**Protocol title/CTA………………………………………………………….**

CHECKLIST OF REQUIRED DOCUMENTS

| **Item** | **Requirement** |  |
| --- | --- | --- |
| Fees | Proof of payment |  |
| CTA | Clinical Trial Application Form |  |
| APPENDIX 1 | Trial Protocol |  |
| APPENDIX 2 | Investigators Brochure |  |
| APPENDIX 3 | Participant Information Leaflet and Informed Consent |  |
| APPENDIX 4 | Certificate of GMP manufacture of the trial medicine or other evidence of manufacture quality, safety and consistency[[1]](#footnote-1) |  |
| APPENDIX 5 | Package Insert(s) for other trial medicines. |  |
| APPENDIX 6 | Certificate of GMP manufacture of the placebo - if appropriate. |  |
| APPENDIX 7 | Evidence of accreditation of the designated Laboratories or other evidence of GLP and assay validation. |  |
| APPENDIX 8 | Insurance Certificate specific for the trial sourced from a local provider or in consultation with NDA |  |
| APPENDIX 9 | Signed and completed Declarations by all Investigators |  |
| APPENDIX 10: | Approval of Ethics Committees for the Protocol2  UNCST Approval |  |
| APPENDIX 11: | Full, legible copies of key, peer-reviewed published articles supporting the application. |  |
| APPENDIX 12: | Sample of the label for the Investigational Medicinal Products. |  |
| APPENDIX 13: | Letter of authorization from the manufacturer/product owner |  |
| APPENDIX 14: | Pharmaceutical Data on dosage form |  |
| APPENDIX 15: | Duly signed declaration of the Monitor |  |
| APPENDIX 16: | Clinical Trial Agreement between the Sponsor and the Principal Investigator |  |
| APPENDIX 17: | Duly signed declaration by Sponsor and Principal Investigator of funds of the Clinical Trial |  |
| APPENDIX 18: | Other supporting documents |  |

1. *Note:*

   *Certificate of Good Manufacturing Practice (GMP) for the investigational product or statement on GMP from the manufacturer/re-packer (whichever is more relevant).*

   * *The GMP certificates or other documents must be issued by an authority recognised by NDA i.e. the authorities listed in the WHO certification Scheme On the Quality of Pharmaceutical Product Moving In International Commerce,*
   * *Or the statement on GMP can be issued by the Quality Assurance Department where the product is manufactured.*
   * *For local product, the manufacturing licence is required.*
   * *For a comparator product, the following is required:*
   1. *a GMP certificate*
   2. *If not available, one of the following can be submitted:*
   * *Approval letter from the regulatory authority*
   * *Annual Registration of Drug Establishment*
   * *Package insert*
   1. *For a repacked product, a statement of GMP must be submitted by the re-packer.*

   *2IRB approvals of study protocols should be submitted along with the CTA to NDA* [↑](#footnote-ref-1)