Joint Research Management Office Standard Operating Procedure for:			
Use of Laboratories for Clinical Research Study Samples			
SOP Number:	**43**	Version Number:	**2.0**
Effective Date:	**4th December 2023**	Review Date:	**4th December 2026**

Authorship and Review:		**Signature and Date:**
Author:	Rebecca Carroll, Quality Assurance Manager	Rebecca Carroll Digitally signed by Rebecca Carroll Date: 2023.11.15 08:22:53 Z
Reviewer:	Marie-Claire Good, Senior GCP & Governance Manager	Marie-Claire Good Digitally signed by Marie-Claire Good Date: 2023.11.15 08:42:32 Z

Authorisation:		**Signature and Date:**
Name/Position:	Mays Jawad, Research Governance Operations Manager	Dr Mays Jawad Digitally signed by Dr Mays Jawad Date: 2023.11.15 09:23:34 Z

This Standard Operating Procedure (SOP) and associated documents have also been reviewed by Nebiyu Kibru, Deputy Laboratory Manager, Blizard Institute, Rebecca Gresham, Principal laboratory Manager, Barts Cancer Institute and Rory Smith, Tissue Bank Manager, Barts Cancer Institute.

Purpose and Scope:

This SOP describes the minimum requirements, selection process, and oversight for laboratories handling samples for a clinical research study.

This SOP applies to all laboratories receiving samples from or conducting analysis for clinical research studies sponsored by Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary), and to all laboratories within those organisations receiving samples externally from a Medicines and Healthcare products Regulatory Agency (MHRA) regulated study.

For the purpose of this SOP, the term laboratories refers to sample processing areas and sample storage such as centrifuges and fridges/freezers as well as designated laboratory departments.

This SOP defines best practice for all sponsored interventional and research studies.

Abbreviations:

Barts Health	Barts Health NHS Trust
CI	Chief Investigator
EMA	European Medicines Agency
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
Queen Mary	Queen Mary University of London
SLA	Service level agreement
SOP	Standard Operating Procedure

SOP Text:		
	Responsibility	**Activity**
Laboratories to be used in Barts Health and Queen Mary MHRA-Sponsored studies		
1.	Centre Lead and/or Laboratory Manager	**Type of analysis** Review the laboratory protocol and confirm if the activity and analysis is clearly explained and deliverable. Ensure any mitigations are put in place if the activity is deemed high risk.
2.	Chief Investigator (CI) in conjunction with Good Clinical Practice (GCP) & Governance Manager and the Centre lead and/or Laboratory Manager	**Selecting a laboratory** *SOP 40 Vendor Assessment* should be followed to facilitate the decision of whether a proposed laboratory is suitable to be used for a study. All laboratories should be identified within the protocol and a vendor assessment should be completed at the latest prior to sponsorship with conditions being issued. The selected laboratory should comply with this SOP. See *SOP 40 Associated Document 1 GCP Compliance Sample Questions (Section 1)* for further guidance on the requirements of selection a laboratory.
3.	CI	**Procurement** Procurement procedures of the sponsoring organisation must be followed. More detailed information can be found via the Joint Research Management Office (JRMO) website *http://www.jrmo.org.uk/manage-your-funding/procurement-guidance/*
4.	Institute Directors and/or Clinical Board Directors	**Responsibilities** It is the responsibility of the Institute Director and/or Clinical Board Directors to ensure that there are procedures in place to evidence awareness of any study samples accepted into their laboratory that originated from an MHRA regulated study is stored and handled in compliance with the European Medicines Agency (EMA) regulation. It is also their responsibility to ensure GCP is complied with.
5.	GCP & Governance Manager	**Establishing suitability of the laboratory selected** The GCP & Governance Manager will work with the CI and coordinating team to establish if a laboratory is suitable and meets the minimum requirements outlined on *Associated document 1*. If there is a dispute or disagreement on the suitability of a laboratory the GCP & Governance Manager will escalate the matter to the Research Governance Operations Manager and subsequently the Sponsor Oversight Group where further escalation deemed necessary.
6.	CI and JRMO contracts team	**Contracts and agreements** A written agreement is needed for all laboratories performing storage or sampling activities. This may take the form of a standalone contract, an appendix to a contract, a Service Level Agreement (SLA), or if the laboratory sits within Barts Health or Queen Mary a work plan. A contract is not required in situations

		where the laboratory is part of the sponsor organisation. The written agreement must detail the roles and responsibilities of both parties (including lines of communication and timelines) and must be in place prior to the initiation of any work. SLA or policy documents should be reviewed by the laboratory manager. This should be done at least yearly or more frequently based on the study risk assessment. Contracts will be required prior to confirmation of sponsorship being issued by the sponsor. If a laboratory is changed or a new laboratory identified during the course of the study, contractual agreements must be in place prior to the initiation of any work, or samples being received by the laboratory. Any contract should include statements confirming: • Adherence to GCP. • Permission to monitor, audit, and inspect the laboratory as required. • Timing and manner of results and/or reports being relayed to CI and Sponsor. • Archiving retention period as per sponsor requirements (See *SOP 20 Archiving for retention periods)*
7.	CI and study/laboratory team	**Ensure laboratory is set up and activated prior to first sample being collected.** All laboratories used as a central facility for a study must be set up prior to the first sample being collected or received. An activation process similar to a site activation checklist should be followed for each laboratory (see *Associated Document 2 Set Up Checklist*). A defined laboratory contact (i.e., Laboratory Manager/Head of department) should be identified that is familiar with the requirements of the protocol and GCP and is in a position to ensure appropriate actions are taken and oversight obtained in order to deliver the study requirements. All laboratories should be issued with a laboratory file *(see Associated Document 3 Laboratory file checklist*).
8.	Centre lead and/or Laboratory Manager	**Laboratory Equipment** All laboratory equipment to be used in the study must be centrally logged (See *Template 2 Equipment Log* for guidance) All equipment must be validated prior to use. Documents relating to this validation and subsequent maintenance, calibration and working temperatures must also be provided by the laboratory (See *Template 3 Laboratory Equipment validation and maintenance Log* for guidance)
9.	CI and study/laboratory team	**Laboratory staff Training** Training should be appropriate to ensure every laboratory activity performed on research samples is completed in accordance with the study protocol, GCP, applicable legislation and guidance, and best laboratory practice. See *SOP 34a Researcher Training* for further guidance.

10.	GCP and Governance Managers	**Laboratory oversight** Academic or NHS facilities within the UK must be monitored in line with *SOP 28 Monitoring*, as a minimum once yearly whilst active. Problems, deviations, and potential breaches of GCP, the protocol, or confidentiality should be escalated to the Sponsor via the GCP and Governance Managers in the JRMO in accordance with *SOP 31 Non-Compliance and Serious Breach reporting*
11.	CI and study team and Laboratory Leads	**Results and reports** Depending on the type and nature of analyses that a laboratory is undertaking, the datasets may be reported as raw data without interpretation, or a report can be produced, including the result(s) and associated interpretation. If raw datasets are not being provided to the Sponsors and CI, the laboratory must have robust quality control checks in place prior to report creation and documentation of this should be included in the report. Regardless of how data are reported they must be accurate and complete. Agreement should be reached at the contract stage detailing what data will be transferred to the CI and sponsor and how this will occur. See *Associated Document 1* for considerations The details for this are agreed prior to laboratory work commencing and will be document in the SLA/Contract. All reporting of results must be in compliance with *SOP 16a Data Protection for Research Studies*
12.	CI and team, Laboratory Leads	**Specimen Transfer and Specimen Destruction** The laboratory may be required to transfer the specimens on completion of the study analysis to agreed tissue banks. *Associated Document 4 Specimen Transfer Log* must be completed and retained for all samples transferred from the approved laboratory. The laboratory may be required to destroy specimens following completion of analysis or should consent to use the specimen be removed. *Associated Document 5 Specimen Destruction Log* must be completed prior to the samples being destroyed.
13.	CI and team, Laboratory Leads	**Lab closeout** For UK based academic and NHS laboratories an onsite close-out meeting should occur where possible, although a telephone phone close out may be appropriate. For commercially run laboratories a telephone close-out meeting is acceptable. See *Associated Document 6 Close Down Checklist* for full details.
14.	Laboratory Leads, Laboratory manager, and Auditors.	**Audit and inspection readiness** All laboratories will be open to audit and inspection as needed. The CI and coordinating team should ensure that the Laboratory team are aware of upcoming audits and inspections and, if needed, assist in the preparation for the audit or inspection. The CI and team should be present during the audit or

		inspection and its close-out as required and assist the laboratory with appropriate corrective and preventative actions as needed.
When Queen Mary or Barts Health laboratories are used for an externally sponsored study		
15.	Institute Directors, Clinical Board Directors, and Laboratory Leads	**Responsibilities** It is the responsibility of the Director or Head of Laboratory to ensure that any sample accepted into their laboratory that originated for a MHRA regulated study is stored and handled in compliance with the regulations and EMA guidelines. It is also their responsibility to ensure GCP in followed and compliant with this SOP.
16.	Institute Directors, Clinical Board Directors, and Laboratory Leads	**Document and log** Institute Directors, Clinical Board Directors, and Laboratory Leads must be able to produce and accurate up to date log of studies (current and past*) in their area that are handling samples from MHRA regulated studies. **Since the sponsor's last MHRA GCP inspection or 3 years, whichever is longer.*

Change control

This section outlines changes from version 1.0 to version 2.0

Section changed	Summary and description of changes
Background	Removal of background section
Purpose and Scope	Merger of both sections
Clarifications	Moved to Associated Document 1 Minimum Requirements
Relevant SOPs	Remove in place of hyperlinks to the relevant document
Section 8	Removal of file requirements list in favour of direct link to Associated Document 3
Section 9	Training guidance moved to Associated Document 1 Minimum Requirements and SPO 34a Researcher Training referenced
Throughout	General administrative changes

List of associated documents

Document ref.	Document name
Associated Document 1	Minimum requirements
Associated Document 2	Set-up Checklist
Associated Document 3	Laboratory file checklist
Associated Document 4	Specimen Transfer Log
Associated Document 5	Specimen Destruction Log
Associated Document 6	Close-down checklist

List of Templates

Template ref.	Template name
Template 1	Laboratory Delegation Log
Template 2	Equipment Log
Template 3	Equipment Validation and Maintenance Log