



Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow – 226014, India

Dr. Subhash B. Yadav
Associate Professor (Endocrinology) and
Member Secretary, Institute Ethics Committee

Communication of decisions of the 80th Institutional Ethics Committee

IEC code: 2014-166-CP-80

PGI/BE/852/2014

Agenda Item No. 13

Date: 22-Oct-14

As per above recommendations of IEC, the project/trial with documents has been reviewed by the Member Secretary and based on the documents submitted by PI following recommendation has been made "Project/trial is cleared by ethics point of view."

Accordingly the project/trial is finally cleared from ethics point of view.

Following points must be noted:

1. IEC should be informed of the date of commencement of study (AN5-V1/SGSOP 06/V1) and annual progress.
2. PI and other investigators should co-operate with IEC, which may monitor the trial from time to time.
3. The decision was arrived at through consensus. Neither PI nor any of proposed study team members was present during the decision making of the IEC.
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD and getting IEC concurrence and submitting status report, including accounts details should be submitted to HOD, IEC and extramural sponsors.



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5. New information or any SAE, which could affect any study, must be communicated to IEC and sponsors. The PI should report SAEs occurred for IEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the Bioethics cell should receive the SAE reporting form within 24 hours of the occurrence.

6. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms

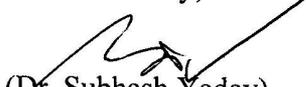
7. Any deviation/violation/waiver in the protocol must be informed to the IEC as detailed in SGSOP 09/V1.

8. If project/drug/device trial initiation not done in next 6 months from date of approval from IEC, further extension will not be granted and it will require resubmission to IEC.

We hereby confirm that the Institutional Ethics Committee is organized and operates as per amended schedule Y (20th Jan 2005), ICH GCP guidelines and applicable regulations.

Thanking You,

Your Sincerely,


(Dr. Subhash Yadav)

Member Secretary

IEC, SGPGI, Lucknow.

King George's Medical University U.P.,
Institutional Ethics Committee
Office of Research Cell
Lucknow - 226003 (UP) India



Prof. R.K. Garg
Member Secretary, IEC &
Faculty Incharge

(Registration No.: ECR/262/Inst/UP/2013)

To

Prof. Apul Goel
Department of Urology
K.G's Medical University U.P.
Lucknow

No. 9339 /Ethics/R.Cell-16

Dated: 04/02/16

Ref. Code: 77th ECM II-A/P14

Sub: Research proposal entitled "*Molecular studies to characterize the biological significance and therapeutic implication of non-steroidal anti-inflammatory drugs (NSAIDs) targeting Wnt/ β -catenin signaling pathway in human urinary bladder cancer*" submitted by you.

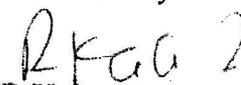
Dear Sir

The Ethics Committee met on 29th January, 2016, the comments and decision of the committee is given below for your information and necessary action accordingly:

EC Decision: Approved

Kindly quote the above reference code in all further communications regarding the above subject.

Yours Sincerely


(R.K. Garg)
Member Secretary
&
Faculty In-charge