**Checklist for Clinical Trial/Study Application**

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| **S. No.** | **Required Documents** |
|  | Application on prescribed form along with Fee |
|  | Investigator Brochure |
|  | Final Protocol |
|  | Informed consent form (English and Urdu) |
|  | List of participating countries (If applicable) |
|  | Phase of trial |
|  | Quantities of Investigational Product to be imported or procured |
|  | Site of the trial |
|  | C.V of investigator |
|  | Ethical committee approval with complete composition of committee i.e Name and designations of the members |
|  | Approval from National Bio-ethics Committee (PHRC) |
|  | GMP certificate along with Free Sale Certificate or Certificate of Pharmaceutical Product (For locally manufactured product GMP Cert., COA of the Product and Registration Letter will be required) |
|  | Pre-clinical, clinical data and safety studies. |
|  | Summary of the protocol |
|  | Summary of the Investigator Brochure |
|  | Adverse Event Reporting form |
|  | No. of Patients to be enrolled in each center |
|  | Name of monitors or clinical research associate |
|  | Evidence of registration in country of origin |
|  | Copy of registration letter (if registered in Pakistan) |
|  | Sample of label of Investigational Product |
|  | Duration of trial |
|  | Undertaking on stamp paper. |