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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** : DA-402 |
| **Title**  **DISPENSING OF INVESTIGATIONAL DRUG** | | |
| **Version Number**: | **Version Date:** | **Effective date**: |
| **Approval name Signature Date** | | |

**Annual Review**

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| **Review date** | **Revision Date** | **Signature** |
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**Document History**

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| **Version number** | **Reason for change** | **Date** |
| 1.0 | Initial release | 28th March 2015 |
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**Distribution List**

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1. **Introduction**

Regulated clinical studies are subject to explicit and detailed regulations governing their conduct, and it is the responsibility of the PI to assure that all applicable regulations are followed, including ethical and GCP compliant IP dispensing

1. **Objectives**

This SOP describes the process for IP dispensing to participants at the site pharmacy. The study-specific SOP is controlled by the Pharmacy team, and will be authorised by the study Pharmacist and Principal Investigator prior to implementation.

1. **Responsibility**

The Principal Investigator, study Pharmacist and Pharmacy team.

1. **Procedure**
2. **Prescribing IP**

When a Participant is recruited into the study, the IP should be prescribed by a qualified and registered Study medical practitioner. The prescriber must be trained on the study, and on the delegation log for the study. Prescribing must comply with the study protocol. Prescribing of the IP must be on study authorise prescriptions, However other concomitant medications could be on other prescriptions such as study specific prescriptions and clinic/hospital prescription.

1. **Dispensing IP**

**Dispensing Accountability for Investigational Drugs**

Prior to dispensing or administering the IP, the following information will be reviewed with each participant:

* Treatment or medication schedule;
* Possible side effects (repeat at follow-up visits as needed);
* Contraindications, including restricted drugs, etc;
* Instructions for the return of the unused IP in its container and any empty containers, as appropriate;
* Storage instructions for participant;
* Other IP-specific administration instructions (e.g. take with food); and
* Emergency and after-hours contact information.

Prior to dispensing or administering the ID, the individual dispensing the IP should check and confirm the accuracy of the following information:

* Study title or study number;
* Investigational drug order;
* Investigational drug name and dosage;
* Manufacturer, lot number, and "use by" (expiration) date;
* Participant's identification #s (SID or PID);
* Any safety monitoring results, and
* Participant has signed a informed consent form as verified by study staff or coordinator prior to sending any participant to pharmacy for their initial drug administration.

It is ***strongly*** recommended that investigators write the initial ID drug order in the participant's source document and include the ID name, dosage form, strength, route, and instructions prior to preparation, administration, or dispensing.

Investigators should write the ID name, dosage form, strength, route, and instructions prior to preparation, administration, or dispensing.

Subsequent dispensing of pre-packaged participant self-administered ID will be based upon the ID dose, route, and frequency instructions written in the specific study protocol. The ID with the assigned participant numbers will be used ***only*** for the specific, assigned, consented participants. Labels should be double checked to assure the accuracy of the following information:

* Study title or study number,
* Participant’s identification (SID or PID),
* Drug name and dosage, and
* “Use by” expiration date.

The use of a commercial drug or another participant’s or protocol’s IP in lieu of the protocol drug is strictly prohibited. Exceptions must have written authorization from the sponsor.

Any discrepancy in IP accountability records that cannot be readily resolved should be discussed with the PI. The PI should discuss any problems with the sponsor.

The study approving IRBs should be notified if the discrepancy qualifies as a protocol violation according to the protocol and has any safety implications for participants.

If an IP dosing error occurs, it should be documented in detail and reported to the PI, sponsor, and the IRB. Documentation should be in compliance with applicable sponsor and regulatory policies.

**Modifying Doses of Investigational Products**

Any IP dose modifications must adhere to protocol guidelines.

The investigator will document the reason and dispensing order of each dose modification in the participant’s medical or research record.

If the ID dosage modification order is calculated on a participant's weight or other algorithm, a second licensed individual should check the protocol instructions for the calculation and the calculation itself to ensure it is correct.

This documentation and a copy of the protocol modification guidelines will be provided to the individual preparing, dispensing, and administering the IP.

**Record keeping and Documentation**

The PI, Site Coordinator, or other designee will ensure that;

* A copy of all ordering, shipping, transferring, and receiving documents be maintained in a secure, orderly, and readily retrievable place in the pharmacy manual provided by the sponsor or in an essential documents binder.
* Copies of the drug accountability logs may be kept at the study site for recording of returned IP.
* The IP orientation and ongoing oversight by the PI will be documented in either meeting minutes or telephone conference minutes.
* A separate Accountability Record will be maintained for each adjunctive drugs supplied by the sponsor during the conduct of the study. If the manufacturer does not provide the form, please use the model form found in Appendix A.
* The IP Accountability Record must be updated and signed whenever the drug is received, dispensed, destroyed, or returned.
* At a minimum, the IP Accountability Record(s) should include:
  + Protocol name or number;
  + PI and site name;
  + Sponsor name;
  + IP name, unit dose and formulation
  + Participant identification number;
  + Transaction dates of: initial and re-supply drug shipments, participant dispensing, and drug transfer, destruction, or return.
  + Number of doses for each entry;
  + Total balance of the drug at each study site; and Recorder's initials.
* All documentation will comply with regulatory, sponsor, and ethical requirements.
* Unused, partially used, and empty returned study medications containers will be retrieved according to protocol instructions to reconcile the use of the IP.
* When making corrections to IP documentation (receiving and packing slips, accountability, and dispensing records, etc.), the following guidelines will apply:
  + Draw a single line through the error.
  + Clearly note the correct entry.
  + Initial and date (month, day, year) all alterations. Please do not date corrected date to avoid confusion.
  + Do not use correction fluid on any IP study document.
  + If a clear resolution of an error is not possible, write a memo detailing the findings, including relevant dates, name(s) of the reviewer, process followed, and the individuals notified of the discrepancy.
  + If a document is illegible, recopy the document and attach the original to the recopied page with a detailed explanation.
  + Any discrepancy in the records that is not resolvable must be documented in detail, including a plan of action.
* The events of failed IP storage equipment (shelf, refrigeration units etc.) and the follow-up plan of action must be documented in writing.
* Documentation of the outcome (either returning or destroying the damaged drug) will be filed in the Essential Documents Binder or in the pharmacy files.
* All IP records will be retained with the other study documents for the period outlined in the protocol guidelines. The sponsor should be notified when these records are moved to a new storage facility or prior to destruction.
* The immediate return of recalled IP lot(s) must be documented, including the recall plan. The IP Accountability Record must also be updated.
* In the event of an early study termination, all steps taken to request that the participant return the drug must be documented, including that a certified letter was sent to the participant, requesting the return of the drug and container. The signed certified postcard or returned letter will be filed in the participant’s medical or research file.

**This SOP has been read and understood by**

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