INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES:SHEIKHPURA: PATNA-14
(AN AUTONOMOUS INSTITUTE OF GOVT. OF BIHAR: (India) Statutory University by an Act of State Legislature)
ETHICS COMMITTEE
Tel.: 0612 - 2297631, 2297099-Ext.: 265: Fax: 0612 - 2297225; Website: www.igims.Org; E-Mail: dean@igims.in

Letter No.:-470/IEC/2018/IGIMS Date: -03../08/2018

To,

Dr. Seema Rani Sinha
Junior Resident
Department of Biochemistry
IGIMS, Patna.

Sub.:- "Assessment of tumor markers CA-19-9, CEA, CA125, CA242 for early diagnosis and predicting prognosis in gall bladder cancer patient ".

Madam,

The Institutional Ethics Committee reviewed and discussed your application to conduct the abovementioned clinical trial entitled Multicentre **"Assessment of tumor markers CA-19-9, CEA, CA125, CA242 for early diagnosis and predicting prognosis in gall bladder cancer patient".** The Institutional Ethics Committee meeting was held on 03/08/2018 at 03:30 P.M. at IGIMS, Patna.

Sl. No.	Name	Designation
1.	Mr. Justice R.N.Prasad	Chairman
2.	Dr. Manish Mandal	Member Secretary
3.	Prof. (Dr.) Arvind Prasad	Clinician(Alternate Member)
4.	Prof. (Dr.) Vijayendra Kumar	Clinician
5.	Prof.(Dr.) S.K.Suman	Clinician(Alternate Member)
6.	Dr.(Mrs.) Rani Indira Sinha	Basic Medical Scientist
7.	Dr. Sanjay Kumar	Basic Medical Scientist
8.	Mrs. Manmeet Kaur	Lay Person
9.	Dr. Victor Alphonse	Lay Person
10.	Mr. Pranav Kumar	Legal Expert
11.	Mr. Fanish Singh	Social Scientist (NGO)

Institutional Ethics Committee approved the research project with the condition that the cost of investigation and monitoring of patient will be borne by the sponsor and necessary Insurance against adverse effect / serious adverse effect will be undertaken by the sponsor. Further the project including investigation shall be done at IGIMS, Patna and the investigation (s) as well as sponsor shall comply with relevant Institute rules. Compliance to be ensured before starting the project and thereafter at all relevant stage by investigator (s) and sponsors.

You are required to follow the guidelines of ICMR and GCP during conduct of the study and to take DCGI permission if required, before starting the study.

As per the notification of the Drug Controller General (India), registration of clinical trials is mandatory with effect from 08.10.15. The clinical trials have to be or registered with the National Registry viz clinical trials registry India (CTRI) website www.ctri.nic.in before recruiting first participant. If your study is a clinical trial it is mandatory to get it registered with CTRI.

The Institutional Ethics Committee expects to be informed about the progress of the study on every six month, any SAE occurring in the course of the study and any change in the protocol and patient information / informed consent and asks to be provided a copy of the final report.

Yours faithfully

Dr. Manish Mandal
Prof. & HOD, GIS Cum
Member Secretary
Institutional Ethics Committee
IGIMS, Patna.