

STANDARD OPERATION PROCEDURE (SOP) FOR THE SUBMISSION OF DOSSIERS FOR INVESTIGATIONAL PRODUCTS

The Department of Pharmacovigilance and Medicines Information of the Liberia Medicines and Health Products Regulatory Authority (LMHRA) is responsible to receive dossiers of investigational products and coordinates same with the Clinical Trial Team of the LMHRA for good and efficient working system in the supreme interest of the participating subjects. The following SOP provides an opportunity for easy and smooth submission of dossiers for investigational products.

OBJECTIVE

The objective is to facilitate the smooth submission of investigational product dossiers. It is intended to give a clear understanding of the procedures in order to avoid delay in the submission and processing of documents.

The SOP therefore provides that:

- 1. An applicant submits a type written application as described in the guideline;
- 2. Make payment of the required fee into the account of the LMHRA;
- 3. Proceed with payment slip to the Finance Department to obtain official LMHRA receipt;
- 4. Present dossier(s) along with official receipt and product samples