Standard Operating Procedures (SOP) for:			
IMP Management – BH/QMUL Sponsored CTIMPs			
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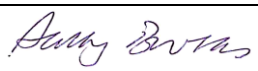
Author:	**Marie-Claire Good, RG and GCP Manager**
Reviewer:	**James Rickard, Deputy Chief Pharmacist – Technical Services**
Reviewer:	**Cheryl Lawrence, Senior Research Pharmacist**

Authorisation:	
Name/Position:	**Sally Burtles, Director of Research Services and Business Development**
Signature:	
Date:	24th July 2017

Purpose and Objective:
To standardise the process of Investigational Medicinal Product (IMP) Management between the Clinical Trials (CT) Pharmacy and the Joint Research Management Office (JRMO) for Barts Health NHS Trust (BH) or Queen Mary University of London (QMUL) sponsored Clinical Trials of IMPs (CTIMPs). To outline CT Pharmacy involvement and responsibilities in ensuring that IMP provision for BH and QMUL sponsored studies is in line with Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and, where required, Good Distribution Practice (GDP) regulations.
Scope:
This SOP covers BH and QMUL Sponsored CTIMPs only. IMP management of studies hosted by either institution is covered in Pharmacy *SOPCT050 - Role of Pharmacy in Clinical Trials and Management of IMP* and JRMO *SOP 42b - Pharmacy Involvement in Hosted Studies*.

Abbreviations:	
BH	Barts Health NHS Trust
CI	Chief Investigator
CT	Clinical Trial
CTIMP	Clinical Trial of an Investigational Medicinal Product
EU	European Union
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GL	Green Light
GMP	Good Manufacturing Practice
IMP	Investigational Medicinal Product
IWRS	Interactive Web Response System
JRMO	Joint Research Management Office
NIMP	Non-Investigational Medicinal Product
QMUL	Queen Mary University of London
ReDA	Research Database Application
RG	Research Governance

SOP	Standard Operating Procedure
TMF	Trial Master File

Definitions:

CT pharmacy: the Lead Clinical Trial Pharmacy Personnel/Clinical Trial Pharmacy Coordinator.

Relevant SOPs:

- JRMO SOP 11a BH/QMUL Sponsorship of CTIMPs, ATMPs and Clinical Trials of Non-CE Marked Medicinal Devices – 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 SOPCT050 Role of Pharmacy in Clinical Trials and Management of IMP

SOP Text:

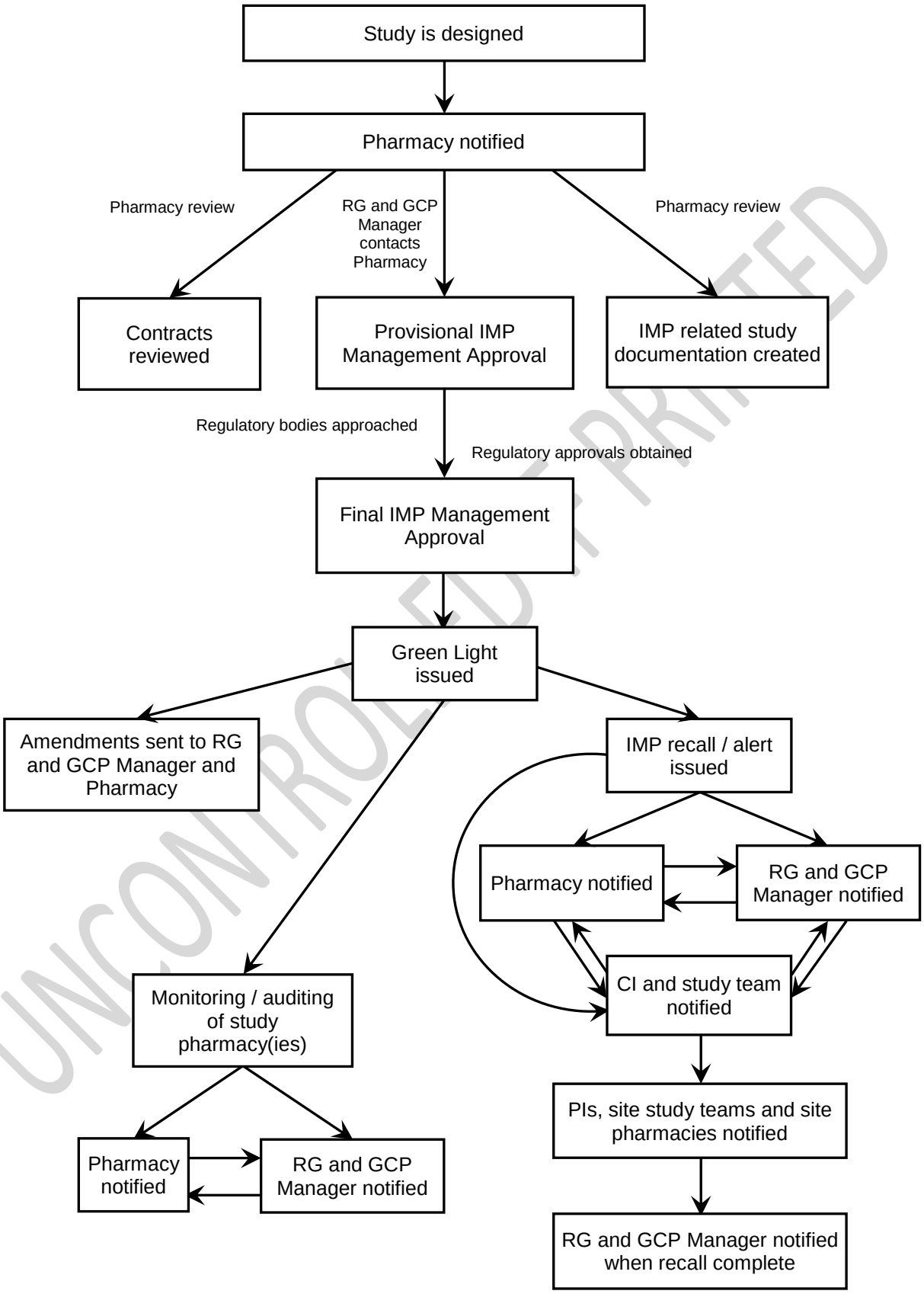
	Responsibility	Activity
1.	CI / RG and GCP Manager	**Initiate contact with the relevant pharmacist(s) when the study is first planned.** Ensure the relevant CT pharmacists are contacted at the study design stage with a draft study proposal. If appropriate or necessary, the lead CT pharmacist will be invited to an initial meeting or will provide a summary of all study involvement to date (see *SOP 11*).
2.	CT Pharmacy	**Work with the CI as the study is designed.** Work with the CI and coordinating team during the protocol writing phase to discuss IMP management for proposed study. This should include (but is not limited to): • The concept of the study • Identification of all IMPs and 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 • IWRS systems (if applicable) • Vendor assessment (if applicable)
3.	RG and GCP Manager	**Request provisional IMP management approval.** Following submission to the JRMO for Provisional Sponsorship approval, the RG and GCP manager will request Provisional IMP Management Approval from Lead CT pharmacist.
4.	CT Pharmacy	**Provide provisional IMP management approval.** The CT pharmacist(s) will review the trial protocol and the regulatory applications ensuring that the IMP sections are in line with the JRMO protocol template, GCP, and GMP regulations.

		Once reviewed, the CT Pharmacist will email the RG and GCP Manager(s) providing Provisional IMP Management Approval to allow the trial to be submitted to the appropriate regulatory bodies. The email subject will be labelled as 'Provisional IMP Management approval'. See *Appendix A* for template wording and content.
5.	CI / study team	**Create an IMP Management Plan, Site Manual, study prescriptions and accountability logs in order to obtain the green light for recruitment.** The CI and / or study team will use the template IMP Management Plan (*Associated Document 1*) to detail the IMP management for the trial. The IMP management plan is for the CI and coordinating team rather than for sites. The CI and / or study team will also use the template Site Manual (*Associated Document 2*) to develop a site pharmacy manual. The CI and / or study team will use *Associated Document 3* to develop study prescriptions. The CI and / or study team will use *Associated Document 4* to develop accountability logs. These four documents are mandatory for all trials to receive the green light. The CI and / or study team will approach the IMP manufacturer and distribution company for additional information and supporting details for the pharmacy manual (where relevant).
6.	CT Pharmacy	**Assist CI and study team in the creation of the IMP Management Plan, Site Pharmacy Manual, study prescriptions and accountability logs** The CT Pharmacist(s) will review and authorise these documents.
7.	CT Pharmacy / JRMO Contracts and Costings Mangers	**Ensure appropriate contracts and / or technical agreements are in place.** The Contracts and Costings Manager(s) will work with the RG and GCP manager(s) 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(s) to ensure that sufficient details regarding technical and quality details relating to IMP management are covered.
8.	JRMO / CT Pharmacy / CI	**The CT Pharmacist will issue Final IMP Management Approval once the IMP Management Document has been finalised and signed off.** The RG and GCP Manager 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 the Green Light (GL): refer to *SOP 11* for information regarding issuing the GL. The IMP Management Document will be reviewed and signed by the CI and a CT pharmacy representative, and copies will be filed in the JRMO Governance file and TMF. The RG and GCP Manager 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*).
9.	RG and GCP Manager	**Notify the CT pharmacy when the Study GL notification is issued.**
10.	CI	**Submit amendments to the JRMO and pharmacy**. Refer to *SOP 17a* for details.
11.	RG and GCP Manager	**Review amendments with regards to impact on IMP management.** If the amendment involves a change to any aspect of IMP management, forward copies of all the amendment documents to the CT pharmacist(s) for review prior to submission to the authorities.
12.	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, Site Pharmacy Manual or any agreements, the CT pharmacist(s) will discuss the changes with the CI, the Contract and Costings Manager, and RG and GCP manager (as appropriate), to ensure the relevant documents are updated.
13.	RG and GCP Manager	**CTIMPs will be recorded by the JRMO. The RG and GCP Manager will meet regularly with the CT Pharmacists.** The RG and GCP Manager will maintain a list of pending, active / live and closed CTIMPs. The CT Pharmacists and RG and GCP Manager will meet on a regular basis to review the trials and any issues.
14.	CI / study team	**Serious Breaches must be reported to the RG and GCP Manager and the CT Pharmacy when they are related to the IMP or the IMP's management.** Should a serious breach occur relating to IMP and / or management of IMP, the person(s) identifying the breach must ensure that the CT Pharmacy and RG and GCP Manager are notified immediately. The CI, study team, CT pharmacist, and RG and GCP Manager must then discuss and agree a corrective and preventative action plan. This plan must adhere to *SOP 37*.

15.	CI and Study Team / CT Pharmacy	**Coordinate IMP alerts and recalls, and notify the RG and GCP 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 RG and GCP managers are aware of all alerts and recalls that affect them.
16.	RG and GCP Manager	**Notify CIs and the CT Pharmacist(s) for affected Sponsored CTIMP studies of any IMP alerts and recalls.** If the RG and GCP Managers become aware of an alert or recall, they will search the ReDA to verify which Sponsored trials use the affected IMP. The RG and GCP Manager will then inform all affected CIs, study teams and CT pharmacist(s). They will also inform the CIs and study teams that all PIs, sites and site pharmacists need to be informed.
17.	CT Pharmacy / CI / Study Team	**Notify other relevant parties about IMP recalls and alerts.** The CT pharmacist(s) 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(s) and chase responses, escalating non-responders and problems to the CT pharmacist and RG and GCP Manager. The CI and study team will then inform the RG and GCP Manager once the recall is complete.
18.	CT Pharmacy	**Monitoring (UK sites only)** To 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 of corrective actions.
19.	CT Pharmacy / RG and GCP Manager / JRMO Study Monitor	**The RG and GCP Manager and CT Pharmacists will keep each other informed when audits and IMP reviews take place.** For JRMO audit and monitoring activities on a CTIMP Sponsored by the JRMO, the RG and GCP Manager will provide the CT pharmacist with a copy of the findings and actions required (as per *SOP 28*). For audits and IMP reviews conducted by the CT pharmacy team, the CT Pharmacist will copy in the RG and GCP Manager(s) to all applicable reports and action plans.
20.	CT Pharmacy	**All CT Pharmacists involved in tasks described in this SOP will be fully trained in GCP.**

Flow Chart



Change Control

This section outlines changes from version **2.0** to version **3.0**

Section Changed	Summary and Description of Changes
All	General grammar and spelling corrections, and streamlining of writing – no change to content or meaning.

List of Appendices

Appendix Ref.	Appendix Name
Appendix A	Template Wording for Provisional IMP Management Approval

List of Associated Documents

Document Ref.	Document Name
Associated Document 1	Template IMP Management Plan
Associated Document 2	Template Pharmacy Site Manual
Associated Document 3	Template Prescription
Associated Document 4	Template Accountability Log

Appendix A - Template wording for Provisional IMP Management 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 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"