

Document Title: Laboratory Procedures

Document Number: 059

Version:	1
Ratified by:	R&D Committee
Date ratified:	30/11/2017
Name of originator/author:	Lucy Parker
Directorate:	Corporate Services
Department:	Research and Development
Name of responsible individual:	Rachel Fay, R&D Manager
Date issued:	04/12/2017
Review date:	04/12/2020
Target audience:	All research staff
Intranet:	NA
Key related documents:	ICH Topic Q (R1) Validation of analytical procedures (CPMP/ICH/381/95)
This document supports: <i>Standards and legislation</i>	ICH Topic Q (R1) Validation of analytical procedures (CPMP/ICH/381/95) ICH E6 Good Clinical Practice http://www.ich.org/products/guidelines/efficacy/efficacysingle/article/good-clinical-practice.html SI 2004/1031
Date equality analysis completed.	30/11/2017
<u>This is a controlled document</u>	
Whilst this document may be printed, the electronic version maintained on the RF website is the controlled copy. Any printed copies of this document are not controlled.	

Version Control

Version	Date	Author	Status	Comment
1.0	26 SEPT 2017	Lucy Parker	Final	New document

Contents

Section		Page
1	Introduction	4
2	Objective	4
3	Definitions	4
4	Scope	4
5	Equality statement	4
6	Duties	5
7	Details of procedure	5
8	Policy	7
9	Risk management/liability/monitoring & audit	7
10	Forms/templates to be used	7
Appendices		
Appendix (1)	SOP reading log	8
Appendix (2)	Equality analysis guide and tool	10

1. INTRODUCTION

The Medicines for Human Use (Clinical Trials) Regulations 2004 (the Regulations) regulate the conduct of clinical trials in the United Kingdom. The regulations relate to persons or organisations that participate in any aspect of a human clinical trial including organisations that analyse or evaluate samples collected as part of a clinical trial. The transposition of the EU Clinical Trials Directive 2001/20/EC into UK law (The Medicines for Human Use (Clinical Trials) Regulations 2004, Statutory Instrument 2004 No.1031. as amended) provides provision for the inspection of laboratories that perform the analysis or evaluation of samples collected as part of a clinical trial. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) has responsibility for monitoring such laboratories for compliance with these Regulations. Compliance is assessed by inspections which will be performed approximately every two years.

The analysis of samples collected from healthy volunteers and patients participating in clinical trials forms a key part of the clinical trials process. Sample analysis or evaluation provides important data on a range of endpoints which is used, for example, to assess the pharmacokinetic profile of investigational medicinal products and to monitor their safety and efficacy. Consequently, it is essential that sample analysis or evaluation is performed to an acceptable standard which will ensure patient safety is not compromised and that data is reliable and accurately reported.

2. OBJECTIVE

This SOP focuses on laboratory procedures for clinical trials that Royal Free Sponsor.

3. DEFINITIONS

None applicable for this SOP.

4. SCOPE

Many studies conducted by RF employees may have contracted the laboratory tests out to certified laboratories. These laboratories have their own SOPs and as such, this SOP will not be an exhaustive operating procedure on all aspects concerning laboratory procedures in clinical trials but rather an overview of what the CI should consider or document.

5. EQUALITY STATEMENT

The Royal Free London NHS Foundation Trust is committed to creating a positive culture of respect for all individuals, including job applicants, employees, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability (including HIV status), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. It is also intended to use the Human Rights Act 1998 to treat fairly and value equality of opportunity regardless of socio-economic status, domestic circumstances, employment status, political affiliation or trade union

membership, and to promote positive practice and value the diversity of all individuals and communities.

This document forms part of the trust’s commitment. You are responsible for ensuring that the trust’s policies, procedures and obligation in respect of promoting equality and diversity are adhered to in relation to both staff and service delivery.

The equality analysis for this SOP is attached at Appendix (2).

6. DUTIES

The Trust is committed to the delivery of world class care and expertise to both staff and patients, and our values of positively welcoming, actively respectful, visibly reassuring and clearly communicating are fundamental to the delivery of this. This policy has been developed with our values in mind, and is intended to be implemented within the spirit of these values.

It is the responsibility of the Chief Investigator (CI) in the clinical trial to ensure that any laboratory that will be used for the trial is adequate for “the foreseen duration of the trial to conduct the trial properly and safely” (ICH GCP 4.2.3 and ICH GCP 5.184b). The CI should also ensure that the laboratory that the study will use has been verified and is in compliance with accreditation standards and that all necessary contracts for the contracted activities have been finalised.

The CI should ensure that if a selected laboratory is used which is external to Royal Free e.g. university lab that they have followed the vendor selection process.

The CI must ensure that a full chain of custody is in place. The chain of custody is the chronological documentation or auditable paper trail showing the collection of, transfer, receipt, analysis, storage and disposal of samples in accordance with the protocol and lab manual

The CI is to ensure that all relevant delegated staff are trained in the sample process at site activation.

7. DETAILS OF THE PROCEDURE

Person Responsible	Task
CI	<p>It is the responsibility of the Chief Investigator to make sure that before a laboratory is used for the clinical trial, it meets the essential requirements of the relevant UK and EC directives as well as local Trust and RF R&D Office policies.</p> <p>The CI should acquire documentation showing the normal value(s)/range(s) for laboratory procedures included in the study (ICH GCP 8.2.11) and have documentation of laboratory processes showing:</p> <ul style="list-style-type: none"> - certification or - accreditation or - established quality control and/or external quality assessment or

	<p>- other validation (where required)</p> <p>There must be documentation to demonstrate the competence of the department or contracted laboratory to perform the required tests and support reliability of results. (ICH GCP 8.2.12).</p> <p>The CI must also ensure that any updates to the normal values or tests are documented and that they are aware of the laboratories maintenance processes.</p> <p>The laboratory equipment being used for research purposes should be included on regular, routine service and maintenance inspection rotas. The CI should request evidence that these requirements have been met –e.g. through reviewing the laboratory equipment service manuals.</p> <p>Specialist, non-standard laboratory equipment may require the initiation of a specialist maintenance contract with an appropriate service provider. These arrangements should be in place prior to study start up.</p> <p>If analysis is performed by a laboratory that is part of the organisation which is Sponsoring the trial, but is located in a department under an independent management line, it is recommended that a service level agreement is implemented between the two departments.</p> <p>The CI must also ensure that if it is an external laboratory that there is an appropriate contract in place by liaison with the Contracts and Costings Manager in the RF R&D Office</p> <p>Data generated in the laboratory may influence key decisions made during the conduct of a study. e.g. interim analysis. Routine chemistry may flag safety concerns which require the investigator’s immediate attention. Key communication lines must be agreed and established prior to study start.</p> <p>The CI must ensure that “adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the Sponsor according to the reporting requirements and within the time periods specified by the Sponsor in the protocol” (ICH GCP 4.11.2).</p> <p>Laboratories that receive blinded samples should have a process in place to ensure that data is not communicated inappropriately to inadvertently compromise the blind.</p> <p>The CI must ensure that the laboratories are provided with the most current version of the protocol and any subsequent</p>
--	--

	<p>amendments and approval documentation. The laboratory manager must ensure that any trial related documents are filed in the study Laboratory File in a timely fashion.</p> <p>For consideration</p> <ul style="list-style-type: none">- Actual Samples - Labelling and identification, transport and receipt, storage and retention,- Data - Reporting, presentation, archiving and subsequent retrieval
--	--

8. POLICY

This SOP is mandatory and non-compliance with it may result in disciplinary procedures.

9. RISK MANAGEMENT/ LIABILITY/MONITORING & AUDIT

- The SOP Working Group will ensure that this SOP and any future changes to this document are adequately disseminated.
- The R&D Office will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).
- In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the R&D Manager/Deputy R&D Director should be gained before any action is taken.
- SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.
- The R&D Office is responsible for the ratification of this procedure.

10. FORMS/TEMPLATES TO BE USED

None applicable.

11. FLOWCHART

None applicable

This page intentionally blank.

APPENDIX 2

Royal Free London NHS Foundation Trust Equality Analysis guide and Tool

An equality analysis is a review of a policy, practice, function, business case, project or service change which establishes whether there is a negative effect or impact on particular social groups. This In turn enables the organisation to demonstrate it does not discriminate and, where possible, it promotes equality to meet the needs of the diverse patients and communities we serve. This check list is a way to help you think carefully about the likely impact on equality groups and take action to improve services. This is also an opportunity to evidence positive practices in our services and demonstrate strategic integrity to ensure that our services and employment practices are fair, accessible and appropriate for all patients, visitors and carers, as well as our talented and diverse workforce.

Name of the policy / function / service development being assessed	SOP on laboratory procedures in research
Briefly describe its aims and objectives:	This SOP focuses on laboratory procedures for clinical trials that Royal Free Sponsor.
Directorate and Lead:	Rachel Fay, R&D Manager
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	ICH Topic Q (R1) Validation of analytical procedures (CPMP/ICH/381/95) ICH E6 Good Clinical Practice http://www.ich.org/products/guidelines/efficacy/efficacysingle/article/good-clinical-practice.html SI 2004/1031
Is the Trust Equality Statement present?	Yes X No if no do not proceed with Equality Analysis (EA)

If you are conducting an EA on a procedural document please identify evidence sources and references, who has been involved in the development of the document, process or strategy, and identify positive or negative impacts. It is the discussion regarding the equality impact of the document that is important.

Equality Analysis Checklist

Go through each protected characteristic below and consider whether the policy, practice, function, business case, project or service change could have any impact on groups from the identified protected characteristic, involve service users where possible and get their opinion, use demographic / census data (available from public health and other sources), surveys (past or maybe carry one out), talk to staff in PALS and Complaints and Patient Experience.

Please ensure any remedial actions are Specific, Measureable, Achievable, Realistic, and Timely (SMART).

Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Age	None identified	R&D administrative document	N/A	N/A	This SOP on laboratory procedures in research introduces a requirement to include the Trust Equality Statement in all SOPs that describe the standard activities used in Research Studies and Clinical Trials at the Royal Free London Hospital NHS Foundation Trust.
Disability	None identified	R&D administrative document	N/A	N/A	
Gender Reassignment	None identified	R&D administrative document	N/A	N/A	
Marriage and Civil Partnership	None identified	R&D administrative document	N/A	N/A	
Pregnancy and maternity	None identified	R&D administrative document	N/A	N/A	
Race	None identified	R&D administrative document	N/A	N/A	

SOP 059: Laboratory Procedures

V1.0 26 SEPT 2017

Uncontrolled document when printed or downloaded. Current SOP versions available <https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Religion or Belief	None identified	R&D administrative document	N/A	N/A	It also introduces a new Equality Analysis Template for the SOPs, that requires the presence of the Equality statement. These actions are designed to embed the equality agenda and promote equality compliance within the Trust.
Sex	None identified	R&D administrative document	N/A	N/A	
Sexual Orientation	None identified	R&D administrative document	N/A	N/A	
Carers	None identified	R&D administrative document	N/A	N/A	

It is important to record the names of everyone who has contributed to the policy, practice, function, business case, project or service change.

Equality Analysis completed by: (please include every person who has read or commented and approval committee(s). Add more lines if necessary)	Organisation	Date
SOP Working Group	Royal Free London NHS Foundation Trust	20/10/2017
R&D Committee	Royal Free London NHS Foundation Trust	30/11/2017