# APPLICATION FOR APPROVAL FOR STUDIES OF DIAGNOSTIC TEST ACCURACY

# 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**
2. **Acronym if any**
3. **Name of the Principal Investigator:**
4. **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**

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

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

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

1. **Name and Designation of Co-Investigator (s) and Address** :
2. **Department(s) of Institution where the research will be carried out:**
3. **Names and addresses of other institutions where research will be carried out:**
4. **Duration of the Study:**
5. **Research Problem**
6. **Objectives of the study**
7. **Summary of proposed research (500 words)**
8. **Present Knowledge and relevant bibliography** (Is there a justification for this study?Please provide a brief review of the relevant literature and appropriate references)
9. **Preliminary work already done by the investigator in this problem:**
10. **List of publications of the investigator in the field:**
11. **Detailed diagrammatic Algorithm of the study**
12. **Detailed research plan:**
	1. **Study population recruitment.** Describe i) the sample selection, with the inclusion and exclusion criteria, ii) setting where data will be collected, iii) whether a sampling strategy will be employed, iv) whether selection will be dependant or independent of results of index test or reference standard, and v) whether the whole or a sub- sample will receive verification with the reference standard of diagnosis.
	2. **Design of data collection.** State whether data will be collected from participants prospectively (before performing the diagnostic tests) or retrospectively.
	3. **Reference standard.** Describe i) the execution of the reference standard in sufficient detail as to enable replication, including cutoffs and categories of results, ii) the likelihood of the reference standard correctly diagnosing the target health condition (cite figures from literature.
	4. **Index or experimental test.** Describe the execution of the index or experimental test in sufficient detail as to enable replication, including cutoffs and categories of results with rationale and, if possible, with supporting citations.
	5. **Personnel. Describe the number, training and expertise of the people executing and interpreting the tests and measures for quality control. Provide Standard Operating Procedures, if available, in Appendices.**
	6. **Timing.** Describe the time period between the index test(s) and the reference standard and explain whether the target health condition is likely to change between the two tests.
	7. **Minimizing bias.** Describe if the index test will be interpreted independently of the reference standard and without knowledge of the results, or whether the index test forms part of the reference standard.
	8. Statistical methods. Describe the methods to be used for calculating or comparing diagnostic accuracy. (Kindly acknowledge your statistician)
	9. **Interpretation. Describe whether the test results will be interpreted using clinical data from participants.**
	10. **Unclear results. Describe how un-interpretable or intermediate test results will be handled.**
	11. **Missing data.** Describe how missing information and drop outs will be handled.

 **19. Performa for Data collection (As enclosure)**

1. **Complete budget plan for all studies**
2. **Informed Consent Documents** (Patient Information sheet and Informed consent document, Please submit all translations with the proposal**)**
3. **Publication Plans:** (List all potential author(s) 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 clinical/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-Investigator’s 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 FOR ALL STUDIES IN HUMAN SUBJECTS OF DIAGNOSTIC TEST ACCURACY**

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 subject 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 of this study?**
8. **Are the risks to subjects reasonable in relation to the benefits that might reasonably be expected as an outcome to the subject 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 subjects 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 subjects? (PLEASE PROVIDE 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. **Will participants be expected to pay for any of the tests or incur any expense in connection with the tests? Please describe.**
2. **Is the study covered by insurance? If yes, please provide insurance documents from an Indian insurance company.**
3. **Please describe the plan for maintaining confidentiality of study subject information.**
4. **Is there a likelihood of injury or death due to participation in this study and if so, is there any provision for compensation of subjects for disability or death resulting from such injury and who will provide it?**
5. **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 and a final report and participate in any audit of this study.
	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 Republic of India.
	5. We also agree to submit the results for publication to a peer reviewed journal 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 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 and Address of the Witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_