अनुसंधान अनुभाग **(Research Section)**
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Annexure II

GUIDELINES FOR WRITING THE RESEARCH PROPOSAL

General Guidelines

i. It should be free from typographical and grammatical error.
ii. Margin- 1"left, right, top and bottom with Gutter of 0.6" on left side
iii. Line spacing - 1.5(for text), 1 (for tables)
iv. Font - Times New roman (only)
v. Font size 12
vi. Page size- A-4

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. (This is purely stylistic choice but the title shall be a declarative sentence that summarizes the key message of the study or stating the title in the form of a research question. Goals in creating a title for the proposal are 1) to stimulate the reader's interest (question format) or 2) to share information (declarative sentence format) as the title may be all that the reader reads. Regardless, make the title as concise as possible.)

2. **Introduction/ Background for the study (up to 500 words):** State the background information to adequately present the problem burden, 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.

   The final paragraph of the introduction should have statements summarizing the following three elements: 1) study purpose or question, 2) hypotheses, and 3) specific aims. Suggested structure: The purpose of this study is to . . . . The investigators hypothesize that . . . . The specific aims of the study are: 1) to measure, compare or estimate some variables of interest

3. **Justification of the Study / 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.

4. **Literature review (up to 1000 words):** Review to be written cohesively to build justification for the research question to be addressed with reference to key publications in the field. Reference maximum up to 20 in Vancouver style to be provided at the end of literature review. (References will not be included in the word count)

5. **Research Question AND/OR Hypothesis.** This shall be structured as per the PICO/PICOT guidelines. Where in **P**- Population/patient/problem, **I**-intervention, **C**- Comparison, control or comparator, **O**- Outcome(s) (e.g. pain, fatigue, nausea, infections, death), **T**- Time/duration.

6. **Study Objectives:** Define the objectives clearly and in measurable terms; AIMS and Objectives should be according to **SMART** goals (**SMART** stands for **S**pecific, **M**easurable, **A**chievable, **R**elevant, and **T**ime-Based). Mention the objectives as primary and secondary objectives if necessary. Do not write too many objectives.

7. **Operational Definitions:** Need to define the operative definitions for all outcome variables to achieve the objectives and shall also mention the indicators/measures of variables.

8. **Material and Methods** (up to 1500 words): Include the following subheads

   8.1. **Study Design:** Proposed study design should be appropriate to fulfill the objectives Mention the study design whether 0bservational/interventional, Retrospective/ Prospective/mixed, Cross sectional/Cohort/Case-control/RCT/Systematic review/Meta-analysis/Pilot etc.

   8.2. **Study Duration: (** To be mentioned in months)

   8.3. **Study Site:** Department/ Unit/ Lab where this study shall be conducted.

   8.4. **Study Population:** Explain the rationale of selection of the research participants and controls (human or laboratory animals), whether chosen randomly, consecutively etc. and adequate description of study population should be provided.

   8.5. **Inclusion & Exclusion criteria** *(separate for cases and control if any)*

   8.6. **Sample Size with Statistical formula**: it shall include the statistical formula (to be used as appropriate to study design), desired precision confidence interval, with power of study and the reference study if any or attribute of assumption. If study group are more than one then sample size for each group to be mentioned.. *[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.*

   8.7. **Methodology**

      i. **Plan of Work** (In FLOW CHART) Describe the overall step wise strategy from enrolment of participants till end of study in a flow chart as plan of work **:** including collaboration with other departments where applicable

      ii. **Step wise Methodology**: shall be written in steps with bullets and shall include process of enrolment of participants (how, where and by whom will the participants be enrolled); what initial work ups; method of Randomization in RCTs; details of interventions in interventional study(drug/device/behavioral intervention/surgical methods etc.); protocol for follow up (how where and when the participants will be followed up); method of collection, storage, and testing of lab samples if applicable; if new tests are being done describe the process of standardization; definition of cases and controls; rules for

discontinuation; how the 'lost to follow up' will be addressed Describe quality assurance processes to accomplish the study objectives.

iii. In case ofRCTs, describe the following

a. Randomization Method
b. Method of Generation of allocation
c. Allocation Concealment
d. Blinding (if any), how will you ensure?
e. Condition for unblinding *(which can be at the end of the study/Serious adverse effect/Emergency Situation/accidental unblinding)*

iv. Treatment details: both control (active/placebo) and intervention arm: Dose, Route, Duration, treatment schedule to be mentioned in details. if any expected or study related side effect/ adverse effects are there, they shall be clearly mentioned

8.8. **Outcome variables:** In the section on study variables, the Investigators need to describe and define the primary predictor variables clearly and unambiguously. The PI shall clearly state the independent variables and outcome variables and shall include the indicators and how they will be measured and the unit of measurements. Each covariate needs to be described and defined carefully. They can be further categorized in continuous or categorical variables which help in statistical calculations

8.9. **Timeline Table**: A table mentioning – timeline for recruitment, various investigations, follow-up intervals, data compilation and analysis and final project writing and submission etc.

9. **Data Collection and Statistical Analysis Plan**: shall mention : a. Brief description of data collection procedure (including data collection tools e.g. questionnaire, any scale etc) b. Specify comprehensively the data collection methods and tools as relevant to the study objectives and study design c. provide structural components like data entry and analytical platforms to be used for analysis d. Present data analysis plan comprehensively mentioning appropriate statistical methods and tests of significance to be used to answer/achieve the study objectives for different outcome variables.

10. **In case of clinical trials please mention**

10.1. The drugs, doses, and route of administration to be studied in trial are approved by FDA or not?
10.2. Is DCGI permission required to conduct of this trial? If no justify if yes DCGI permission is to be taken before the start of the study
10.3. CTRI registry is must for all clinical trials.

11. **Expected Outcomes:** (up to 100 words)
12. **Limitations of the study:** *if any* (up to 100 words)*:* Any Similar Study has been conducted in our institute or elsewhere (if yes mention the reasonfor planning the study again)
13. **Future plans based on expected outcomes:** if any. (up to 100 words)
14. **Keywords:** keywords separated by comma which best describe your project may be provided.

15. **Abbreviations:** Only standard abbreviations should be used in the text. List of abbreviations is to be given as a list. Avoid using abbreviations in the title of the study.

16. **Budget details with Justification**: Kindly refer point number Five of SOP (Annexure -1)– utilization of funds in the SOP for intramural funds. Budget needs to be in a table format and Justification for staff along with their roles and responsibilities and the other heading for fund utilization in the project is to be provided as per the format in the excel sheet provided with the proposal format

17. **Case Record Form**: Shall include
    i. Title of the study
    ii. Name of the investigator *(shall be left black for blinded review)*
    iii. Case/control number/code
    iv. Inclusion & exclusion criteria
    v. Demographic details
    vi. Data to generate all the primary and the secondary objectives.
    vii. Confounders for the variables
    viii. Any study related adverse effects
    ix. Images/diagrammatic representation and tables as required
    x. Any other
18. **Validated/standardized Questionnaire**, Scale, interview guide etc. if applicable
19. **Any other document relevant to study**