

Appendix D

CHECK LIST FOR APPLICANT BEFORE SUBMISSION OF APPLICATION

- Application Form – Annexure E ()
- Project proposal - 14 copies ()
- Curriculum Vitae of Investigators ()
- Brief description of proposal/summary ()
- Copy of the Protocol/Project questionnaire (if any) ()
- Investigator's Brochure, if applicable ()
- Copy of Patient information sheet & Consent form in local language ()
- Copy of Advertisements/Information brochures ()
- DCGI/DBT/BARC clearance if obtained ()
- Copy of Insurance Policy ()
- Copy of Clinical trial agreement ()
- Copy of Principal Investigator undertaking ()
- Copy of Case Report Form ()