**Annexure No. 4 A**

**Ananya Institutional Ethics Committee**

**Ananya Medical College and Research, Kalol**

**Initial Review Submission Form for Research Proposal**

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualifications and designation
4. Name of the Institute / Hospital / Field area where research will be conducted
5. Forwarding letter from the Head of the Department / Institution / Guide.
6. Protocol of the proposed research: Clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, review of literature with references, inclusion and exclusion criteria for entry of participants. Precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures/interventions if any, criteria for termination of study, Plan to withdraw or withhold standard therapies in the course of research. Plan for statistical analysis of the study. Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures, if any, Informed consent process, including patient information sheet and informed consent form in English and local language(s). Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances. Source of funding and financial requirements for the project.
8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / other countries, if available.
9. Usefulness of the project / trial.
10. Expected ‘benefits’ to volunteers / community. ‘Benefits’ to other categories if any
11. Explain all anticipated ‘risks’ (adverse events, injury, and discomfort) of the project. Efforts taken to minimize the ‘risks’. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.
12. Agreement to report all Serious Adverse Events (SAE) to Ananya IEC.

13. Other financial issues including those related to insurance.

14. An account of storage and maintenance of all data collected during the trial.

1. Statement of conflicts of interest, if any.
2. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided
3. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
4. Curriculum vitae of all the investigators with relevant publications in last three years.
5. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
6. Any other information relevant to the study.

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Signature of the Principal Investigator with date.