Ethics Committee Certificate

JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION & RESEARCH
(स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार के अधीन राष्ट्रीय महत्व का संस्थान)
भारत सरकार / GOVERNMENT OF INDIA
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INSTITUTIONAL ETHICS COMMITTEE (HUMAN STUDIES) CERTIFICATE

Date: 25/01/2019

To,

Dr. Gurram Ram Prakash, Senior Resident,
Department of Surgical Gastroenterology,

Ref: Your project no. **JIP/IEC/2018/500** entitled, **"Correlation between Preoperative Pancreatic CT Attenuation Index, Pancreatic Enhancement Radio and Post Pancreatoduodenectomy Pancreatic Fistula."**

Dear Dr. Gurram Ram Prakash,

The following documents of the above mentioned project were reviewed and approved through an **expedited board review** process.

1. Research Protocol
2. Data Collection Performa
3. Consent form
4. Participant Information Sheet
5. Minutes of the departmental committee meeting
6. CV of Guide and Co- Guides
7. Declaration by the Guide for overall responsibility and accountability for the project

It is understood that the study will be conducted under the supervision of Dr. Senthil G, Assistant Professor, Department of Surgical Gastroenterology (Guide) Dr. Kalayarasan R, Associate Professor, Department of Surgical Gastroenterology, Dr. Biju Pottokkat, Additional Professor & Head, Department of Surgical Gastroenterology, Dr. Srinivas B H, Associate Professor, Department of Pathology and Dr. A. Ramesh, Additional Professor & Head, Department of Radiology (Co-Guide) in a total of **60** research participants, as per the submitted protocol.

The IEC approves the above mentioned study.

This approval is valid for three years, the entire duration of the project or a shorter period based on the risk whichever is less.

It is the policy of IEC that, it be informed about any onsite serious adverse event or any unexpected adverse event report within 24 hours as per the formats specified in SOP 09 to IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the chairman of IEC and the head of the institution where the trial is been conducted within 14 calendar days of SAE or death.

In case of injury or death of participant(s) occurring during the trial, the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to the IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before 20/12/2019.

A copy of the final report should be submitted to IEC for review.

Sincerely yours

Dr. M. Jayanthi,
Member Secretary
Date of approval of the study: 21/01/2019

Member Secretary
Institutional Ethics Committee
(Human Studies)
JIPMER, Puri...