

INSTITUTIONAL ETHICS COMMITTEE
(Reg No. ECR/660/Inst/AP/2014/RR-17)

Date: 4th January 2019

To
Dr. Srinivas Mantha
MD (Anesthesiology)
Consultant Anesthesiologist and Pain Physician
Indo-US Hospital, Ameerpet
Hyderabad 500016
Telangana, India.

Study Title: Determinants of Common Carotid Intima-Media Thickness (CCIMT) Measured by Ultrasound Echo-tracking Method in Asymptomatic Individuals

Protocol No: MHC/CCIMT/001 **Version No. :** 01 **Date:** 30th November 2018

Dear Dr. Srinivas Mantha

The following documents were reviewed:

S. No	Document Title	Version	Date
1.	Protocol	Version 01	30.11.2018
2.	Investigator's Brochure	Version 01	30.11.2018
3.	ICF English	Version 01	30.11.2018
4.	ICF Telugu	Version 01	30.11.2018
5.	ICF Hindi	Version 01	30.11.2018
6.	ICF Urdu	Version 01	30.11.2018
7.	ICF Telugu Back Translation (Back Translated From Telugu to English)	Version 01	30.11.2018
8.	ICF Hindi Back Translation (Back Translated From Hindi to English)	Version 01	30.11.2018
9.	ICF Urdu Back Translation (Back Translated From Urdu to English)	Version 01	30.11.2018
10.	ICF Telugu Translation & Back Translation Certificate	NA	5.12.2018
11.	ICF Hindi Translation & Back Translation Certificate	NA	5.12.2018
12.	ICF Urdu Translation & Back Translation Certificate	NA	5.12.2018
13.	Case Report form (CRF)	Version 01	30.11.2018
14.	Undertaking by the Investigator	NA	30.11.2018
15.	Curriculum Vitae (CV) & MRC of the Principal Investigator	NA	30.11.2018
16.	Draft Indemnification	NA	
17.	Draft Clinical Trial Agreement	NA	

The following members were present in the meeting:

1. Hon'ble Mr. Justice K Ramaswamy
2. Dr. M. Ravi Kumar
3. Prof. Dr. M.U.R Naidu
4. Dr. V. Rajesh
5. Prof. (Dr) Y .F. Jaya Kumar
6. Sri Potturi Venkteswara Rao
7. Mr. P. Yadagiri
8. Dr. A Veerabhadra Rao

At the Ethics Committee meeting held on 24th December 2018, Saturday (Time 2:30 -05:30 PM) at Indo-US Superspecialty Hospital, Ameerpet Hyderabad 500016 Telangana (India), your referenced letter and the above documents were examined and discussed.

The following Documents were submitted by the PI on 29.12.2018:

- | | |
|---|-------------------|
| 1. Signed Indemnification letter | Dated: 26.12.2018 |
| 2. Signed CTA | Dated: 26.12.2018 |
| 3. MOU | Dated: 26.12.2018 |
| 4. Insurance policy (No:551802491610000150 valid upto 27.03.2019) | Dated: 28.03.2018 |

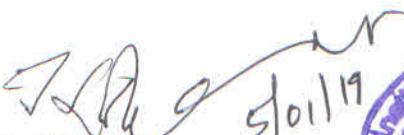
After due consideration, the committee has decided to approve the conduct of the aforementioned study under your direction at Indo-US Superspecialty Hospital, Ameerpet Hyderabad 500016 Telangana (India). The Ethics Committee expects to be informed about the progress of the study and any change in the protocol/ patient information/ informed consent. You are also expected to provide us with periodic reports on the progress of the study.


The study is approved in its present form. The approval is valid until **one year from the date of sanction.**

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Ethics Committee.

- The Institutional Ethics Committee (IEC) expects that the following Standard Operating Procedures should be strictly adhered to in all clinical studies undertaken in Indo-US Superspecialty Hospital, Ameerpet Hyderabad 500016 Telangana (India).
1. Notwithstanding any statement that has been made in this regard during consideration of the study, it is understood that the biological samples taken from any individual involved in the study shall not be used under any circumstances for any other purpose excepting that indicated in the approved protocol.
 2. Travel expenses of participants must be met for each visit, and this fact should be included in the Consent Form.
 3. The drug which is used on patient in the clinical study shall be supplied free of cost by the sponsor till the requirement of the study subject.
 4. The Jurisdiction for all legal disputes shall be Hyderabad, Telangana (India).
 5. The progress of the study including any SAES shall be communicated to the Institutional Ethics Committee (IEC), and also any changes in the protocol and patient information/informed consent.
 6. The final report of the study shall be submitted to the Institutional Ethics Committee (IEC) in all cases even when the study is abandoned for any reason(s).
 7. The Hospital Ethics Committee has working procedures in compliance with ICMR Guidelines, ICH GCP Guidelines, Schedule Y and applicable local laws.

Yours truly


5/01/19



The Chairman
Institutional Ethics Committee
Indo-US Superspecialty Hospital,
Anand bagh, Shyam Karan road,
Ameerpet, Hyderabad,
Telangana.