



संजय गाँधी स्नातकोत्तर आयुर्विज्ञान संस्थान, लखनऊ
SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
Raebareli Road, Lucknow- 226014 (India)

Dr. Vinita Agrawal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the EXP-24th Institutional Ethics Committee

IEC code: 2020-185-IP-EXP-24

PGI/BE/390 /2020

Agenda Item No. 14

Date: 30-Jun-20

Title of project: Long term outcomes of Cohen's cross trigonal reimplantation for primary VUR in poorly functioning kidney.

Principal Investigator: Dr Priyank yadav

Department: Urology

Name and Address of Institution: Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Raebareli Road, Lucknow, 226014

New/Re-review project: New

Date, time and venue of meeting: 18-Jun-20 10.00 AM at SGPGI

Dear Dr.

Institutional Ethics Committee reviewed and discussed your application to conduct the research study during the IEC meeting held on 18-Jun-20

List of documents reviewed:

1. Project Submission Form
2. Study Protocol
3. Case Report Form
4. Consent of Head of the PI's Department
5. Research Committee/Department committee /Doctoral Committee/Scientific Committee Approval
6. Undertaking by the PI
7. Conflict of Interest Statement by PI
8. CV of investigator outside SGPGI or of the student
9. ~~Participant Information document (PID) consent forms~~ CF) in English and Hindi



Dr. Vinita Agrawal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the EXP-24th Institutional Ethics Committee

IEC code: 2020-185-IP-EXP-24

PGI/BE/ 390 /2020

Agenda Item No. 14

Date: 30-Jun-20

The following members of the Institutional Ethics committee (IEC) were present at the meeting held on 18-Jun-20

Prof. Amita Panday, Dept. of Obst. & Gynae., KGMU, Lucknow - Member

Dr. Mohan Gurjar, Additional Prof., Department of C.C.M, S G P I M S, Lucknow - Member

Prof. Vinita Agrawal, Professor, Dept. of Pathology, S G P I M S, Lucknow - Member Secretary

Scientific issues and ethical aspects were discussed.

Decision: Approved.


Waiver of consent granted.

The study is approved in its presented form. The approval is valid until one year or duration of project whichever is later from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of annual status report.

Following points must be noted:

1. IEC should be informed of the date of commencement of study (AN5-V2/SGSOP 06/V3) 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.
 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 AN1-V3/SGSOP 09/V3.
 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. Vinita Agrawal)
Member Secretary