

FORMAT OF RESEARCH PLAN

1. **Title of the proposed research project:** should be **concise** and yet sufficiently descriptive and informative. Title may include study design such as randomized controlled trial; an observational study; a case-control study etc.
2. **Summary (up to 250 words):** A structured summary should contain the following subheadings: *Background, Novelty, Objectives, Methods, and Expected outcome.*
3. **Keywords:** Six keywords separated by comma which best describe your project may be provided.
4. **Abbreviations:** Only standard abbreviations should be used in the text. List of abbreviations maximum of ten may be given as a list.
5. **Background (up to 500 words):** State the background information to adequately present the problem, mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capability, and/or programmatic/clinical/lab practice and its relevance to local, national and international context.
6. **Literature review (up to 1000 words):** Review to be written cohesively to build justification for the research question to be addressed with reference of key publications in the field. Reference up to 30 in Vancouver style may be provided at the end of literature review. (*References will not be included in the word count*)
7. **Novelty/Innovation (up to 250 words):** Describe how the proposal challenges and seeks to shift the current research/knowledge/clinical practice paradigms etc. by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions etc. Mention if there is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions in the proposed study.
8. **Study Objectives:** Define the objectives clearly and in measurable terms; mention as primary and secondary objectives if necessary. Do not write too many objectives.
9. **Methodology (up to 2000 words): Include the following subheads**
 - i. **Study Design:** Proposed study design should be appropriate to fulfill all the objectives; details of study design whether descriptive, analytical, experimental, operational, a combination of these or any other; and adequate description of study population should be provided. Explain the rationale of selection of the research participants and controls (human or laboratory animals), whether chosen randomly, consecutively etc. with inclusion and exclusion criteria, rules for discontinuation, definitions of cases, controls and lost to follow up etc.; in case of Intervention studies a detailed description of Intervention (drug/device/behavioral intervention) should be given. The use of quantitative and qualitative methods may be specified if any.
 - ii. **Sample Size:** Details of sample size and/or power calculation should be described with references where needed. [*Please note: the sample size calculation should provide*

adequate power to the study to satisfactorily answer all the primary objectives, data from pilot studies can also be used for sample size calculation]. Operational definitions for key variables should be presented. A flow chart indicating study design with number of participants should be given where applicable.

iii. Project Implementation Plan: Describe the overall strategy for enrollment of participants including collaboration with other departments where applicable, process of enrollment of participants – how, where and by whom will the participants be enrolled, how and when and where will they be followed up; collection, storage and testing of samples; if new tests are being done describe the process of standardization etc. Describe quality assurance processes to accomplish the study objectives.

iv. Ethics Review: Address review requirements including ethics review [human or animal], approval for use of stem cells, biological etc. and other regulatory reviews/approvals as applicable. Details of obtaining informed consent and its documentation should be described along with risks and benefits to the participants. *[Ethics and other regulatory guidelines related to Bio-medical research are available on ICMR website]*

v. Data collection & statistical analysis plan: Describe the key variables of the study, how will they be measured and unit of measurement. Specify comprehensively the data collection methods and tools are relevant to the study objectives and study design and provide structural components like data entry and analytical platforms to be used for analysis. Present data analysis plan comprehensively mentioning appropriate statistical methods to be used in order to answer/achieve the study objectives.

10. Expected Outcomes (up to 100 words)

11. Limitations of this study (up to 100 words)

12. Future plans based on expected outcomes if any (up to 100 words)

13. Timelines: Details of activities to be carried out along with timelines during preparatory phase, data collection, analysis & report writing to be provided.

14. Institutional Support: Mention the efforts made to achieve inter-departmental or inter-institutional collaboration needed for study implementation, details of coordination between clinical, laboratory and data management procedures, mention the institutional resources such as equipment and other physical resources available for use in the project proposed.

15. Budget: Should be appropriate and as per ICMR guidelines available on the website. Justification for staff along with their roles and responsibilities in the project to be provided.

Justification for all the components of the budget projected in the proposal to be provided in detail.