**IADVL Research Grants-2021**

**Application form II**

**Details of the research project**

(Please provide details, including technical references, in the following format)

Please Note:

* To enable blinded review, NO IDENTIFIER (i.e name of the Institution/ college where the research project is to be carried out, name of the investigators, name of the ethics committee, CTRI No etc) should figure in this application including Case Record Form and Consent Form.
* Only IADVL life members can apply as Principal Investigator

1. **Title of the project:**

**1.1: Acronym (if any)**

1. **Has the proposal been previously submitted (if yes which year)?**
2. **Executive Summary of Project (Not more than 500 words including research question/research hypothesis)**
3. **Field of research (Please give upto 3 key words/subheadings)**
4. **Project Objective(s):**
5. **Background (Existing knowledge in field, working hypothesis in context of previous work done, can add up to 10 relevant references, not more than 1500 words)**
6. **Methodology:** 
   1. Study design (suitable to fulfil objectives)
   2. Duration of study
   3. Study population (from whom study subjects will be drawn)
   4. Study subjects {specifying study groups (Both cases and controls if any)}
      1. Inclusion criteria including methods of inclusion (Clinical and/or investigational)
      2. Exclusion criteria including methods of exclusion (Clinical and/or investigational)
      3. Withdrawal criteria (Situations warranting exclusion during the study)
      4. Rescue criteria in case of occurrence of expected adverse outcomes
   5. Sample size (including details of estimation & sampling technique)
   6. Randomization, allocation concealment and blinding methods (if applicable)
   7. Methods of collection of data
      1. Demographic and personal data
      2. Clinical data
      3. Laboratory data: [For investigative/experimental studies, details of procedure of investigation(s) studied and measurement of efficacy of investigation(s)]
      4. Therapeutic response data: Details of intervention(s) and measurement(s) of efficacy and safety of intervention(s) if any
      5. Data safety monitoring plans in case of clinical trials
   8. Study variables (data to be recorded to fulfil the objectives): (For therapeutic studies, primary and secondary end point measurements, safety data)
   9. Statistical methods: Describe in detail the methods used to present and analyze different study variables with reference to objective(s) of the study
   10. Operational definitions
   11. References
7. **Evaluation Criteria- Definition of success/failure:**
8. **Proposed Deadlines:**

* Project Beginning Date:
* Project Ending Date:

1. **Detailed research plan & Timing (work-flow):** Describe in detail project timeline and specific milestones in a Gantt chart format.
2. **Significance of project/originality**
3. **Impact & benefits for IADVL**
4. **Budget requirements:** Detailed break-up and justification with proper use of nomenclature of items to be bought

**Please Note:**

* Equipment cannot be purchased
* If Project is for >1 year, specify Year Wise Requirement of budget
* If multicentric, specify budget for each center separately in the following format

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Items** (provide details with quantity under each head) | **Source of supply (wherever applicable)** | **Justification for budget** | **Amount (Rs)** |
| **1** | Accessories of equipment |  |  |  |
| **i** |  |  |  |  |
| **ii…** |  |  |  |  |
| **2** | Chemicals/Reagents/Other Consumables |  |  |  |
| **i** |  |  |  |  |
| **ii…** |  |  |  |  |
| **3** | Stationery and contingencies |  |  |  |
| **i** |  |  |  |  |
| **ii..** |  |  |  |  |
| 4 | Miscellaneous expenses, i.e.  Ethics Committee fees  Trial Insurance fees (if required) |  |  |  |
| 6 | GST (if applicable) |  |  |  |
| 7. | Institute administrative charges |  |  |  |
|  | Total |  |  |  |
|  | Desired fund flow |  | | |
|  | 1. Initial Funding 2. First Quarter 3. Second Quarter (accompanied by half year Progress 4. Final (After completion and submission of report) |  | | |

1. Link with other projects (Ad-hoc, taskforce, or collaborative)
2. What are the other facilities/services (technology, infrastructure, equipment and human resource) required for this research project (please be informed that equipment cannot be funded in these grants):
3. Confirm that these facilities/services (technology, infrastructure, equipment and human resource) required for the project are available at the research centre:
4. Is the necessary support from various other specialities required for conduct of the project available? If so, specify.
5. Has letter of consent regarding utilization of facilities/services been obtained from Head(s) of Department(s) involved in the research project? (It is mandatory to submit the Letter separately while submitting the research proposal)
6. Does the research project require collaboration with external agency/service provider? If yes, the nature and terms of collaboration and also the status of MoU with the collaborator to be submitted before initiation of the project.
7. Do you consider the proposed number of subjects will be available within the proposed period of study?

Has Ethics committee approval been obtained? (if obtained, to be attached separately while submitting the project and if not, to be submitted within 6 months of approval of grant. Ethics committee approval from all centres will need to be submitted, for a multi-centric study)

1. Has the study been registered with the Clinical Trials Registry-India? (if obtained, to be attached separately while submitting the project and if not, to be submitted within 6 months of approval of grant)

**Please note:** Submission of Ethics Committee Approval and CTRI number is mandatory for release of grant for all projects that are sanctioned IADVL Research grant

**Appendix 1:** Case Record Form/Questionnaire (Specific to objectives of the study and study variables): Avoid identifiers

**Appendix 2:** Consent form in English and local language: Avoid identifiers

**Check list: To be submitted separately**

**Mandatory at the time of submission**

* 1. Application form I
  2. Application form II
  3. CV of Principal Investigator
  4. CV of Coordinators (In case of a multicentric study)
  5. Letter of Consent from Head/s of the Department/s involved in the research projects (Principal investigator/s and Co-investigator/s)
  6. Letter of consent from Head/s of Institution/s or Centre/s involved in the research project. This letter has to include a statement that the institute is willing to receive grant money directly to their own account and facilitate the research.
  7. Undertaking by the investigators

**Mandatory before release of grant**

1. Ethics committee approval from each study center/s
2. CTRI registration submission acknowledgement
3. MoU with Collaborators, if applicable
4. Clinical trial Insurance, if applicable
5. GST registration details, if applicable