Pharmacy Feasibility Assessment (PFA) Form

A robust site feasibility assessment is an essential part of ensuring successful study delivery.

**Instructions to the UoL Research Team:**

1. A Pharmacy Feasibility Assessment PFA must be completed **per site** involved in the delivery of a research study.
2. Please complete Sections 1 and 2 (as well as any other relevant information within the questions) prior to sending the PFA to the potential site.
3. Provide the PFA to the individual(s) at a site who is/are best placed to accurately complete the form.
4. Appended to this PFA should be the latest version of the protocol and/or study summary and information about any funding allocated to the site.
5. The completed PFA should be included with the application for Sponsorship (or amendment, where a site is added via an amendment).
6. Guidance text is provided in blue and should be removed prior to submission of the PFA

**Instructions for the Site undergoing Feasibility Assessment:**

1. Please complete Section 3 onwards.
2. The PFA should be completed prior to your site being named on the IRAS form, or being added as a research site via an amendment.
3. Please complete the PFA accurately and ensure that you obtain the relevant input and sign-off from responsible individuals at your site and in accordance with your local policies.
4. Please add comments/background detail where applicable to help us understand how the study/trial may be implemented at your site.
5. It is important that anything that is atypical or not standard for your site is fully explained (we may be able to amend the protocol to address foreseen issues).
6. Sections and/or statements should be marked as ‘N/A’ where these are not relevant to the site or protocol requirements.
7. Guidance text is provided in blue and should be removed prior to submission of the PFA

# General Study Information and Management - to be completed by the Chief Investigator/Lead Site

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| --- | --- |
| **Study Title/Acronym:** |  |
| **Sponsor reference number:** | XXXX |
| **Chief Investigator:** |  |
| **IRAS Number:** |  |
| **Type of study:** | *i.e., whether this is a CTIMP (including the Phase etc)/Non-CTIMP/Interventional study/Randomised/Blinded* |
| **Total recruitment target:** | *Please enter the overall recruitment target for the study* |
| **Is recruitment competitive?** | *Yes/No; provide additional details if required* |
| **Study duration:** | *Start date* |  | *End date* |  |
| **Recruitment period:** |  |
| **Version of the Protocol:** | *Provided to the site for feasibility assessment* |
| **Funding summary:** | *Please provide an overview of the funding that will be provided to the Pharmacy department (if applicable)* |
| **IMP summary:**  | *Please provide an overview* IMP provision, management and storage requirements |

# Site Information – to be completed by the Chief Investigator/Lead Site

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| --- | --- |
| **Site Name/Number:** | *Please enter the details for the site undergoing feasibility* |
| **NHS Trust Name:** |  |
| **Proposed site recruitment target:** |  |
| **Proposed site start date:** |  |
| **Proposed site recruitment period:** |  |

*The questions below should be adapted to suit the protocol requirements prior to issuing to the site to ensure the information gathered enables a full feasibility assessment.*

# Pharmacy Contact Details - to be completed by the pharmacy department at the site

|  |  |  |
| --- | --- | --- |
|  | **Name** | **Email** |
| **Principal Investigator (PI):** |  |  |
| **Trial Pharmacist:** |  |  |
| **Pharmacy Point of Contact:** |  |  |
| **Other relevant contacts:** |  |  |
| **Pharmacy Address for IMP deliveries:** |  |

# Pharmacy Feasibility Assessment - to be completed by pharmacy

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| **1. Pharmacy Procedures and Facilities** |
| **Are all IMPs stored and dispensed from clinical trials pharmacy?** | [ ]  Yes[ ]  No, please explain: |
| **Does the pharmacy have systems to allow for IMPs to be segregated from normal pharmacy stock in an area with limited access?** | [ ]  Yes[ ]  No, please explain: |
| **Are IMPs that are returned by patients or have expired stored separately from unused IMPs?** | [ ]  Yes[ ]  No, please explain: |
| **Is there an automated facilities temperature monitoring system in place and will this alarm system alert staff if the temperature falls outside the specified range?** | [ ]  Yes, please detail system used:[ ]  No, please explain: |
| **Does the pharmacy have written procedures in place that specify the actions to take when the storage conditions fall outside the specified range?** | [ ]  Yes[ ]  No, please explain: |
| **Do you have sufficient facilities to prepare, store and dispense the IMP required as per the protocol?**  | [ ]  Yes[ ]  No, please explain: |
| **Is there a process in place to ensure the regular maintenance and calibration of pharmacy equipment?** | [ ]  Yes[ ]  No, please explain: |
| **Do you have facilities/capabilities to print labels that comply with the provisions of Annex 13?** | [ ]  Yes[ ]  No, please explain: |
| **Does pharmacy check the packaging and labels of IMPs to ensure they comply with the protocol and CTA?** | [ ]  Yes[ ]  No, please explain: |
| **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?** | [ ]  Yes[ ]  No, please explain: |
| **2. Staff** |
| **Are clinical trial services provided by designated clinical trials pharmacy staff?** | [ ]  Yes[ ]  No, please explain the provision of pharmacy services at your site: |
| **Will all staff complete the required GCP and study specific training?**  | [ ]  Yes[ ]  No, please specify: |
| **Do pharmacy staff review each amendment/iteration of the protocol?**  | [ ]  Yes[ ]  No, please explain: |
| **Will pharmacy clinical trials staff be available to participate in the site initiation meeting?** | [ ]  Yes[ ]  No, please explain: |
| **Who is responsible for the maintenance of the pharmacy site file (PSF)?** |  |
| **Does the pharmacy hold the code breaks for emergency un-blinding?** | [ ]  Yes[ ]  No, please explain: |
| **Is there 24/7 out of hours emergency cover for code break access (where applicable)?** | [ ]  Yes[ ]  No, please explain: |
| **3. Approvals (Regulatory Green Light)** |
| **Does the pharmacy issue a green light confirmation to ensure that all of the required approvals and documentation are in place before IMP can be released from pharmacy?** | [ ]  Yes[ ]  No, please explain: |
| **4. IMP Management (Pharmacy Policies & Procedures)** |
| **Does pharmacy have written clinical trials Standard Operating Procedures (SOPs) to cover the processes of receipt, storage, monitoring, dispensing and destruction of IMP?** | [ ]  Yes[ ]  No, please explain: |
| **Are the pharmacy SOPs authorised and reviewed at regular intervals?** | [ ]  Yes[ ]  No, please explain: |
| **Does pharmacy generate trial specific procedures (dispensing guidelines) for each trial?** | [ ]  Yes[ ]  No, please explain: |
| **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) | [ ]  Yes[ ]  No, please explain: |
| **5. Clinical Trial Prescriptions** |
| **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?** |   |
| **Do pharmacy have a system for recall of marketed drugs (including where used as IMP)?** |   |

# Site sign-off – to be completed by a representative from the site Pharmacy department and the Chief Investigator/Lead Site

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| **Outcome of feasibility assessment:** | [ ]  Feasible – no further action(s) required[ ]  Potentially feasible – areas to be addressed/resolved[ ]  Not feasible at this time |
| **Approved by:** | *This should be a representative from the site Pharmacy* |
| **Date:** |  |
| **Reviewed and approved by:** | *This should be the CI/Lead Site delegate* |
| **Date:** |  |