**INSTRUCTIONS**

An application for review of the ethics of proposed biomedical research should be submitted by a qualified applicant responsible for the ethical and scientific conduct of the research. Principal Investigator can submit the documents for IRB for review and approval. All relevant documents should be enclosed with a covering letter and Submission Checklist.

## Submission Requirements

* + - The application (the unsigned soft copy) should be submitted ONLINE to pushpagiriirb@pushpagiri.in two weeks before the IRB meeting date.
		- IRB Secretariat will review the documents submitted
		- If any missing documents and/or details are there IRB will inform the applicant to submit the required documents
		- If the application is intact, the member secretary will give intimation via mail to submit the hard copies of the proposal; along with the application, documents in prescribed format, and a covering letter
		- **Prescribed fee as per the Fee Structure should be remitted along with the application**
		- The following list of documents to be submitted by Applicant for review by IRB
1. Trial Protocol: Submit the latest protocol along with all the amendments mentioning the version no. (s) and date(s).
2. Patient Information Sheet and Informed Consent Form: Submit the latest Patient Information Sheet(s) and Informed Consent Form (s) in English and all the applicable vernacular languages mentioning the version no . (s) and date(s).
3. Proposed methods for patient accrual including advertisement if applicable (s) etc. proposed to be used for the purpose.
4. Principal Investigator‘s signed and dated current CV along with medical registration certificate.
5. Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
6. Investigator‘s Agreement with the Sponsor.
7. The Regulatory approval / submission status from sponsor for the conduct of study.
8. Description of site facilities using in the study including available emergency facilities
9. A description of the process to be used to obtain the informed consent.