

Checklist for Submission of Research Proposal for Ethical Clearance

Document	Yes/No/ N.A.	P a g e No.
i) The title with signature of Principal Investigator (PI) and Co-investigators as attestation for conducting the study.		
ii) Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.		
iii) Recent curriculum vitae of the Investigators indicating qualification and experience for the kind of work to be undertaken if required.		
iv) Participant recruitment procedures and brochures, if any.		
v) Inclusion and exclusion criteria for entry of participants.		
vi) 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, if any.		
vii) Plan for statistical analysis of the study.		
viii) Procedure for seeking and obtaining informed consent with sample of respondent information sheet and informed consent forms in English and local languages (Format available with IEC secretariat).		
ix) Safety of proposed intervention, including results of relevant laboratory, animal and human research where applicable.		
x) For research involving more than minimal risk, an account of management of such risk or injury.		
xi) Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.		
xii) A statement on probable ethical issues and steps taken to tackle the same		
xiii) Details of Funding agency/ Sponsors and fund allocation.		

xiv) For international collaborative study details about foreign collaborators and documents for review by appropriate Committees under other agencies/authority		
xv) For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.		
xvi) An undertaking from supervisor of research project stating that comments made by the Technical Review Committee have been adhered to.		
xvii) A statement on conflict-of-interest (COI), if any.		