A robust feasibility is an essential part of ensuring study delivery. Please pass this Study Feasibility Assessment (SFA) and a copy of the protocol to the individual(s) who are most appropriate to accurately complete the form.

Appended to this SFA should be the latest version of the protocol and information about any funding allocated to your site. In addition, if the study uses Investigational Medicinal Products, a pharmacy feasibility document should also be attached.

Any queries, please contact the study coordinator or the Research Governance Manager at UoL.

|  |  |  |
| --- | --- | --- |
| **Site Name:**  **Site Reference No:**  (if applicable)  Point of Contact Name:  (if different to PI)  POC Email:  POC Phone No: |  | **PI Name:**  **PI Email Address:**  **PI Phone No:** |
| **Research & Development / Research and Innovation:**  Contact Name:  Email address:  Phone Number: |  | **Contracts Contacts:**  Contact Name:  Email address:  Phone Number: |
| **Postal Address for Research & Development / Research and Innovation:** |  | **Registered Address for inclusion in the contract:** |
| **Pharmacy :**  Contact Name:  Email address:  Phone Number: |  | **Radiology :**  Contact Name:  Email address:  Phone Number: |
| **Laboratories :**  Contact Name:  Email address:  Phone Number: |  | **Medical Physics :**  Contact Name:  Email address:  Phone Number: |
| **Recruitment Target for Site:** |  |  |

**PHARMACY FEASIBILITY CHECKLIST VERSION 1**

|  |  |
| --- | --- |
| **Lead Pharmacy Address:** |  |
| **Other pharmacy Address:** |  |
| **Completed by:** |  |
| **Date:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Pharmacy Staff & Training** | | | |
| **♯** | **Details** | **Yes/No (or N/A where appropriate)** | **Comments** |
| **1** | **Do pharmacy have a policy document covering the safe handling of medicines used in clinical trials, including a statement listing the responsibilities the clinical trial investigator will delegate to the pharmacy department?** |  |  |
| **2** | **Is there a designated member of staff appointed who has overall responsibility for the pharmacy clinical trial service?** |  |  |
| **3** | **Are clinical trial services provided by designated pharmacy staff?** |  |  |
| **4** | **Are pharmacy staff that provide clinical trial services adequately qualified, experienced, trained (have a ‘CV & Training’ file that clearly documents responsibility for clinical trials and that includes training records, CV and Job Descriptions)?** |  |  |
| **5** | **Have they all received GCP training (frequency and type as appropriate to their roles)?** |  |  |
| **6** | **Is there a system for documenting protocol specific training for pharmacy staff involved in the trial?** |  |  |
| **7** | **Does the pharmacy hold on file completed delegation/signature logs for medical and nursing staff involved in clinical trial activities?** |  |  |
| **8** | **Is there a system to ensure that all key pharmacy personnel have signed the delegation/pharmacy signature log before undertaking trial specific activities?** |  |  |
| **Pharmacy Facilities** | | | |
| **9** | **Are all IMPs stored and dispensed from pharmacy?** |  |  |
| **10** | **Does pharmacy have oversight of IMP stored outside of pharmacy?** |  |  |
| **11** | **Does the pharmacy have systems to allow for IMPs to be segregated from normal pharmacy stock in an area with limited access? (The degree of segregation can be based on the risk of the IMP)** |  |  |
| **12** | **Are IMPs that are returned by patients or have expired stored separately from unused IMPs?** |  |  |
| **13** | **Is there an alarm system to alert staff if the temperature falls outside the specified range?** |  |  |
| **14** | **Does the pharmacy have written procedures in place that specify the actions to take when the storage conditions fall outside the specified range?** |  |  |
| **15** | **Is regular temperature monitoring of IMPs undertaken and these records archived?** |  |  |
| **16** | **Do you have IMP storage room that ensures controlled room temperature (between 15-25 C)?** |  |  |
| **17** | **Do you have a fridge to store the IMP? (2-8C)?** |  |  |
| **18** | **Do you have a -20 (minus 20 degrees) freezer to store IMP?** |  |  |
| **19** | **Do you have a -80 (minus 80 degrees) freezer to store IMP?** |  |  |
| **20** | **Does your pharmacy unit have facilities for the preparation of the IMP in sterile conditions?** |  |  |
| **21** | **Do you have an external contractor for the above mentioned activities that holds a licence appropriate to the type of activities undertaken?** |  |  |
| **21b** | **If answer to the above is yes, do you have a contract and does this have provisions to allow for a prompt identification of the input ingredients batch number (if not applicable, state N/A)?** |  |  |
| **22** | **Do you have facilities/capabilities to print labels that comply with the provisions of Annex 13?** |  |  |
| **22b** | **Are there limits to the length and space?** |  |  |
| **23** | **Is there a system to ensure that pharmacy trial files are archived?** |  |  |
| **Pharmacy Resources** | | | |
| **24** | **Has a management system been established within the Trust whereby pharmacy is contacted in advance of the Trust agreeing and signing the Clinical Trial Site Agreement?** |  |  |
| **25** | **Do pharmacy staff review each protocol and feasibility of the study?** |  |  |
| **26** | **Is it standard practice for pharmacy clinical trials staff to participate in the site initiation meeting?** |  |  |
| **27** | **Is notification of pharmacy part of the R&D approval process?** |  |  |
| **28** | **Does pharmacy check the packaging and labels of IMPs to ensure they comply with the protocol and CTA?** |  |  |
| **29** | **Where drug accountability forms, prescription forms and other associated forms are supplied by the Sponsor, does the pharmacy department review these with regard to the data they are designed to capture and their suitability for use within the pharmacy department?** |  |  |
| **30** | **Does the pharmacy ever hold the code breaks for emergency un-blinding?** |  |  |
| **31** | **Is there 24/7 out of hours emergency cover for code break access (where applicable)?** |  |  |
| **Approvals (Regulatory Green Light)** | | | |
| **32** | **Does the pharmacy have a system in place to ensure that all of the required approvals and documentation are in place before IMP can be released from pharmacy, including (list not exhaustive): • Appropriate regulatory documentation in place i.e. clinical trial authorization? • Favourable opinion by the appropriate Research Ethics Committee(s)? • Approval by the local R&D Department? • Received an activation letter from the Sponsor?** |  |  |
| **33** | **Does pharmacy have a system that ensures confirmation of QP certification for each batch of IMP (where applicable)?** |  |  |
| **34** | **Does pharmacy maintain a study-specific filing system for essential clinical trial documents (e.g. a ‘pharmacy File’) for each clinical trial?** |  |  |
| **IMP Management (Pharmacy Policies & Procedures)** | | | |
| **35** | **Does pharmacy have written clinical trials Standard Operating Procedures (SOPs) to cover the following?:** |  |  |
| **• Receipt and recording of the safe delivery of IMPs** |  |  |
| **• Safe handling and storage of IMPs** |  |  |
| **• Temperature monitoring** |  |  |
| **• Un-blinding (only if willing to provide the service)** |  |  |
| **• Preparation and dispensing of IMPs in accordance with professional standards (including dispensing against an appropriate prescription, maintaining drug accountability records and ensuring that all IMPs are labelled with the appropriate pharmacy label)** |  |  |
| **• Return and disposal of unused IMPs** |  |  |
| **• Reconciliation of IMPs** |  | This is included in Return and Destruction SOP. |
| **• Maintaining a pharmacy study file** |  |  |
| **• Training of clinical trial pharmacy staff** |  |  |
| **• Archiving of clinical trials documentation** |  |  |
| **36** | **Are the pharmacy SOPs authorised and reviewed at regular intervals?** |  |  |
| **37** | **Does pharmacy generate trial specific procedures (dispensing guidelines) for each trial?** |  |  |
| **38** | **Does pharmacy keep accurate records with sufficient information to provide a full audit trail from the receipt of the IMPs to their use, removal from site or destruction?** |  |  |
| **39** | **Does pharmacy maintain the following documentation relating to preparation of IMP (e.g. reconstitution, dilution)?: • Prescription or order form • Randomisation code (where applicable) • Drug accountability or dispensing records • Production worksheet or batch sheet • Evidence of professional release** (if this activity is not undertaken by pharmacy, select N/A) |  |  |
| **40** | **Are IMPs always labelled with the patient's name and date dispensed?** |  |  |
| **41** | **Is the patient identity removed from the IMP before it is returned to the Sponsor?** |  |  |
| **42** | **Are clinical trial participants counselled on the correct use of the IMP in addition to any written information, which is provided e.g. clinical trial patient information sheet or the patient information leaflet (PIL)?** |  |  |
| **43** | **Are pharmacy staff aware of (and trained on) the reporting requirements and procedures for possible adverse events experienced by patients in a clinical trial?** |  |  |
| **Clinical Trial Prescriptions** | | | |
| **44** | **Do pharmacy check that IMPs prescribed on a hospital drug chart or a prescription form are signed by a prescriber who is listed on the delegation log for the clinical trial?** |  |  |
| **45** | **Are study-specific clinical trial prescription forms used to facilitate the prompt identification of the clinical trial and dispensing procedures and to reduce the risk of dispensing errors?** |  |  |
| **Recall** | | | |
| **46** | **Do prescriptions/drug charts for IMPs clearly identify the clinical trial, the subject and medication required?** |  |  |
| **47** | **Does pharmacy have documented procedures (SOPs) describing the process(es) to follow when dealing with IMP complaints, recall and/or quarantine?** |  |  |
| **48** | **If so, does the SOP cover the following?: • Procedure for triaging IMP complaints • IMP audit trail system that will enable recall • Dealing with drug alerts from the MHRA Defective Medicines Report Centre • Dealing with drug recalls initiated by a trial Sponsor/manufacturer/supplier • Informing Investigators and Clinical Trial participants • Recall and quarantine of IMP** |  |  |
| **49** | **Do pharmacy have a system for recall of marketed drugs (including where used as IMP)?** |  |  |
| **50** | **Do pharmacy have a specified secure area for storage of quarantined IMP?** |  |  |

|  |  |
| --- | --- |
| **Reviewed by:** | **Date:** |
|  |  |
| **Approved for suitability by:** | **Date:** |
|  |  |