Laboratory Procedures

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Author: Dr Thomas Lewis, Ethics and Research Governance Coordinator	
Approved by: Ruth Nicholson, Head of Research Governance and Integrity	Date: Ruth Nicholson Digitally signed by Ruth Nicholson Date: 2024.01.09 12:53:50 Z

Version	Date	Reason for Change
Version 1.0	20 Jun 2007	
Version 2.0	24 Jun 2008	Annual Review
Version 3.0	08 Feb 2010	Formation of Joint Research Office
Version 4.0	14 Jul 20011	Annual Review
Version 5.0	03 Dec 2012	Annual Review
Version 6.0	18 Feb 2015	Scheduled Review
Version 7.0	25 Oct 2017	Scheduled Review
Version 8.0	19 Oct 2020	Scheduled Review Templates removed and administrative changes to SOP. JRCO name change to RGIT
Version 9.0	09 Jan 2024	Scheduled Review

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1. PURPOSE

This SOP focuses on laboratory procedures for clinical trials and other research studies that Imperial College Academic Health Science Centre (AHSC) sponsors. Many clinical trials conducted by Imperial College London or Imperial College Healthcare NHS Trust employees contract 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.

2. INTRODUCTION

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 in terms of staff, facilities and equipment for "the foreseen duration of the trial to conduct the trial properly and safely" (ICH GCP 4.2.3 and ICH GCP 5.18. b).

The CI should also ensure that the laboratory being used in the study has been verified and is in compliance with accreditation standards. The Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial should be recorded within the Clinical Trial Protocol (ICH GCP 6.1.7).

3. PROCEDURE

It is the responsibility of the Principal 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 Imperial College AHSC policies. The CI should acquire documentation showing the normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the study protocol (ICH GCP 8.2.11).

3.1. Laboratory Management

There must be documentation on the competence of the facility to perform the required test(s) 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 must have documentation of laboratory processes showing:

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

Where applicable, a copy of the Material Transfer Agreement must be kept, and a sample log of any material sent to the laboratory must be maintained along with copies of the shipping records for each batch of samples shipped. The receiving site should also log all received samples related to the trial.

The laboratory equipment being used for research purposes should be inspected and tested by the local relevant department to ensure it meets the technical and safety requirements before trial start-up, for further information refer to RGIT_SOP_027which can be found on the SOP, Associated Documents & Templates page *(cited on 17 May 2023)*.

All documentation required for the trial/study should be received to ensure the management of the laboratory activities are adequate and can be followed easily. This may involve the creation of work instructions, a Laboratory Manual and/or SOPs detailing how a member of the laboratory team can conduct the analysis or evaluation required for the trial.

It is a requirement for the following documents to be maintained within the TMF as stated within the RGIT_TEMP_012 – Essential Documents to be maintained within the TMF:

- Normal laboratory reference ranges for any tests used or medical/technical procedures included in protocol (includes central labs)
- Copies of calibration records for technical equipment
- Lab/technical procedures/tests certification or accreitation
- Record of any body fluids/tissues retained (if any)

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 1.2, ICH GCP 4.11.2). All investigators should be given instructions on following the protocol and complying with a uniform set of standards for the assessment of clinical and laboratory findings (ICH GCP 5.23.4).

3.2. Sample Management

All samples created, collected and evaluated should be labelled in a way to allow for clear concise identification that has been set in place during the trial design. A process for tracking the movement of each sample from the arrival stage through to the analysis and evaluation of the sample, should be implemented and maintained by all the staff involved in the trial.

It is the responsibility of the laboratory team to ensure that the sample storage has been reviewed and the necessary documentation has been created detailing the process for monitoring and measuring of the sample and the equipment's used (i.e. refrigerator, used to refrigerate the samples at a fixed temperature).

Where required, the CI must ensure that the documentations required to record the sample receipt, transfer and destruction has been completed by the appropriate team member.

4. REFERENCES

ICH: E 6 (R2): Guideline for good clinical practice - Step 5 (europa.eu) (cited 25 Mar 2023)

Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples *(cited 17 May 2023)*

Essential Documents to be maintained within a TMF - RGIT_TEMP_012