Standard Operating Procedure (SOP)
Laboratory Procedures

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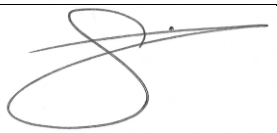
Signature of Authorisor			

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They may print off this document for training and reference purpose.

SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	Original Version	Lucy H H Parker
V2.0	Updated logo & Trust status; external links; equipment maintenance, communication in relation to safety, blinding, sample labelling, storage, data reporting	Debs Rolfe
V3.0	Amendments to text in all sections including update of JREO to JRES. Addition of associated JRES documents table. Addition of information relating to vendor assessment.	Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESDOCSOP0006 Reporting of Adverse Events for CTIMPs Sponsored by St George's JRESGOVSOP0033 Safety Reporting for Non-CTIMPs	JRESWPD0023 General Research Definitions	JRESDOC0122 Vendor Assessment Checklist	

Contents

1. Background

The analysis of biological samples collected from participants on clinical trials provides important data on a range of trial endpoints which is used, for example, to assess the pharmacokinetic profile of IMPs and to monitor their safety and efficacy. 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.

ICH-GCP requires documentary evidence (in the TMF and ISF) of laboratory values/ranges for the tests outlined in the trial protocol and/or laboratory manual, as well as evidence that the laboratory is competent to perform the tests and has quality control procedures in place to support the reliability of the results.

The Clinical Trials Regulations provide provision for the inspection of laboratories that perform the analysis or evaluation of samples collected as part of a clinical trial. The MHRA has responsibility for inspecting such laboratories for compliance with the regulations.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

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

3. Scope

This SOP focuses on laboratory procedures for clinical trials that are sponsored by St George's.

Some studies may contract out the analysis of samples to external certified laboratories. These laboratories will have their own SOPs. Thus this SOP is not an exhaustive operating procedure on all aspects of laboratory procedures in clinical trials but rather an overview of what the Chief Investigator (CI) should consider or document.

4. Definitions

For general research-related acronyms used in this SOP, refer to General Research Definitions Working Practice Document (JRESWPD0023).

5. Responsibilities

It is the responsibility of the CI to:

- Ensure that any laboratory that will be used for the trial is adequate for the duration of the trial.
- Ensure that the laboratory has been verified and compliant with accreditation standards.
- Ensure that any necessary contracts or Service Level Agreements are implemented.
- Ensure that the protocol and/or laboratory manual contains sufficient information in relation to the collection, labelling, processing, analysis, transportation, storage and retention of samples.
- Provide the laboratory with the current protocol/laboratory manual and any subsequent amendments and approvals.

It is the responsibility of the PI at each trial site to:

- Review the trial protocol and ensure that the sample collection requirements of the trial are feasible given the resources provided.

It is the responsibility of the Laboratory Manager to:

- Ensure that any trial-related documents are filed in the Laboratory File in a timely manner.

6. Procedure

Documentation:

The CI will acquire documentary evidence from the laboratory which is to be used for the analysis of the trial samples for:

- Normal value(s) / range(s) for the laboratory procedures included in the trial.
- Certification or accreditation.
- Quality control / validation procedures.
- The ability of the laboratory to perform the tests.

Contracts / Vendor Assessments:

If analysis is performed by a laboratory that is part of the sponsoring organisation but is located in a department under an independent management line, it is recommended that an informal agreement is implemented between the two departments.

The CI must also ensure that if an external laboratory is used, an appropriate contract/ Service Level Agreement is put in place by liaising with the appropriate team within the JRES.

For CTIMPs sponsored by St George's, the JRES also requires a Vendor Assessment to be completed by external laboratories to ensure that the laboratory is GCP-compliant. JRESDOC0122 will be provided to the laboratory by the CI or the JRES for completion, and this will be reviewed and signed off by the JRES.

Equipment:

The laboratory equipment being used for research purposes should be routinely serviced/calibrated and service reports should be available as evidence that these requirements have been met. Specialist, non-standard laboratory equipment may require a specialist maintenance contract with an appropriate service provider. These arrangements should be in place prior to the start of the trial.

Reporting of Laboratory Results:

Communication lines must be in place prior to the start of the trial for laboratory results/data which needs to be prioritised, for example: data required for the interim analysis; patient safety concerns identified on chemistry/haematology tests which require the immediate attention of the Investigator.

An abnormal laboratory test result may meet the definition of an Adverse Event which needs to be documented and reported according to the protocol and relevant JRES SOP.

Blinded Trials:

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

7. References

ICH GCP and Clinical Trials Regulations.

8. Appendices

None associated with this SOP.