The Regulatory Framework for the conduct of Clinical Trial in Liberia.

Background

Clinical trial is a research within the health sector that requires appropriate coordination amongst stakeholders. By an act of legislature, the regulation of Clinical Trials in Liberia is a direct responsibility of the Liberia Medicines and Health Products Regulatory Authority (LMHRA). In an effort to ensure efficiency and effectiveness in exercising this enacted responsibility, the LMHRA, through key stakeholder meeting held at The Passion Hotel & Guest House in Gbarnga City, Bong County (February 23 to 24, 2017, developed a draft regulatory framework that clearly symbolizes the coordination amongst stakeholders in health institutions and also to govern the conduct of clinical trials in the Republic of Liberia. The LMHRA serving as the center of coordination receives protocols or requests from various research institutions and contract research organizations.

Through the establishment of the Electronic Platform, the ethical review and approval as well as the approval of the Institutional Review Board which are pre-requisites to the regulatory approval will be appropriately coordinated by the medicines and health research coordinating committee (MHRCC) at the LMHRA. The MHRCC reviewed reports shall be forwarded to the Clinical Scientific Advisory Committee (SAC) for verification and validation. The SAC will advise the LMHRA Management to take the appropriate actions.

Besides the coordination of the key actors involved in regulating clinical trials, the LMHRA effectively uses the Guidelines, Regulations, Standard Operation Procedures (SOPs), Checklists, and the Clinical Trial Registry in controlling the conduct of clinical trials in Liberia.

The key objective of coordination and monitoring the conduct of clinical trials is to ensure participants' safety.

In view of the above, the draft regulatory framework design on the next page clearly demonstrates the envisaged coordination amongst stakeholders from healthcare institutions that are involved with the conduct of clinical trials and research involving humans in Liberia.

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REGULATORY FRAMEWORK DESIGN