## (Version 3.0, Date – 27.06.2020)

## General Guidelines

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 and Institution.
6. Date of approval by Institute Research Cell:
7. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, 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 if any, 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.
8. 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 Hindi/Other 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.
9. 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.
10. Usefulness of the project / trial
11. Expected ‘benefits’ to volunteers / community. ‘Benefits’ to other categories if any.
12. Explain all anticipated ‘risks’ (adverse events, injury, 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.
13. Agreement to report all Serious Adverse Events (SAE) to IEC-AIIMS Raipur
14. Other financial issues including those related to insurance.
15. An account of storage and maintenance of all data collected during the trial.
16. Research proposals approval by scientific advisory committee/Research Cell
17. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee (HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)
18. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
19. Statement of conflicts of interest, if any.
20. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
21. 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
22. 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.
23. Curriculum vitae of all the investigators with relevant publications in last five years.
24. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
25. Any other information relevant to the study.
26. Signature of the Principal Investigator with date.

**Note:**

1. No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institute Ethics Committee.
2. Submit one (01) copy of the Research Proposal along with Covering letter and ‘soft copy’ via e-EC portal. (www.iecmanager.org) (updated – as that has been submitted in hard copy).
3. Proforma must be accompanied by Informed Consent Document [Participant information sheet and Consent form (Form 3A/3B/3C)] in English and Hindi/Other local language if applicable.
4. The patient/participant information sheet should be in simple language and it should address to the subjects, in dialogue format.
5. Submissions will be received on all working days.
6. While submitting replies raised by the IEC, the candidates are advised to mention IEC reference number/s and also attach a copy of the comments of the IEC.
7. While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not affect the safety of the subject in anyway.