**NIMH Investigational Product (IP) Management Standard Operating Procedure (SOP) Template**

***Tool Summary*** *(Remove Tool Summary before finalizing and distributing the document)*

***Purpose:*** *This template may be used to record and document the standard operating procedures for the management of investigational product.*

***Audience/User:*** *Principal Investigator and study team members who are delegated to manage investigational products*

***How to Use This Template***

*This template contains two types of text: instruction/explanatory and example text.* ***Instruction/ explanatory text*** *are indicated by italics and should be deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.* ***Example text*** *is included to further aid in document development and should either be modified or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.*

***Version control*** *is important to track document development, revisions, and amendments. It is also necessary to ensure that the correct version of this document is used by all staff conducting the study. With each revision, the version number and date located in the header of each page should be updated.*

**PROTOCOL TITLE: *< Protocol Title>***

**PROTOCOL NO.: *<Protocol No.>***

**DOCUMENT: Investigational Product Management Standard Operating Procedure**

**VERSION DATE: *< Version Date>***

**DRAFTED BY:**

Name Title Signature Date

**APPROVED BY:**

Name Title Signature Date

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1. **GOALS OF INVESTIGATIONAL PRODUCT (IP) MANAGEMENT**
   1. The goals of IP management for this clinical trial include the following:

(a) To ensure protection of the subject and traceability;

(b) To enable identification of the product and the trial;

(c) To facilitate proper use and storage of the product;

(d) To ensure the reliability and robustness of data generated in the trial.

1. **ROLES AND RESPONSIBILITIES**
   1. **ROLES AND RESPONSIBILITIES OF SITE** 
      1. The following study staff will be responsible for IP management:
2. IP Shipment and receipt: *<roles of study staff>*
3. IP Storage: *<roles of study staff>*
4. IP Repackaging and Relabelling: *<roles of study staff>*
5. IP Dispensing and Accountability: *<roles of study staff>*
6. IP Return and Destruction: *< roles of study staff>*
   * 1. The roles and responsibilities of the study staff involved in IP management for this clinical trial will be documented in a Signed Signature Sheet. Study staff will be trained on IP management procedures.
        1. Training will be documented and maintained in the Investigator Site Files.

*For sites involved in IP repackaging and relabelling, describe the roles and responsibilities of the blinded and unblinded study teams as follows:*

1. *[The blinded study team will comprise of the Principal Investigator, Sub-investigators, Blinded Clinical Research Coordinators (Blinded CRC) etc.]*
2. *[The unblinded study team will comprise of the Study Pharmacists / Unblinded Clinical Research Coordinators (Unblinded CRC) etc.]*
   1. **ROLES AND RESPONSIBILITIES OF SPONSOR**

2.2.1The Sponsor for this clinical trial is *<Name of Sponsor>.* This clinical trial will be monitored by the Sponsor monitor.

*For sites involved in IP repackaging and relabelling, describe that there will be two separate monitors:*

1. *[The blinded monitor will be responsible for monitoring all aspects of the clinical trial except IP management.]*
2. *[The unblinded monitor will be responsible for monitoring the IP management of this clinical trial).]*
3. **SOURCE OF IP**
   1. Table 1 summarizes the name(s), manufacturer(s), source(s) and recommended storage temperature(s) of the IP(s) used in this clinical trial.

**Table 1: Summary of products used**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Product | Use in Study <i.e. Test/ Reference/ Auxiliary Product> | Manufacturer | Source of IP | Recommended Storage Temperature (OC) |
| *[Drug X]* | *[Test]* | *[ABC Pharmaceuticals]* | *[Care Bear Hospital Pharmacy]* | *[15-30 oC]* |
| *[Placebo]* | *[Reference]* | *[DEF Pharmaceuticals]* | *[DEF Pharmaceuticals]* | *[15-30 oC]* |

1. **IP SHIPMENT AND RECEIPT**
   1. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should file *<receipts of purchase / IP Shipping Documentation>* and the GMP certificate / Certificate of Analysis (COA) / Product Insert of the IP in the Pharmacy Binder.
      1. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should ensure that the contents of the *<receipts of purchase / IP Shipping Documentation>* are in compliance with Section 4.6.3 of ICH E6 Guideline for Good Clinical Practice.

*For sites involved in IP repackaging and relabelling, the receipts of purchase / IP Shipping Documentation should be filed in the Pharmacy Binder with access secure and limited to the unblinded study team.*

* 1. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should verify the inventory of the IP and update the IP Inventory Log(s). The IP Inventory Log(s) will be filed in the Pharmacy Binder.
     1. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should ensure that the contents of IP Inventory Log(s) are in compliance with Section 4.6.3 of ICH E6 Guideline for Good Clinical Practice.

*For sites involved in IP repackaging and relabelling, separate IP Inventory Logs should be maintained for each IP, and the IP Inventory Logs should be kept in the Pharmacy Binder with access secure and limited to the unblinded study team.*

1. **IP STORAGE**
   1. The IP will be stored at *<storage location of IP>.*
   2. The <*Blinded CRC / Unblinded CRC / Study Pharmacist>* should monitor the storage temperature of the IP on *< frequency of temperature monitoring>.*
      1. IP Storage Temperature Logs will be maintained in the Pharmacy Binder.
   3. In the event of excursions from the recommended storage temperature of the IP as referenced in Table 1, the *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should complete the IP Storage Temperature Excursion Report and notify the *<Principal Investigator and/or Sponsor>* for appropriate action to be taken.
      1. The IP affected by the temperature excursion should be quarantined until a decision has been made by the *<Principal Investigator and/or Sponsor>* to use or destroy the IP.
      2. All relevant documentation and correspondences pertaining to temperature excursions should be filed in the Pharmacy Binder.
2. ***[IP REPACKAGING AND RELABELLING (if applicable)]***
   1. *[The unblinded study team should perform IP repackaging and relabelling in accordance with the protocol and Good Manufacturing Practice (GMP) guidelines.]*
   2. *[The unblinded study team should apply the following GMP principles during IP repackaging and relabelling:]*
      1. *[IP repackaging and relabelling should be performed by delegated and trained unblinded study staff.]*
      2. *[IP repackaging and relabelling should be witnessed by an unblinded study staff.]*
      3. *[Line clearance should be observed during IP repackaging and relabelling whereby one IP will be repackaged and relabelled at a time.]*
      4. *[Label reconciliation should be performed and documented on the IP Repackaging and Relabelling Form.]*
      5. *[The IP Repackaging and Relabelling will be documented on the IP Repackaging and Relabelling Form.]*
      6. *[The IP Inventory Logs for the IP(s) will be updated accordingly.]*
   3. *[The unblinded study team will perform IP repackaging and relabelling <prior to study initiation / at each subject visit/ etc.>.]*
   4. *[The unblinded study team will assign a dummy batch number and dummy expiry date for the repackaged and relabelled IP and document it on the relevant IP Repackaging and Relabelling Form.]*
      1. *[For example, the dummy batch number will be set as ‘YYYYMMDD’ in accordance with the date of IP repackaging, and the dummy expiry date will be set as the earlier expiry date of the IP.]*
   5. *[The unblinded study team should ensure that all documentation pertaining to IP shipment, receipt, inventory, storage, repackaging and relabelling, transfer, return and destruction should be filed in the Pharmacy Binder with access secure and limited to the unblinded study team.]*
3. **IP DISPENSING AND ACCOUNTABILITY**
   1. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should dispense the IP to the subject.
      1. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should advise the subject on the proper use of the IP in accordance with the protocol.
      2. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should advise the subject to return all used and unused to the site at the next study visit for determination of compliance.
   2. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should update the IP Dispensing and Accountability Logs and file it in the *<Investigator Site File / Subject CRF>.*
      1. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should ensure that the contents of the IP Dispensing and Accountability Logs are in compliance with Section 4.6.3 of ICH E6 Guideline for Good Clinical Practice.

*For sites involved in IP repackaging and relabelling, the transfer of the repackaged IP from the unblinded study team to the blinded study team should be documented on the IP Dispensing and Accountability Logs.*

1. **IP RETURN AND DESTRUCTION**
   1. The *<Blinded CRC / Unblinded CRC / Study Pharmacist> should* collect the used and unused IP from the subject at the next study visit.
      1. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should document the returns in the IP Dispensing and Accountability Logs.
   2. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should *<return the used and unused IP to the Sponsor for destruction / send the used and unused IP for destruction in accordance with institution policy>*.
      1. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should send the used and unused IP for destruction once a final IP Accountability has been performed by the monitor; all discrepancies have been investigated, satisfactorily explained and reconciliation accepted; and written approval has been sought from the *<Sponsor / Principal Investigator>*.
      2. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should ensure that IP Return and / or Destruction is documented on the IP Return and Destruction Forms. The IP Return and Destruction Forms will be filed in the Pharmacy Binder.
      3. The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should ensure that the contents of the IP Return and Destruction Forms are in compliance with Section 4.6.3 of ICH E6 Guideline for Good Clinical Practice.

*For sites involved in IP repackaging and relabelling, the unblinded study team should be responsible for IP Return and Destruction.*

**9. IP LABELLING**

9.1 The *<Blinded CRC / Unblinded CRC / Study Pharmacist>* should ensure that the IP is labelled in accordance with Regulation 26 of the Health Products (Clinical Trials) Regulations/ Medicines (Clinical Trials) Regulations.

9.2The sample labels will be as follows:

9.2.1 Sample IP label for Investigational Product *<name>*

*[Insert sample label]*

* + 1. Sample IP label for Auxiliary Product *<name>*

*[Insert sample label]*

**10 IP MANAGEMENT FORMS**

Table 2 summarizes the IP management forms that will be used for this clinical trial.

**Table 2: Summary of IP Management Forms**

*Customise according to the needs of the study*

IP management forms containing unblinded information should be maintained with secure and limited access by the Unblinded Study Team

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Form | Location | Responsibility |
| 1 | Master Randomisation List | Pharmacy Binder | *< CRC / Study Pharmacist/ Unblinded Team>* |
| 2 | IP shipping documentation | Pharmacy Binder / Investigator Site File | *<CRC / Study Pharmacist/ Unblinded Team >* |
| 3 | IP Inventory Log | Pharmacy Binder / Investigator Site File | *<CRC / Study Pharmacist/ Unblinded Team >* |
| 4 | GMP certificate / Certificate of Analysis (COA) / Product Insert | Pharmacy Binder / Investigator Site File | *<CRC / Study Pharmacist/ Unblinded Team >* |
| 5 | IP Storage Temperature Logs | Pharmacy Binder / Investigator Site File | *<CRC / Study Pharmacist/ Unblinded Team >* |
| 6 | IP Storage Temperature Excursion Report | Pharmacy Binder / Investigator Site File | *<CRC / Study Pharmacist/ Unblinded Team >* |
| 7 | IP Repackaging and Relabelling Form | Pharmacy Binder / Investigator Site File | *<CRC / Study Pharmacist/ Unblinded Team >* |
| 8 | IP Dispensing and Accountability Log | Pharmacy Binder / Investigator Site File | *<CRC / Study Pharmacist/ Unblinded Team >* |
| 9 | IP Return and Destruction Form | Pharmacy Binder / Investigator Site File | *<CRC / Study Pharmacist/ Unblinded Team>* |

1. **REFERENCES**
   1. Health Products (Clinical Trials) Regulations
   2. Medicines (Clinical Trials) Regulations
   3. ICH E6 Guideline for Good Clinical Practice
   4. <*HSA Guideline for IP Repackaging on Site (if applicable*)>
   5. PICS GMP Annex 13
2. **LIST OF ABBREVIATIONS**

*As applicable>*