**ETAF Section 1. Identification of the Trial**

1.1 Title of the study

1.2 Contact person and contact details

1.3[Space for NDA Reference Number]

1.4 Declaration of intent signed by the Contracted Research Organisation

|  |
| --- |
| We, the undersigned have submitted all the required documentation and have disclosed all the information required for approval of this application.  We have developed the Protocol and read the Investigators brochure, appended.  We agree to ensure that the trial will be conducted according to the Protocol and all legal, ethical and regulatory requirements in Uganda. |
| Applicant (Local Contact): Name date:  Signature:  Designation |
| Principal Investigator: Name date:  Signature:  Designation |

**EFTA Section 2. Basic Administrative Data on the Application**

Name and address of the registered office of the Applicant

|  |  |  |  |
| --- | --- | --- | --- |
| Particulars | Sponsor | Manufacturer | Applicant |
| Name |  |  |  |
| Physical address |  |  |  |
| Postal address |  |  |  |
| Telephone number |  |  |  |
| Email |  |  |  |
| Fax |  |  |  |

**ETAF Section 3. Product to be used in the Trial**

3.1 Investigational product

3.1.1 Identifier or name of investigational product (code if applicable)

3.1.2 Registration number (if product is already on the market)

3.1.3 Manufacturer (Include all sites)

3.1.4 Active ingredient, complete composition, potency and presentation

3.1.5 Evidence of manufacture under conditions compliant with current codes of good manufacturing practice

3.1.6 Release specifications and tests. Include Certificate of Analysis.

3.1.7 Current approved package insert if available.

3.2 Comparator, concomitant and rescue medications (antidotes) and

Placebo

3.2.1 Proprietary name and INN

3.2.2 Active ingredient, composition, and presentation

3.2.3 Registration number (country)

3.2.4 Approved package insert to be appended to application.

3.2.5 Evidence that placebo is manufactured under good manufacturing practice.

3.3 Details of handling trial product.

3.3.1 Shipping, delivery and distribution of trial product.

3.3.2 Details of storage requirements and arrangements where necessary and monitoring during distribution.

3.3.3 Details of dispensing trial products and waste disposal procedures.

3.3.4 Packaging and labeling of the trial products

3.4 Estimates of quantities of each product to be used for the trial, and for which an import permit is needed.

**ETAFSection 4. History of previous and in-progress trials**

4.1 List the titles of previous trials with this (or similar) trial product in Uganda or in other countries.

4.2 Include a letter or certificate from the regulatory authorities in countries where previous trials have been undertaken (including those in-progress) that these trials have been GCP compliant.

4.3 Append interim or final report-summaries of these trials to this application. (This may be in the investigators brochure