# APPLICATION FOR APPROVAL OF INTERVENTIONAL STUDIES

## PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES AND RESEARCH CENTRE, TIRUVALLA(AFFILIATED TO THE KERALA UNIVERSITY OF HEALTH SCIENCES, THRISSUR)

## Please complete and submit Sections 1 and 2 with all supporting documents.

**SECTION I**

**Internal Funding/External Funding (delete as appropriate)**

**If for external funding, please provide name of funding agency and the application for submission in the funding agency’s format, in addition to this application.**

1. **Title of Research Project:**
2. **Acronym, if any:**
3. **Name of the Principal Investigator:**

**Designation / Department / Unit / of Principal Investigator:**

**If Post Graduate Resident / Fellowship:**

**Enrollment date of PG Course: mm/yyyy**

**Completion date of PG Course: mm/yyyy**

**Address for communication** (including telephone and fax numbers and email id):

1. **Name of Guide (for Post-Graduate Resident / Fellowship)**

**Address for communication** (including telephone and fax numbers and email id):

1. **Name and Designation of Co-Investigator (s) and Department** :
2. **Sites of the study (including departments where the study will recruit participants):**
3. **Has necessary governmental clearances been obtained: Yes/No/In the process**
4. **Research Problem**
5. **Objectives of the study:**
6. **Brief Summary (in 500 words):**
7. **Health Condition or problem studied:**

**12.Study Type:**

**13.Present Knowledge and relevant bibliography** (Is there a justification for this trial? Please provide a brief review of the relevant literature and appropriate references)

**14.Preliminary work already done by the investigator in this problem**

1. **List of publications of the investigator in the field**

**16.Detailed diagrammatic Algorithm of the study**

**17.Methods in detail:**

1. **Intervention and Comparator agent**
2. **Key Criteria**
	* 1. Inclusion Criteria:
	1. Exclusion Criteria:
3. **Method of randomization:**
4. **Method of allocation concealment:**
5. **Blinding and masking:**
6. **Primary Outcome:**
7. **Secondary Outcome/s:**
8. **Target sample size and rationale: (It may be suitable to have a statistician as a co-investigator)**
9. **Phase of trial:**
10. **Expected date of first enrolment:**
11. **Estimated duration of trial:**
12. **Protocol variations: Any rules for**
	1. interim analyses
	2. For withdrawal of participants
	3. For premature stopping of trial
13. **Has a Data monitoring committee been appointed?** Yes / No
14. **Post Trial benefits and care:** Has provision been made for post-trial access to the best proven intervention from this trial or best available care for participants after the study is completed?
15. **Statistical Analyses:**
	* 1. Statistical methods to be used for the primary outcome; include description of methods to estimate the strength of the effect (e.g.: Odds ratios, relative risks, etc)
		2. Methods for additional analyses, if indicated**.**
			+ 1. **Complete budget plan for all studies** (**As enclosure)**
				2. **Performa for Data collection (As enclosure)**

**20. Informed Consent Documents (patient information sheet and informed consent document)** please submit all translations with the proposal

**31. Publication Plans:** (List all potential authors and their likely contributions)

(Please tick √ appropriate box)

|  |  |
| --- | --- |
|  | Responsibilities |
| Author(s)Name | Research and Study design | Data collection & analysis | Laboratoryanalysis | Interpretation and conclusion | Preparation of Manuscript | Review of Manuscript | Guide and criticalrevision | Administration | Technical Support |
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**21. Inter-departmental cooperation:** (Please describe the arrangements with institutional diagnostic service units/departments that are being used for this research project, if applicable).

**22.Signature of Principal Investigator**

**23. Signature of Guide/Head of the Department/ Unit**

**24.Co-Investigators’ Consent (all co-investigators have to sign this form or supply separate letters of consent)**

I/We give my/our consent to be a Co-Investigator and provide my/our expertise to the project. I/We have approved this version of the protocol and have contributed substantially to its development.

**Name Department Signature Date**

**Note: If the project is a resubmission a fresh copy of signatures needs to be obtained for**

**IRB submission.**

**Section II**

**APPLICATION FOR ETHICS APPROVAL FOR ALL INTERVENTIONAL STUDIES IN HUMAN PARTICIPANTS**

1. **Please provide a brief summary of the justification, objectives and methods in lay language, avoiding technical terms.**
2. **Please describe if the study uses procedures already being performed on patients for diagnosis or treatment or if modified or novel procedures are to be used?**
3. **Please describe what benefits might be reasonably be expected by the participant as an outcome of participation**
4. **Please describe what benefits to others or new knowledge might be expected as a result of this study**
5. **Who are to be enrolled?**
6. **If any vulnerable groups (e.g., pregnant women, children) are to be enrolled, please provide a justification for their inclusion.**
7. **What are the potential risks to participants in this study?**
8. **Are the risks to participants reasonable in relation to the benefits that might reasonably be expected as an outcome to the participant or to others, or the importance of the knowledge that may reasonably be expected to result? Please provide a detailed description of the above.**

1. **What is the risk of death from this study?**
2. **Regarding informed consent to obtained from research participants or their legally authorized representative(s):**
	1. **Does the informed consent document include all the required elements (See appendix IV)?**

* 1. **Are the participant information sheet and the consent document in language understandable to participants? (PLEASE PROVIDE WITH THIS SUBMISSION TRANSLATIONS IN ALL LOCAL LANGUAGES ANTICIPATED TO BE USED).**
	2. **Who will obtain informed consent (PI, nurse, other?) and in what setting?**
	3. **If appropriate, is there a children’s assent? If yes, please submit a copy of this form.**
	4. **Is the EC requested to waive or alter any informed consent requirement?**
1. **Is there provision of free treatment for research related injury? If yes, who will**

 **provide it?**

1. **Is there provision for compensation of participants for disability or death resulting**

 **from research related injury? If yes, who will provide it?**

1. **Is the study covered by insurance? If yes, please provide insurance documents from**

 **an Indian insurance company.**

1. **Please describe the plan for maintaining confidentiality of study participant**

 **information.**

1. **Please describe the plans for monitoring the safety of participants, reporting and**

 **managing adverse events. If this is an externally funded study with a Data Safety**

 **Monitoring Board, please provide the name and contact information of the DSMB**

 **chairperson.**

1. **If appropriate, has permission from the Drug Controller General of India been obtained?**
2. **If this is international collaborative research, has permission from the Health Minstry’s Screening Committee been obtained?**
3. **Declaration (to be signed by all investigators)**

By signing this form we give our consent to provide our expertise to the project. In addition:

* 1. We confirm that all investigators have approved this version of the protocol and have contributed substantially to its development.
	2. We confirm that all potential authors are included in this protocol.
	3. We also affirm that we shall register the trial in the Clinical Trials Registry- India ([http://ctri.nic.in](http://ctri.nic.in/)) in accordance with the details submitted here and submit the registration details before getting final ethics committee approval and enrolling the first participant.
	4. We confirm that we shall submit any protocol amendments, adverse events reports, progress reports (if required) and a final report and participate in any audit of this study.
	5. We confirm that we shall conduct this study in accordance with the Declaration of Helsinki; the ICMR Guidelines for Biomedical Research in Human Subjects 2006, with any subsequent amendments; Schedule Y of the Drugs and Cosmetics Act; GCP guidelines; and all applicable laws of the Republic of India.
	6. We agree to submit the results of this study for publication to a peer reviewed journal, within two years of completion.
	7. We declare that we have no conflicts of interest that may affect the conduct or reporting of this study (OR) we declare the following conflicts of interest below.
	8. We are aware of the institution’s policies regarding scientific misconduct and agree to abide by them.
1. **Signature of Principal Investigator**
2. **Signature of Guide/Head of the Department/ Unit**
3. **Co-Investigator’s Consent (all co-investigators have to sign this form or supply separate letters of consent)**

**Name Department Signature Date**

**Conflicts of interest if any:**

**Note: If the project is a resubmission a fresh copy of signatures needs to be obtained for**

**IRB submission.**

**Format for Informed Consent Form for Subjects**

Informed Consent form to participate in a research study

**Study Title:**

**Study Number: \_\_\_\_\_\_\_\_\_\_\_\_**

**Subject’s Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of Birth / Age: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

(Subject)

(i) I confirm that I have read and understood the information sheet dated \_\_\_\_\_\_\_\_\_\_\_\_ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor’s behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

(vi) I am aware of the Audio-visual recording of the Informed Consent. [ ]

(Click here for Audio Visual guidelines)

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_

Signatory’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature:

Or

Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_

Signatory’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_

Study Investigator’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature or thumb impression of the Witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_

Name & Address of the Witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_