

DAYANAND MEDICAL COLLEGE & HOSPITAL LUDHIANA



Institutional Ethics Committee (DTEC)

Ref No. DMCH/DTEC/2013/ 429

Date: 26/10/13

Dr Gagandeep Singh
Professor & Head,
Deptt. of Neurology,
DMCH, Ludhiana

Ref.: "Towards developing a national epilepsy control program: A Pilot, community-based, randomized trial of delivery of care to people with epilepsy (PWE)

Subject: Ethics Committee Conditional Approval

Dear Dr. Gagandeep,

The Drug Trial Ethics Committee reviewed, discussed & conditional approved your project documents submitted with respect to the above referenced clinical trial in meeting held on **12-10-2013** at **02:00 pm** in **Conference Room**, Research & Development Centre, DMC & Hospital, Ludhiana.

The following members of the Institutional Ethics Committee were present/voted in the meeting held on 12-10-2013 and were involved in the approval process

Sr. no	Members	Designation
1.	Dr. S C Chopra	Chairperson
2.	Dr. Sandeep Kaushal	Member Secretary
3.	Dr. Anurag Chaudhary	Joint Secretary, Member
4.	Dr. Puneet Aulakh Pooni	Member
5.	Dr. H S Pannu	Member
6.	Dr. Shalini Arora	Member
7.	Mr. S.S Saini	Member
8.	Adv. A K Jindal	Member
9.	Prof. Arvind Malhotra	Member
10.	Mrs. Bharti Satija	Member

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Vice Principal : 0161 4687502
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Decision: The DTEC **conditionally approved** the project documents from the Ethics point of view to be conducted in its presented form at DMCH under your direction. Dr. Anurag Chaudhary did not participate in the voting process being a part of the study, rest all of the voting members present evaluated & discussed project's documents and concluded that the project is **conditionally approved**.

Subject to: 1) Submission of CTRI Number.

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The Drug Trial Ethics Committee should be informed

1. About the progress of the study.
2. Any Serious Adverse Events occurring in the course of the study within 7 calendar days of their occurrence.
3. Any changes in ICF and other documents.
4. Protocol Deviation(s).
5. Any change in the protocol and patient information/informed consent documents, prior to their implementation.
6. Final report of the study shall be submitted to Ethics Committee in all cases, even when the study is abandoned for any reason(s).
7. Inform DTEC in case of any change of study procedure, site and investigator. This permission is only for period mentioned above. Annual report to be submitted to DTEC.
8. Members of DTEC have right to monitor the trial with prior intimation.

With regards,


Dr. Sandeep Kaushal

Secretary

Drug Trial Ethics Committee

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