
	Date:	3rd December 2015

This SOP will normally be reviewed every 2 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

Contents

1 Introduction, Background and Purpose

The analysis of samples collected from patients and healthy volunteers participating in research studies forms a key part of the research process, providing important data. Consequently, it is essential that laboratory analysis is performed to an acceptable standard which will ensure patient safety is not compromised and that data are unbiased, accurate and complete.

The Medicines for Human Use (Clinical Trials) Regulations provide for the inspection of clinical laboratories by the Medicines and Healthcare products Regulatory Agency (MHRA) to ensure compliance with the legal standard. Laboratories involved in CTIMP work must therefore meet the essential requirements of the UK Clinical Trial Regulations.

For non-CTIMP studies, the principles of GCP should also apply although this is not a legal requirement.

The purpose of this SOP is to provide a 'due diligence' procedure aimed at ensuring that laboratories selected to undertake sample analysis and evaluation are fit for purpose.

2 Who Should Use This SOP

This SOP is relevant to all CI/PIs planning a clinical research study sponsored or co-sponsored by York Foundation Trust and to the R&D Unit staff who, on behalf of the trial Sponsor, will review the due diligence activities undertaken prior to contracting with the selected laboratory..

3 When this SOP Should be Used

The procedure described in this SOP should be followed when setting up a research study sponsored or co-sponsored by York Foundation Trust.

4 Procedure(s)

4.1 Checking the competence of the proposed laboratory

The CI/PI must ensure that discussions take place with the proposed laboratory whilst the protocol is in early stages of development. Check that the laboratory has the capability to perform all the tests required within the scope of the study.

For Clinical Trials of Investigational Medicinal Products (CTIMPs) the CI/PI (or delegate) must agree with the R&D Unit *in advance* what due diligence activities need to be undertaken (as this may vary depending on the laboratory being proposed) and who will be responsible for undertaking such activities. It will be usual to work from checklist R&D/F60 to assess competence of prospective external laboratory organisations against GCP requirements.

The completed form(s), and copies of any associated documentation must be forwarded to the R&D Unit as evidence and copies should be placed into the Trial Master File / Investigator Site File (TMF / ISF).

The R&D Unit will, on behalf of the Sponsor, review the completed checklist and any additional supporting documentation prior to executing contracts. The advice of the R&D Group (or others) may be sought where this is considered appropriate.

Completion of R&D/F60 is not essential but may be useful when contracting with an external laboratory organisation for non-CTIMP work.

4.2 Laboratory staff training

Staff involved in the analysis or evaluation of clinical trial samples should receive GCP training commensurate with their roles and responsibilities. A record of training should be maintained for each individual involved and should be retained should a staff member leave. It is the responsibility of the PI to ensure that staff employed to work on the trial are qualified by education, qualification and experience to carry out the role designated to them.

For non-CTIMP studies, GCP training is not a requirement for laboratory staff although it would be considered desirable where possible.

4.3 Responsibilities during the Study

A contract between the Sponsor and external laboratory organisation will be executed to define obligations and responsibilities. This contract should clearly state any specific requirements with regard to sample handling/storage and/or processing and should refer to any additional SOPs that may be applicable. There should be clearly documented instructions for the reporting of results, including format, timescale and recipient.

Periodic checks should be undertaken and documented to ensure the suitability and performance of the laboratory during the study. If a Monitoring Plan has been devised for the study then this should include provision for a visit to the laboratory where appropriate.

Any issues regarding suitability and performance of the laboratory should be raised with the Sponsor via the R&D Unit in a timely manner.

If there are any changes to laboratory procedures/SOPs which may impact on laboratory testing for a study then the laboratory must inform the Principal Investigator who should in turn notify the R&D Unit.

5 Related SOPs and Documents

R&D/F60 Laboratory Checklist

Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/05/WC500127124.pdf