| Standard Operating Procedures (SOP) for: | | | |
|---|---|---|---|
| **Pharmacy Involvement in Hosted Studies** | | | |
| SOP Number: | *42b* | Version Number: | *2.0* |
| Effective Date: | *23rd November 2015* | Review Date: | *2nd November 2017* |

| | |
|---|---|
| Author: | **Marie-Claire Rickard, RG and GCP Manager** |
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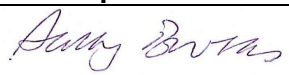
| Signature: |  |
| Date: | **9th November 2015** |

| 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) hosted studies.<br><br>To outline CT Pharmacy's involvement in and responsibilities in ensuring that IMP provision for BH and QMUL hosted studies are in line with Good Clinical Practice (GCP) and Good manufacturing practice (GMP) regulations. |
| Scope: |
| This SOP covers BH and QMUL hosted CTIMPs only.<br><br>IMP management of studies sponsored by either institution is covered in Pharmacy SOPCT050 (Role of Pharmacy in Clinical Trials and Management of IMP) and JRMO SOP 42a IMP management.<br><br>For purposes of this SOP, "CT pharmacy" is defined as the Lead Clinical Trial Pharmacy Personnel / Clinical Trial Pharmacy Coordinator.<br><br>Pharmacy SOPs for specific activities should be consulted and adhered to in addition to this SOP. |

| 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 |
| GMP | Good Manufacturing Practice |
| IMP | Investigational Medicinal Product |
| JRMO | Joint Research Management Office |
| NIMP | Non-Investigational Medicinal Product |
| PI | Principal Investigator |
| PSF | Pharmacy Site File |
| QMUL | Queen Mary University of London |
| ReDA | Research Database Application |

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|---|---|
| RG | Research Governance |
| SIV | Site Initiation Visit |
| SOP | Standard Operating Procedure |
| UTIN | Unique Trial Identification Number |
| Definitions *(if needed):* | |
| CT pharmacy: the Lead Clinical Trial Pharmacy Personnel / Clinical Trial Pharmacy Coordinator. | |
| Relevant SOPs: | |
| JRMO SOP 42a Pharmacy involvement for sponsored CTIMP studies,<br>Pharmacy SOPCT047 (Archiving of Pharmacy Clinical Trial Records),<br>Pharmacy SOPCT050 Role of Pharmacy in Clinical Trials and Management of IMP. | |

| **SOP text** | | |
|---|---|---|
| | **Responsibility** | **Activity** |
| 1. | Principal Investigator (PI) | **Contact CT Pharmacy coordinator to make them aware of any potential CTIMP.** |
| 2. | CT Pharmacy | **Review, cost and approve studies as per UCLP processes.**<br><br>This process should include identifying suitable CT pharmacy locations within the host institution. |
| 3. | CT pharmacy | **Identify suitable CT pharmacies, and liaise with the PI, study team and Sponsor.**<br><br>Identify suitable CT pharmacy locations within the host institution, and work with the PI, Study team and Sponsor to ensure arrangements for IMP handing (e.g. storage and dispensing) are compliant with GCP and GMP regulations. |
| 4. | PI | **Provide the CT Pharmacy with a copy of the pharmacy manual. Inform the CT Pharmacy about SIVs (and ensure CT Pharmacy staff are invited), site activation, and first prescription. Notify CT Pharmacy of UTINs for each new script created.**<br><br>If a pharmacy manual has not already been created by the CI and coordinating study team, liaise with the CT Pharmacy to establish what information they require and ensure they are provided with this.<br><br>Ensure CT Pharmacy coordinator is aware of the study and is invited to all Pre-Study Visits and Site Initiation Visits (SIVs). Ensure CT Pharmacy is informed of site activation by sponsor, and inform the CT Pharmacy coordinator when the CT pharmacy can expect the first trial prescription. The pharmacy team must be sent a registration document / randomisation document (or email) by the study team with the participant's unique trial number each time a new participant's script is created. |
| 5. | CT pharmacy | **Consider out of pharmacy storage in local pharmacy approval.**<br><br>If out-of-pharmacy storage is needed, follow CT pharmacy form |

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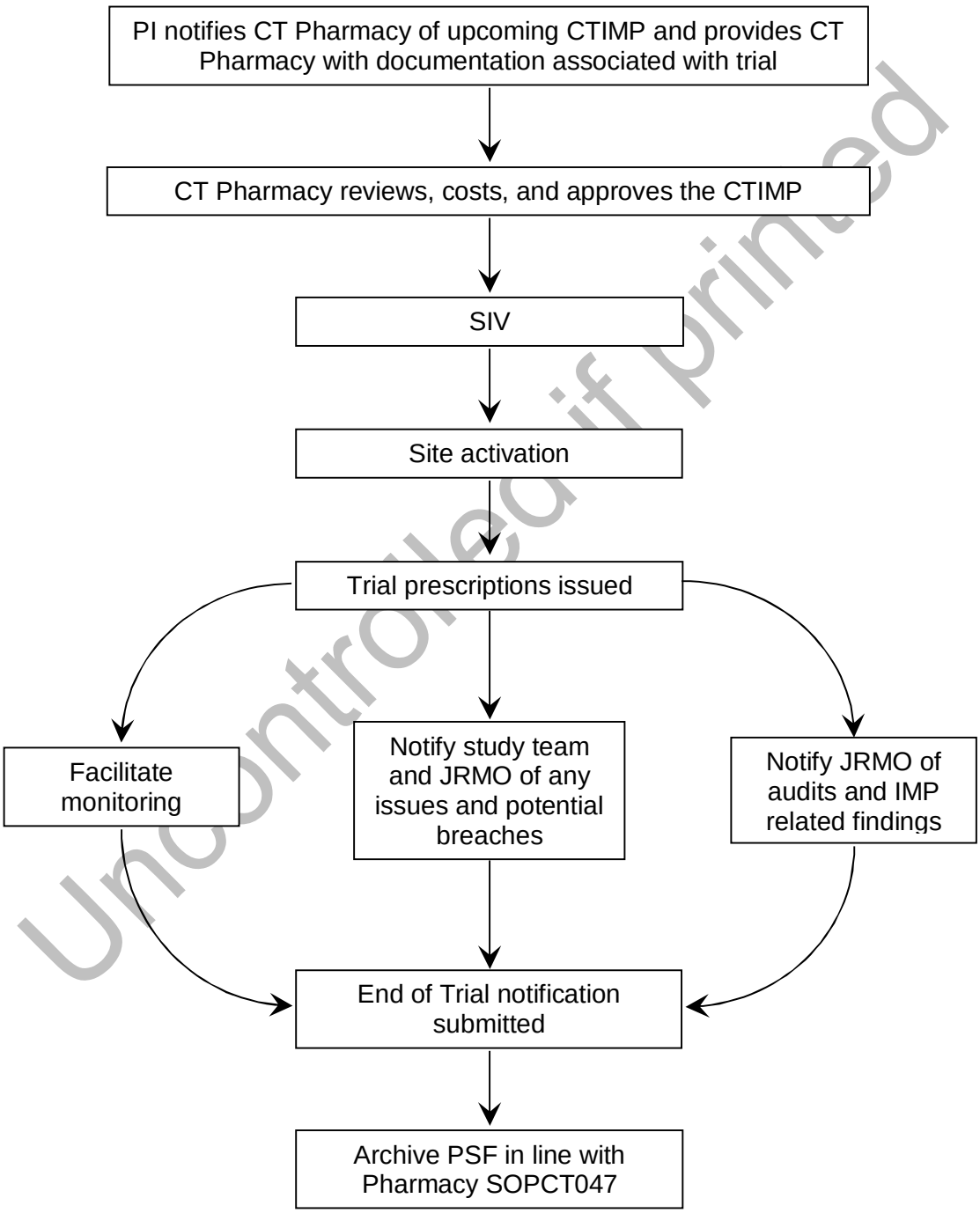
| | | FORCT031 (Non-Pharmacy Storage of IMP – Location Assessment Form) for set up, on-going review and audit. Use of out-of-pharmacy storage should be included in Local Pharmacy approval.<br><br>CT pharmacy will maintain a list of all out-of-Pharmacy IMP storage areas. A list of out of pharmacy storage areas will be discussed in regular JRMO and pharmacy meetings. |
| 6. | CT pharmacy | **Create and maintain a pharmacy site file (PSF), and fulfil agreed / contracted roles.**<br><br>The PSF must be maintained according to local Pharmacy SOPS, GCP, and GMP requirements. The CT pharmacy will be aware and fulfil any specific roles outlined in agreements and / or contracts. |
| 7. | PI | **Provide CT Pharmacy with details of all amendments.**<br><br>All documents and approvals must be forwarded to the CT Pharmacy. Ensure that all relevant correspondence with sponsor and JRMO is forwarded to the CT pharmacy in a timely manner. |
| 8. | CT pharmacy | **Facilitate monitoring.**<br><br>Liaise with Sponsors to arrange suitable time and space for monitoring visits to occur. All reasonable efforts should be made to accommodate monitoring visits and provide requested information. Respond to monitoring reports and queries in a timely manner. |
| 9. | CT pharmacy | **Notify JRMO of audits and IMP related findings.**<br><br>Ensure that the JRMO are made aware of any audits being conducted for hosted studies. Advise JRMO of any IMP related findings following the audit. |
| 10. | CT pharmacy and study team | **Inform the JRMO in a timely manner of any issues, and / or potential breach that may affect study/ies.** |
| 11. | PI and Study team | **Notify the CT pharmacy at the end of pharmacy involvement and provide copies of the End of Trial notifications.**<br><br>Inform the CT pharmacy in a timely manner when pharmacy involvement is at an end (e.g. last prescription, last returned medication etc.). Forward official end of trial notifications when received. |
| 12. | RG and GCP Manager | **CT pharmacy and JRMO meetings will take place regularly.**<br><br>Arrange for Pharmacy CT and RG and GCP managers to meet on a regular basis to review the list of pharmacy areas and trials. |
| 13. | CT pharmacy | **Conclude pharmacy involvement in a timely manner.**<br><br>Work with the PI, study team, and sponsor to ensure pharmacy involvement is completed in a timely manner in line with CT pharmacy SOPCT050 (Role of Pharmacy in Clinical Trials and |

| | | |
|---|---|---|
| | | Management of IMP), GCP, and GMP regulations. Study files are archived as per Pharmacy SOPCT047 (Archiving of Pharmacy Clinical Trial Records). |

**Flow Chart**



## List of Appendices

There are no appendices associated with this SOP.

## List of Associated Documents

There are no associated documents for this SOP.

## Change Control

This section outlines changed from version 1.0 to version 2.0.

| Section changed | Summary and description of change |
|---|---|
| All | Spelling, punctuation, grammar and general phrasing. Headings added to each section. |
| Abbreviations, Definitions, Relevant SOPs, Flow Chart | Sections added. |
| 4 | Added a sentence indicating that the PI is responsible for providing the pharmacy manual. |