# APPLICATION FOR APPROVAL OF OBSERVATIONAL

# (CASE-CONTROL / COHORT/ CROSS-SECTIONAL) STUDIES

# PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES & RESEARCH CENTRE, TIRUVALLA

**(AFFILIATED TO THE KERALA UNIVERSITY OF HEALTH SCIENCES, THRISSUR)**

(Please complete Sections **1 and 2** and submit 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**
2. **Acronym if any**
3. **Name of the Principal Investigator:**
4. **Designation / Department / Unit / of Principal Investigator:**
5. **Address for communication** (including telephone and fax numbers and email id):

**If Post Graduate Resident / Fellowship:**

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

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

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

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

**7. Name and Designation of Co-Investigator(s) and Address :**

1. **Department of Institution where the research will be carried out**
2. **Names and addresses of other institutions where research will be carried out**
3. **Duration of the Scheme**
4. **Research Problem**
5. **Objectives and aims of study** (*including any hypotheses).*
6. **Summary of the proposed research scheme (500 words).**
7. **Present Knowledge and relevant bibliography** *(Is there a justification for this study based on a detailed literature review or other sources of evidence? Please provide details)*
8. **Preliminary work already done by the investigator in this problem**
9. **List of publications of the investigator in the field**
10. **Detailed research plan:**
11. **Setting:** Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
12. **Participants:** Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases (and controls, if applicable). For matched studies, give matching criteria and the number of controls per case
13. **Variables:** Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
14. **Data Sources/measurement:** For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
15. **Bias:** Describe any efforts to address potential sources of bias
16. **Sample size:(It may be suitable to have a statistician as a co-investigator)**

 Explain how the study size was calculated

1. **Quantitative variables:** Explain how quantitative variables will be handled in the analyses. If applicable, describe which groupings were chosen and why
2. **Statistical methods:** Describe all statistical methods, including those used to control for confounding and examine subgroups and interactions. How will missing data be handled? If applicable, how will matching of cases and controls be handled? Describe any proposed sensitivity analyses.
3. **Complete budget plan (As enclosure)**
4. **Performa for Data collection(As enclosure)**
5. **Informed Consent Documents (patient information sheet and informed consent document)** please submit all relevant translations with the proposal**.**
6. **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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1. **Inter-departmental cooperation:** (Please describe the arrangements with institutional diagnostic service units/departments that are being used for this research project, if applicable).
2. **Signature of Principal Investigator**
3. **Signature of Guide/Head of the Department/ Unit**
4. **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 APPROVAL FROM ETHICS COMMITTEE OF PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES AND RESEARCH CENTRE, FOR ALL OBSERVATIONAL (CASE CONTROL, COHORT & OBSERVATIONAL) STUDIES IN HUMAN SUBJECTS**

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.**
9. **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?**

* 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. **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 confirm that we shall submit any protocol amendments, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of this study, if required.
	4. 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; and all applicable laws of the land.
	5. We also agree to submit for publication to a peer reviewed journal the complete results of this study within two years of completion of this study.
	6. 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.
	7. We are aware of the institution’s policies regarding scientific misconduct (Falsification/fabrication/plagiarism) 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**

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

**Conflicts of interest if any:**

**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. [ ]

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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_