Shri Dhirubhai Mehta Memorial Scheme for the Promotion of Research at MGIMS

Guidance document for filling the format for submission of Research proposal for seed grant

PART I – SUMMARY INFORMATION

PROJECT TITLE (up to 25 words)		
Title should be clear, brief and reflect the primary objective(s) and the Study design		
PROJECT SUMMARY (up to 300 words) The project summary should be a stand-alone description that should give the Reviewers all the necessary details about your proposed project in sufficient detail. It should provide a structured summary of the detailed proposal highlighting the Background, Novelty, Objectives, Methods and Expected outcome.		
PRINCIPAL INVESTIGATOR (PI)		
Name		
Designation		
OTHER INVESTIGATORS AND COLLABORATING DEPARTMENTS (IF APPLICABLE)		
Name	Designation	Role in Project
PROJECT DURATION (in months)**:**		
TOTAL BUDGET requested:		
Plans for raising a larger Grant/application to external funding agency (up to 200 words): (up to 300 words): Describe the proposed plan for building upon this seed grant to generate a larger grant. You may specify the exact details of the external funding agency or scheme to whom you intend to apply		

PART II – PROJECT DETAILS

1a. Rationale & Background Including Novelty/Innovation (up to 500 words):

State the background information to adequately present the problem. Explain the rationale highlighting how the research question addresses the evidence gap in scientific knowledge, technical capability, and/or programmatic/clinical/lab practice and its relevance to local, national and international context. You may include and highlight novelty/innovativeness of the proposal if any and how it seeks to contribute to the available body of scientific evidence

1b. Study goals & objectives (up to 300 words):

Goal is the broad statements of what the proposal hopes to accomplish. They create a setting for the proposal.

Specific objectives are statements of the research question(s).

Define the objectives clearly and in measurable terms; mention as primary and secondary objectives if necessary.

2. Review of available Evidence (up to 1000 words):

Present available evidence including relevant references (in Vancouver style) of articles relating to the problem/gap in evidence.

You may summarize the inference based on the RoL either in a paragraph or tabular form at the end of the RoL.

3. Methodology

The methodology section is the most important part of the protocol and should include the below mentioned points in details with specifications.

- **Study design, study setting and study population**

  The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology.
  - Proposed study design should be appropriate to fulfill all the objectives; details of study design (descriptive, analytical, experimental, operational, a combination of these or any other) and adequate description of study population should be provided.
  - Provide information on the study setting as to where the study would be implemented and who would be the study population and participate in the study
  - The use of quantitative and qualitative methods or participatory methods may be specified if any

- **Sample Size and Sampling Strategy:**
  - 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].*
  - If you intend to do a pilot study and feel that sample size may not be relevant to your research question than kindly mention the same explaining the rationale
  - Kindly include details regarding the sampling frame and specify the sampling strategy of how you intend to select the proposed numbers (Random sampling or Convenience sampling or purposive sampling etc)

- **Selection of Study participants specifying inclusion, exclusion criteria**
  - Explain the rationale of selection of the research participants and controls (human or laboratory animals) with inclusion and exclusion criteria, rules for discontinuation if any, definitions of cases, controls and lost to follow up etc) should be given.

- **Operational definitions**

  Operational definitions for key exposure and outcome variables should be presented. Wherever feasible try to adhere to the standard definitions and give references for the same.

- **Study variables**
  - Specify all the exposure, outcome and confounding variables that you intend to capture in the study. You may also present them in a tabular form

- **Study tools/questionnaire**

- Kindly provide details about the tools/Instruments which are to be used to collect information (questionnaires, FGD guides, observation recording form, case report forms etc.)
- Kindly choose standardized and validated questionnaires/tools/scales wherever feasible. If you plan to use a non-validated tool, then provide details about pre-testing and/or expert validation based on whatever you intend to do.
- must also be provided as part of the Appendices

- **Methods of Data collection**
  - It should include detailed information on the procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done etc. The methodology should be standardized and clearly defined.
  - 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.
  - Procedures could be biomedical (collection of blood or sputum samples to develop a diagnostic test), or in the domain of social sciences (doing a questionnaire survey, carrying out a focus group discussion as part of formative research, observation of the participant's environment, etc.).
  - Standardized and/or documented procedures/techniques should be described and bibliographic references, if not provided earlier should be provided.
  - A graphic outline of the study design and procedures using a flow diagram must be provided. This should include the timing of assessments

  <u>For interventional studies/ Randomized Controlled Trials (RCTs)</u>
  - In case of Intervention studies a detailed description of Intervention (drug/device/behavioral intervention) should be given.
  - In the case of a randomized controlled trial additional information on the process of randomization and blinding, description of stopping rules for individuals, for part of the study or entire study, the procedures and conditions for breaking the codes etc. should also be described.
  - Approach to analysis whether Intention-to-Treat or Per-Protocol including the proposed sub-group analysis should be specified
  - Details/plan for registration of the trial in the CTRI or other registries

  <u>For Case Control studies</u>
  - Definition of Cases and Controls and criteria for their selection should be explicitly stated. The definition and criteria should be objective in nature and provide references wherever possible

  <u>For Cohort studies</u>
  - Criteria for Exposed and Non-exposed group and their measurement, details about follow-up of study participants should be specified. Details of the follow-up (by whom, when and how – whether in person or telephonic) should be provided

  <u>For Systematic Review/Meta-analysis</u>
  - Mention the intended databases to be searched, Search strategy, procedures for initial and full-text screening of articles, methods for data extraction and plan for analysis and synthesis of findings including grading of evidence if applicable
  - Details/plan for registration of the Systematic review in the Prospero

- **Data management**

  Provide information on how the data will be managed, including data handling and storage, coding for computer analysis, verification, archiving and destruction if applicable.
  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.

- **Data analysis**
  The statistical methods proposed to be used for the analysis of data should be clearly outlined, level of significance to be used, procedures for accounting for any missing or spurious data etc. For projects involving qualitative approaches, specify in sufficient detail how the data will be analysed (e.g. how saturation of data will be assessed, Thematic analysis or content analysis etc)

4. Expected outcomes of the study and its applicability/generalizability to other settings

Indicate how the study will contribute to advancement of knowledge, how the results will be utilized, not only in publications but also how they will likely affect health care, health systems, or health policies.

5. Dissemination of results and publication plan

Specify not only dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where relevant.

6. Project timeline

Specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken. Kindly provide a Gantt chart or timeline

7. References

List all references used throughout the proposal in Vancouver style

6. Budget

Project budget by type of expenditure item and adequate justification in a tabular form as applicable

APPENDICES

Create the list of appendices to be submitted along with the completed proposal form. The appendices should include the following documents, as applicable:

- Research team members' curriculum vitae
- Informed consent form to be used with study participants

Other study instruments (e.g. questionnaires, interview guides)