Joint Research Management Office Standard Operating Procedure for:			
IMP Management: Barts Health/Queen Mary sponsored MHRA regulated studies.			
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Purpose:

This Standard Operating Procedure (SOP) describes the Investigational Medicinal Product (IMP) management processes that the Clinical Trials (CT) Pharmacy and the Joint Research Management Office (JRMO) complete for Clinical Trials of Investigational Medicinal Products (CTIMPs) sponsored by Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary).

The SOP outlines the CT Pharmacy's responsibilities in ensuring that the provision of IMP in Barts Health and Queen Mary sponsored studies is compliant with Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) guidelines.

Scope:

This SOP applies to Barts Health and Queen Mary Medicines and Healthcare products Regulatory Agency (MHRA) regulated sponsored studies only.

IMP management procedures for studies hosted by either institution are described in Pharmacy *SOPCT050 - Role of Pharmacy in Clinical Trials and Management of IMP* and *JRMO SOP 42b - Pharmacy Involvement in Hosted Studies.*

Abbreviations:	
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CT	Clinical Trial
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IWRS	Interactive Web Response System
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
Queen Mary	Queen Mary University of London
QP	Qualified Person
SOP	Standard Operating Procedure

Definitions:
CT pharmacy: The Lead CT Pharmacy Personnel/CT Pharmacy Coordinator.

Relevant SOPs:	
• JRMO SOP 11a	Barts Health/Queen Mary sponsorship of MHRA-regulated trials: Process for researchers
• JRMO SOP 17a	Amendments for sponsored studies: Process for researchers
• JRMO SOP 28	Monitoring
• JRMO SOP 37	Reporting serious breaches of GCP or trial protocol
• JRMO SOP 42b	Pharmacy involvement in hosted studies
• Pharmacy SOP CTS01	Reviewing and Confirming a Clinical Trial on Capacity and Capability

SOP Text:		
	Responsibility	**Activity**
Study Set up		
1.	Chief Investigator (CI)/GCP and Governance Manager	**Initiate contact with the relevant pharmacist(s) when the study is first planned.** Ensure the relevant CT pharmacists are contacted at the study design stage and are provided with a draft study proposal. If necessary, the lead CT pharmacist will be invited to an initial meeting or will be provided a summary of all study

		involvement to date (see *SOP 11a Barts Health/ QMUL sponsorship process for researchers*).
2.	CT Pharmacy	**Work with the CI as the study is designed.** Work with the CI and Costing team to prepare costings. If a rough or initial only costing is needed this can be an estimated costing, but should be updated where possible (see point 3 below). Work with the CI and coordinating team during the grant application and protocol writing phases to discuss IMP management for the proposed study. Topics for consideration include (but is not limited to): • The concept of the study • Identification of all IMPs and Non-Investigational Medicinal Product (NIMPs) • IMP sourcing • IMP manufacturing/packaging plan(s) • Calculation of overall IMP requirements for the study • IMP distribution plan • IMP blinding processes (if applicable) • IMP labelling • IMP costing/funding arrangements • Interactive Web Response System (IWRS) systems (if applicable) • Vendor assessment (if applicable) • IMP out of pharmacy storage assessment (if applicable). • Sponsor pharmacy responsibilities and costs. Please see *SOP 1 Research Study application* and *SOP 11b Barts Health/ Queen Mary sponsorship of MHRA-regulated studies: Process for JRMO* for details. At times there may be insufficient notice to allow for a full costing prior to the grant application deadline. In this case the CT Pharmacist or GCP and Governance manager will advise on a costing estimate to be included. The CI will be informed that these are estimated maximum costings and if there is still a shortfall the CI will need to find the additional funding or the study may not be granted sponsorship. For avoidance of doubt these discussions will be entered into the project comments on the costing system Worktribe. (*See SOP 11b Barts Health/ Queen Mary sponsorship of MHRA-regulated studies: Process for JRMO*).
3.	CT pharmacy and Contracts team	**Work together to execute IMP related agreements.** CT pharmacy should review the relevant sections of contracts and technical appendices. Work together to ensure that contracts and technical appendices accurately describe IMP management arrangements prior to execution. Subsequent amendments to contract should also be reviewed by CT pharmacy if they affect IMP management.
4.	CI	**Request sponsor pharmacy provisional approval.** Once the sponsorship application has been submitted to the JRMO, request sponsor pharmacy provisional approval from the CT pharmacist.
5.	CT Pharmacy	**Provide sponsor pharmacy provisional approval.** Attend the governance kick-off meeting for the study. Sponsor pharmacy provisional approval should not be issued until the kick-off meeting has taken place.

		Review the study protocol and the regulatory applications to confirm that the IMP sections are compliant with the JRMO protocol template, GCP, GMP and UK regulations. Confirm that all required IMP essential documents are in place, such as the Investigator Brochure, IMP Dossier, Qualified Person (QP) Declaration, Certificate of Analysis and Transmissible Spongiform Encephalopathy Statement. If study specific IMP labels will be used, confirm that they are acceptable and assist the study team in developing them where required. If vendors will be engaged to complete IMP related activities (e.g. secondary packaging or labelling), confirm that the arrangements are acceptable. Review the agreement(s) relating to IMP supply. Once the review is complete, email the GCP and Governance Manager confirming sponsor pharmacy provisional approval. See *Appendix A* for template wording and content.
	CT Pharmacy	**Attend the Final Governance Meeting** The GCP and Governance Manager will arrange a Final Governance Meeting once Health Research Authority (HRA) approval has been issued for the study. The CT pharmacist should attend the Final Governance Meeting and complete any actions arising from the meeting. Final sponsor pharmacy approval must not be issued until the Final Governance Meeting has taken place.
6.	CI / study team	**Create an IMP management plan, a pharmacy manual, study prescriptions and accountability logs.** Use the template IMP Management Plan (*Associated Document 1*) and pharmacy manual (*Associated Document 2*) to detail the IMP management procedures for the study. The IMP management plan describes overall IMP management by the CI and coordinating team, while the pharmacy manual describes site-level procedures. For single-centre trials, the pharmacy manual and IMP management plan can be combined into a single document. Use the pharmacy template to develop study prescriptions unless the study protocol and risk assessment explicitly state that study specific prescriptions will not be used. The prescription template should include details of any protocol dose alterations, escalations and treatment breaks to prompt the study team to prescribe correctly. Use the pharmacy template to develop accountability logs. These documents must be finalised before the study begins. Where required, approach the IMP manufacturer and distribution company for additional information for the IMP documents.
7.	CT Pharmacy	**Assist the CI and study team in the creation of the IMP Management Plan, Pharmacy Manual, study prescriptions and accountability logs.** Review and authorise the IMP documents.
8.	CT Pharmacy / JRMO Contracts and Costings Mangers	**Ensure appropriate contracts and / or technical agreements are in place.** The Contracts and Costings Manager will work with the GCP and Governance manager to ensure a suitable IMP agreement and / or technical agreement is in place.

		The CT pharmacist will identify the need for a technical agreement and work with the CI, study team and Contracts and Costing Manager to ensure the content is appropriate and complies with all applicable regulations. Where a technical agreement is not deemed necessary, IMP clauses within the main contract should be reviewed by the CT Pharmacist to ensure that there is sufficient detail on IMP management.
9.	CT Pharmacy	**Issue sponsor pharmacy final approval once the IMP Management Document has been finalised and signed off.** The CI or delegate will send the CT pharmacy the details of all regulatory approvals and relevant communications (including any conditions) when these become available. The final IMP management document will be reviewed and finalised prior to the Sponsor issuing permission to activate sties. Refer to *SOP 11a Barts Health/ QMUL sponsorship process for researchers* for information regarding sponsor permission to activate sites. The CI or delegate will request Final IMP Management Approval from the CT pharmacist. The email subject from the CT pharmacist will be labelled as 'Final IMP Management approval'. Please note this is not the same as local pharmacy approval, which is detailed in *SOP 42b Pharmacy involvement in hosted*. It is advisable to complete the two processes simultaneously in order to avoid delays.
10.	GCP and Governance Manager	**Notify the CT pharmacy when permission to activate sites is issued.**
Study Management		
11.	CI	**Submit amendments to the JRMO and pharmacy**. Any amendments which change IMP administration, or which affect IMP management should be submitted to the CT pharmacy. CT pharmacy approval is a condition of sponsor approval of these amendments. Refer to *SOP 17a Amendments for sponsored studies - process for JRMO* for details.
13.	CT Pharmacy	**Review the impact of amendments on IMP management and regulatory requirements.** Review the proposed amendment to ensure the study continues to comply with GCP and GMP regulations. If an amendment indicates that changes are required to the IMP Management Plan, Pharmacy Manual or any agreements, the CT pharmacist(s) will discuss the changes with the CI, the Contract and Costings Manager, and GCP and Governance manager (as appropriate), to ensure the relevant documents are updated.
14.	GCP and Governance Manager	**Maintain oversight of CTIMPs. Meet regularly with the CT Pharmacists.** The GCP and Governance Manager will maintain a list of pending, active / live and closed CTIMPs. The CT Pharmacists and GCP and Governance Manager will meet on a regular basis to review the studies and any issues.
15.	CI / study team	**Potential Serious Breaches must be reported to the GCP and Governance Manager and the CT Pharmacy when they are related to the IMP or the IMP's management.**

		Should a potential serious breach occur which relates to IMP and/or management of IMP, the person identifying the breach must notify the CT Pharmacy and GCP and Governance Manager immediately. The CI, study team, CT pharmacist, and GCP and Governance Manager must then discuss and agree a corrective and preventative action plan. This plan must adhere to *SOP 37 Reporting Serious Breaches*.
16.	CI and Study Team and CT Pharmacy	**Coordinate IMP alerts and recalls and notify the GCP and Governance Manager.** The CT Pharmacy will work with the study team to coordinate alert and recall activities for any sponsored study IMPs. The CI, study team, and CT Pharmacy will ensure that the GCP and Governance managers are aware of all alerts and recalls that affect them. The CT pharmacist will assist the CI and study team in creating emails regarding IMP alerts and recalls, and with requesting all the relevant information within the appropriate timeline (which is dependent on the type of IMP and the class of the alert). The CI and study team will then distribute the email and chase responses, escalating non-responders and problems to the CT pharmacist and GCP and Governance Manager. The CI and study team will inform the GCP and Governance Manager once the recall is complete.
17.	GCP and Governance Manager	**Notify CIs and the CT Pharmacist of any IMP alerts and recalls.** If the GCP and Governance Managers become aware of an alert or recall, they will search EDGE to verify which Sponsored studies use the affected IMP. The GCP and Governance Manager will then inform all affected CIs, study teams and CT pharmacist(s). They will also inform the CIs and study teams that all Principal Investigators (PI), sites and site pharmacists need to be informed.
19.	Lead CT Pharmacist	**Review monitoring reports of all UK sites** Review the pharmacy monitoring reports of all UK sites in a timely manner prior to finalising and sending of report. The review should focus on ensuring GCP and GMP compliance.
20.	CT Pharmacy	**Maintain oversight of study closure activities.** This includes but is not limited to final IMP reconciliation/destruction at sites and vendors, and review of pharmacy closeout reports.
21.	All	**Notify other parties when audits, inspections and IMP reviews are due to take place.** The GCP and Governance Manager will provide the CT pharmacist with a copy of relevant audit and monitoring reports, including the findings and actions required (as per *SOP 28 Monitoring*). For audits and IMP reviews conducted by the CT pharmacy team, the CT Pharmacist will copy in the GCP and Governance Manager(s) to all applicable reports and action plans.
22.	CT Pharmacy	**All CT Pharmacists involved in tasks described in this SOP will be fully trained in GCP and have a contractual relationship (substantive or honorary) with both organisations.**

Change control

This section outlines changes from version **3.0** to version **4.0**

Section changed	Summary and description of changes
All	General administrative changes

List of appendices

Appendix ref.	Appendix name
Appendix A	Template wording for IMP management approval with conditions
Appendix B	Template wording for sponsor pharmacy approval

List of associated documents

Document ref.	Document name
Associated Document 1	Template IMP Management Plan
Associated Document 2	Template Pharmacy Site Manual

Appendix A - Template wording for provisional sponsor pharmacy approval

Please note the below wording is a template and any additional IMP management specific arrangements should be included.

“I can confirm that I am aware of << Insert name of CI>>, << Insert short name of study>>. <<Insert EudraCT>>, <<JRMO IRAS/ReDa number (where possible)>>, <<Protocol version>>. I can confirm it has been set up to comply with all relevant SOPs and regulations.

I have been directly involved in the set up processes for the IMP management of the study.

- IMP is << insert IMP(s) (Insert type of storage). <<insert any NIMP and supplier>>
- IMP is provided by <<insert >>
- <<Insert any distributor/ third-party involved>> is the contracted vendor for IMP activities – << as appropriate QP release, labelling, and distribution>>.
- Insert how IMP will be provided to site including any financial arrangements
- I have reviewed the IMP sections of the IRAS application.
- IMP <<insert name>> labels for the UK sites have been approved by me on behalf of the Sponsor.
- IMP<<insert name>> is manufactured within the EU
- IMP<<insert name>> is << insert route>> and the scheduling is<<insert schedule>>– patients are given diary cards.
- Insert statement of randomisation / User Acceptance Testing if applicable
- If applicable: I was involved in preparation of the technical agreement between the Sponsor, XXXX and XXXXX which has been signed and agreed by all parties.
- A study specific IMP Management Plan will be produced for use by the Coordinating staff involved in the study
- Supporting documentation for sites will be provided by the Coordinating staff e.g. pharmacy manual, template accountability logs, template prescriptions
- IMPs and NIMPs will be stored within pharmacy departments (as appropriate)
- Pharmacy monitoring will be in line with the agreed monitoring plan

From a Sponsor perspective I do not foresee there being any problems from the IMP side.

Please let me know if you need any further information”

Appendix B- Template wording for final sponsor pharmacy approval

Please note the below wording is a template and any additional IMP management specific arrangements should be included, this email should contain and capture the absolute requirements for the study.

“Study name: XXX

IRAS: XXX

PI: XXXX

Pharmacy study Site: XXXXX

I confirm that I have reviewed the provisional sponsor pharmacy approval for this study issued by [pharmacist name] on [date]. I confirm that the details the same, [no changes have been made / the following changes have been made].

I have reviewed the IMP Management Plan, Pharmacy Manual, study prescription and accountability log and have approved them.

Please accept this email as confirmation of pharmacy final approval for the above study”