Institutional Ethics Committee

GOVERNMENT MEDICAL COLLEGE

MEDICAL COLLEGE P.O., THRISSUR - 680596

ETHICAL COMMITTEE CLEARANCE CERTIFICATE

IRC PROTOCOL NO : **IEC/GMCTSR/244/2021** Date:**30.11.2021**

The Institutional Ethical committee reviewd the Project proposal submitted by **Dr. SANTHOSH T V, ASSOCIATE PROFESSOR, Dept. of GENERAL SURGERY, GMCTSR, PH.9447436770, E-mail -**

Title : A STUDY TO ESTIMATE THE PREVALANCE OF BRAF MUTATION AND PAPILLARY THYROID CARCINOMA AND ITS ASSCIATION WITH CLINICO PATHOLOGICAL FEATURES : A CROSS SECTIONAL STUDY

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

1. Application Form 2. Research proposal 3. Consent form

It is understood that the study will be conducted under your direction, in a total of **150** research participants, at as per the submitted protocol.

The IEC approves the above mentioned study, which is valid for the entire duration of the study/One year.

Sincerely yours

Member Secretary/ Chairperson with date

Dr.Ravindran.C.
30.11.2021

Note:

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 or by email if it is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the chairman of IEC and to the head of the institution where the trial is been conducted within 10 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. The IEC expects that the investigator shall 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

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

Sincerely yours

Dr.Ravindran.C.
Member Secretary
30.11.2021