St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

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Standard Operating Procedure (SOP)
Laboratory Procedures

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1	Original Version	Lucy H H Parker
V2	Updated logo & Trust status; external links; equipment maintenance, communication in relation to safety, blinding, sample labelling, ,storage, data reporting	Debs Rolfe

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1. Background

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. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JREO acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This SOP focuses on laboratory procedures for clinical trials that St George's sponsors. Many studies conducted by SGUL or SGHT 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

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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.

4. Definitions

Not applicable for this SOP.

5. Responsibilities

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 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.

6. Procedure

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 JREO policies. 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:

- certification or
- accreditation or
- established quality control and/or external quality assessment or
- other validation (where required)

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). 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.

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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. 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.

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. 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 Executive via the Research Governance Officer (RGO)

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.

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).

Laboratories that receive blinded samples should have a process in place to ensure that data is not communicated inappropriately to inadvertently compromise the blind.

The CI must ensure that the laboratories are provided with the most current version of the protocol and any subsequent 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.

For consideration

– Actual Samples - Labelling and identification, transport and receipt, storage and retention,
- Data – Reporting, presentation, archiving and subsequent retrieval

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7. References

ICH E6 Good Clinical Practice http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html

ICH Topic Q (R1) Validation of analytical procedures (CPMP/ICH/381/95)

SI 2004/1031

JREOSOP0006 Reporting of AEs for CTIMPs

JREOSOP0033 Safety Reporting for Non CTIMP

8. Appendices

There are no associated appendices for this SOP.

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